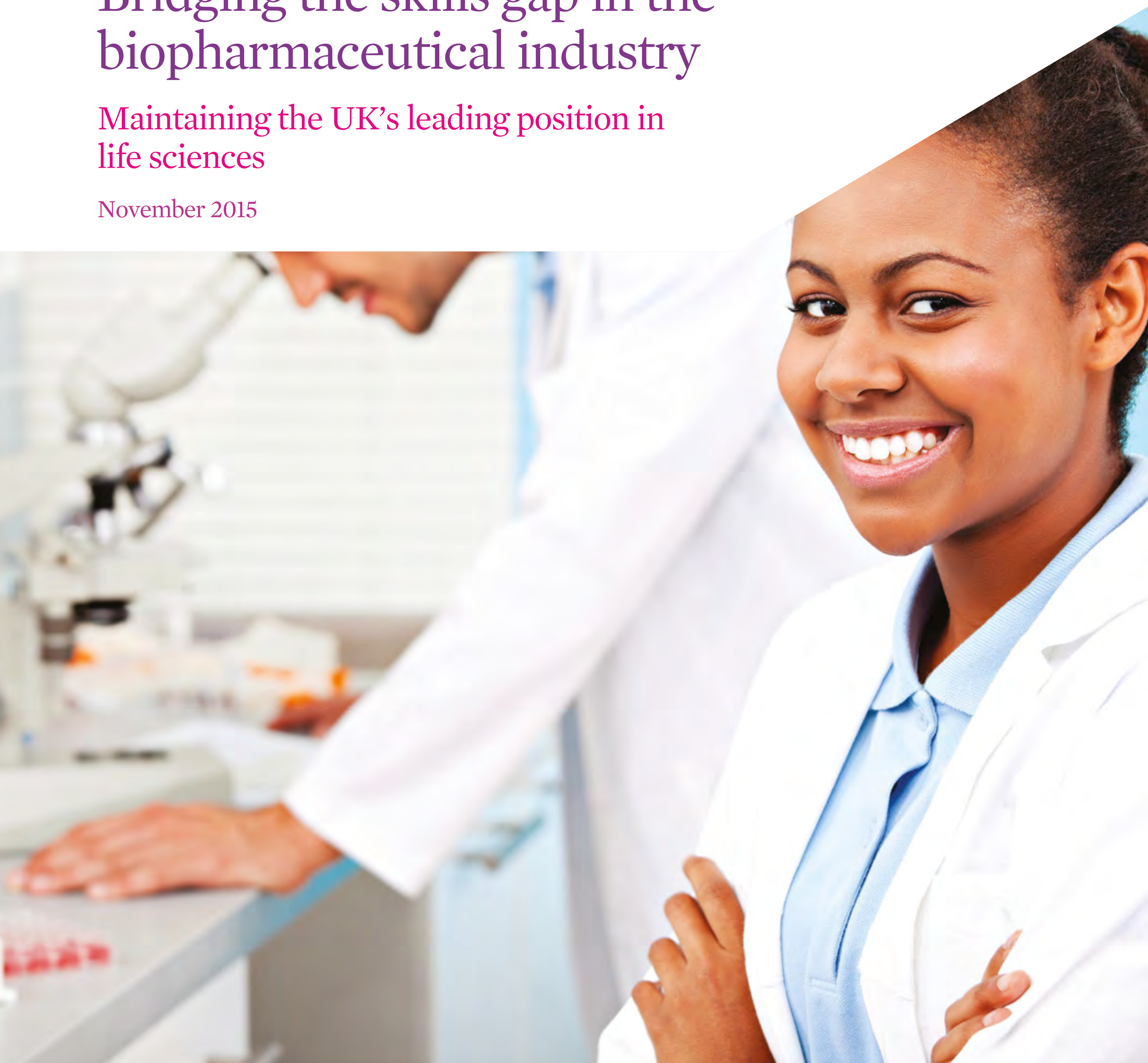
Bridging the skills gap in the biopharmaceutical industry

Maintaining the UK's leading position in life sciences

November 2015



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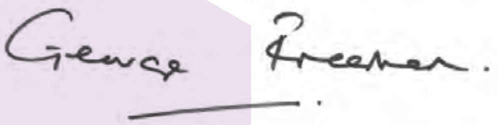
Contents

Foreword

The UK has one of the strongest and most productive life sciences industries in the world, generating turnover of over £56 billion per annum. The pharmaceuticals sector alone accounts for more UK-based business R&D than any other manufacturing sector, accounting for over 22 per cent of all business R&D. There is significant opportunity to be grasped, with global health and life science markets predicted to grow up to 10 per cent per annum in the next decade.

Skills is an increasingly important part of the picture. Across the whole life science sector, over a quarter of employment involves highly skilled research and development roles and commands a wage premium. This is why this ABPI survey of current and future skills needs for the pharmaceuticals industry is so important. It highlights the need for skills in areas such as bioinformatics, statistics, data and informatics, many of which were not even highlighted as issues in 2008, the year ABPI last carried out this survey. At the same time it shows the continued importance of long-standing skills challenges including translational medicine and clinical pharmacology.

It is essential that the sector continues to have access to a highly skilled R&D, manufacturing and technical workforce in order to achieve its potential, maintain the UK's position at the forefront of life sciences and help to meet the challenge of addressing the productivity gap. This ABPI report will provide invaluable evidence for industry and policymakers to develop and deliver the right skills initiatives to ensure that the sector continues to thrive in the future.



George Freeman MP

Parliamentary Under Secretary of State for Life Sciences,
Department for Business, Innovation and Skills

1 Executive summary

‘The fundamental driver behind any innovation process is the human factor associated with it’[1]

As the Government set out in *Fixing the Foundations*, weaknesses in the UK skills base have contributed to its long-standing productivity gap with peer nations, and ‘[i]t is imperative that the UK addresses these shortfalls if productivity is to improve.’[2] As a leading industry for growth and innovation in the UK, the biopharmaceutical industry agrees that developing an appropriate skills base is vital to maintain growth and investment in the UK. We are the most research-intensive business sector in the UK, spending over £4 billion on research and development in 2013. We are also a major contributor to the economy of the UK, bringing life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases. The skills required for research, development, manufacturing and commercialisation of medicines are often very specific, and are key to the ability of the industry to deliver innovative medicines to patients.

This report provides an up-to-date and robust view on the skills needed now and in the near future for the industry to thrive in the UK. Notably, it highlights **major skills gaps in mathematical and computational areas**, which have emerged due to the rapid development of new disciplines such as systems biology and health informatics. Other skills shortages are more long-standing, such as in **translational medicine/clinical pharmacology**, which requires complex understanding to bridge the gap between bench and bedside. We believe that this evidence will be invaluable to Government, the Science Industry Partnership (SIP), research funders and academia, to inform education and skills policy and investment, and to ensure the right skills base in the UK develops and thrives.

The skills required for research, development, manufacturing and commercialisation of medicines are often very specific, and are key to the ability of the industry to deliver innovative medicines to patients.

The ABPI last reported the skills needs of the biopharmaceutical sector in 2008, following on from our 2005 report. Since 2008, both the industry itself and the science behind new medicines have gone through substantial changes. There have been a number of mergers of large companies, downsizing of UK research and development (R&D) activities and closure of some R&D sites. New medicines often arise following collaboration with academics or small to medium sized companies (SMEs) and, as a result of this, in the future the biopharmaceutical company may be less likely to be the discoverer of the drug molecule. An increasing proportion of new medicines are biologics[3] rather than chemically-processed small molecule medicines, and new medicines are less likely to have been identified through high-throughput screening of banks of compounds and more likely to have been created following mining of data. The medicine may also only be intended for a small subgroup of patients, i.e. a stratified medicine[4] which will be prescribed only after a diagnostic test has confirmed that the medicine is likely to be effective for that patient. These changes will have greatly influenced the skills required by the industry.

With this 2015 report, we benchmark the results of our recent survey, carried out to establish the current and future skills needs for the pharmaceutical industry, against those identified in 2008. Respondents were primarily from pharmaceutical companies and contract research organisations (CROs), with small numbers of respondents from small companies and other organisations. The skills areas identified as the highest priority for action, where over 50% of respondents said that immediate action was required to address difficulties in recruitment, are shown in the chart on page 6.

1 Cornell University, INSEAD, and the World Intellectual Property Organization (WIPO). (2014) *The Global Innovation Index 2014: The Human Factor in Innovation.* http://www.wipo.int/edocs/pubdocs/en/economics/gii/gii_2014.pdf

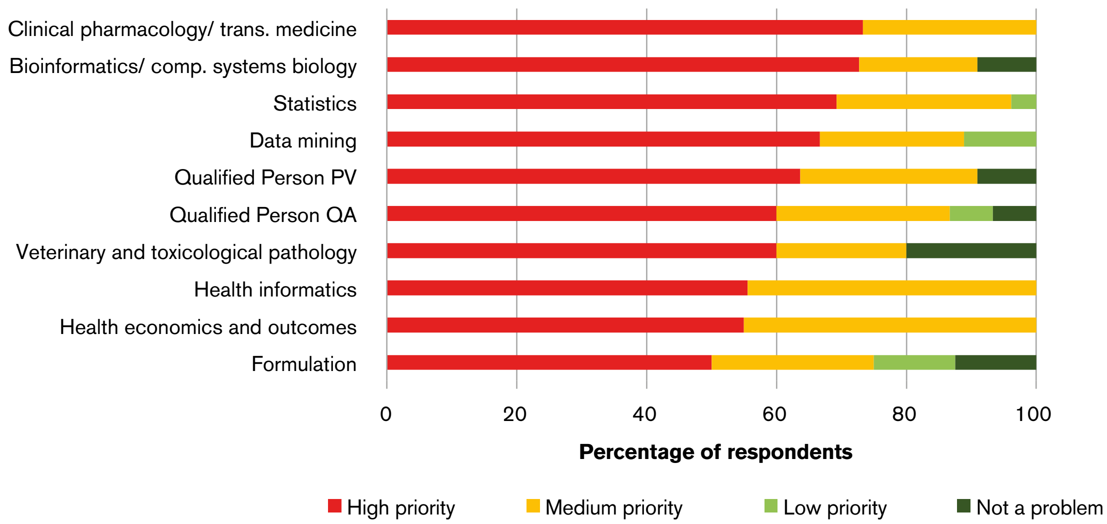
2 The Rt Hon George Osborne MP and The Rt Hon Sajid Javid MP. 2015. ‘Fixing the foundations: creating a more prosperous nation.’ London: HM Treasury, Department for Business, Innovation & Skills.

3 Biopharmaceuticals that need to be manufactured in cells.

4 For further details on stratified medicines (sometimes also referred to as precision or personalised medicines), please see 2014 ABPI report *The Stratification of Disease for Personalised Medicines.* http://www.abpi.org.uk/our-work/library/medical-disease/Pages/100914.aspx

Many of the areas of highest concern relate to mathematical and computational skills, including **bioinformatics, statistics, data mining, health informatics**, and **health economics and outcomes**. Many of these are new fields which were not even raised as future concerns in 2008. In contrast, other disciplines, such as clinical pharmacology/translational medicine and veterinary and toxicological pathology, are long-standing concerns which were previously highlighted by the ABPI.[5] Other disciplines where the skills base is weak include **Qualified Persons**,[6] and **pharmacy formulation**. Generally, the weaknesses relate to both the number and quality of applicants. Recruitment of experienced staff is a concern across all these areas but, for many, there are also issues with recruiting recently qualified graduates and/or PhD/ post-docs.

We have also identified some disciplines which, although not currently areas of high concern, are expected to become more difficult to recruit for in future. Notable amongst these are **device technology** and **materials science, physiological modelling and physical chemistry**. These areas should be taken into account when horizon scanning and defining education, training and professional development strategies for the future.



Highest priority concerns

Our research has also identified that **some of the top skills gaps in 2008 no longer feature** as areas of high concern, including bioscience areas such as drug metabolism and ADME, pharmacokinetics and pharmacodynamics, and *in vivo* sciences. This may in part be due to the changing landscape of the pharmaceutical industry, but is also likely due to a number of initiatives that were funded and taken forward in response to the ABPI findings. These included collaborative capacity-building activity involving both industry and other funders, such as the Integrative Mammalian Biology Centres funded by BBSRC, HEFCE, MRC, SFC, BPS Integrative Pharmacology Fund and BIS; and Advanced Accreditation of undergraduate bioscience degrees by the Royal Society of Biology. Our members conclude that these initiatives have been effective and it is essential that, as funding for some such initiatives approaches its end, activity in these areas continues to avoid recurrence of skills gaps in these areas.

Most core or transferable skills, such as problem solving and application of scientific knowledge, are now less of a concern than in 2008, with the **notable exception of communication and teamworking skills** which seem to be a growing concern for respondents.

5 *Skills needs for biomedical research* (2008) http://www.abpi.org.uk/our-work/library/industry/Pages/skills-biomedical-research.aspx

6 In quality assurance (QA) a Qualified Person is responsible for certifying batches of medicinal products prior to use in a clinical trial or release for sale. Under the European Pharmacovigilance (PV) regulations the QPPV is responsible for creating and maintaining the marketing authorisation holder's pharmacovigilance system which must fulfil the legal obligations regarding product safety.

Recommendations

Based on the findings reported here, we make the following recommendations to address both current and future skills needs for the pharmaceutical and biopharmaceutical industries, and ensure the continued viability of this important sector in the UK:

- The Science Industry Partnership (SIP) Board[7] should review the evidence and consider action that could be taken through the SIP to address the skills concerns identified.

- In areas where evidence suggests that high level and professional skills are concerns across both industry and academia, action will be sought through the Research Councils and appropriate Professional Bodies.

- The pipeline for the development of appropriate mathematical skills must be considered. This extends from opportunities for students to study maths alongside science subjects post-16, through universities putting increased emphasis on maths in bioscience courses, to raising awareness and uptake by UK and EU graduates of Masters and PhD level training in statistics, data mining, mathematical modelling and related disciplines.

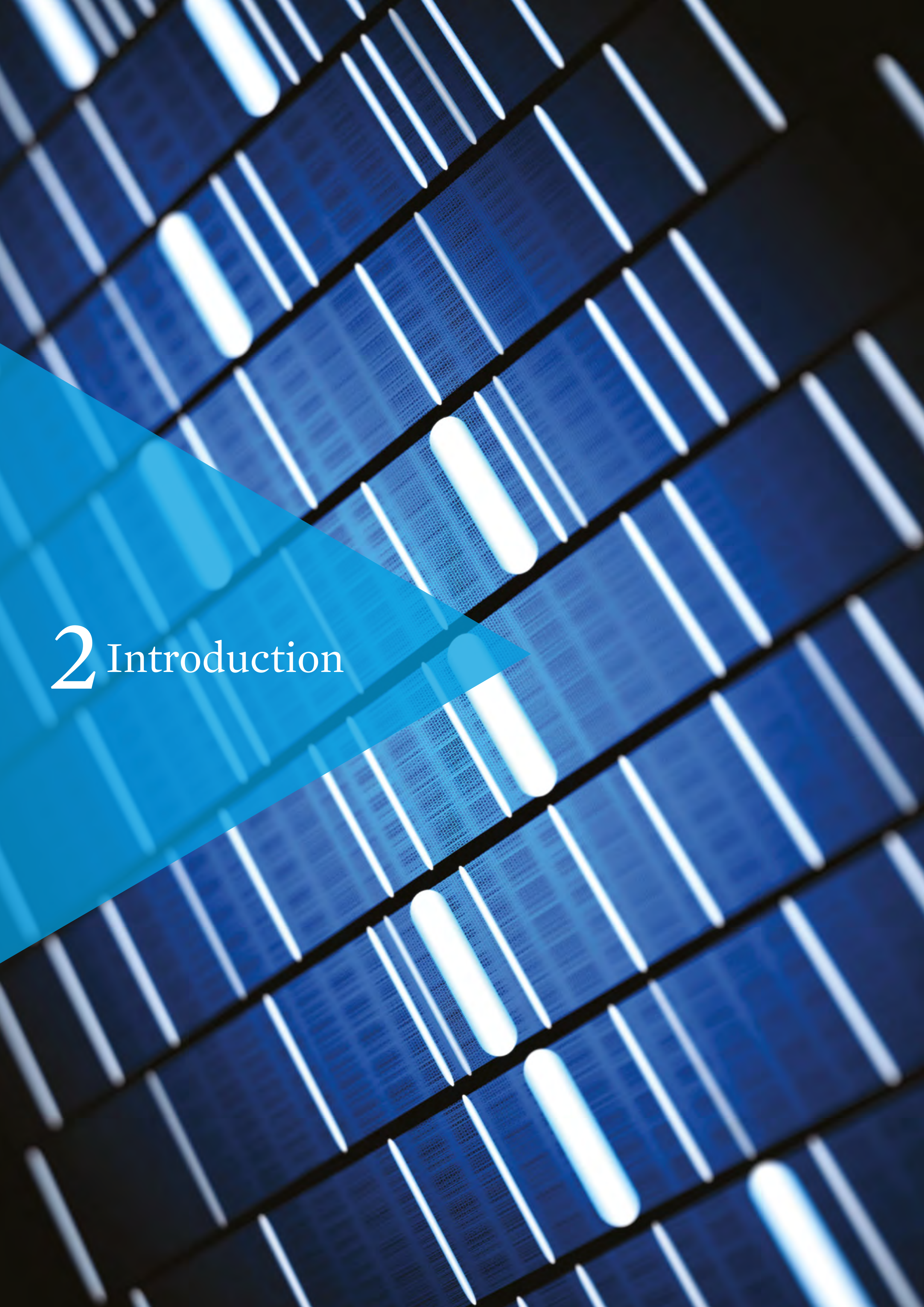
- ABPI Expert Network Groups,[8] and the Medicines Manufacturing Industry Partnership (MMIP) Skills group[9] (for manufacturing concerns), should monitor the critical disciplines in their area and raise concerns when it is becoming more difficult to recruit people with the skills required or when new needs are identified. The Expert Networks, through discussion with stakeholder organisations and the ABPI's Academic Liaison Expert Network, should also consider what action is required and how best it should be taken forward.

7 http://www.scienceindustrypartnership.com/home/

8 http://www.abpi.org.uk/about-us/how-we-work/Pages/working-members.aspx

9 http://www.abpi.org.uk/our-work/mandi/Pages/manufacturing.aspx

2 Introduction



2.1 Industry landscape

In 2013, the pharmaceutical industry accounted for 22% of all R&D expenditure in the UK investing around £4.1 billion. This was double the amount invested by the second highest placed product group (motor vehicles and parts). However, this was the second consecutive year the industry has decreased its expenditure (Figure 1).[10] The pharmaceutical industry in the UK is facing various challenges such as the slow uptake of innovative medicines and the increasing savings pressure from the NHS.[11] These trends must be reversed to ensure that the leading position of the industry is maintained. One of the key aspects is investing in the skills needs and ensuring that the industry's requirements are met across all discipline areas as well as for core competencies.

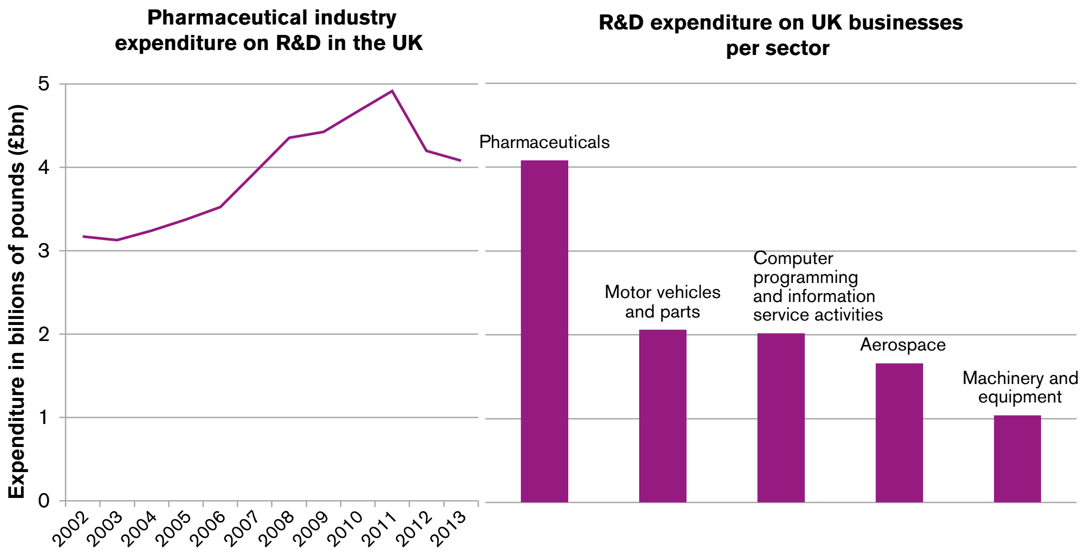


Figure 1: R&D expenditure in the UK by the pharmaceutical industry since 2002 and per sector in 2013[10]

2.2 Recruitment trends

70,000 people

Employed in the pharmaceutical industry

6,200 people

Employed by specialist companies providing services to the industry

In the UK, the industry employs over 70,000 people with a further 6,200 people working for specialist companies supplying services to the sector.[12] Nevertheless, in recent years, top pharmaceutical companies have closed down research facilities and data suggest that, between 2000 and 2010, the global pharmaceutical industry's headcount was reduced by over 300,000.[13] This will have created a pool of experienced and skilled individuals who can be distributed into other companies, SMEs, or CROs, reducing some pressure on current recruitment. However, this means that in the future, recruitment of skilled individuals may become an increasing concern, as the sector settles to a new equilibrium, and the pool of experienced staff dissipates. Given that this report highlights skills areas which are a concern even in the current recruitment environment, these concerns are likely to increase in the coming years.

10 Office for National Statistics (ONS). (2014) *Business Enterprise Research and Development*. Available from: http://www.ons.gov.uk/ons/dcp171778_385959.pdf

11 ABPI. (2014) *Delivering value to the UK: the contribution of the pharmaceutical industry to patients, the NHS and the economy*. Available from: http://www.abpi.org.uk/ourwork/library/Documents/delivering_values_dec2014.pdf

12 Department for Business, Innovation and Skills (BIS). (2013) *Strength and Opportunity 2013*. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/298819/bis-14-p90- strength-opportunity-2013.pdf

13 LaMattina, John. 'The Silver Lining in Big Pharma Layoffs and Site Closures? A Redistribution of Talent and Resources.' *Forbes*, 12 March 2015. Available from: http://www.forbes.com/sites/johnlamattina/2015/03/12/a-silver-lining-in-big-pharma-lay-offs-and-site-closures-a-redistribution-of-talent-and-resources/

2.3 Education

The number of science graduates from UK universities has increased over the past few years, however this increase has not been as great as in countries such as the US and Germany. The number of science, technology, engineering and maths (STEM) graduates increased by 18% over the past 10 years in the UK. This increase is mainly due to an increased number of students with other EU (non-UK) and non-EU domiciles, which was 72.1% and 50.9% respectively, whereas the number of graduates with UK domicile only increased by 14.2%. The subject areas with the greatest increases in number of graduates were mathematical sciences (51.1%), veterinary sciences (44.6%) and biological sciences (44.0%) while the number of computer science graduates decreased by 26.7%.[14]

In terms of apprenticeships, both level 2 and level 3 science, engineering and technology (SET) apprenticeships have increased since the early 2000s, though the increase has been less dramatic than in non-SET areas. Only a small number of people started a SET-related Level 4 or above apprenticeship in 2012-13. Furthermore, entry into separate science (Biology, Chemistry and Physics) GCSEs has been increasing significantly over the past 10 years, although 2014 saw the first decrease since 2005. The increasing numbers taking separate science GCSEs has been reflected in an increase in take-up of all these subjects at A-level, along with significant increases in the numbers of students taking A-level maths and further maths. (The Gatsby Charitable Foundation 2014).

Biological sciences and subjects allied to medicine are still amongst the three most popular subjects in higher education, together with business and administrative studies, while mathematical sciences, for example, is studied by few undergraduates (HESA 2014). It is essential that the number of science graduates and students is sustained and keeps increasing in the future.

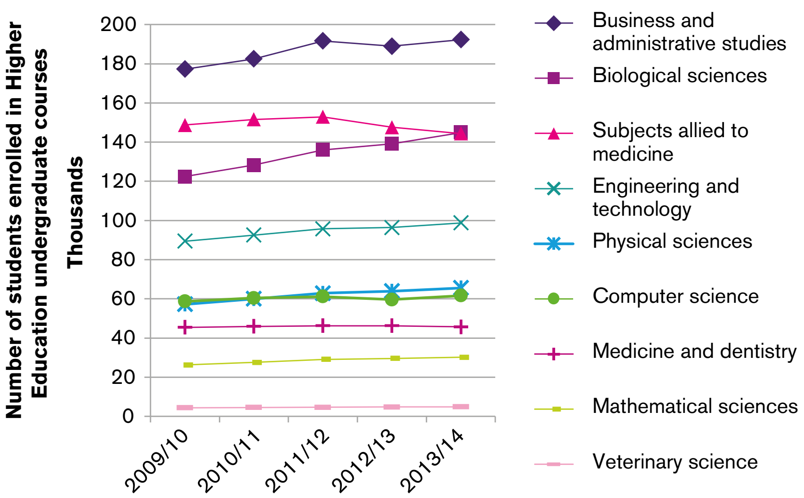


Figure 2: Number of students enrolled in HE per subject between 2009 and 2014 (HESA 2014)

2.4 Aims and objectives

The objective of this survey and report is to generate robust evidence of the current skills needs and future concerns in the pharmaceutical and biopharmaceutical industries, particularly comparing these to the areas identified in our 2008 report. This can be described in three main aims:

- Benchmark changes in the current and future skills needs for the pharmaceutical industry against those identified in 2008.
- Assess how well the UK education and skills system is meeting these needs.
- Identify activities and actions by the various stakeholders, including Government, research and training funders, academy and industry which could address new or ongoing skills needs identified.

14 The Gatsby Charitable Foundation. (2014) *Key Indicators in STEM Education*. Available from: http://www.gatsby.org.uk/uploads/education/reports/pdf/key-indicators-in-stem-education-gatsby.pdf

3 Methodology

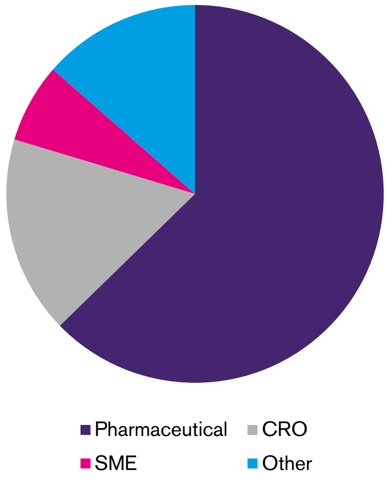


Figure 3: Proportion of participating companies in each sector

An online survey seeking views on the difficulty of recruiting suitably qualified and skilled people to work in the sector was created. The survey was designed to provide data which could, as far as possible, be compared with those obtained in 2008 when the ABPI last reported data on the skills concerns of the sector.

Responses were sought from pharmaceutical and biopharmaceutical companies, contract research organisations (CROs), specialist recruiters and other organisations. The survey data were collected between September 2014 and May 2015.

In total there were 93 respondents from 59 different companies. Twelve companies gave more than one response covering different discipline areas. The majority of respondents were from pharmaceutical companies, with other respondents from CROs, small to medium enterprises (SMEs), higher education institutions, learned societies, recruitment companies and healthcare agencies (Figure 3).

The survey was grouped into the overarching science areas of biological science, chemical science, clinical, pharmacy, informatics, computational, mathematical and statistics, and regulatory areas. Within each of these overarching areas individual disciplines were listed. The definitions for these disciplines were the same as those used for our earlier survey if the discipline was included in 2008. Participants were asked to comment on concerns with recruitment into the discipline areas that were relevant to them and/or their companies, as well as general questions about core competencies.

For each discipline area respondents were asked:

- Whether there is a problem with the number and/or quality of candidates
- Whether recruitment for this area is expected to become more difficult in future
- To rank the area's priority as low, medium or high
- What qualification level of candidate recruitment is affected
- To rate the level of concern with practical skills (where applicable).

Additional general questions sought information on core competencies, which were rated in terms of how much of a concern they are. Information on the qualification level of individuals that companies are recruiting and where these individuals are being recruited from was also sought. (For a general version of the questionnaire and a list of discipline areas included, see Appendix 6.1, Survey.)

Data from the Medicines Manufacturing Industry Partnership (MMIP) process development and manufacturing skills survey gathered during 2014 have also been included in this report, by merging responses for overlapping areas and adding discipline areas not included in the ABPI skills survey. There were 26 responses to the MMIP survey from 16 different companies grouped into five sectors (Figure 4). This survey was divided into three parts, the first one addressing core competencies, the second determining the skills needs for specific areas and finally a section to drill down into five major concerns.

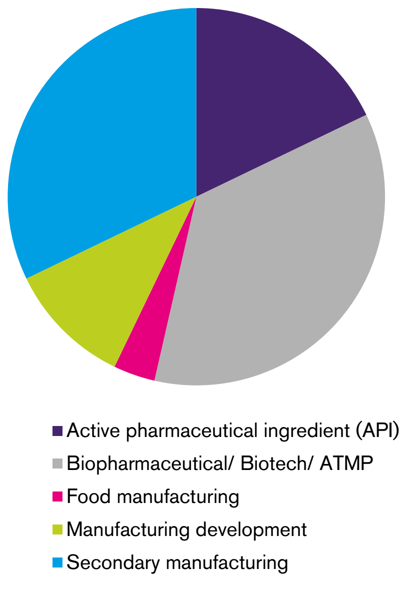


Figure 4: Proportion of respondents from each sector in the MMIP skills survey

These three parts included the following questions:

- Core competencies:
    - Importance to organisation
    - Ease of acquisition of people with these competencies (develop or recruit)
- Skills needs for specific areas (Appendix 6.5):
    - Importance to organisation
    - Size of skills gap
- Drill down into respondent's top five areas of major concern in the areas of skills need: in particular ranking concerns relating to:
    - Recruitment
    - Retention
    - Training and development
    - Need for additional resource over next three years
    - Qualification and experience requirements of these new candidates

4 Findings and discussion

4.1 Top priorities

The data obtained were analysed in order to determine top priority areas where immediate action is required to address skills gaps. Any discipline area with over 50% of respondents identifying it a high priority was considered a top concern and thus was further analysed. Results and findings for other discipline areas can be found in the appendices. In this section we identify the disciplines of highest priority. These are then discussed further below under their broad scientific areas.

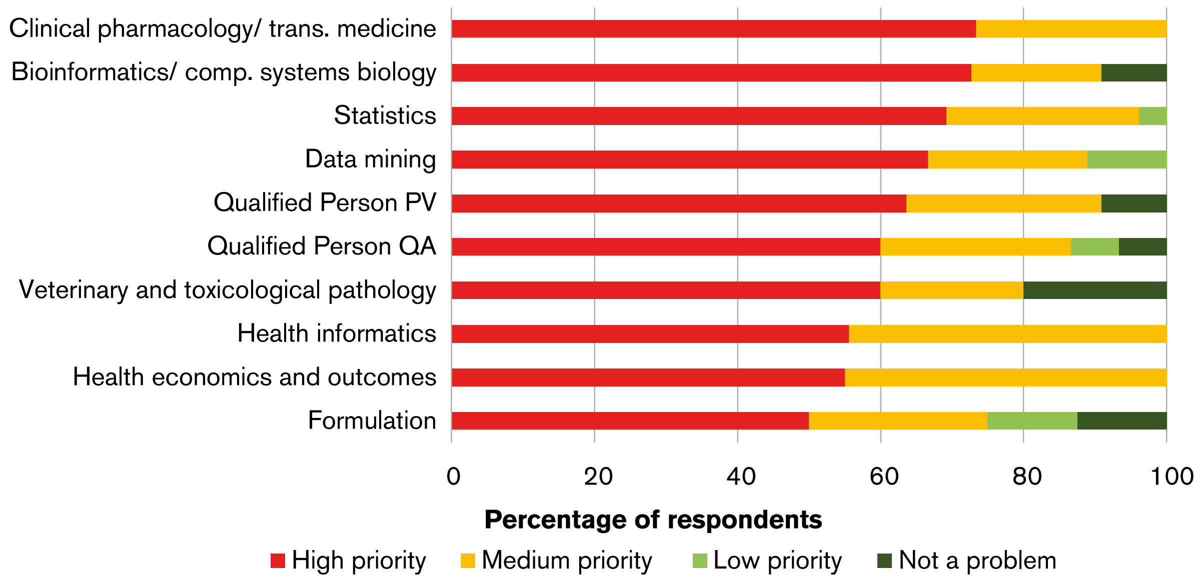


Figure 5: Percentage of respondents rating each top priority discipline as high, medium or low priority or identifying it as 'not a problem'

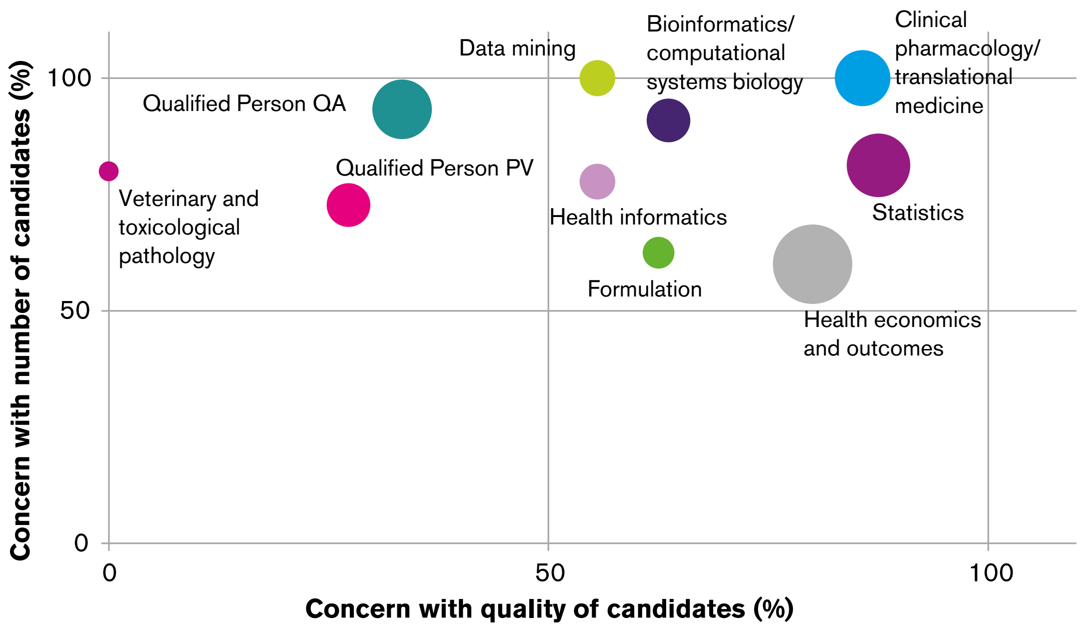


Figure 6: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area

Many of the highest priority areas fell into the informatics, computational and mathematical category. This included statistics, health informatics, health economics and outcomes, data mining, and bioinformatics/ computational systems biology. For all of these disciplines, over 90% of respondents rated them medium or high priority, and raised concerns around both quantity and quality of candidates. This highlights the area of computational and mathematical skills as a key concern for the industry, and this is reflected in the recommendations of this report.

Other top priority areas include clinical pharmacology/ translational medicine, which has been highlighted as a key skill gap in other reports, and is vital for translating basic research into medicines for patients. Additionally, Qualified Persons, both in pharmacovigilance (PV), and quality assurance (QA), were top priorities.

The disciplines epidemiology and pharmacoepidemiology and clinicians were also very close to having 50% of respondents rating them as high priority (45% and 48% respectively).

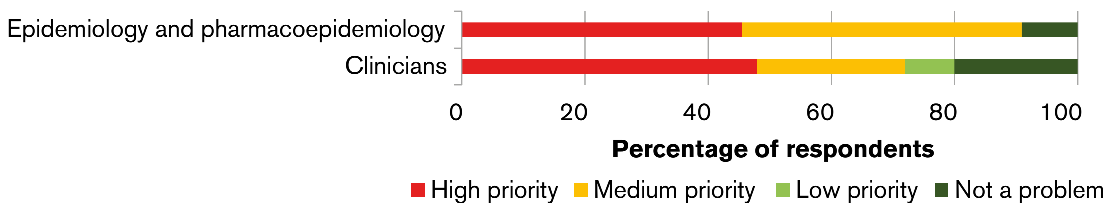


Figure 7: Percentage of respondents rating each top priority discipline as high, medium or low priority or identifying it as 'not a problem'

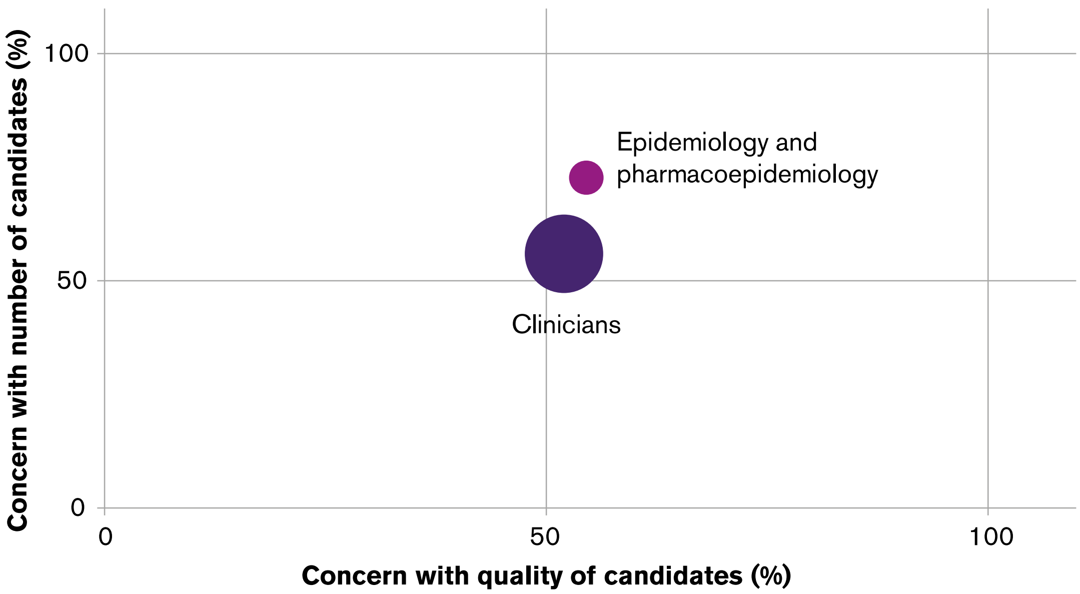


Figure 8: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area

The following areas also appear to be high priority but, as each of these disciplines was only commented on by a small number of individuals, further work is required to confirm this.

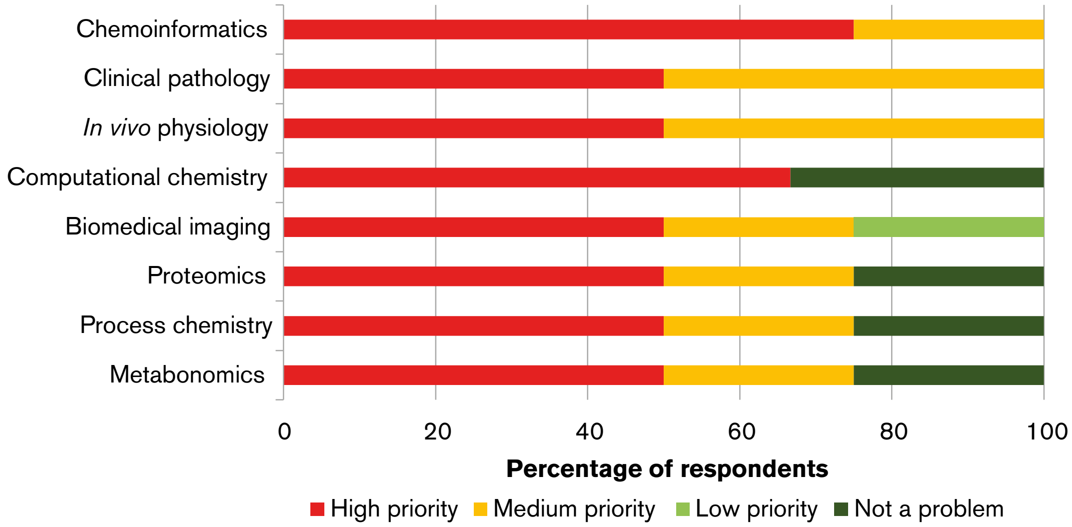


Figure 9: Percentage of respondents rating each top priority discipline as high, medium or low priority or identifying it as 'not a problem'

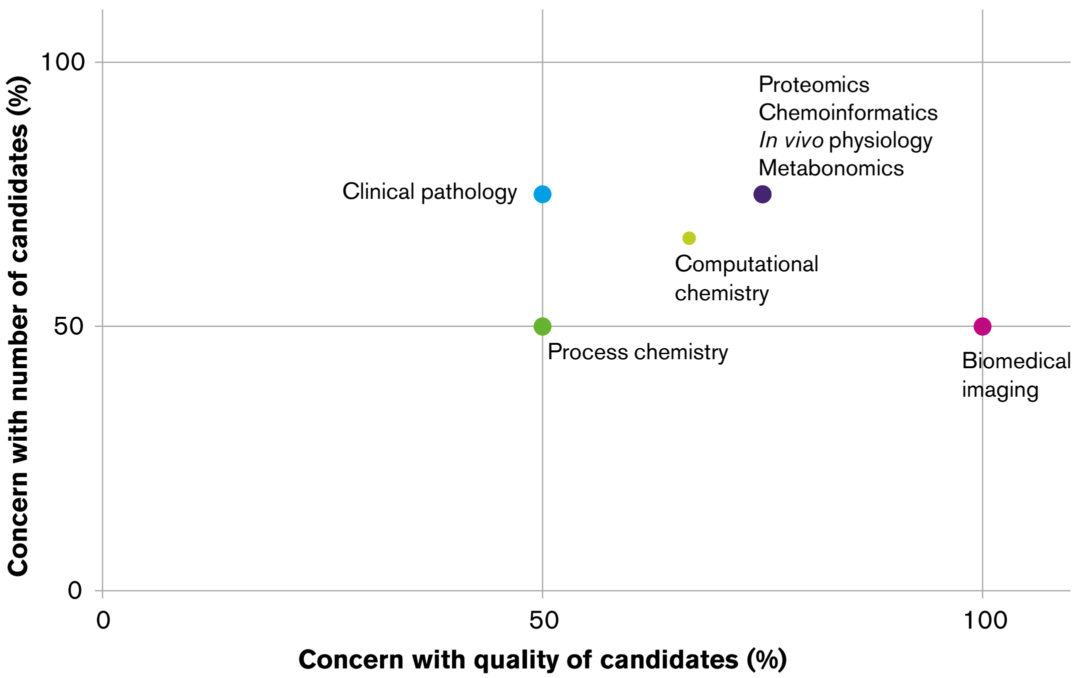


Figure 10: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area (chemoinformatics, proteomics, in vivo physiology and metabonomics have overlapping results)

For areas within manufacturing, the MMIP survey found difficulties in finding the right skills and know-how in several areas, particularly advanced therapy medicinal products (ATMP), vaccines and biologics. Within quality operations, validation skills were identified as a significant gap and statistics skills is also an area of concern.

Process engineering skills and, more specifically, the skills required for process development and scale-up, are seen as a significant issue, as are skills for sterile product manufacture and aseptic processing.

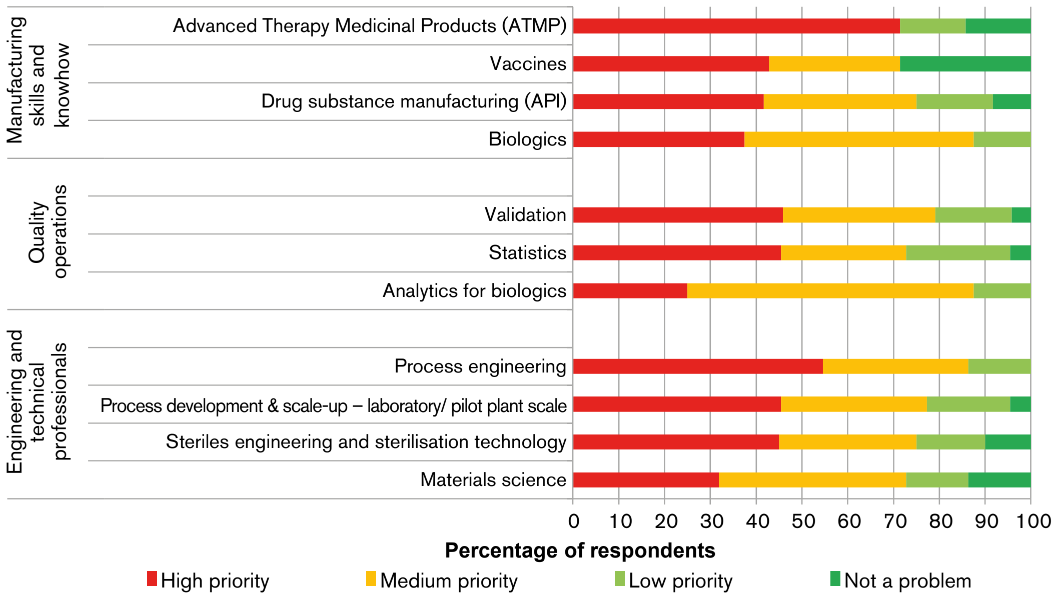


Figure 11: Percentage of respondents rating each high priority manufacturing discipline as high, medium or low priority or identifying it as 'not a problem'

4.1.1 Biological science areas

For detailed data on these areas see Appendix Section 6.4.1.

Some concerns were highlighted over both the quality and number of candidates in the biological sciences, although this area was overall of a lower concern than informatics, for example, and a lower concern than in previous years. Within the biological sciences the disciplines of highest concern were veterinary and toxicological pathology, *in vivo* physiology, proteomics and metabonomics, which over 50% of respondents rated as a high priority. Other areas, such as molecular/ translational toxicology and genomics, did not have as many high priority ratings but were not identified by any respondents as a low priority or not a problem. Thus, although with less urgency than top priorities, action is still required to address concerns over skills for these disciplines.

Subjects with over 70% combined medium and high priority ratings, including biotechnology, drug metabolism and ADME, toxicology, *in vivo* pharmacology and biopharmaceuticals/biologics, should also be considered concerns and further evaluation of skills in theses disciplines would be useful to determine the extent of the issue.

Practical skills are a major concern in *in vivo* physiology and genomics, while the majority of respondents rated practical skills for most other disciplines as a concern. In contrast, in areas such as structural biology and microbiology there was a much lower level of concern over practical skills.

Concerns identified for some biological science areas in 2008 led to our recommendation for accreditation schemes to be designed and implemented for biological science courses. The Royal Society of Biology now has in place two types of accreditation: advanced accreditation, which can be sought for degrees that deliver the skills and experience needed to enter a successful research career in the biosciences; and degree accreditation for programmes which contain a solid academic foundation in biological knowledge and key skills, and prepare graduates to address the needs of employers.

Veterinary and toxicological pathology

In industry, pathologists establish disease models to be used in assessing drug candidates by measuring changes caused by medicines. Veterinary pathologists analyse histopathological evidence from toxicity studies to determine whether any changes recorded are due to normal processes or caused by the medicine under investigation.

'Recruitment and training of toxicological pathologists is a long-term commitment in terms of time of experienced pathologists and in financial terms'

'Small pool of experienced pathologists available'

This discipline was the area of highest concern in the biological sciences. High levels of concern were expressed about the number of candidates available. Veterinary pathology training is not only an economic investment for employers, but is also very time demanding, requiring several years training beyond a veterinary degree.

In vivo physiology

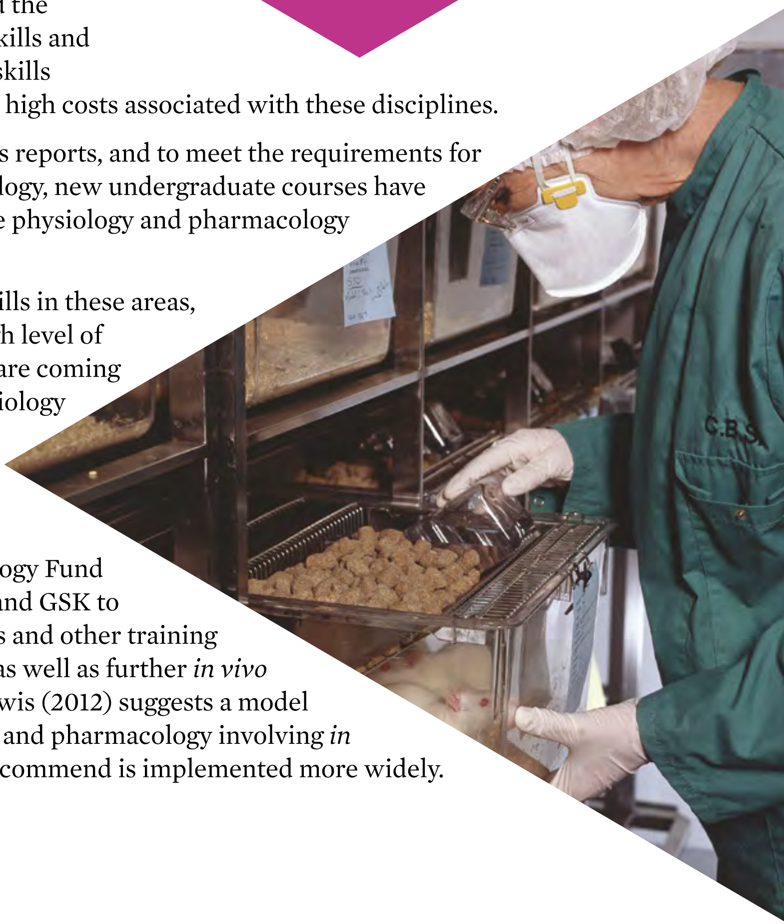
In vivo physiologists set up animal models to understand the disease processes, helping to identify therapeutic targets and to elucidate the underlying mechanism of potential drugs. *In vivo* areas were one of the top priorities in 2008 and, although concerns over *in vivo* pharmacology and animal technology have reduced slightly, they are still medium priorities. Very few people rated these areas as low priority or stated that they are not a problem. *In vivo* physiology is still a major concern in both quality of and number of candidates.

Practical skills are a concern, but not a major one. The qualification levels most affected by these problems are graduates/MScs, PhDs and post-docs. No respondents indicated that recruitment of non-graduates or experienced staff was an issue.

'Most graduates don't understand how everything in vitro comes together to have an effect on the whole animal phenotype'

Our findings parallel those identified by the Biotechnology and Biological Sciences Research Council (BBSRC) and the Medical Research Council (MRC) in their vulnerable skills and capabilities survey from 2014.[15] They identified strong skills needs in both academia and industry, in part due to the high costs associated with these disciplines.

In response to the concerns raised in our previous skills reports, and to meet the requirements for Advanced Accreditation set by the Royal Society of Biology, new undergraduate courses have been created to deliver increased training in integrative physiology and pharmacology and develop strong experimental skills.



Although various efforts have been made to develop skills in these areas, including the undergraduate courses, there is still a high level of concern as many of the current funding commitments are coming to an end. Initiatives such as Integrative Mammalian Biology (IMB) centres and joint British Pharmacological Society (BPS) and Physiological Society short courses in integrative pharmacology and physiology are facing challenges as funding for these comes to an end. Other interventions have included the Integrative Pharmacology Fund (IPF), a £4 million donation from AstraZeneca, Pfizer and GSK to support *in vivo* research and training at UK universities and other training opportunities. These approaches need to be sustained as well as further *in vivo* exposure included at undergraduate and MSc level. Lewis (2012) suggests a model for an undergraduate module in integrative physiology and pharmacology involving *in vivo* practical and theoretical experience[16] which we recommend is implemented more widely.

15 BBSRC and MRC. (2014) *Review of Vulnerable Skills and Capabilities*. Available from: http://www.mrc.ac.uk/documents/pdf/review-of-vulnerable-skills-and-capabilities/

16 Lewis, D. 'Educating the Next Generation of In Vivo Scientists: Meeting the Needs of Industry and Academia.' *ALTEX Proceedings 1*, no. 1 (2012): 361-364. Available from: http://www.altex.ch/resources/361364_Lewis131.pdf

Proteomics and Metabonomics

Proteomics is the large-scale study of proteins' structure and function to identify new biomarkers and potential drug targets. Metabonomics looks at changes in metabolites in a cell or organism to determine the toxicity of potential drug targets. In 2008, 'omics' disciplines were rated together and were considered a medium priority but predicted to become high priority in the future. In 2014, these areas only had two participants identifying them as 'not a problem', while everyone else rated them as medium or high priority.

'It is a very varied discipline and achieving sufficient exposure and experience to cover the breadth of the discipline is a challenge'

'Training from experienced staff is crucial in this role, academia must work with industry to improve data interpretation skills'

'A lot of candidates seem to have a poor grasp of issues such as quality control, technical noise minimisation and multi-test correction'

Proteomics and metabonomics are the 'omics' areas with the greatest number of high priority ratings and where concern was expressed around both quality and number of candidates. However, for genomics there is a greater worry about the quality of candidates. Again, this was an issue affecting mainly graduates/ MScs, PhDs and post-docs although some concern was also identified in recruitment of experienced staff. Practical skills are a concern, but not a major one.

4.1.2 Chemical science areas

For detailed data on these areas see Appendix Section 6.4.2.

Chemical science areas were generally not rated as high priority areas, with the exception of process chemistry, where a problem was identified across all qualification levels except experienced staff and non-graduates in the small number of responses received for this discipline. Practical skills were also a major concern in process chemistry although not so much in other chemical science areas.

'Scarcity of experienced people available in the job market with a suitable blend of experimental and theoretical knowledge'

Process chemistry

Process chemists develop the chemical syntheses for the large-scale preparation of molecules progressing into advanced clinical studies and the synthetic routes for commercial manufacture. In 2008 this area was rated as a medium priority together with medicinal or synthetic organic chemistry. Whilst in 2008 this affected mainly PhD and post-doc recruitment, graduate recruitment is now also rated high priority. This suggests that the situation in process chemistry has worsened slightly, which was predicted in 2008 due to the increase in the use of biotechnology processes in the pharmaceutical industry.

Skills Development Scotland also identified a shortage in chemical process technicians (HNC/D) and the potential growth of industrial biotechnology requiring new skills entering the labour market.[17] Furthermore the Chemistry Growth Strategy Group recommends addressing the specific need for more professionally accredited technicians and apprentices, promoting training and qualifications that meet the 'Cogent gold standard' and reinforcing accredited training at graduate, masters and post graduate level.[18]

4.1.3 Clinical areas

For detailed data on these areas see Appendix Section 6.4.3.

The only clinical area rated as a high priority in 2008 was clinical pharmacology/ translational medicine, which was considered a crucial top priority, as it was in 2005. In 2014, it is still rated as an important area that requires immediate action. Although a majority of respondents did not rank clinicians and clinical research operations as high priority, both areas were rated at least as a medium priority by more than 60% of respondents, which indicates that some action is required. A problem with recruitment of experienced staff is seen across all clinical areas.

17 Skills Development Scotland. (2014) *Skills Investment Plan: For Scotland's chemical sciences sector.* Available from: http://www.skillsdevelopmentscotland.co.uk/media/1266192/chemical_sciences_digital_skills_investment_plan.pdf

18 Chemistry Growth Strategy Group. (2013) *Strategy for Delivering Chemistry-Fuelled Growth of the UK Economy.* Available from: http://www.cia.org.uk/Portals/0/Documents/Growth%20Strategy%20FINAL.PDF

Clinical pharmacology/ translational medicine

Clinical pharmacology provides industry with analysis of wanted and unwanted effects of medicines on patients and clinical trial participants. Translational medicine covers the research done at the interface between basic scientific discoveries and patient care through use of medicines. Experts in this area are key for industry, as they provide critical knowledge on both the pharmacokinetic/ pharmacodynamic properties of medicines, as well as in-depth expertise on the pathophysiology of diseases. They have a key role in clinical research and their contribution is essential to improve the success rate of early phase trials.

'A high priority as this is an existing problem to find good clinical pharmacologists with a good knowledge of the R&D requirements in industry'

Survey results show that this is a solid priority area, with over 70% of respondents rating it as high priority and the remaining as medium priority. This trend follows on from 2008, where this discipline was already considered a top priority and both the quality and number of candidates were an issue. This is still a major issue now, as almost every respondent in this discipline stated that there was a problem with both the quality and number of candidates. There is an issue with recruitment across all levels other than non-graduates, with recruitment of medically qualified staff and those with MD/ PhD qualifications standing out as slightly higher concerns and recruitment of graduates/MSc marginally less of an issue. Practical skills were also rated as a major concern by the majority of respondents, with no one marking it as 'not a problem'.

Again, these findings are aligned with those of the vulnerable skills and capabilities survey from the BBSRC and MRC. Their report indicates a limited pool of individuals able to bridge the gap between basic research and clinical interface due to a lack of experience in both basic and clinically-applied approaches, which is seen as an unattractive career path.[19]

This area has been a long-standing problem and reports from the BPS concur with these findings, stating the urgent need for clinical pharmacologists with broader training and industry awareness. Training schemes launched to address this need have included a substantial investment by the MRC in a clinical pharmacology and pathology programme, and programmes by the Wellcome Trust.[20] However, continued attention and investment is required to maintain and build capacity in this area. Other initiatives include the Translational Research Partnerships (TRP) developed by the National Institute for Health Research (NIHR) Office for Clinical Research Infrastructure (NOCRI), which aim to increase collaboration between academia and industry and overcome challenges in early clinical development.

In 2014 the number of Clinical Pharmacology and Therapeutics (CPT) consultants in the UK was only 77, while the Royal College of Physicians in London has recommended a workforce of 440, one in each large district general hospital and one per 180 training medical students.[21]

Overall, these findings confirm the importance of clinical pharmacology and translational medicine in the UK pharmaceutical industry and highlight the skills shortages and the urgent need for development of a skilled workforce.

Clinicians

Doctors have various important functions within the pharmaceutical industry, especially in supporting clinical research and clinical trials. This is a high priority issue affecting all qualification levels relevant to the discipline (MD, MD/PhD and experienced staff). This discipline was rated as a high priority by nearly 50% of respondents and was one of the areas with the greatest number of respondents, indicating a very high level of concern. This has risen since 2008 when it was considered a medium priority. One of the biggest problems in industry is attracting graduates into the pharma sector; awareness of the roles available for clinicians in the pharmaceutical industry needs to be increased amongst medical students and doctors in the early stages of their careers.

19 BBSRC and MRC. (2014) *Review of Vulnerable Skills and Capabilities*. Available from: http://www.mrc.ac.uk/documents/pdf/review-of-vulnerable-skills-and-capabilities/

20 http://www.wellcome.ac.uk/Funding/Biomedical-science/index.htm

21 British Pharmacological Society. (2014) *A prescription for the NHS: Recognising the value of clinical pharmacology and therapeutics*. Available from: http://www.bps.ac.uk/BPSMemberPortal/media/BPSWebsite/BPS_A_prescription_for_the_NHS_FINAL_SP%281%29.pdf

Clinical pathology

Clinical pathologists study the nature of diseases and the structural and functional changes they cause, to establish disease models and assess potential therapies. Clinical pathology skills shortages were identified mainly at PhD and experienced level, where the main problem is the low number of candidates available and to a lesser extent their quality. Most respondents agreed that the practical skills gap was a concern, but not a major one. In 2008, pathology was rated overall as a high priority and seen as an increasing problem for the future.

4.1.4 Pharmacy

For detailed data on these areas see Appendix Section 6.4.4.

Within the pharmacy section, formulation stands out as a top priority, with 50% of people rating it a high priority and just over 20% rating it as a low priority or not a problem.

Device technology did not have a majority of high priority ratings but still requires action, as a large number of participants rated it medium priority and no one identified it as being a low priority or not a problem at all. It is also considered an increasing concern for the future by the majority; the main issue lies in the number of candidates as opposed to their quality.

There is a significant concern (>60% of the respondents) in recruiting experienced staff across all three areas and although issues in recruitment occur for other qualification levels, none were specified by a majority of respondents.

Formulation

Formulation involves the generation of a medicine to deliver the active substance to its target in the body, at the right concentration and at a suitable rate. Survey findings show a problem with recruitment around both the quality and the number of candidates and a major concern regarding the practical skills of applicants.

'Main issues are recruiting anyone with relevant experience (...) Best approach is to bring in new graduates from a scientific background or non-graduates with an interest in science. Relevant skills are then taught on employment.'

Formulation is an important discipline in the pharmaceutical industry: economically, formulation technology has a gross value added (GVA) of £172,000 per employee.[22] Nevertheless, apart from a few undergraduate and postgraduate qualifications (such as the MSc in Formulation Science offered by a small number of universities), there is a lack of vocational, undergraduate or postgraduate courses that focus on formulation. This is mainly due to its multidisciplinary nature, and although elements of this discipline are taught within some other science subjects, and a few short courses are available, they do not provide a comprehensive enough approach. Therefore, companies tend to rely heavily on in-house training rather than on external training bodies. According to a 2013 report,[23] the main skills gaps are in the technical and R&D workforce. Cogent is working with iFormulate to address skills and training gaps, by developing modules leading to a Masters-level qualification and Gold Standards for formulation technology. The Gold Standard scheme provides a set of skills and training standards for each role and the appropriate training to close these gaps, as well as access to qualifications from National Skills Academy accredited training providers.

4.1.5 Informatics, Computational, Mathematical and Statistics areas

For detailed data on these areas see Appendix Section 6.4.5.

This is the scientific area with the greatest skills needs reported in this survey. Many of the disciplines within this section have over 50% of respondents listing them as a high priority. Many of these are emerging subjects which were not rated in the ABPI's 2008 survey but now have a high skills demand. Only 9% of all respondents in this section rated a discipline as low priority or not a problem, meaning that 91% of participants agree that disciplines in these areas are either medium or high priority, requiring action or urgent action.

There is also a general concern around recruiting experienced individuals, in the main due to the multi-disciplinary and emerging nature of these subjects. Companies find it difficult to recruit individuals with the right set of skills and relevant experience. Recruitment for graduates/MScs, PhDs and post-docs are also

22 UKCES, Cogent and The National Skills Academy (2013) *Formulation Technology: A Market Profile*. Available from: http://www.cogentskills.com/media/1071/lmi-formulation-report.pdf
23 UKCES, Cogent and The National Skills Academy (2013) *Formulation Technology: A Market Profile*. Available from: http://www.cogentskills.com/media/1071/lmi-formulation-report.pdf

important concerns within this section, but the level of concern differs between disciplines. Moreover, skills in this area are in high demand in various industry sectors and academia across the globe. Pharmaceutical companies are finding it difficult to recruit people with knowledge of clinical practice, public health or health economics who are also proficient in analysis of health data.[24]

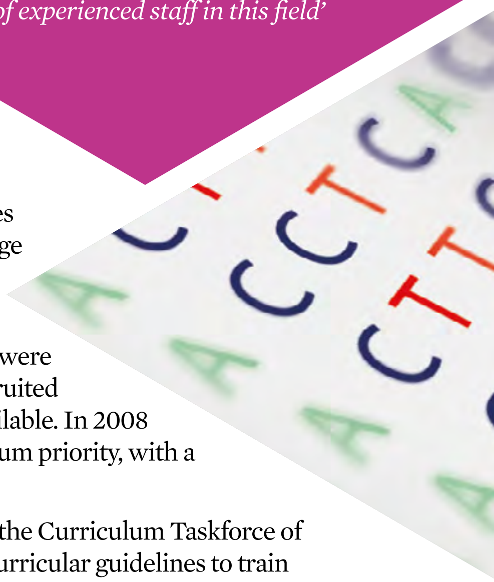
'Lack of candidates with in-depth experience in working with complex UK healthcare data and the combination of theoretical and practical skills'

When looking at the percentage of respondents identifying a concern with the number of applicants and their quality for each high priority discipline (Figure 6), almost all these subjects fall into the highest concern quadrant. This indicates a significant level of concern over both the quality and the number of candidates from the majority of respondents. Around half of the areas in this section are seen as potentially becoming worse in future.

'There is a lot of competition for these skills both in academia and in the industry'

The amount of data available for analysis is increasing and new sources of health data are likely to become available in the UK through initiatives such as the Clinical Practice Research Datalink, the Farr Health Informatics Research Institute and the Health and Social Care Information Centre. Analysis of large data sets helps to increase efficiency of research and development to create new medicines and to monitor the effectiveness and safety of these medicines. Industry therefore needs to ensure that IT talent is nurtured and retained to take full advantage of the wealth of data being generated to improve health outcomes.

'lack of candidates with in-depth experience'
'lack of candidates with industry experience'
'lack of experienced staff in this field'



Bioinformatics/ computational systems biology

Computational systems biology integrates experimental and computational research to understand complex biological systems. Bioinformatics uses statistical techniques and methods to model and simulate biological systems, using large data sets to predict the activity of medicines in development.

This discipline was rated as medium or high priority by 90% of respondents, indicating the urgent need for action to address skills shortages in this area. Problems were identified at all qualification levels except non-graduates, which are unlikely to be recruited for this area. There are major concerns over the quality and number of candidates available. In 2008 bioinformatics was combined with computational science and was considered a medium priority, with a major concern only around recruiting at PhD and post-doc level.

The skills needs in bioinformatics have been considered by various other authors and the Curriculum Taskforce of the International Society of Computational Biology (ISCB) is developing up-to-date curricular guidelines to train and educate bioinformaticians. Others mentioned by Welch et al. also suggest that bioinformatics content should be incorporated into undergraduate life sciences curricula.[25]

Data mining

The process of analysing data to find correlations or patterns in large sets of data is known as data mining. This is an emerging discipline that was not rated in 2008, but is a high priority in 2015. More than 60% of respondents agreed that urgent action is needed, while only around 10% thought it was a low priority area. There is a recruitment issue across all qualification levels except non-graduates and there is a unanimous problem with the low number of candidates, while the quality of candidates is also considered an issue by most respondents.

'High level of competition for these skills with other industries (...) Data mining overlaps with other domains and often requires multidisciplinary training'

A report by Nesta in 2014[26] also describes the shortage of UK data talent with the skill set that industry experts and managers are seeking. One approach being used by pharmaceutical and healthcare companies is hiring data analysts from other industries and giving them life sciences training, rather than training current employees in technology. Nesta also suggests that the UK data workforce should be developed through targeted training and continuing professional development, as well as raising awareness of the profession, creating better links between employers and higher education and ensuring that immigration laws allow companies to recruit data talent from overseas to fill current skills gaps.

24 PwC Health Research Institute. (2013) *Solving the talent equation for health IT*. Available from: http://www.pwc.com/us/en/health-industries/health-research-institute/publications/healthcare-it-staffing-strategies.html

25 Welch, L. et al. 'Bioinformatics Curriculum Guideline: Toward a Definition of Core Competencies.' *PLOS Computational Biology 10*, no. 3 (2014). Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3945096/pdf/pcbi.1003496.pdf

26 Nesta. (2014) *Model Workers: How leading companies are recruiting and managing their data talent*. Available from: http://www.nesta.org.uk/sites/default/files/model_workers_web_2.pdf

Statistics

Statistics again was a very high concern area with only one person out of twenty-six not identifying it as a high or medium priority. Over 70% of respondents agreed that urgent action is needed to address skills gaps in statistics. This is mainly a problem for graduates/MScs and experienced staff, although recruitment of PhDs and post-docs is also an issue. It is also considered an increasing problem for the future with both the quality and number of graduates available having to be addressed.

Elixir UK provides training in these areas and has conducted a survey amongst bioinformaticians and wet-lab scientists in industry to determine the main skills issues from their point of view. Results show that the most crucial skills for participants were 'data mining of large biological sets' and 'ability to use statistical analysis software packages' chosen by 71.1% and 68.8% of respondents respectively. It also concluded that the most valued bioinformatics training was 'data analysis skills' and 'statistical methodologies', highlighting the importance of this discipline in their roles in industry. Furthermore, around 60% of wet-lab scientists stated that they were 'not so confident' with statistics and over 70% have no programming experience.[27]

'Advanced statistical skills are required (...) We need data scientists – multidisciplinary people with stats, computer programming, health insight and understanding of the data'

It is therefore imperative that new talent is developed through strengthening education systems and providing enough training to enlarge the pool of graduates available and improve their quality. Efforts also need to be made in providing continuing professional development (CPD) for experienced individuals to ensure that they are up to date with technological advances. An Elixir initiative has established a Statistics Working Group to consider this skills gap and find ways to address it. This could include developing career related training tools, such as online or short-course training, which might be provided via a web-based portal to increase visibility and access to quality existing training.

Health informatics

Health informatics deals with the resources, devices and methods required to optimise the acquisition, storage, linkage, retrieval and use of health-related data to improve healthcare outcomes and optimise the development and use of medicines. The increased importance of real world evidence and big data is driving a demand for health informaticians with clinical research and public health knowledge as well as an understanding of analytical methods, such as modelling, programming and biostatistics. Not surprisingly, these people are not easy to recruit and again, this was considered a medium or high priority by all survey participants, with a majority rating it as high priority.

Problems in this discipline are mainly linked to graduates, PhDs and experienced staff, with only around 30% expressing a concern with post-docs and just over 20% identifying an issue at non-graduate level. Similarly to most other areas in this section, there is a general concern with both the number and quality of candidates and health informatics is considered an increasing concern for the future.

Health economics and outcomes

Another key informatics area is health economics and outcomes research (HEOR), which is a branch of economics linked to the supply and demand for healthcare and market equilibrium, including researching healthcare system design and reform as well as aspects of financing, expenditure and purchasing. Again, no one marked this discipline as less than a medium priority and the majority identified it as a high priority where urgent action is needed.

'This is a key area of growth and one which the UK government is investing heavily in, yet we have variable quality candidates and few appearing that are highly skilled in this area'

27 Elixir UK. (2014) *Industry Engagement*. Available from: http://elixir-uk.org/industry-engagement

It is a problem that affects the recruitment of graduates/ MScs, PhDs and post-docs to a certain extent, but mainly experienced staff, identified as an issue by 90% of survey participants. The skills gap is due to both quality and number of candidates and is also considered an issue for the future. This trend follows on from 2008 when, although the area was only considered medium priority, there was already a large concern with the number of candidates available and it was seen as an increasing future concern.

This increased demand is due to a growing set of IT skills becoming desirable to take advantage of emerging research methods and the rising need to prove the value of medicines to public and private payers. A 2013 report by PwC Health shows that many drug and device companies are now starting to prioritise applicants with HEOR or bioinformatics expertise, highlighting once again the importance of these disciplines to industry.[28]

'Technical HEOR skills need to be supplemented with understanding of the uses of HEOR data in HTA/pricing/ reimbursement decision making (...) and an appreciation of the drug development process'

There are a number of established, highly regarded Masters courses that prepare people for this area. However, the demand for these skills is such that additional approaches may be required. Current efforts described in the BBSRC and MRC review of vulnerable skills and capabilities include the UK Health Economics Study Group's early career fellowships in economics of health at early post-doctoral level supported by the MRC, Masters studentship funding by the NIHR and co-funding of PhD students by industry.

Chemoinformatics

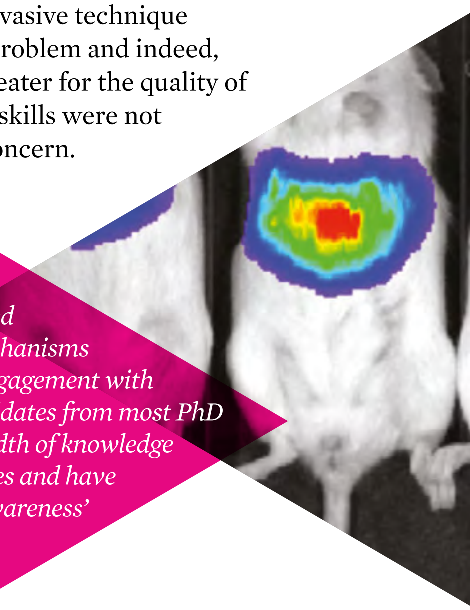
None of the survey participants marked chemoinformatics as less than a medium priority and all qualification levels are affected by the talent concern apart from non-graduates, which is not a level at which people are recruited for this discipline. Like most other subjects in this section, there is a problem with both quality and number of candidates and it is also considered an increasing issue for the future.

Computational chemistry

Companies employing computational chemists had problems finding talent mostly at higher qualification levels including PhDs, post-docs and experienced staff. This was already a major issue in 2008 and was predicted to be an increasing concern for the future. The issue was, and still is, a problem with the quality and number of candidates and participants agree that this problem is likely to be a recurring one.

Biomedical imaging

Biomedical imaging is increasingly used in the pharmaceutical industry as a non-invasive technique during preclinical and clinical studies. In 2008 this area was identified as a future problem and indeed, 50% of respondents marked it as high priority in the current survey. The issue is greater for the quality of candidates than the number of applicants, but this is still a large concern. Practical skills were not identified as a major concern by any respondents, but the majority marked it as a concern.



'We need to develop mechanisms for more industry engagement with PhD programmes (...) candidates from most PhD programmes lack breadth of knowledge about technologies and have no industry awareness'

28 PwC Health Research Institute. (2013) *Solving the talent equation for health IT*. http://www.pwc.com/us/en/health-industries/health-research-institute/publications/healthcare-it-staffing-strategies.html

Epidemiology and pharmacoepidemiology

Pharmacoepidemiology uses epidemiology study techniques to analyse uses and effects of medicines in large, well-defined populations. Although epidemiology and pharmacoepidemiology were not rated as a high priority by the majority, the number of high priority ratings was just under 50% and, together with medium priority responses, they accounted for over 90% of the total. There was also a high concern over the quality and number of candidates available, with a majority of respondents marking it as an increasing problem for the future.

'Increasing demand for epidemiologists and pharmaco-epidemiologists, to satisfy the evidence/ RWD (Real World Data) needs of industry'

'This is both an issue of availability of suitable candidates and of the industry attracting the best of the available talent in this field'

4.1.6 Regulatory areas

For detailed data on these areas see Appendix Section 6.4.6.

All regulatory areas were rated as a medium or high priority area by a majority of respondents. However, recruitment of the Qualified Person (QP) for both pharmacovigilance (PV) and quality assurance (QA) were the top priorities in this section. The level showing the biggest concern for regulatory functions is recruitment of experienced staff, being identified as an issue by over 70% of participants in every area.

Qualified Person PV

A QPPV has an essential function in industry, as European PV regulations require each marketing authorisations holder (MAH) to appoint a QPPV to create and maintain its pharmacovigilance system (PV). This system must fulfil the legal obligations regarding product safety and must be adequately resourced.

Although this was mainly a problem with recruitment of experienced staff, a few people also identified a problem with graduates/ MScs in this field. It is mainly a concern over the number of candidates available rather than their quality. This is probably due to the extensive training required to become a QP.

Qualified Person QA

Qualified Persons working in quality assurance are legally responsible for certifying batches of medicinal products prior to use in clinical trial or release for sale. The skills gap in this area has previously been investigated by Cogent in a report[29] released in 2014 which suggests that although the number of QPs appear to be balanced with the number of manufacturing licences, mapping of these numbers is complex and thus the situation might not be sustainable. The low rate at which new QPs are being certified by professional bodies is also a concern. Our survey findings show that the main issue for QPQAs is with experienced staff and graduates/ MScs to a smaller extent, and similarly to QPPVs, the main problem lies in the size of the candidate pool.

Cogent also reported that this was mainly an issue for small companies, publicly-funded organisations and companies producing novel, niche products. It was reported that from the training QP's perspective, expectations are too rigid and experience and knowledge requirements are too demanding, which contributes to the reduced number of newly qualified QPs. Another trend currently observed amongst QPs was the preference for contract employment rather than direct employment. This is more lucrative and usually involves shorter hours, but for employers, this can have both advantages and disadvantages. While it may be useful to have a contract QP for a specific project with specific knowledge requirements, employers usually find directly employing QPs more beneficial in terms of organisational commitment, continuity, inclusion in management structure and lower costs.

QP certification for both PV and QA not only requires extensive experience and a large investment, but is also difficult to schedule with existing operational demands. This is also seen as a problem for the future.

29 Cogent. (2014) *Qualified Persons in Medicine Manufacture: An Overview.* Available from: http://www.cogentskills.com/media/1068/qualified-personsmainreportoutline_120814.pdf

4.2 Manufacturing top priority areas

For detailed data on these areas see Appendix Section 6.5.

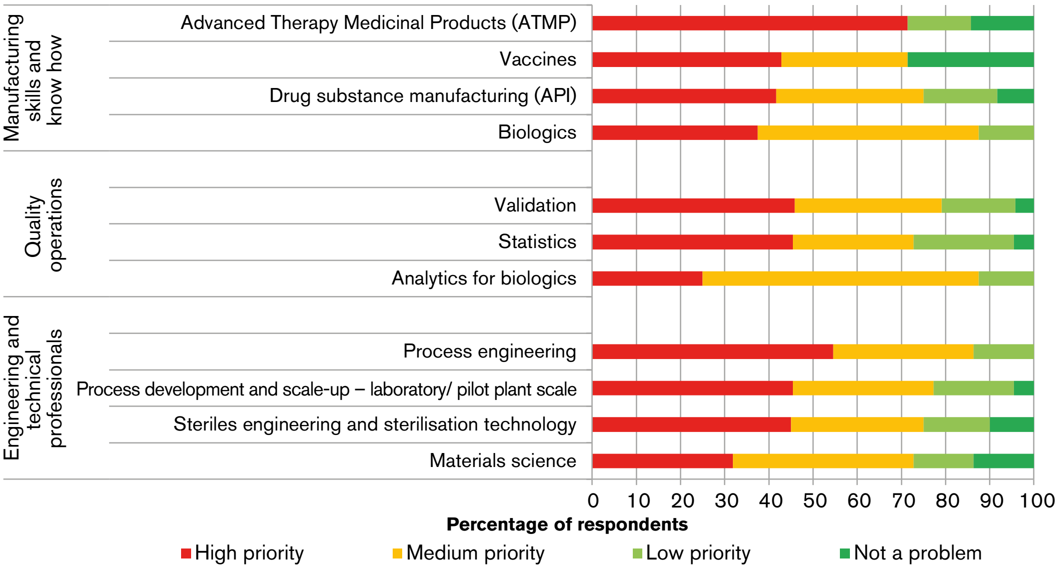


Figure 12: Percentage of respondents rating each manufacturing top priority discipline as high, medium or low priority or identifying it as 'not a problem'

Note: due to differences between the ABPI Skills Survey and the MMIP Manufacturing Skills Survey, a slightly different criterion has been used to identify the priority areas shown above in Figure 12. Figure 12 shows the areas where greater than 70% of respondents rated the area as high or medium priority. Full definitions of each area are given in Appendix 6.5.

Manufacturing skills and know-how

Medicines manufacturing is seeing growth from a relatively or very small base in the large molecule/ biotechnology areas. The survey reports difficulties in finding the right manufacturing skills and know-how in many of these areas, particularly Advanced Therapy Medicinal Products, Vaccines and Biologics. Although it is beyond the scope of the survey to specifically confirm this, this is likely to be due to the relatively small number of trained and experienced people who currently work in this sector, with increased demand from growth due to the rapid development of these new technologies outstripping supply.

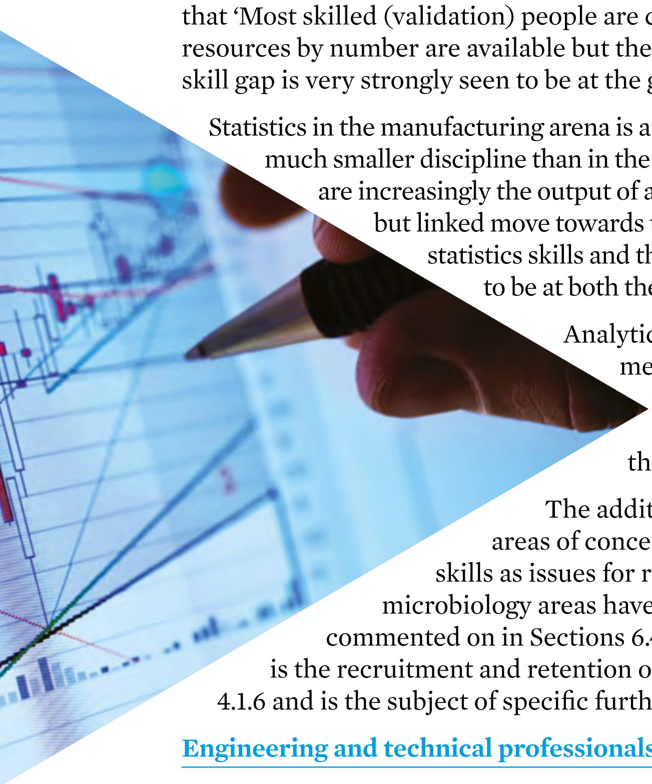
In contrast, drug substance manufacturing in the UK has declined in recent years as companies have outsourced manufacture and/or built-up operations elsewhere, often due to the potential for fiscal incentives and cost savings. This has reduced the size of the UK workforce in this area, making it harder to find skilled and experienced people. This is likely to be exacerbated in the short term as some companies seek to increase their activities in this area in the UK over the next few years.

Graduate/ MSc candidates are identified as the main level of need for most of the areas within manufacturing skills and know-how. In some areas (notably vaccines and drug substance manufacturing amongst the priority areas, and also clinical trial manufacturing) the largest concerns are finding appropriate candidates at the PhD level. For drug substance manufacturing, the levels of concconcern for the graduate/ MSc and the non-graduate levels are equal at >20% of respondents.

In addition to the quantitative questions, the Manufacturing Skills (MMIP) Survey also asked respondents to identify the top five areas of concern with regard to skill gaps. Combining these data with the quantitative data identifies some additional areas of concern, these being drug product manufacturing and aseptic manufacturing. For drug product manufacturing, graduate/ MSc candidates were again identified as the main level of need, although >20% of respondents also identified concerns at the non-graduate level. However, for aseptic manufacturing, the graduate/ MSc and non-graduate levels were identified as being of approximately equal concern, emphasising the importance of skilled and experienced operators in aseptic manufacturing.

Quality operations

Validation skills are identified as a significant gap. The responses recognise that this is a skill set that is learnt in industry rather than the outcome of an academic qualification. Specific issues commented on indicate that the most severe gaps exist in the topics which have increased in importance or emerged more recently – for example validation relevant to a Quality by Design development programme, computer systems validation, cleaning validation (noting the recently revised EU guidelines for health-based cleaning criteria). Responses differ with regard to the capability of contract resource in this area; one response notes that 'Most skilled (validation) people are contractors', whereas another notes that significant contract resources by number are available but their 'scientific and engineering competency is generally low'. The skill gap is very strongly seen to be at the graduate/ MSc level.



Statistics in the manufacturing arena is a critical tool for problem analysis and problem solving, but has been a much smaller discipline than in the R&D space. However, as products entering commercial manufacture are increasingly the output of a Quality by Design development programme, and with the separate but linked move towards the adoption of Continuous Process Verification, the importance of statistics skills and the demand for them in manufacturing will increase. The gap is seen to be at both the graduate/ MSc and PhD levels.

Analytics for biologics is flagged as a priority via the data analysis methodology used, but is mostly noted as a large but medium priority area for action by respondents, suggesting that the concerns relate mostly to meeting future needs as the sector grows rather than immediate skill gaps today.

The additional comments from the responses to the question on the top five areas of concern also identify quality operations, regulatory and microbiology skills as issues for respondents. The MMIP Survey data for the regulatory and microbiology areas have been combined with the similar data from the ABPI Survey and is commented on in Sections 6.4.6 and 6.4.1 respectively. In Quality Operations, the strong theme is the recruitment and retention of Qualified Persons (QPs) – this is also commented on in Section 4.1.6 and is the subject of specific further follow-up work by the ABPI currently.

Engineering and technical professionals

The MMIP Survey data for materials science have been combined with the similar data from the ABPI Survey and are commented on in Section 6.4.2.

Process engineering skills at both the graduate/ MSc and PhD level are seen as a significant issue. This area was explored via two questions in the survey, one on process engineering as a whole and one on the more specific area of process development and scale-up – both received numerous comments on the difficulty of finding candidates with appropriate skills.

Skills for sterile product manufacture and aseptic processing are seen as an issue. The specific question on steriles engineering and sterilisation technology skills attracted numerous comments of concern, and this area was also commented on in the process engineering area. Overall, the respondents' comments indicate that this is an area where skills are mostly built via training and experience in industry rather than as the outcome of an academic qualification, but felt that more could be done to include at least some topics of direct relevance to this area in degree courses. Similar to the comments on aseptic manufacturing under the manufacturing skills and know-how section above, the main skills gap is seen to be at the graduate/ MSc level but the non-graduate level is also seen to be important.

Level of skills gaps

Across all the areas in the manufacturing survey, the graduate/ MSc level is very strongly the level of skill of most concern to respondents. In manufacturing, PhD-level qualifications are not commonly required except in some specialist disciplines, for example process engineering/ process development and the newer/ emerging biologics areas. Recognising the large number of non-graduates employed in medicines manufacturing, the relatively lower levels of concern about the non-graduate level is potentially a surprise. This may be as a result of the more recent emphasis on apprenticeships and workforce development advanced by the Science Industry Partnership, but the survey data do not allow this to be drawn as a firm conclusion. Education trends are discussed in Section 2 of this report, and the survey data do show that the relatively lower numbers of STEM graduates in the UK (compared with peer countries) is resulting in respondents seeing difficulties in finding the graduate/ MSc skills (by capability and number) that they need in many areas.

The data and conclusions from the MMIP Manufacturing Skills Survey are also being incorporated into the Science Industry Partnership (SIP) Skills Strategy that is currently being developed by Cogent on behalf of the SIP. Recommendations and actions specific to skills for medicines manufacturing will be addressed as part of the SIP Skills Strategy, which is due to be published in March 2016.

4.3 Core skills

Overall, most core skills show a marked decrease in the proportion of people rating them as a major concern compared to 2008; one exception was communication skills, where the percentage of respondents classifying it as a major concern has increased, and teamworking skills, where the decrease was only about 2%. In both cases the number of respondents indicating it as a concern increased markedly such that close to 90% of respondents indicated concern over new recruits demonstrating competency in these areas. Hence these skills are now more of a concern.

Whilst the rating of core skills as high concerns decreased, their rating as a concern increased. All categories were rated as a concern or major concern by at least 78% of respondents. For communication and team-working skills this figure was closer to 90%. All of these core skills are still a significant concern to recruiters for the biopharmaceutical sector.

Core competencies that were considered priorities in 2008 were application of knowledge, mathematics and practical skills. Our 2008 report, *Skills needs for biomedical research*, made recommendations to enhance these through improving the mathematical capabilities of science students at school, augmenting the funding formula for higher education teaching and an increase in the provision of integrated Masters undergraduate courses, particularly in bioscience subjects. The Royal Society of Biology responded to our recommendation by introducing accreditation for bioscience undergraduate degrees. To achieve Advanced Accreditation, undergraduate courses need to include a substantial work placement to prepare students for a research career; this has driven growth in integrated Masters courses. As noted in Section 2.3, more students are now studying maths post-GCSE and the upcoming introduction of Level 3 certificates to provide higher-level maths for students who are not taking maths A-level is a positive step. These areas are now seen as less of a problem than they were in 2008; however, they are still a concern and actions to address these needs should be continued and further developed.

Team-work training was also identified by the BBSRC and MRC as a vulnerability, lacking at both undergraduate and postgraduate level.[30] Their report also mentioned a lack of communication skills amongst researchers, creating a barrier to wider engagement, understanding, collaboration and advocacy. Furthermore, the lack of numeracy amongst researchers, mainly recent graduates, was also highlighted.

The UK Commission for Employment and Skills (UKCES), on the other hand, showed a greater concern regarding technical and practical skills, followed by both oral and written communication capabilities, then problem-solving skills, team-work and finally numeracy skills. Therefore, although there is widespread information regarding the strong need for the development of core competencies, the specific area requirements vary. There is nevertheless a consensus that these skills are crucial and action needs to be taken to continuously develop them both amongst academics and within the industrial workforce.[31]

30 BBSRC and MRC. (2014) *Review of Vulnerable Skills and Capabilities*. Available from: http://www.mrc.ac.uk/documents/pdf/review-of-vulnerable-skills-and-capabilities/
31 UKCES. (2014) *UK Commission's Employer Skills Survey 2013: UK results*. Available from: https://www.gov.uk/government/collections/ukces-employer-skills-survey-2013

A key resource available for postgraduate academics is the Vitae Community (www.vitae.ac.uk) which provides various training courses, workshops and online resources to develop skills such as leadership, communication and team-work. An example is the Effective Researcher scheme, which is a set of five programmes relevant to different postdoctoral levels, teaching researchers different sets of skills required at different stages of their academic careers.

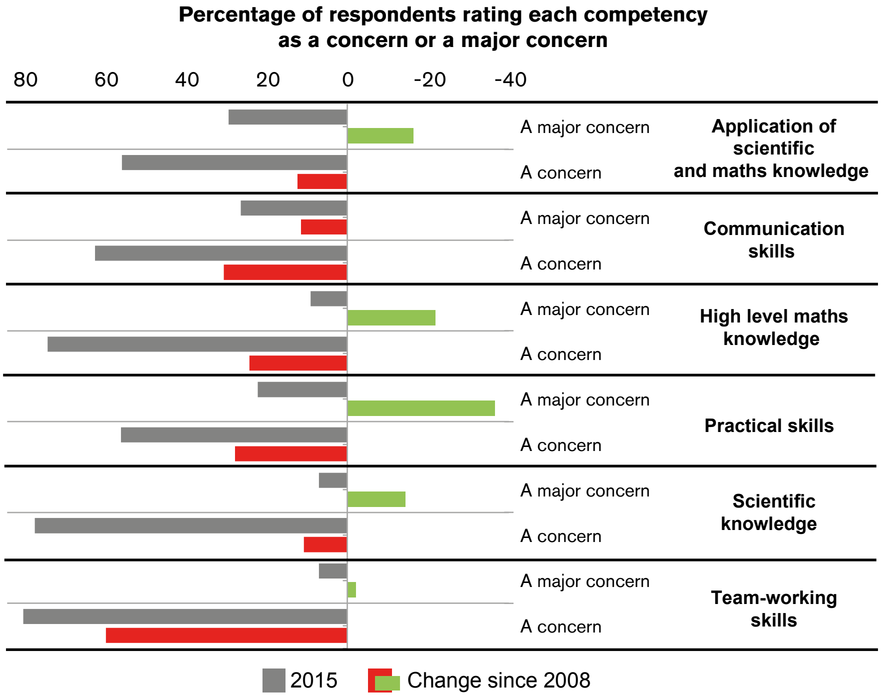


Figure 13: Percentage of respondents who rated each core skill area as a major concern or a concern in 2015, with the percentage difference from 2008's ratings. (Practical experience was rated individually for each discipline area and the average across all areas was used in this graph. Detailed data for each discipline area's practical skills concern level are shown in the appendices.)

Research Councils have also identified core skills relevant to their areas and have developed various resources to improve these. BBSRC, for example, requires all of the PhD students funded through its Doctoral Training Partnerships to undergo placements to help early career researchers understand the context of their research and to expose them to the range of opportunities in which they can apply their PhD skills and training after they graduate. Vitae, through the development of the Researcher Development Framework, also aids researchers in planning, promoting and enhancing their professional and career development.[32]

All categories were rated as a concern or major concern by at least 78% of respondents. For communication and team-working skills this figure was closer to 90%

32 Vitae Careers Research and Advisory Centre (CRAC). (2011) *Research Development Framework*. Available from: https://www.vitae.ac.uk/vitae-publications/rdf-related/researcher-developmentframework- rdf-vitae.pdf

4.4 Recruitment

One survey question sought overview information on the type of individual being recruited; their qualification level and whether they were from the UK, EU or outside the EU. The responses sought information on whether recruitment of this type of person had increased or decreased in recent years. The chart below summarises these responses.

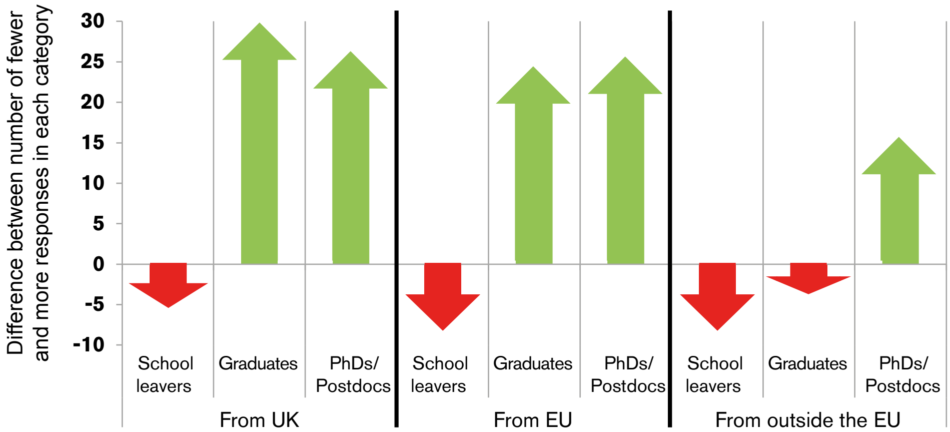


Figure 14: Respondents hiring more or fewer employees at different qualification levels from the UK, EU or outside the EU

Figure 14 indicates increasing levels of recruitment of graduates and PhDs/ post-docs from the UK and the EU, and fewer graduates from outside the EU. The indicated decrease in recruitment of school leavers is surprising as anecdotal evidence suggests that many more apprentices are being recruited and trained.

The largest increase is in recruitment of UK graduates; however, comments indicate that most companies recognise that a new graduate will not demonstrate all the skills required for a role and that on the job training will be required. This is particularly true of practical skills.

There were also some specific discipline concerns raised by survey respondents; including this comment on PK/PD modelling:

'A number of undergraduate courses cover metabolism and its role in the drug development process at a high level, hence graduates generally have a basic understanding of the subject. There is, however, a practical skills gap in use of basic laboratory equipment'

The concerns are not universal and in other areas, including synthetic chemistry and clinical research operations, recruitment of high-calibre graduates appears not to be an issue.

It is also pleasing to note that concerns over recruitment for some disciplines appear to have reduced since 2008. In some instances this can be linked to specific interventions. For example, recruitment for *in vivo* pharmacology and *in vivo* physiology at PhD and post-doc level has most likely been impacted by the capacity-building schemes described in Section 4.1.1. PhD recruitment of clinical pathologists and PhD/ post-doc recruitment of clinical pharmacology/ translational medicine specialists has also eased due, at least in part, to programmes described in Section 4.1.3. For other areas, including biopharmaceuticals/biologics, genomics, proteomics and health economics and outcomes research, the discipline is now more mature and it is likely that the pool of recruits is larger than in 2008.

At graduate recruitment level there are, however, some disciplines where recruitment has become more difficult. These are genomics, proteomics, metabonomics, *in vitro* and *in vivo* pharmacology and process chemistry. At non-graduate level only animal technology was identified as an area of high concern for recruitment.

A range of other disciplines reveal major concerns with recruitment at graduate, PhD or postdoc levels, but these disciplines were not rated in 2008 so we cannot speculate on whether the issues have worsened. Some of these are relatively new disciplines, such as health informatics, automation and analytics for biologics, so graduates and postgraduates may not be aware of the opportunities available within these areas.

The apparent decrease in recruitment of non-graduate school leavers is unexpected, as other evidence indicates increasing apprenticeship opportunities for young people. In 2013 the ABPI collected data for the first time on the numbers and types of apprenticeships offered by pharmaceutical companies. These indicated that a total of 141 apprentices were training at that time, across manufacturing, engineering and laboratory areas. The majority, 69%, were at Level 3; nearly all the remainder were at Levels 4 or 5. This survey will be repeated at the end of 2015 to establish the change in numbers of apprentices over the last two years.

Some comments suggest that industry could do more to equip graduates with the skills they need to succeed in the workplace. These ranged from proposals to work with universities to ensure that course structure reflects the rapidly evolving discipline, to offering additional six to twelve month placements to undergraduates. This is challenging to implement. Evidence collected by the ABPI since 2007 shows that the number of R&D placements for this type in pharmaceutical companies has more than halved; in 2007 530 placements were offered, in 2013 this had decreased to 250.[33] During this period a number of large research and development sites have closed and others have contracted.

Since 2011 government policy has discouraged migration from outside of the EU. Changes introduced mean that highly-skilled people from outside of the EU being recruited, or transferred by their company to work in the UK, (Tier 2) have to meet specific requirements and be paid above a set salary. Our data indicate that this has impacted on recruitment at levels below PhD. Further changes are now being proposed to Tier 2 regulations; global companies are concerned that additional restrictions should not be placed on their recruitment or intra-company transfer of people with the skills needed to enable the company to flourish in the UK.

33 ABPI. https://www.abpi.org.uk/partnerships/ (accessed 9 July 2015)

4.5 Future issues

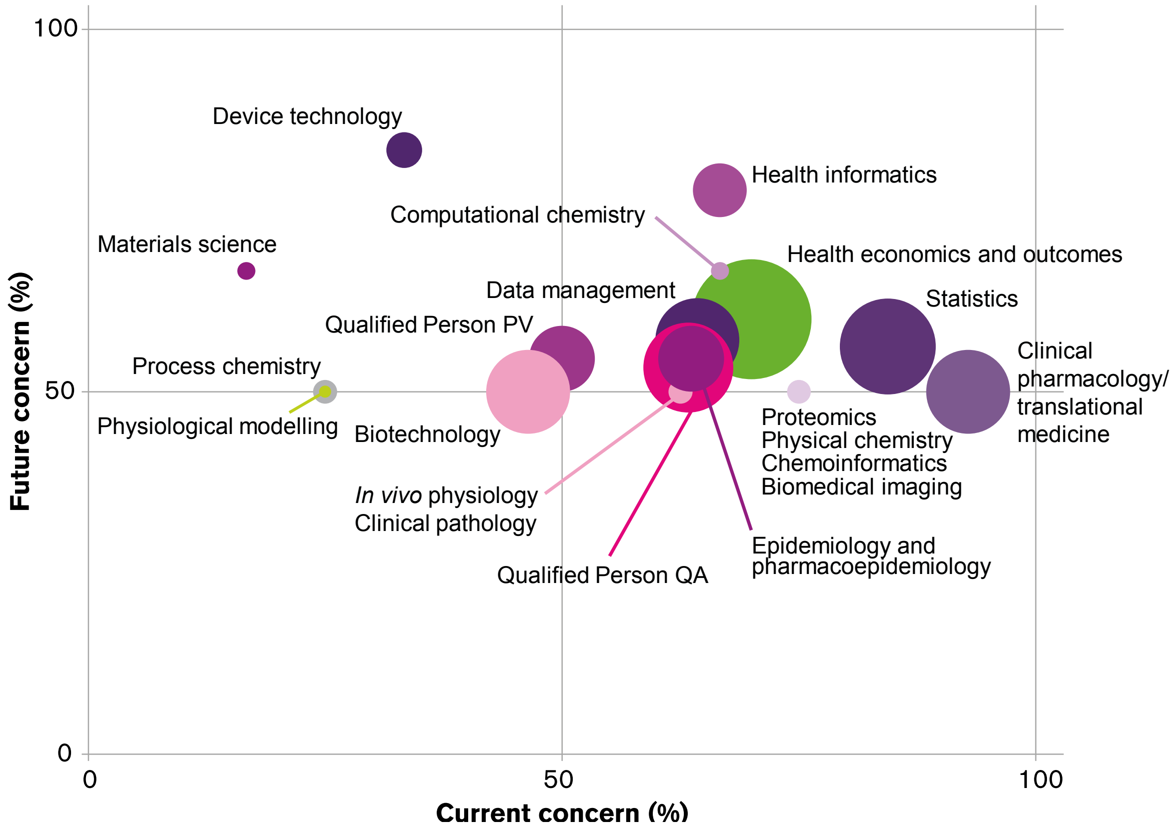


Figure 15: Percentage of respondents rating each discipline area as a future concern vs. a current concern. (Only areas rated as a future concern by at least 50% of respondents are shown, for clarity.) (In vivo physiology and clinical pathology have overlapping data, as have proteomics, physical chemistry, chemoinformatics and biomedical imaging.) Size of bubbles represents the number of respondents in each area

Most of the areas that were identified as future issues by the majority of respondents were also top priorities and thus have been discussed in further detail in the top priorities section of this report. Once again, the highest level of concern is expressed in the informatics, computational, mathematics and statistics areas, comprising almost half of the areas predicted to be increasing concerns in future. Actions taken to address these top priorities need to be continuous and sustainable to ensure that current and future needs are both addressed.

Areas that are not currently top priorities but are a potential concern for the future are shown in Figure 16. Although probably no urgent action is needed to address needs in these discipline areas, they should be taken into account when defining strategies for the future, concerning education, training and professional development.

Future concerns that are not current top priorities	Device technology
	Materials science
	Physiological modelling
	Physical chemistry
	Biotechnology
	Data management

Figure 16: Potential future concerns which are currently not considered top priorities

5 Recommendations

The survey we have carried out provides up-to-date, robust evidence of these issues in recruitment for the wider biopharmaceutical sector – from SMEs to global pharmaceutical companies. The findings of this report build on comments that have been made by a number of different organisations in recent years, including individual companies, research councils and the NHS, based on their own data or anecdotal evidence.

Some of the disciplines we have identified as areas of concern, such as clinical pharmacology/ translational medicine and veterinary and toxicological pathology, are long-standing concerns which have previously been highlighted by the ABPI.[34] Action has been taken in the past to build capacity in these areas with funding from a number of organisations, including the industry itself. These have been successful in the short term but long-term issues remain.

In the past *in vivo* sciences were also an area of high concern. The reason they are not currently a high priority concern is, at least in part, due to initiatives such as creation of Integrative Mammalian Biology (IMB) centres and provision of joint British Pharmacological Society (BPS) and Physiological Society short courses in *in vivo* pharmacology and physiology. However, the funding for these is coming to an end and it is possible that the previously identified issues will reappear in a few years' time.

'Although we have been aware of many of these concerns anecdotally, the survey provides confirmation of the scale of the issue...'

Other areas, including health informatics and formulation, have been flagged up in our survey for the first time – they were not even raised as future concerns in our 2008 report. Although we have been aware of many of these concerns anecdotally, the survey provides confirmation of the scale of the issue and the specific recruitment needs. Action has been initiated by a number of organisations, including the Farr Institute and iFormulate, to address these needs, but our evidence suggests that this has been patchy and, in some instances, has not yet made a noticeable difference.

We have also identified some disciplines which, although not currently areas of high concern, are expected to become more difficult to recruit for in future. Notable amongst these are device technology and materials science, physiological modelling and physical chemistry. These areas should be taken into account when horizon scanning and defining education, training and professional development strategies for the future.

For some discipline areas there are concerns over both the number and quality of applicants; for others the quality is not an issue, but there are too few people with appropriate skills and/or experience. Recruitment of experienced staff is a concern across many areas but for several disciplines there are also issues around recruiting recently qualified graduates and/or recently qualified PhDs or people with a PhD and postdoctoral research experience.

Going forward we plan to hold discussions with the SIP and with organisations such as the Farr Institute, Elixir, research councils, professional bodies and the NHS to develop new initiatives or reinvigorate existing ones with the aim of addressing the needs we have identified.

34 *Skills needs for biomedical research*. (2008) http://www.abpi.org.uk/our-work/library/industry/Pages/skills-biomedical-research.aspx

Recommendations

- The Science Industry Partnership (SIP) Board should review the evidence and consider action that could be taken through the SIP to address the skills concerns identified.

- In areas where evidence suggests that high level and professional skills are concerns across both industry and academia, action will be sought through the Research Councils and appropriate Professional Bodies.

- The pipeline for the development of appropriate mathematical skills must be considered. This extends from opportunities for students to study maths alongside science subjects post-16, through universities putting increased emphasis on maths in bioscience courses, to raising awareness and uptake by UK and EU graduates of Masters and PhD level training in statistics, data mining, mathematical modelling and related disciplines.

- ABPI Expert Network Groups, and the Medicines Manufacturing Industry Partnership (MMIP) Skills group (for manufacturing concerns), should monitor the critical disciplines in their area and raise concerns when it is becoming more difficult to recruit people with the skills required or when new needs are identified. The Expert Networks, through discussion with stakeholder organisations and the ABPI's Academic Liaison Expert Network, should also consider what action is required and how best it should be taken forward.

Addressing the skills needs identified in 2015 is not expected to be easy, in particular taking into consideration the challenging financial climate, but it is essential that they are addressed if the life science and health sectors are to continue to flourish in the UK. Many of the skills requirements identified in this report affect not only biopharmaceutical companies, but other life science companies, the academic science base and the NHS. In addition, by addressing the concerns identified, the UK could become a world-leading destination for the growth of the life science sector.

6 Appendices

6.1 Survey

The survey was divided into a number of broad scientific areas and allowed respondents to select only those disciplines which they wished to comment on. Further questions on generic skills concerns were asked of all respondents.

Section 1 Biological science areas

- Animal technology
- Biochemistry
- Biopharmaceuticals/biologics
- Biotechnology
- Drug metabolism and ADME
- Genomics
- *In vitro* pharmacology
- *In vivo* pharmacology
- *In vivo* physiology
- Metabonomics
- Microbiology
- Molecular biology
- Molecular/translational toxicology
- Proteomics
- Structural biology
- Toxicology
- Veterinary medicine
- Veterinary and toxicological pathology

Section 2 Chemical science areas

- Analytical chemistry
- Chemical biology
- Materials science
- Medicinal and synthetic organic chemistry
- Physical chemistry
- Process chemistry

Section 3 Clinical areas

- Clinical pathology
- Clinical pharmacology/translational medicine
- Clinical research operations
- Clinicians

Section 4 Pharmacy

- Device technology
- Formulation
- Pharmacy

Section 5 Informatics, Computational, Mathematical and Statistics areas

- Automation
- Biomedical imaging
- Bioinformatics/computational systems biology
- Chemoinformatics
- Chemometrics
- Computational chemistry
- Computational science
- Data management
- Data mining
- Epidemiology and pharmacoepidemiology
- Health economics and outcomes
- Health informatics

Section 5 Informatics, Computational, Mathematical and Statistics areas *continued*
• Pharmacokinetic/ pharmacodynamics modelling
• Physiological modelling
• Statistics

Section 6 Regulatory areas
• Pharmacovigilance
• Quality assurance
• Qualified Person (QA)
• Qualified Person (PV)
• Regulatory affairs

Generic skills issues (to be completed by all respondents)
Rate as 'a major concern', 'a concern', 'less of a concern now than in 2008', or 'not a problem':
• Scientific knowledge
• High level maths knowledge
• Application of scientific and maths knowledge
• Problem solving skills
• Communication skills
• Team-working skills

The following questions were asked for each discipline selected:

In 2014, is there: *(select as many as apply)*
☐ A problem with the quality of candidates
☐ A problem with the number of candidates
☐ A problem for the future
☐ Not a problem as far as I am aware *(skip logic – no further questions on this discipline)*

Is this: *(select one)*
☐ Low priority – an important area to watch
☐ Medium priority – requires action
☐ High priority – requires immediate action

Does this affect: *(select as many as apply)*[35]
☐ Non-graduate recruitment
☐ Graduate/MSc recruitment
☐ PhD recruitment
☐ Post-doc recruitment
☐ MD recruitment[36]
☐ MD/PhD recruitment[36]
☐ Recruitment of experienced staff

Are practical skills for this discipline[37]
☐ A major concern
☐ A concern
☐ Not a problem

Please provide additional comments if you wish
(Free text answer)

35 Clinical Research Operations question did not include non-graduate recruitment as an option and the Clinicians question only had three options: MD, MD/PhD and experienced recruitment.
36 MD and MD/PhD recruitment answer options were only included in clinical areas.
37 Practical skills question asked for Biological science areas: all disciplines, Chemical Science areas: all disciplines, Clinical areas: only Clinical pathology and Clinical pharmacology/ translational medicine, Pharmacy: all disciplines, Informatics, Computational, Mathematical and Statistics areas: only Automation, Biomedical Imaging, Regulatory areas: none.

The final section of the survey for completion by all respondents evaluated core skills:

In our 2008 survey, the following skills gaps were identified across new recruits; please indicate whether they are still problematical:

Skills issue	A major concern	A concern	Less of a concern now	Not a problem
Scientific knowledge	*(tick boxes – one per line to be ticked)*			
High level maths knowledge				
Application of scientific and maths knowledge				
Problem solving skills				
Communication skills				
Team-working skills				

What type of individuals are you recruiting, and from where?

	More school leavers	Fewer school leavers	More graduates	Fewer graduates	More PhD/ postdocs	Fewer PhD/ postdocs
From UK	*(tick boxes – can tick up to 3 per line)*					
From EU						
From outside the EU						

Data were also collected through a separate survey run by the Medicines Manufacturing Industry Partnership (MMIP).

6.2 Survey respondents

Pharmaceutical companies

- Abbott
- AbbVie Ltd
- Actelion Pharmaceuticals UK Ltd
- Alexion Pharma UK
- Alliance Pharmaceuticals Ltd
- Amgen Limited
- Astellas Pharma Ltd
- AstraZeneca
- Aventis Pharma Ltd trading as Sanofi
- Baxter Healthcare
- Bayer Plc
- BCM
- Biogen Idec Limited
- Biosceptre
- Boehringer-Ingelheim
- Bristol-Myers Squibb
- Celgene
- Eisai Europe Limited
- Fujifilm Diosynth Biotechnologies
- GlaxoSmithKline Research and Development Ltd
- Grunenthal Ltd
- iQur Ltd
- Janssen Cilag
- Lilly UK
- MedImmune
- MSD UK Ltd
- Napp Pharmaceuticals Ltd
- Novartis
- Orion Pharma (UK) Ltd
- Pfizer
- RIC Chemicals Ltd
- Rosemont Pharmaceuticals Limited
- Sanofi
- Servier
- SGS M-Scan
- Takeda
- UCB

Contract Research Organisations (CROs)

- Covance
- Huntingdon Life Sciences
- Onorach Clinical
- Pera Technology
- PRA Health Sciences
- QED Clinical Services Limited
- Quintiles
- Quotient Clinical
- Simbec-Orion

Small and medium enterprises (SMEs)

- Biosignatures Ltd
- Health iQ
- Sphere Fluidics Ltd
- Varion Limited

Other
- Aurora
- British Pharmacological Society
- DHR International
- Goffin Consultancy Ltd
- Star
- The Open University
- University of Surrey
- Vermilion Life Sciences Ltd

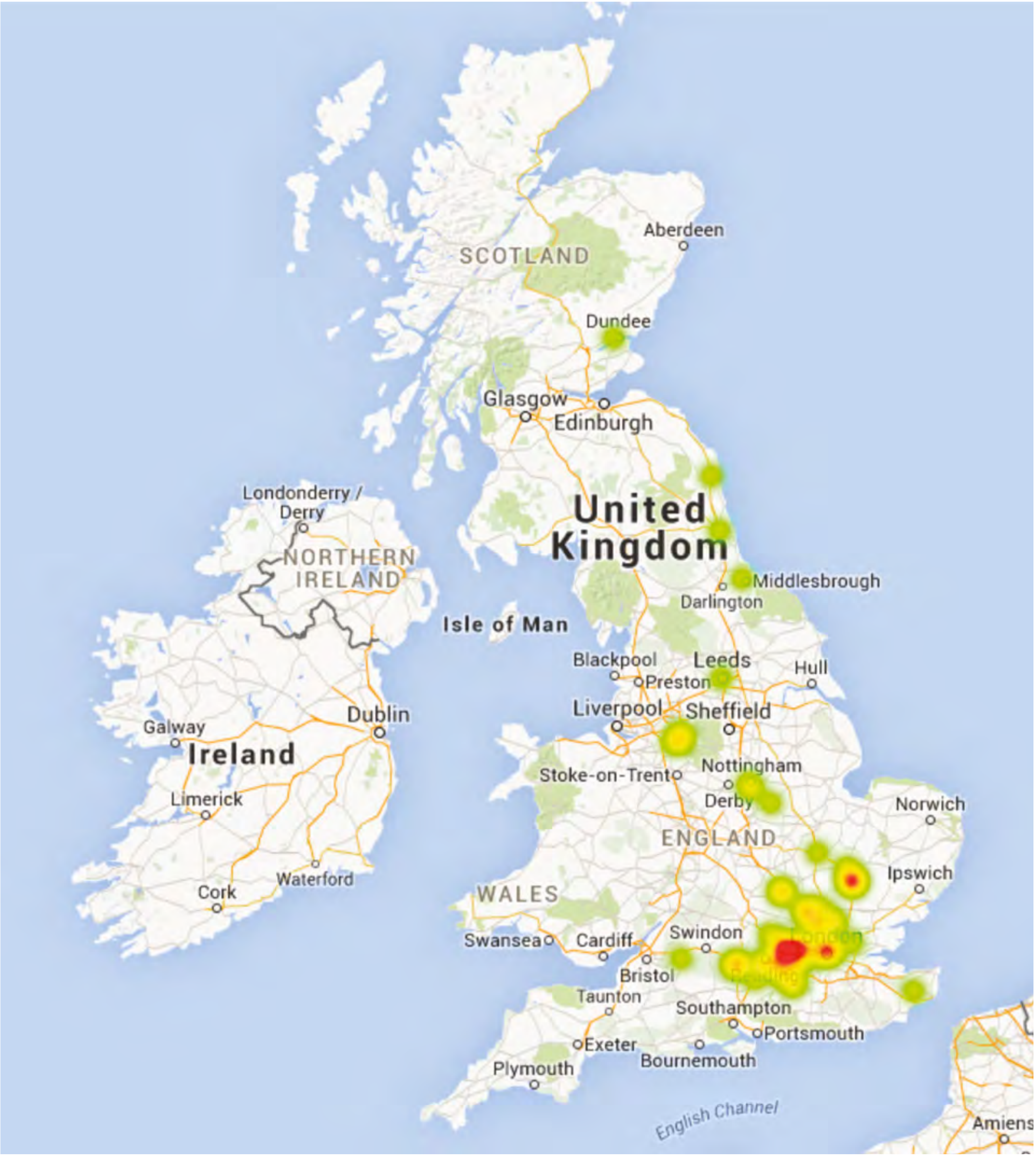


Figure 17: Heat map of companies who participated in the survey. Dynamic online version available at https://www.google.com/fusiontables/DataSource?docid=1bEtZzJUMpoWwY UdlNkBGdJP0coErRuWe5MXBmH99

6.3 Data analysis methodology

Data collected from the online survey were analysed using Microsoft Excel 2010. The first step in data analysis was checking for overlapping company answers for each discipline. Any discipline with more than one reply from the same company was analysed and responses were merged.

Due to the variability in number of respondents per area (survey participants could choose which areas they wished to respond on) the percentage of respondents rather than number of respondents was used to present the data collected.

Priority graphs show the percentage of people per discipline area that rated that area as high priority, medium priority and low priority, or stated it was not a problem as far as they were aware. This is represented as a bar graph with discipline area titles on the vertical axis and percentage of respondents on the horizontal axis.

Bubble charts were used to represent responses from the questions which asked about the quality and number of candidates available for each discipline area as well as whether this area would be expected to become an increasing concern in the future. These were divided into two charts, one representing the level of concern over the number of candidates (vertical axis) vs. the level of concern around the quality of candidates (horizontal axis) and the other one representing the level of concern for the future (vertical axis) vs. the average current level of concern (horizontal axis). The average current level of concern was determined by calculating the mean number of people who identified a problem with the quality of candidates and the number of people who identified a problem with the number of candidates available.

Qualification level data are represented as column graphs, with each column showing the percentage of people who reported an issue with recruitment at each level.

Concerns over practical skills are displayed in tables showing the percentage of respondents rating practical skills for each discipline area as a major concern, a concern or not a problem.

Core competencies data were collected from all survey participants and every response was included in data analysis, without removing any overlapping answers from the same company. Figure 13 shows the percentage of respondents who rated each core skill as a major concern or a concern in 2015 and the difference in the percentage of respondents rating it as each level of concern compared to 2008. Grey bars represent the percentage of people rating it as a concern or major concern in 2015. Red bars represent an increase in the number of people rating it at each concern level and green bars represent a decrease, indicating that fewer people believed that core skill to be a major concern or concern in 2015 compared to 2008.

Information and data on levels of recruitment from the UK, EU and outside of the EU were also collected from all respondents and the graph represents the difference between the number of people who said they recruited more or fewer candidates from each geographical area at each education level.

Detailed information from the survey responses for all disciplines is given in Appendix 6.4. Each section covers one scientific area, showing responses for all disciplines within that area. Responses for all questions are given by percentages of respondents.

In the detailed overview for each discipline, the overall priority colour band indicates the priority level with the greatest percentage of respondents. For comparison with data from 2008, concerns over the quality and number of candidates have also been coded as red, yellow or green based on responses for that discipline, as has the level of concern over recruitment at each qualification level. The cut-offs applied were:

- 0–29% respondents = Low priority (green)
- 30–59% respondents = Medium priority (yellow)
- 60–100% respondents = High priority (red)
- Any symbol shown in grey is not applicable to that discipline

Data from the MMIP survey were adapted to fit the graph format used in the rest of the report. All responses were used, without excluding responses from different sites of the same company due to the small number of companies responding. The priority of each area was determined based on the skills gap rating provided by respondents. Rating the skills gap between 4 and 5 was considered high priority, 3 was medium priority, 2 was low priority and a rating of 1 translated as 'not a problem as far as I am aware'.

Since only two areas had a majority of respondents rating them as high priority (4 and above skills gap rating), the criteria were widened to include areas where combined medium and high priority ratings were at least 70%. These data were then presented on a bar chart in the same way as all other non-MMIP discipline areas.

Qualification level priorities in the detailed summary section for manufacturing areas were divided into the same levels as the one used for other disciplines by finding the average percentage of respondents selecting the options as ideal qualifications. Qualifications up to and including HNC, HND and Foundation degree were classed as 'non-graduate'.

6.4 Section summaries

6.4.1 Section 1 – Biological science areas

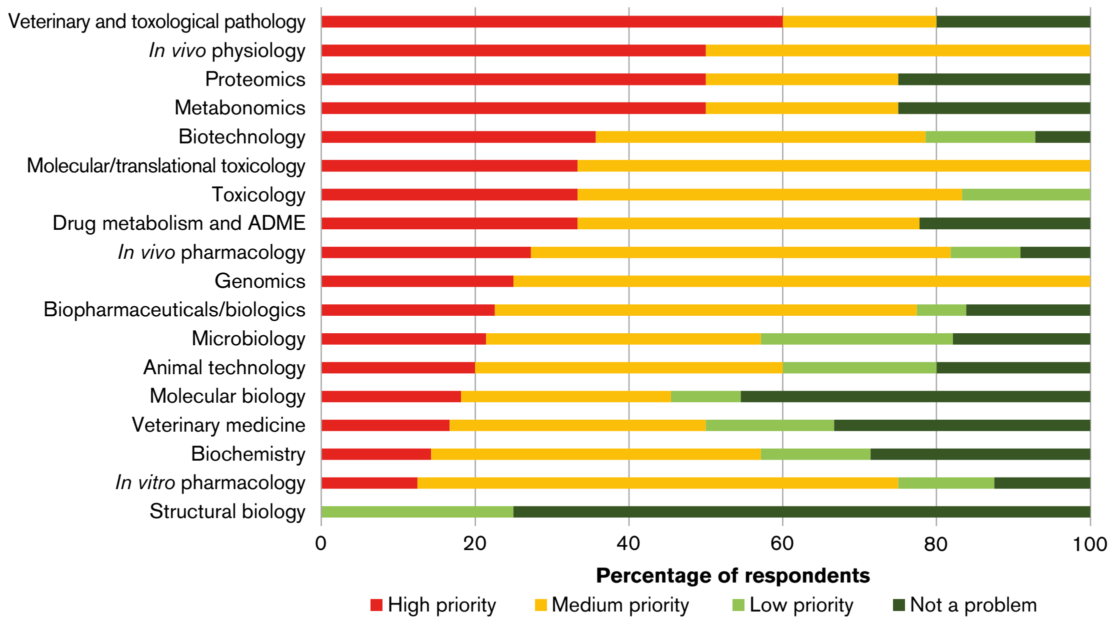


Figure 18: Percentage of respondents rating each biological science discipline as high, medium or low priority or identifying it as 'not a problem'

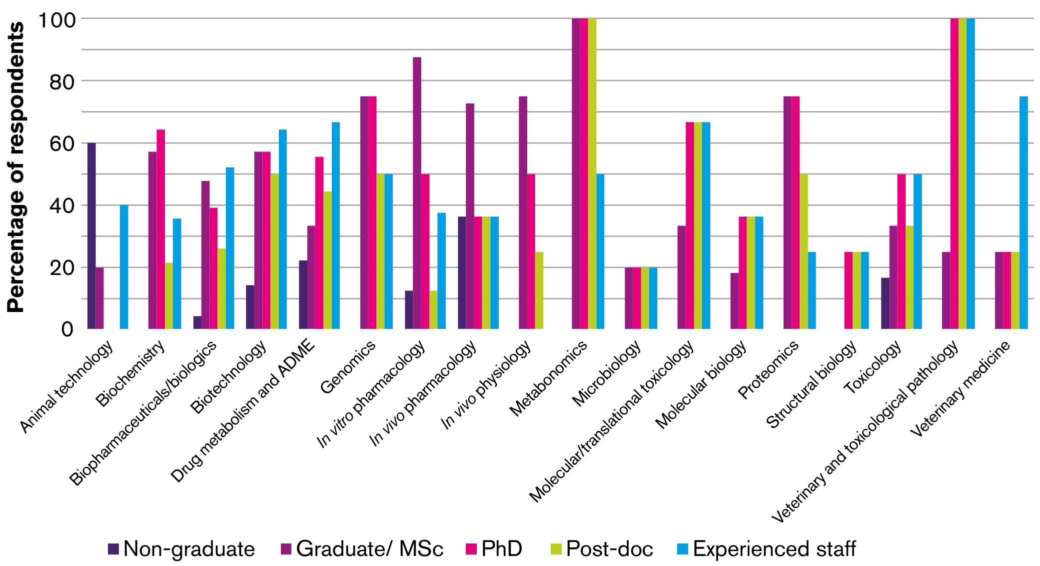


Figure 19: Percentage of respondents identifying each qualification level as an issue within the biological science disciplines

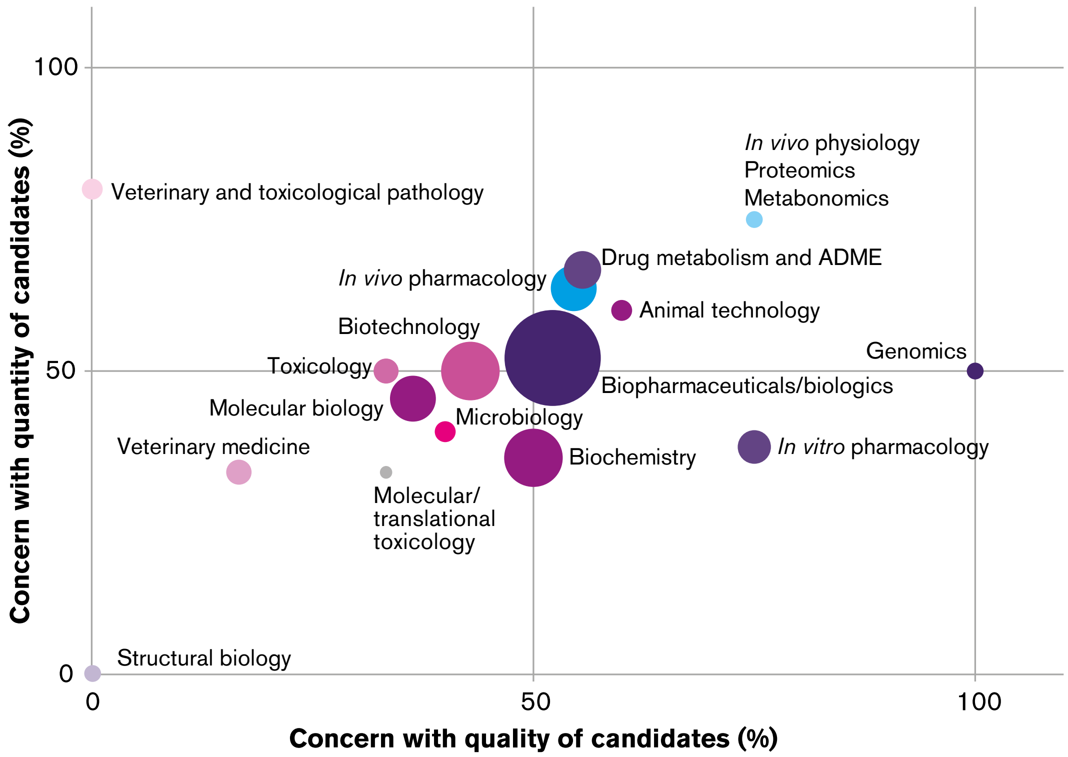


Figure 20: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area. (Proteomics, metabonomics and in vivo physiology have overlapping results.)

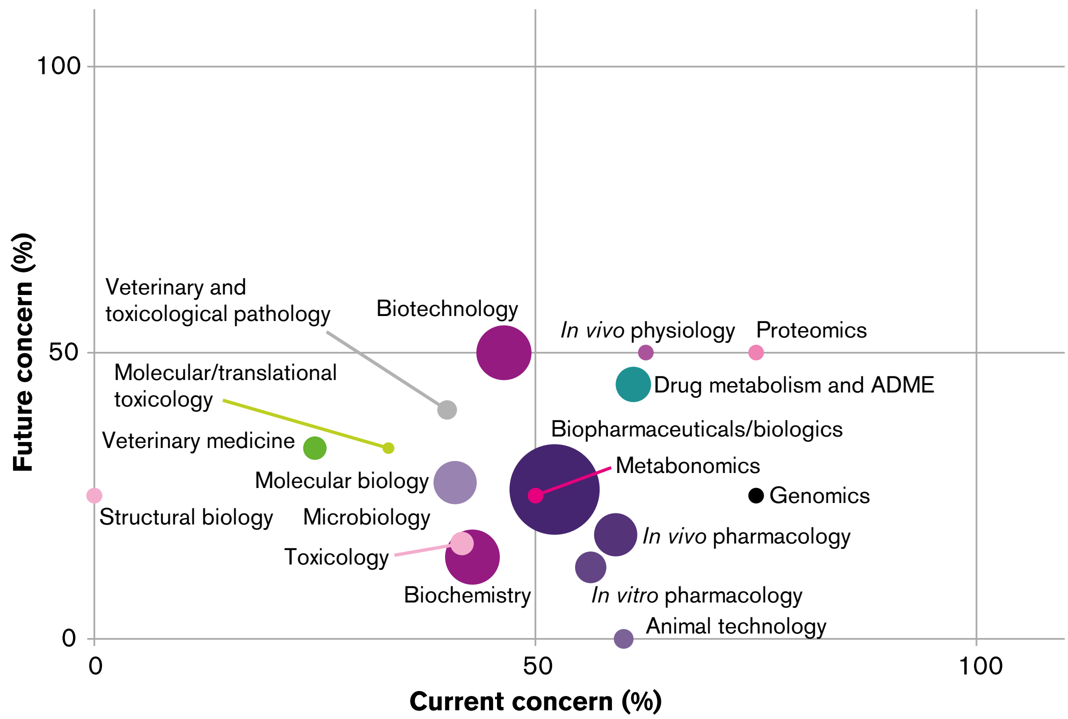


Figure 21: Percentage of respondents rating each discipline area as a future concern vs. a current concern. Size of bubbles represents the number of respondents in each area

Table 1: Percentage of respondents identifying practical skills as a 'major concern', 'concern' or 'not a problem' within the biological science areas (numbers may not total 100% due to rounding)

	Major concern (%)	Concern (%)	Not a problem (%)
Genomics	50	50	0
In vivo physiology	50	50	0
In vitro pharmacology	38	50	13
Metabonomics	33	50	0
In vivo pharmacology	25	58	17
Proteomics	25	50	25
Biotechnology	21	64	14
Biochemistry	21	50	29
Veterinary and toxicological pathology	20	60	0
Microbiology	20	20	60
Molecular biology	18	36	45
Biopharmaceuticals/ biologics	17	43	39
Drug metabolism and ADME	11	67	22
Molecular / translational toxicology	0	100	0
Toxicology	0	100	0
Animal technology	0	80	20
Veterinary medicine	0	50	50
Structural biology	0	25	75

Table 2: Detailed biological science results (including 2008 results and survey comments)

(green)	**Low priority** – an important area to watch
(amber)	**Medium priority** – requires action
(red)	**High priority** – requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

Table 2: Detailed biological science results (including 2008 results and survey comments)

	2008		2014/15		
Animal technology	Animal technicians are responsible for the day to day welfare of the animals used in *in vivo* research work. Tasks range from general animal care and husbandry to monitoring the health and development of the animals and ensuring environmental conditions are correct. Qualified animal technicians conduct technical procedures such as administering medicines and collecting clinical data as part of experimental protocols.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Generally lower numbers of animal technicians in the UK currently than desirable. ▪ Proportionally more work within the academic sector as the pharmaceutical sector contracts but many roles in academia are very focused, particularly on transgenic mice, hence skills in some of the areas required by industry are in shorter supply, particularly with respect to non-rodent species. ▪ Can be difficult to find licensed and pharmaceutical experienced technicians. Shift-work needs to be undertaken, so can be difficult to find people willing to do this also.
Biochemistry	Biochemists study chemical processes in living organisms, looking at the structure and function of biomolecules such as proteins and DNA. In the pharmaceutical industry, biochemists are employed in the area of drug discovery, identifying and validating new drug targets against which new chemicals will be tested in order to identify potential new medicines.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Often graduate-level candidates have surprisingly poor practical skills and little relevant laboratory experience. ▪ Some good candidates, but many more mediocre ones to sift through. ▪ Too many diluted courses that don't cover the core aspects of biochemistry. Impacts ability to work independently in biochemistry R+D. ▪ We have recruited a number of people with Biochemistry skill-set this year and are delighted by the calibre both practical and theoretical, but several have relocated from other companies so whilst the skill set feels very strong, we are sourcing from a decreasing pool. ▪ We find suitable candidates apply; no problem in attracting candidates with the correct skill set this year. ▪ There appears to be a scarcity of experienced people with a suitable blend of experimental and theoretical knowledge. ▪ New graduates' level of understanding against contemporary practices and industry perspective requires a protracted on-boarding and in-house training. ▪ Degree courses MUST include practical elements.

Biopharm-aceuticals/ biologics[38]	Biopharmaceuticals are medicinal compounds produced in cells, usually in bio-fermenters, and purified using a range of upstream and downstream processes to produce purified drug substance. Critical skills involved are cell and fermenter sciences, protein purification and analysis. Biopharmaceuticals are growing rapidly in importance in the pharmaceutical industry and include vaccines, medicines and diagnostic tests.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Real dearth of good candidates with experience. ▪ Practical appreciation of biopharmaceuticals very limited. ▪ No major problems in attracting suitable candidates but for more senior roles, the candidate pool is quite limited with candidates not meeting all requirements; but having skills that can be applied. ▪ It can be difficult to find candidates with the right mix of knowledge and experience. ▪ Ideally we would be seeking to recruit candidates who have already had some industrial experience rather than just an academic background. ▪ Not a great number of candidates seem to be coming through and of those that are, quality not always great.
Biotech-nology[39]	Biotechnology is the combination of biological and microbiological sciences and protein engineering to discover and optimise biologic drug candidates to be medicines or to use biological molecules to perform specific processes to enable their discovery. Use of stem cell biology tools and technologies to assemble biologically relevant, predictive assays and cell models. Bringing cell therapy tools and technologies into clinical practice.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Both practical skills such as molecular biology and data analysis skills are important. Candidates can often seem promising on paper, but then fail to instil confidence in real life! ▪ Without having enough experienced people in this sector, the UK risks losing its biotech skill-base to competitors in other countries. ▪ Very superficial coverage of biotechnology.
Drug metabolism and ADME	This is the study of how the body affects a drug following its administration, through the rate and extent of absorption, distribution, metabolism and excretion (ADME). A good understanding of pharmacokinetics (PK) is crucial to the understanding of whether or not a drug will be safe for use in humans and gives information about dose size and frequency.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Undergraduate student recruitment is good with high numbers of applicants. We need to ensure ADME is part of a degree course going forward. Students who have spent time in industry and have knowledge/experience of DMPK are better. ▪ Struggle to find niche skill-set, suitable candidates with relevant experience. ▪ Graduates generally have a basic understanding of the subject. There is, however, a practical skills gap in use of basic laboratory equipment. ▪ Our ideal graduate applicant would have practical experience in the workplace.

38 In 2008 Biopharmaceuticals was linked with Biotechnology
39 In 2008 Biotechnology was linked with Biopharmaceuticals

Genomics[40]	Genomics is a discipline where techniques to sequence, assemble and analyse genomes are used to establish their structure and function.						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	• Omics and synthetic biology should be linked to increase depth of coverage during training. • Need for quality candidates with the expertise to translate genomics for drug discovery and development. • This is a growing field across academic and industry leading to increased competition for quality candidates – struggle to find niche skill-set, suitable candidates with relevant experience. • Skill shortages range from use of basic equipment to lack of research skills or basic scientific thinking. • Graduates are aware of the basic theory but are not aware of recent advances in technology. Academia could address these weaknesses by increasing the practical aspects of the course.
In vitro pharma-cology	*In vitro* pharmacology is the study of how medicines interact with cells and tissues, with the aim of predicting what effects a medicine might have in humans. All experiments are carried out in a controlled environment outside a living organism. This work is essential to develop an understanding of how compounds that have the potential to become medicines act at both the cellular and molecular level.						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	• *In vitro* pharmacology and physiology are important skills for postgraduate research in both higher education and the pharmaceutical sector. • While computer-aided learning can be very useful in teaching, there is concern that technical knowledge is lacking behind instrumentation, planning and delivering such experiments. • We only recruited for electrophysiology. General knowledge of electrophysiology ion channel was usually limited.
In vivo pharma-cology	*In vivo* pharmacology is the study of how medicines interact with living organisms, with the aim of predicting what effects a medicine might have in humans. *In vivo* pharmacologists investigate how effective a compound is in living biological systems (pharmacodynamic effects) and establish whether a new compound could produce side effects (safety pharmacology).						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	• *In vivo* experience is rarely available at university. • *In vivo* pharmacology skills are crucial for translation of research findings to the clinic. • Best places for these skills are universities where industry has previously funded these activities. Now funding is reduced, many facilities are closing. We are generally doing less work in this area but there is still a need. • The economic downturn has reduced the amount of recruitment required and when we have needed to recruit there has tended to be a supply of experienced candidates as unfortunately other institutions have closed sites or made redundancies making it possible to recruit quality people. • We have forged closer relationships with universities and had students work with us for short-term contracts over several years; from frankly very poor people who we would not employ, to excellent people, one of whom we have employed on a full-time basis and is now embarking on a part-time PhD. This approach has become necessary due to the poor quality of new undergraduates and the total lack of *in vivo* knowledge.

40 In 2008 the 'omics' disciplines were merged into a single area

Area	2008	2011	Comments
In vivo physiology	*In vivo* physiology is the study of the physical, chemical and biochemical properties of the functions of living organisms. In the pharmaceutical industry *in vivo* physiologists work to set up new animal models to understand the disease processes, helping to identify sites for therapeutic intervention and to elucidate the desired and undesired mechanisms of action of potential drugs.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Most graduates do not understand how everything *in vitro* comes together to have an effect on the whole animal phenotype.
Metab-onomics[41]	Metabonomics looks at changes in the metabolites present in a cell or organism and can be used to determine the toxicity of potential new drug targets.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Recruiting and training in drug metabolism is difficult due to the fact that candidates 'end up' in drug metabolism from a variety of different disciplines. It is also a very varied discipline and achieving sufficient exposure and experience to cover the breadth of this discipline is a challenge. This is reflected in the experience of new recruits. ▪ Whilst it is likely that someone working in metabonomics will have a stronger chemistry background, a sound biological knowledge base is required to put the data into context. ▪ An understanding of the drug R&D process is vital to ensure data is interpreted correctly and understood in a clinical setting. ▪ Training from experienced staff is crucial in this role; academia must work with industry to improve data interpretation skills.
Micro-biology	The study of microscopic organisms. It includes the sub-disciplines of virology, mycology, parasitology and bacteriology.		
	In 2008 this area was not rated.	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Very limited knowledge demonstrated of microbiology. Important vs future R&D capabilities.
Molecular biology[42]	Molecular biology is the study of biology at a molecular level, particularly looking at the way in which various systems within a cell interact and how they are regulated. In the pharmaceutical industry, molecular biologists and bio-scientists are employed in the area of drug discovery, identifying and validating new drug targets against which new chemicals will be tested in order to identify potential new medicines to go into development.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Poor depth of knowledge and skills currently. ▪ A scarcity of experienced people with a suitable blend of experiential and theoretical knowledge. ▪ New graduates' level of understanding of contemporary practices and industry perspectives requires a protracted onboarding and in-house training regime before they can be efficient.

41 In 2008 the 'omics' disciplines were merged into a single area
42 In 2008 Molecular biology was linked with Bioscience

Molecular/ translational toxicology	Molecular and translational toxicologists study the adverse effects that drugs can have on living organisms, from the level of molecules and cells to whole organs. Their work increases the understanding of the safety of a drug before it is trialled in humans. This discipline does not include animal-based toxicology.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ No comments
Proteomics[43]	This is the large-scale study of the structure and function of proteins. Proteomics can be used to identify new biomarkers of disease as well as potential new drugs and drug targets.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ A lot of candidates seem to have a poor grasp of issues such as quality control, technical noise minimisation and multi-test correction. There still seem to be a large number of researchers carrying out poor-quality studies in the apparent belief that 'the technology will save them'. ▪ This is a highly specialised area and candidates with the right practical knowledge and experience are required.
Structural biology	This involves the determination of the molecular structure of biological macromolecules, especially proteins and nucleic acids, as well as the structure of compounds complexed to these macromolecules. This information can be used in compound design by medicinal and computational chemists, as well as in developing an understanding of the relationship between structure and biological function.		
	In 2008 this area was not rated.	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ No comments
Toxicology	Toxicologists study the adverse effects of chemicals on living organisms. Compounds that have the potential to become medicines are assessed for toxicity in both *in vitro* and *in vivo* experiments that are required by law for preclinical studies.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Unpopular field and lack of *in vivo* experience. ▪ Practical skills (needed) include aptitude in report writing as well as lab/*in vivo* work. ▪ Not enough hands-on experience from graduates.

43 In 2008 the 'omics' disciplines were merged into a single area

Veterinary medicine[44]	In industry, vets advise on animal health and welfare, ensuring that all procedures requiring the use of animals are compliant with the principles of humane experimentation (the '3Rs' – refinement, reduction and replacement). Vets monitor animal health and will often advise scientists on techniques to minimise or prevent any pain, suffering or distress to the animals.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ We believe that there are sufficient veterinarians interested in careers in laboratory animal medicine to fill the current needs of the industry, but there is a potential issue of reduced numbers with sufficient levels of experience within the pharmaceutical industry. Many will only have experience in academia or general practice. ▪ Transition from practice into a commercial business environment (is a concern).
Veterinary and toxicological pathology[45]	Pathology is the study of the nature of disease and the structural and functional changes it causes. In industry pathologists work to establish disease models to assess potential therapies, and to characterise the structural changes in the disease state that occur in response to medicines. Veterinary pathologists examine histopathological evidence from routine toxicity studies to establish whether changes seen in tissues are due to normal variation and spontaneous natural disease processes or may have arisen due to the substance under test.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Small pool of experienced pathologists available [especially with Pharma/drug development experience]. ▪ Low turnover, limited candidate pool. Skill-set requirement is evolving further limiting the external candidate pool. ▪ Recruitment of experienced toxicological pathologists who can come into the post and start productive work straight away is difficult. ▪ A limited pool of experienced people available, and attracting people from Pharma companies to work in CROs is difficult because of the differential salary expectations. ▪ There is a greater number of candidates with suitable educational qualifications, but their understanding of the type of work performed in a CRO can be limited. People with experience in diagnostic pathology come better prepared for the type of work we perform, but still need extensive training in the different species and study types that we work with. They also need to be trained in the practical and interpretive skills needed for reporting preclinical toxicity studies. ▪ Recruitment and training of toxicological pathologists is a long-term commitment in terms of the time of experienced pathologists, and also in financial terms.

44 In 2008 this area was merged with Veterinary science
45 In 2008 this area was described as Pathology

6.4.2 Section 2 – Chemical science areas

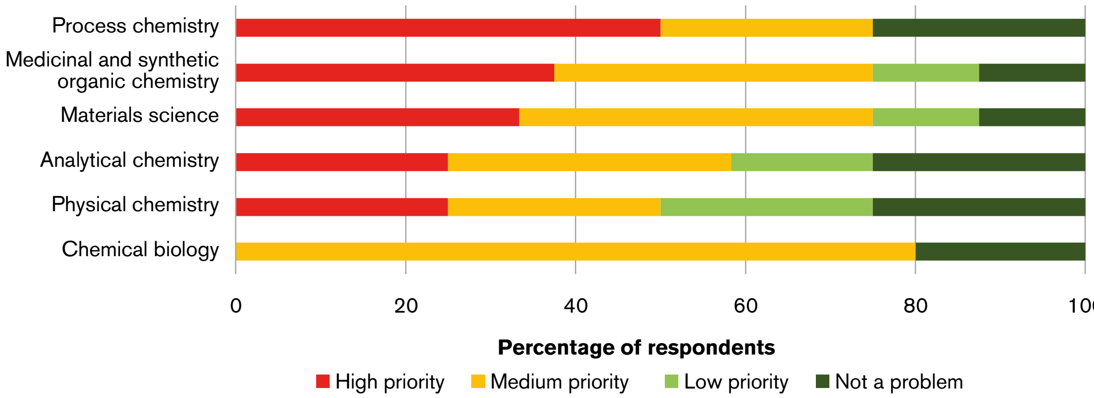


Figure 22: Percentage of respondents rating each chemical science discipline as high, medium or low priority or identifying it as 'not a problem'

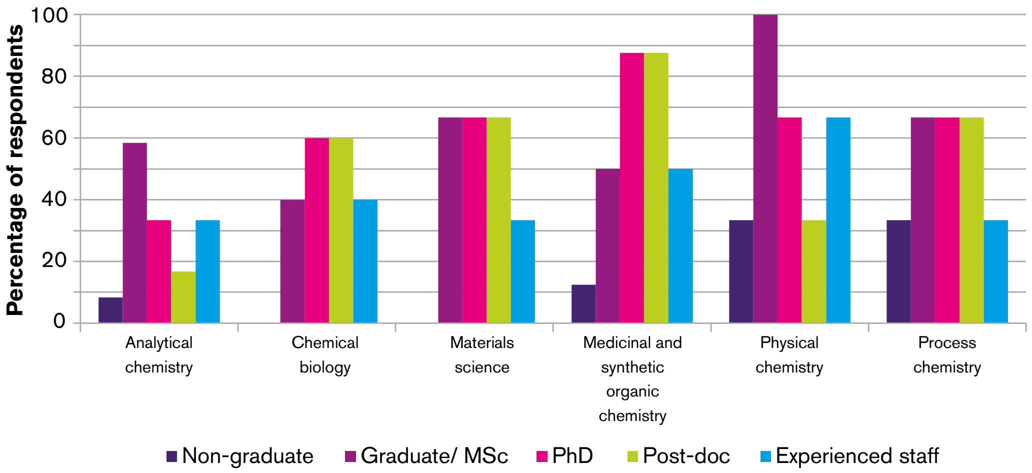


Figure 23: Percentage of respondents identifying each qualification level as an issue within the chemical science disciplines

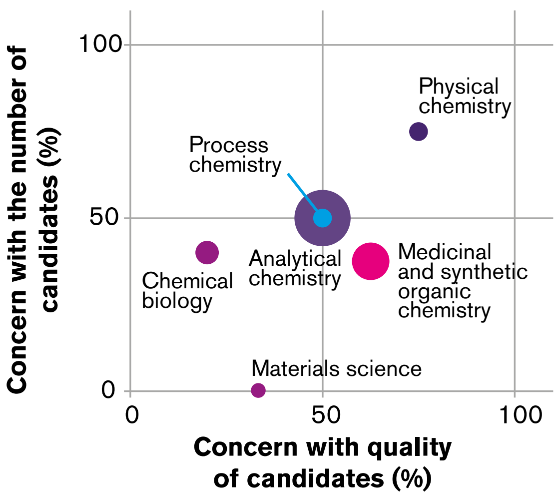


Figure 24: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area

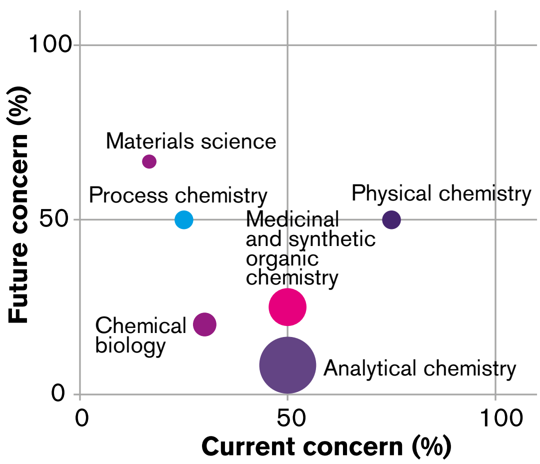


Figure 25: Percentage of respondents rating each discipline area as a future concern vs. a current concern. Size of bubbles represents the number of respondents in each area

Table 3: Percentage of respondents identifying practical skills as a 'major concern', 'concern' or 'not a problem' within the chemical science areas (numbers may not total 100% due to rounding)

	Major concern (%)	Concern (%)	Not a problem (%)
Process chemistry	25	25	50
Chemical biology	20	60	20
Analytical chemistry	18	45	36
Medicinal and synthetic organic chemistry	17	50	33
Physical chemistry	25	50	25
Materials science	0	67	33

Table 4: Detailed chemical science results (including 2008 results and survey comments)

	Low priority – an important area to watch
	Medium priority – requires action
	High priority – requires immediate action
	Not applicable or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

	2008			2014/15			
	Priority	Refer to key	Recruitment level	Priority	Refer to key	Recruitment level	Comments
Analytical chemistry/ biochemistry[46]	Analytical chemists/biochemists work at every stage of development of a medicine, from confirming the structure of a compound that has been made for the first time, to checking the purity of a batch of medicine that is about to be released for sale. Analytical chemists/biochemists may be involved in investigating biological targets, using biophysical techniques to screen and validate targets and studying how molecular properties affect biological activity. Analytical chemists/biochemists also develop techniques for biomarker identification and detection and probe design (mass spectrometry, PET, SPECT, MRI, labelling).						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ The current situation is still the same as in 2008. Main concern is lack of practical skills, method development and troubleshooting skills. In-depth knowledge of analysis is lacking. This is now accepted as the status quo and full training is given on employment. ▪ No real change since 2008.

46 In 2008 this was merged with Physical chemistry

Area	2008		2014		Comments
Chemical biology	Chemical biology uses chemical techniques and tools, and compounds synthesised by chemists, to understand the biological processes that cause disease.				
	In 2008 this area was not rated.		Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ We recruited a number of PhD/post-doc level medicinal chemists in 2014, and were excited to see a wide range of applicants who had trained in chemical biology. ▪ There appears to be a scarcity of experienced people available in the job market with a suitable blend of experiential and theoretical knowledge. New graduates are available, but the level of their understanding against contemporary practices and industry perspectives requires a protracted onboarding and in-house training regime before they can be efficient.
Materials science	Materials science is an interdisciplinary field which deals with the discovery and design of new materials to meet a specific need. Pharmaceutical materials science applies physical principles from materials science to challenges in such areas as drug delivery, control of drug form, manufacture and processing of nanoscopic and microscopic particle systems, and the structure and properties of bulk powders and creation of dosage forms such as tablets or capsules.				
	In 2008 this area was not rated.		Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Drug product design is a key area and is critical to deliver effective medicines for patients. Need graduates and PhDs with increased breadth of knowledge across this space. There is some feeling that Materials science courses are too traditional and not offering what industry needs. There are some problems attracting candidates.
Medicinal and synthetic organic chemistry[47]	Synthetic chemists are involved in making chemical compounds, which are then tested for their potential as new medicines. Medicinal chemists are involved in the design of these compounds. Peptide chemists use synthetic organic chemistry techniques to make, purify and analyse compounds for use as medicines. In medicinal chemistry various techniques are used to design and predict the activity of compounds at a biological target such as a receptor or enzyme, as well as its likely pharmacokinetic profile and safety properties. Medicinal chemists are likely to have a background in synthetic organic chemistry but may have additional knowledge and skills around molecular understanding of biological systems and processes through application of synthetic, physical, analytical and computational methods. In many organisations chemists perform the role of both synthetic and medicinal chemist at the same time.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ No difficulty in recruiting the number of synthetic chemists we required in both medicinal and process chemistry. The quality of graduate was generally very high. ▪ For postgraduate recruitment, many struggled with technical questions which were not related to their own areas of research. In some cases, there was a complete lack of knowledge of undergraduate chemistry demonstrated by students from excellent universities.
Physical chemistry[48]	Physical chemists generate high quality physicochemical property data on compounds prepared as part of a drug discovery programme. These data are used by medicinal chemists in compound design. Structural chemists try to elucidate the structures and shapes of molecules. This approach can be used in the design of new medicines.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Can be difficult to find candidates as it's not an area many choose to pursue.

47 In 2008 this was merged with Process chemistry
48 In 2008 Physical chemistry was merged with Analytical chemistry

Process chemistry[49]	Process chemists design suitable chemical syntheses for the large-scale preparation of molecules that are being progressed to advanced clinical studies as potential drugs. For approved drugs, process chemists will have devised the synthetic route that will be used in commercial manufacture.					
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Shortage of high talent within graduate population.

6.4.3 Section 3 – Clinical areas

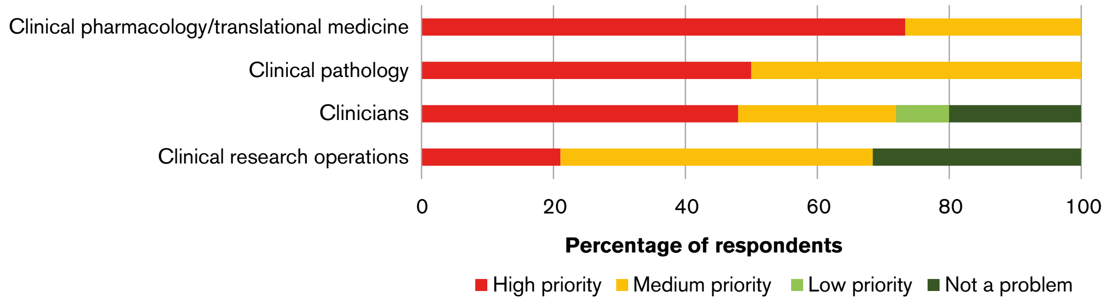


Figure 26: Percentage of respondents rating each clinical science discipline as high, medium or low priority or identifying it as 'not a problem'

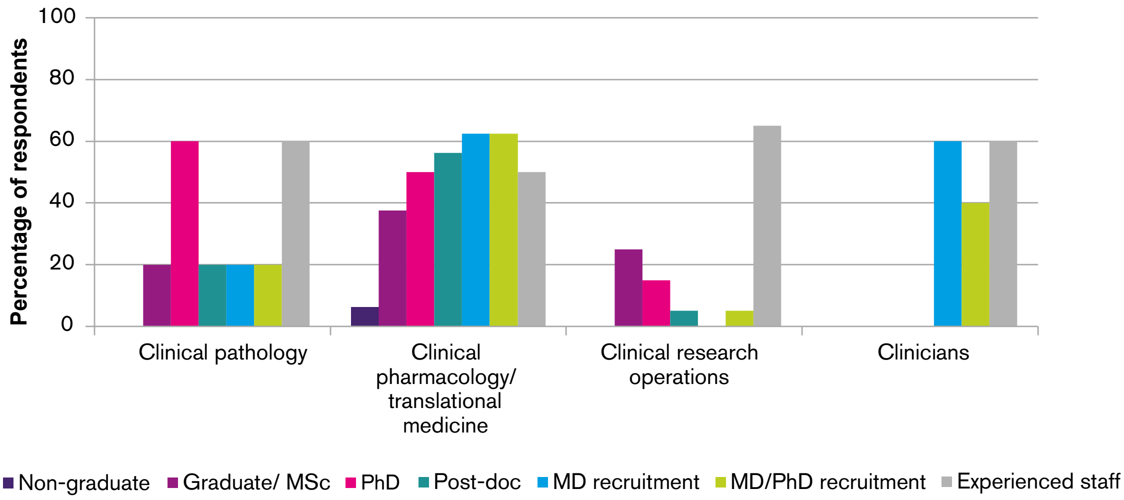


Figure 27: Percentage of respondents identifying each qualification level as an issue within the clinical science disciplines

49 In 2008 this was merged with Medicinal or Synthetic organic chemistry

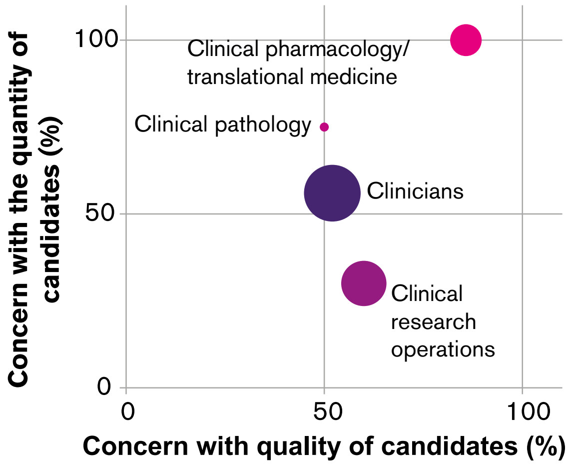


Figure 28: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area

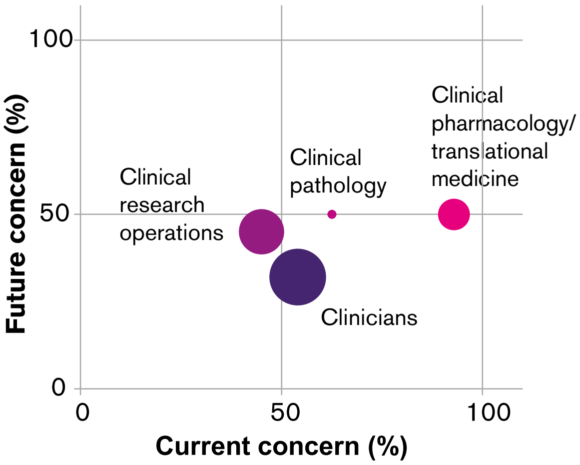


Figure 29: Percentage of respondents rating each discipline area as a future concern vs. a current concern. Size of bubbles represents the number of respondents in each area

Table 5: Percentage of respondents identifying practical skills as a 'major concern', 'concern' or 'not a problem' within the clinical science areas (numbers may not total 100% due to rounding)

	Major concern (%)	Concern (%)	Not a problem (%)
Clinical pharmacology/translational medicine	67	33	0
Clinical pathology	25	75	0

Table 6: Detailed clinical areas results (including 2008 results and survey comments)

(green)	**Low priority** – an important area to watch
(amber)	**Medium priority** – requires action
(red)	**High priority** – requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

Table 6: Detailed clinical areas results (including 2008 results and survey comments)

	2008			2014/15			
	Priority	Refer to key	Recruitment level	Priority	Refer to key	Recruitment level	Comments
Clinical pathology[50]	Clinical pathology is the study of the nature of disease and the structural and functional changes it causes. In industry, pathologists work to establish disease models to assess potential therapies, and to characterise the structural changes in the disease state that occur in response to medicines.						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F	Non-graduate Graduate/ MSc PhD Post-doc MD MD/ PhD Experienced staff	• A major problem and is impacting on our ability to deliver experimental medicine studies. There is an important gap of those able to unpick disease processes and design animal studies that are informative. • Appears to be a scarcity of experienced people with a suitable blend of experimental and theoretical knowledge. New graduates are available, but the level of their understanding against contemporary practices and industry perspectives requires a protracted onboarding and in-house training regime before they can be efficient.
Clinical pharma-cology / translational medicine	Clinical pharmacology is the study of drugs and their clinical use. Clinical pharmacologists carry out work involving the analysis of the effects of medicines on people within clinical trial studies. Translational medicine is a discipline that aims to bridge the divide between basic scientific research and patient care through translating scientific discoveries into real therapies and medicines (also known as 'bench to bedside').						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F	Non-graduate Graduate/ MSc PhD Post-doc MD MD/ PhD Experienced staff	• We have identified a pressing need for more clinical pharmacology and therapeutics consultants in the NHS. These consultants would be well placed to work with industry and to run experimental medicine studies within the NHS. • Still a major gap; it is still easier to do an animal study PhD than one involving a human experiment. • Getting this step right may avoid potential Phase III disasters but the work is often not done early enough, particularly when coupled with discovery/toxicology work. • A high priority as this is an existing problem to find good clinical pharmacologists with good knowledge of the R&D requirements in industry. • Not many candidates available and quality not always great in terms of scientific understanding, motivation and attention to detail.

50 In 2008 this area was merged with Toxicological and veterinary pathology

Clinicians	There are many areas where doctors play an important part within the pharmaceutical industry, including clinical development, regulatory affairs, drug safety and clinical pharmacology. They have a key role in supporting clinical research and clinical trials.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F Non-graduate Graduate/ MSc PhD Post-doc MD MD/ PhD Experienced staff	▪ Too many jobs, not enough good candidates. ▪ Very limited supply of candidates with 'commercial'/ industry experience. ▪ Not enough well qualified medics to satisfy the pharmaceutical industry's demands. This is both a problem of attracting medics into the industry and of the suitability of available candidates. ▪ Quality of medics applying is generally not very high and it is hard to find candidates with relevant therapy area experience. The number with any real experience of clinical research and a demonstrated aptitude is very small. ▪ Too often it seems that smaller companies do not understand what an experienced medically-qualified person can bring to the company. ▪ Challenge to find medics interested in moving into a commercial environment – this element is not addressed anywhere as a career option through medical schools. ▪ I believe this should be an area of focus as medical departments and medical activities play an increasingly important role in drug commercialisation. ▪ Not a priority. ▪ I think there are gaps regarding several aspects. There seem at the moment to be a lot of NHS clinicians (many high quality) who would be keen to move into industry. However, now that industry is watching budgets much more carefully some roles which would traditionally have been medics have gone to nonmedics and therefore new to industry roles are restricted. New to industry medics can't hit the ground running and need a good 3–4 months generally before they can add significant value.
Clinical research operations	This discipline involves working operationally in the field of clinical research trials, to ensure correct set-up monitoring and close-down of clinical trials. This includes developing protocols, identifying trial sites/locations, setting up and monitoring trial progress, ensuring complete documentation throughout the trial and resolving any issues that arise with a view to high quality data being obtained in a timely fashion. Job titles include Project/Study Managers, Clinical Research Associates (CRAs) and Clinical Trial Assistants (CTAs).		
	In 2008 this area was not rated.	Q N F M Non-graduate Graduate/ MSc PhD Post-doc MD MD/ PhD Experienced staff	▪ Poorer quality of CVs when recruiting. A large number of candidates with minimal amount of experience are freelancers but have minimal experience. ▪ Many clinical ops staff have experience of clinical trials of investigational medicinal products; experience of highquality studies on medical devices/ *in vitro* diagnostics (IVDs) is rarer. ▪ Very limited pool from which to select candidates; currently training interns as an immediate action. ▪ Recruitment of high-calibre graduates is not an issue but recruitment of hire-calibre experienced staff is an issue. Experienced staff are often looking for junior project management positions and there are not sufficient training programs to convert graduates to experienced staff. ▪ Post-doc – lower number of years is more desirable than a longer career in academia. ▪ Too many staff have a single process mindset approach and not enough innovation to look for new methods.

6.4.4 Section 4 – Pharmacy

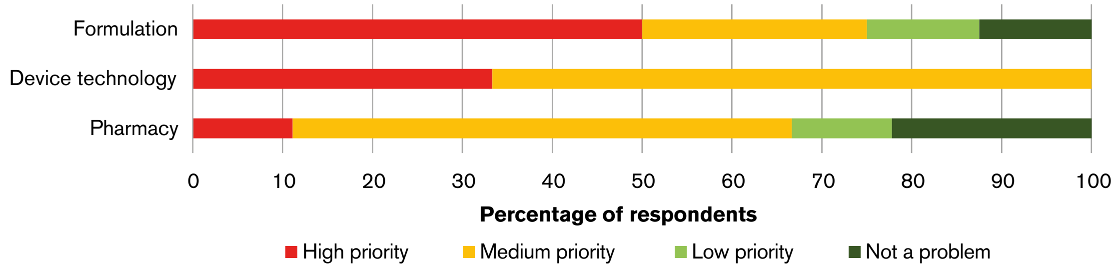


Figure 30: Percentage of respondents rating each pharmacy discipline as high, medium or low priority or identifying it as 'not a problem'

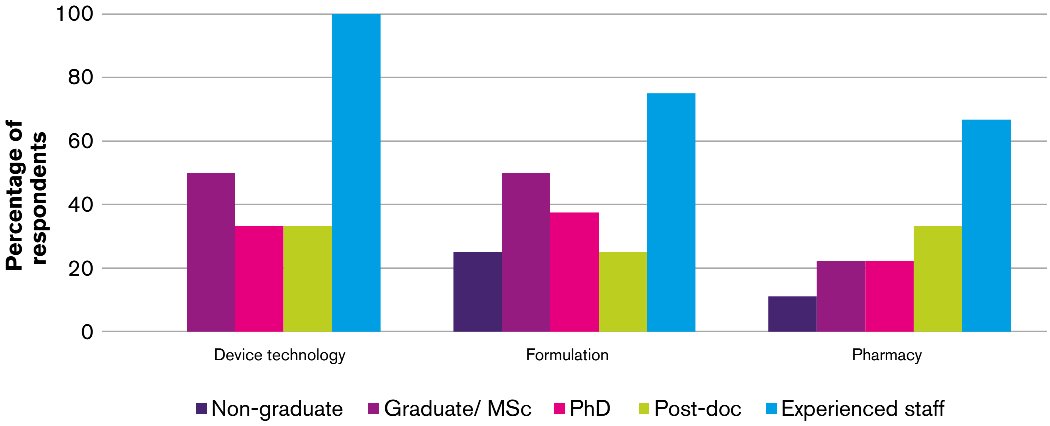


Figure 31: Percentage of respondents identifying each qualification level as an issue within pharmacy disciplines

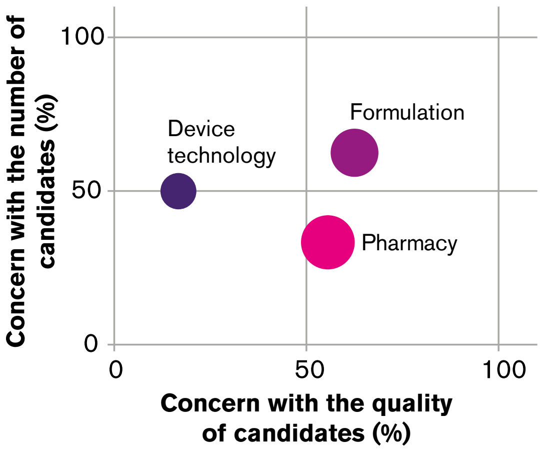


Figure 32: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area

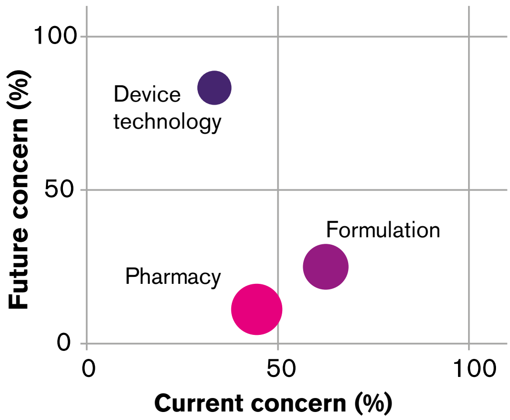


Figure 33: Percentage of respondents rating each discipline area as a future concern vs. a current concern. Size of bubbles represents the number of respondents in each area

Table 7: Percentage of respondents identifying practical skills as a 'major concern', 'concern' or 'not a problem' within the clinical science areas (numbers may not total 100% due to rounding)

	Major concern (%)	Concern (%)	Not a problem (%)
Formulation	50	38	13
Pharmacy	11	56	33
Device technology	0	100	0

Table 8: Detailed pharmacy areas results (including 2008 results and survey comments)

	Low priority – an important area to watch
	Medium priority – requires action
	High priority – requires immediate action
	Not applicable or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

	2008			2014/15			
	Priority	Refer to key	Recruitment level	Priority	Refer to key	Recruitment level	Comments
Device technology	Medical devices include drug delivery systems such as inhalers, injections and stents, and also clinical diagnostic tools.						
	In 2008 this area was not rated.				Q N F M	Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Key issue has been about the number of people with the skills we require being aware that a device engineering function resides within big pharma. ▪ Technology pushes for a fast deployment of devices used for diagnostics or data capturing and there is a need for a robust legal and regulatory framework knowledge.
Formulation	This involves creation of a dose of a medicine (such as a tablet, capsule or injection) which will deliver the active substance to the correct part of the body, in the right concentration, and at an appropriate rate. For biopharmaceuticals, formulation involves determining the appropriate excipients to add to the drug compound to deliver the desired dose via the desired delivery mechanism to the target organ or system in the body.						
	In 2008 this area was not rated.				Q N F M	Non-graduate Graduate PhD Post-doc Experienced staff	▪ Candidates failed to appreciate some basic principles such as the impact of solubility on biopharmaceutics and how to resolve this or the impact of other physicochemical attributes on drug product stability. ▪ Candidates would have benefited from more exposure to some real manufacturing production lines, the risk based development of those and ongoing quality assurance associated with them even at a basic level. ▪ Formulation and clinical improvement goes hand in hand. Right target in quality and quantity both.

Pharmacy	Pharmacists work across the industry in areas such as the assessment of safety and efficacy of new medicines and the formulation of medicines and could be responsible for the release of medicines to the market.				
	Q N F M	Non-graduate Graduate PhD Post-doc	Q N F M	Non-graduate Graduate PhD Post-doc Experienced staff	▪ The effect of regulatory necessity for QP responsibilities requires specific training and knowledge.

6.4.5 Section 5 – Informatics, Computational, Mathematical and Statistics areas

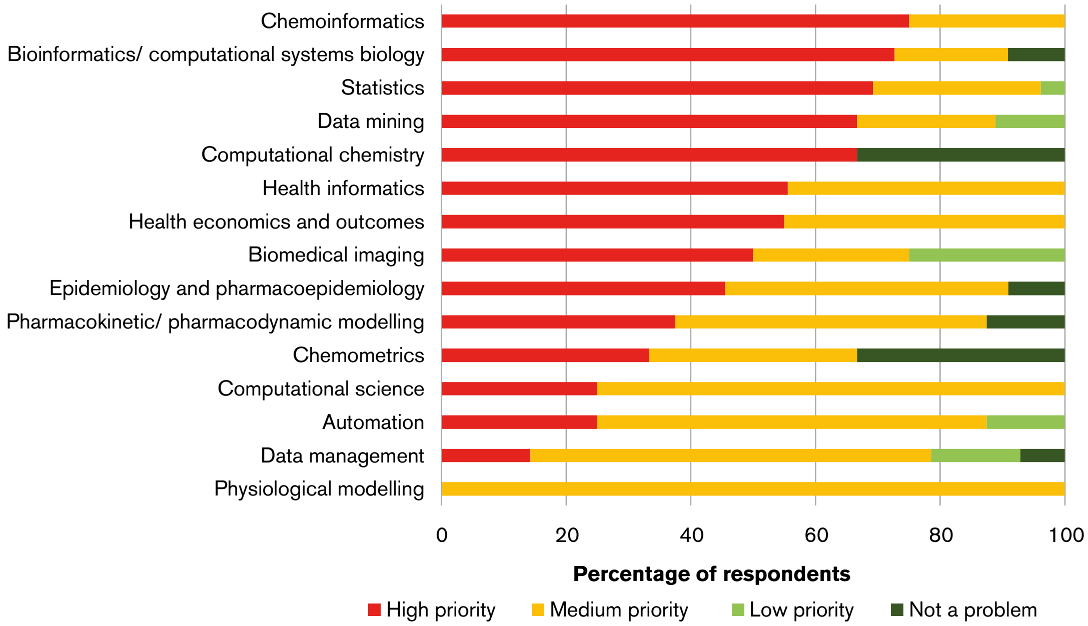


Figure 34: Percentage of respondents rating each discipline as high, medium or low priority or identifying it as ‘not a problem’

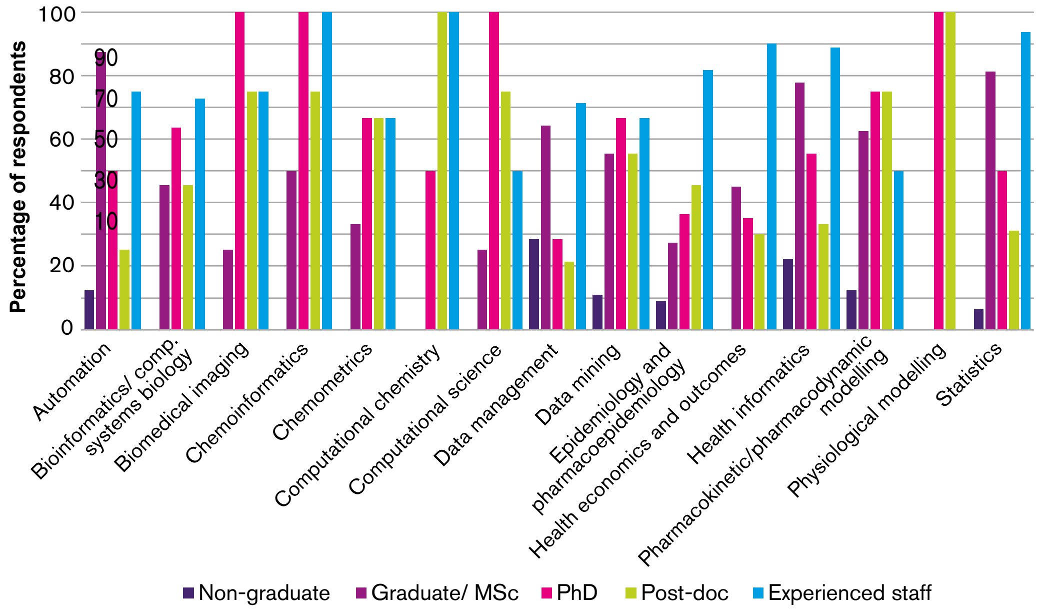


Figure 35: Percentage of respondents identifying each qualification level as an issue within the informatics disciplines

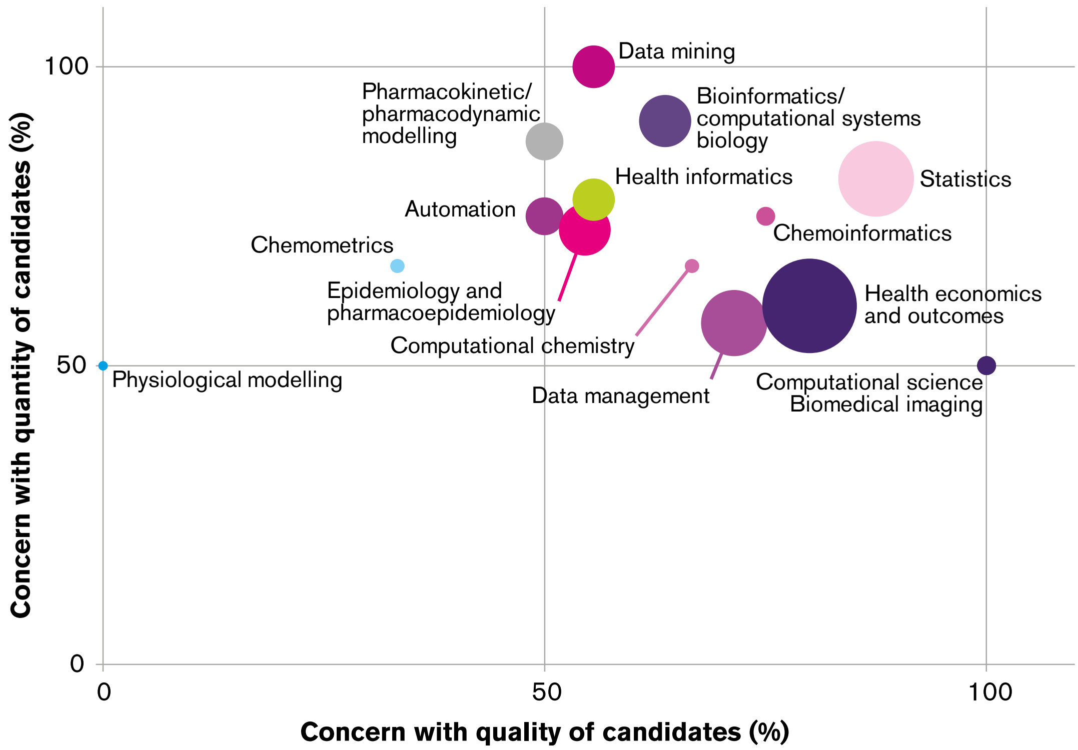


Figure 36: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area (Computational science and Biomedical imaging have overlapping results)

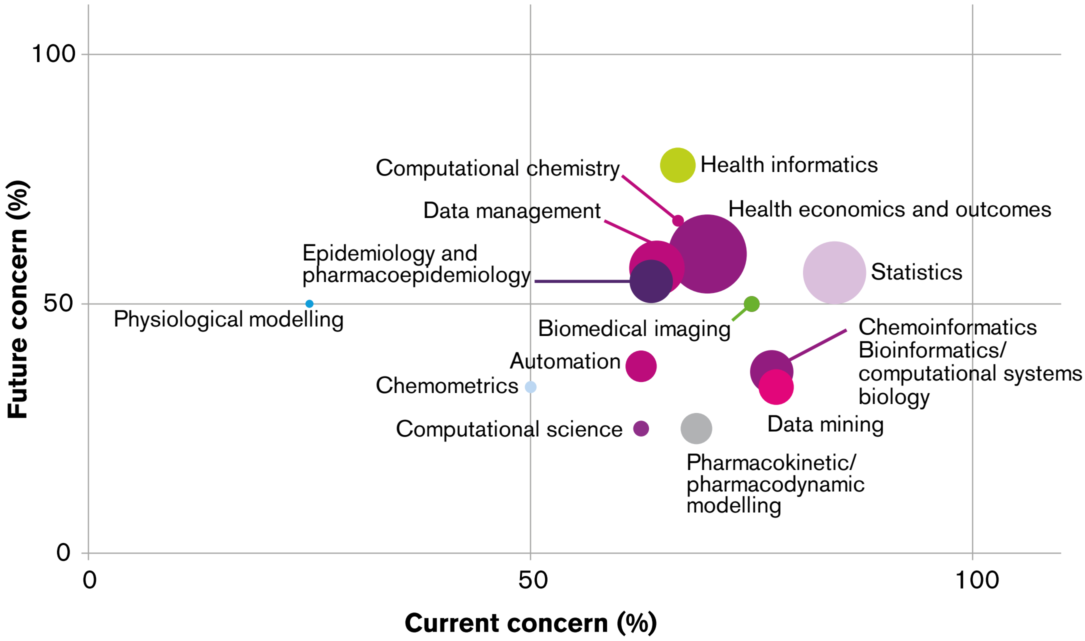


Figure 37: Percentage of respondents rating each discipline as a future concern vs. a current concern. Size of bubbles represents the number of respondents in each area

Table 9: Percentage of respondents identifying practical skills as a 'major concern', a 'concern' or 'not a problem' within the informatics disciplines (numbers may not total 100% due to rounding)

	Major concern (%)	Concern (%)	Not a problem (%)
Automation	25	75	0
Biomedical imaging	0	50	50

Table 10: Detailed informatics, computational, mathematical and statistics areas results (including 2008 results and survey comments)

(green)	**Low priority** – an important area to watch
(amber)	**Medium priority** – requires action
(red)	**High priority** – requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

Table 10: Detailed informatics, computational, mathematical and statistics areas results (including 2008 results and survey comments)

	2008			2014/15			
	Priority	Refer to key	Recruitment level	Priority	Refer to key	Recruitment level	Comments
Automation	Laboratory automation is a multi-disciplinary strategy to research, develop, optimise and capitalise on technologies in the laboratory that enable new and improved processes.						
	In 2008 this area was not rated.				Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Very limited pool of experienced people, who generally develop their skills on the job rather than during their education. ▪ A lot of applicants but most do not satisfy the basic requirements. Limited pool of viable candidates, required to source globally especially for management candidates. ▪ Many programmers apply for vacancies, but few are of the required quality. ▪ Lack of relevant skills in the market.
Biomedical imaging	Biomedical imaging is increasingly used in the pharmaceutical industry as a non-invasive technique during preclinical studies and clinical. It can be used, for example, to evaluate whether or not a medicine has had a biological effect, or if it reaches the target organ. Imaging techniques can also provide data on biomarkers of disease, providing an efficient way to accurately evaluate the effectiveness of some new medicines.						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Candidates from most PhD programmes lack breadth of knowledge about technologies and have no industry awareness; newer EPSRC Doctoral Training Centre approaches will make an important improvement to address potential issues in the future. ▪ We tend to employ more experienced candidates to fill immediate expertise gaps in R&D but would really like to employ less experienced (e.g. newly completed PhD) if they had good awareness of industry but it's been hard to identify such candidates. ▪ Expertise is really needed in the biology discipline rather than specific technical know-how. ▪ Considered a high priority as there needs to be more engagement to what imaging provides especially with respect to 3Rs and clinical translation.
Bio-informatics/ computa-tional systems biology[51]	Systems biology integrates experimental and computational research to better understand complex biological processes. Bioinformatics and computational systems biology use statistical techniques, including Bayesian methods, to interpret large sets of biological data. Modelling and simulation of biological systems are used as an aid to predicting activity of a potential medicines.						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Very difficult to find high quality candidates (especially at PhD and Post-doc levels) unless you have good connections with various universities/institutes and a strong reputation. In addition there is a lot of competition for these skills both in academia and in the industry. ▪ Recent investment in medical bioinformatics, for example by the MRC in the UK, should help longer term; however, I expect to see a growing demand for these skills driven by biology and biomedical data generation, technology and scientific questions. ▪ Skills/ experience gap is core computational statistical skills underpinning bioinformatics, or informatics analysis applied to answering of biological or clinical phase related questions.

51 In 2008 Bioinformatics was linked with Computational science

Area	Description / 2008	2012	Comments
Chemo-informatics	Chemoinformatics involves the application of computational techniques to existing data sets to address a range of chemical problems. Chemoinformatics toolkits allow virtual screening, chemical database mining and structure-activity studies.		
	In 2008 this area was not rated.	Q N F M Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Number of qualified and experienced candidates has risen from previous years; however, the pool is still limited for this niche area.
Chemo-metrics	Chemometrics is the science of extracting information from chemical systems by data-driven means using methods such as multivariate statistics, applied mathematics and computer science, in order to address problems in chemistry, biochemistry, medicine, biology and chemical engineering.		
	In 2008 this area was not rated.	Q N F M Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Very limited number of qualified candidates.
Comput-ational chemistry[52]	This discipline involves the use of computational approaches in drug design and in lead identification. The properties of molecules and target proteins are modelled to predict and gain insight into how these will interact. Computational chemists often work with structural chemists, who in turn try to elucidate the structures and shapes of molecules, protein targets and protein-molecule complexes. These approaches are widely used in the design of new medicines.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ No comments
Comput-ational science[53]	Computational scientists use mathematical modelling techniques along with information from published literature to build hypotheses for drug targets. The use of computational science allows large data sets to be collected and analysed quickly.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/MSc PhD Post-doc Experienced staff	▪ Whilst there are a large number of potential candidates on the market, in my experience the majority of them seem to have poor skills. ▪ We are looking for candidates at least at PhD level often with interdisciplinary training. There are growing public funds available in this domain (e.g. Systems Medicine in the EU for Horizon 2020) and many more training schemes than a few years ago. This should lead to a growing pool of computational scientists. However, there is also a great competition for these skills with growing demands from industry and academia.

52 In 2008 Computational chemistry was merged with Structural chemistry
53 In 2008 Computational science was linked with Bioinformatics

Data management	Broadly this involves the development, execution and supervision of plans, policies, programmes and practices that control, protect, deliver and enhance the value of data and information assets. Clinical research data management is the application of informatics theories and methods to the definition, collection and processing of data for clinical studies and the design of associated work and data flow.			
	In 2008 this area was not rated.	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ The key area is real world data around outcomes. The NHS and healthcare generally is losing the ability to manage data well and the industry is increasingly being asked to fill the gap. We need more people in data management. ▪ This area can be hard to recruit. Many school and university leavers have not heard about the area of data management and therefore cannot consider it as a career possibility. The combination of programming skills with an eye for detail and knowledge of the complex data formats makes finding applicants with all these skills challenging.
Data mining	The process of analysing data to find correlations or patterns in large sets of data, possibly from multiple sources.			
	In 2008 this area was not rated.	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ There is a high level of competition for these skills with other industries using data mining. We can't see this changing rapidly in the future. ▪ Data mining overlaps with other domains and often requires multidisciplinary training. ▪ This is a highly specialised area with other industries taking the best people. Data mining is key in healthcare. ▪ Industry is behind the evolution of reality and NHS on that area. Opportunity to change our model of generating data for UK is big and unexploited so far.
Epidemiology and pharmaco-epidemiology	Epidemiology is the study of health and disease conditions in a defined population to identify patterns. Pharmacoepidemiology uses these techniques to study the uses and effects of medicines in large, well defined, populations.			
	In 2008 this area was not rated.	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ There is a lack of candidates with in-depth experience in working with complex UK healthcare data and the combination of theoretical and practical skills to deliver or lead on research projects. Related roles such as programmers with relevant experience are also hard to recruit. ▪ This issue is likely to increase with the growth in available UK healthcare data and the need to generate evidence to support HTA submissions at launch, the potential for adaptive licensing, and generation of real world evidence throughout the product life-cycle. ▪ The industry has an increasing demand of epidemiologists and pharmaco-epidemiologists, to satisfy the evidence / real world data needs of the industry. This is both an issue of availability of suitable candidates and of the industry attracting the best of the available talent in this field. ▪ This is still an area where we struggle to get many well qualified candidates in the UK compared to the USA. Although those that are available in the UK are appropriately trained/skilled, it is the numbers we need now and might expect to need in the future that will be a challenge. ▪ UK market has a significant lack of skills in comparison to US and Asian markets. ▪ It is linked with data mining. We need to see how we combine skills in those two areas.

Health economics and outcomes	Health economics is a branch of economics concerned with issues relating to the allocation of health and healthcare. Health economists study factors that affect the supply and demand for healthcare and the market equilibrium, and look at healthcare system design and reform as well as aspects of financing, expenditure and purchasing.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	• Whilst there are a number of candidates who are adequately academically qualified (e.g. MSc or PhD) there is a lack of candidates with industry experience. • HEOR continues to be a key area of growth for the industry and there are not enough well qualified candidates to satisfy the demand. Partly also an issue of candidate perception of the industry. • The greatest need is for experienced scientists able to shape drug development strategies – including integrated analytical programmes – in advance of market authorisation and HTA assessment. • Technical HEOR skills need to be supplemented with understanding of the uses of HEOR data in HTA/ pricing/ reimbursement decision-making in different countries and an appreciation of the drug development process. • There seems to be a dichotomy between academic health economists and the realities of the industry. MSc and PhD too often take a purist approach largely because they simply do not understand the commercial necessities. • We've not actively recruited in this area; however, we know there is a lack of experienced staff in this field. • There is a pool of quality staff available in the area but not enough of them. • Lots of new entrants to this field but still limited numbers of experienced candidates today.
Health informatics	Health informatics deals with the resources, devices, and methods required to optimise the acquisition, storage, linkage, retrieval, and use of health-related data to improve healthcare outcomes and optimise the development and use of medicines.		
	In 2008 this area was not rated.	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	• This is a key area of growth at the moment and one which the UK government is investing heavily in, yet we have variable quality candidates and few appearing that are highly skilled in the area. This may change as the Farr Institute starts to deliver against its objectives, but we have yet to see tangible progress of this. • The level is atrocious – the NHS lost the best health informaticians during the reorganisation. Academics are filling the gap but they are academic without real world or NHS experience and therefore limited. • New and growing market candidates with limited experience.
Pharmaco-kinetic/ pharmaco-dynamics modelling	Pharmacokinetics (PK) focuses on how the body processes a drug, resulting in a drug concentration. Pharmacodynamics (PD) is concerned with how the drug acts on the body, resulting in a measurable drug effect. Through PK/PD modelling and simulation, which combines the two disciplines, pharmaceutical scientists acquire an earlier understanding of the link between drug and response, and can better characterise a drug's absorption, distribution and elimination properties.		
	Q N F M Non-graduate Graduate PhD Post-doc	Q N F M Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	• Too few qualified candidates/experienced candidates. • Comments in 2008 still relevant. Skill shortages are the lack of people trained in pharmacokinetics and pharmacodynamics, probably because this is rarely taught at undergraduate level and there are relatively few postgraduate training courses available either in the industry or academia. • This is probably the only area of pharmaceuticals/ biotech that has been consistently seeing increases in demand and salary across all regions of the globe. Emerging competition from graduates in China and India – direct recruitment from these areas is beginning to happen. So, we need to crank up the number and quality of graduates in order to not be left behind in this hot area.

Physiological modelling	Modelling and simulation at the pre-clinical stage of drug development involves integration of data on physicochemical properties, pharmacokinetics, pharmacodynamics, formulation and safety. Physiologically based pharmacokinetic (PBPK) modelling and simulation is a tool that can help predict the pharmacokinetics of drugs in humans and evaluate the effects of intrinsic and extrinsic factors, alone or in combinations, on drug exposure. The use of this tool is increasing at all stages of the drug development process.						
	In 2008 this area was not rated.				Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Not an immediate concern, but is likely to become one in the next 3–5 years. ▪ Physiological modelling requires practical skills in whole animal physiology. The latter is a gap.
Statistics	Statisticians are a fundamental part of a drug development project team across the whole life-cycle of a pharmaceutical product – from laboratory work through to trials in humans (clinical trials) and finally to manufacturing and marketing. Pharmaceutical statisticians are closely involved with activities such as experimental design, sample size calculations, data collection, and the analysis, interpretation and presentation of results.						
		Q N F M	Non-graduate Graduate PhD Post-doc		Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Very limited pool of suitably skilled people. ▪ Communication and influencing skill issues are often still observed in new candidates, including the ability to explain technically difficult concepts to nonstatisticians in a simple way in order to ensure their buy-in. As the need for more complex methods is increasing, this skill becomes ever more important. ▪ Still too few qualified and experienced candidates overall; in addition, there is an increasing demand for higher qualifications than previously (i.e. more candidates to PhD level now desired). It is simpler to recruit PhD statistician graduates in the USA than in the UK. ▪ Very difficult to recruit experience people and can take 6–9 months to fill a vacancy. Even harder to find statisticians who have some feel for/ understanding of biology/bioinformatics e.g. statistical geneticists. ▪ Advanced statistical skills are required to work with new data sets and new methods of working including with big data. We need data scientists – multidisciplinary people with stats, computer programming, health insight and understanding of the data, but most statisticians are very narrow in focus. ▪ Little change from 2008 comments. Seeing high number of candidates only interested in contractor opportunities. ▪ Another critical area. Standard statistics is not good enough – applied biostatistics in the area of study design is required. Not an easy skill to get.

6.4.6 Section 6 – Regulatory areas

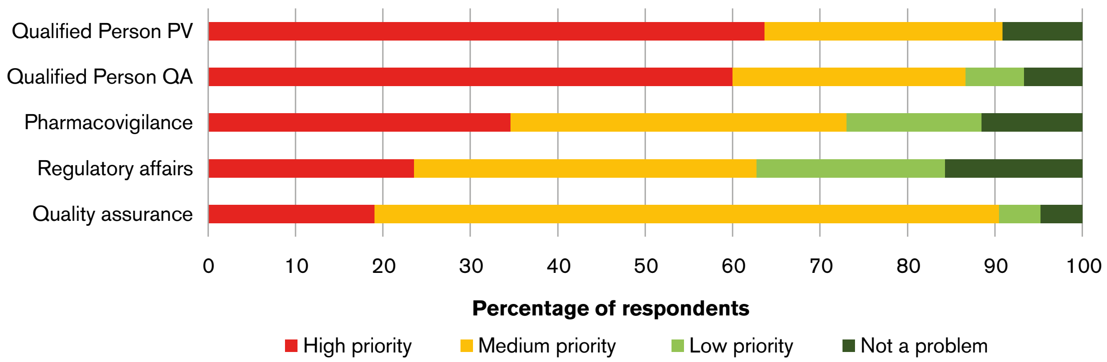


Figure 38: Percentage of respondents rating each regulatory discipline as high, medium or low priority or dentifying it as 'not a problem'

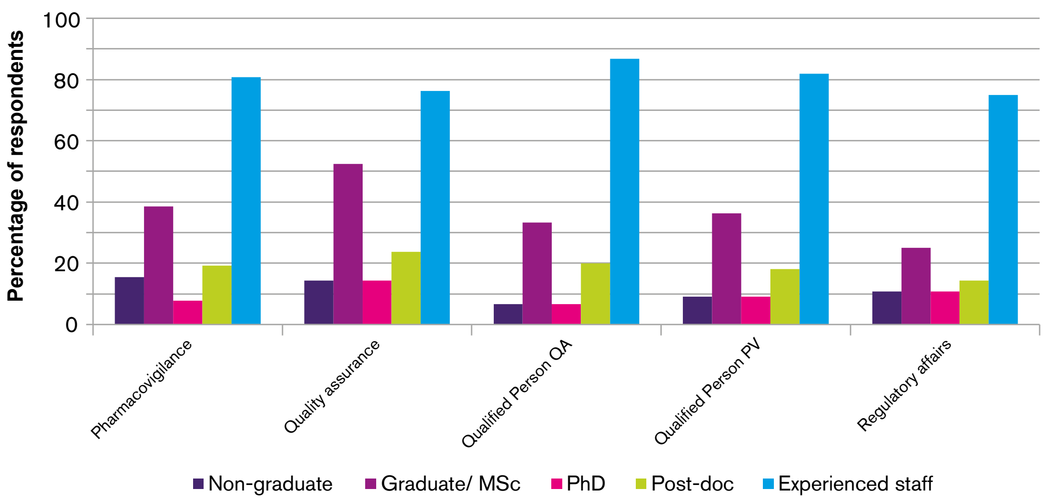


Figure 39: Percentage of respondents identifying each qualification level as an issue within the regulatory disciplines

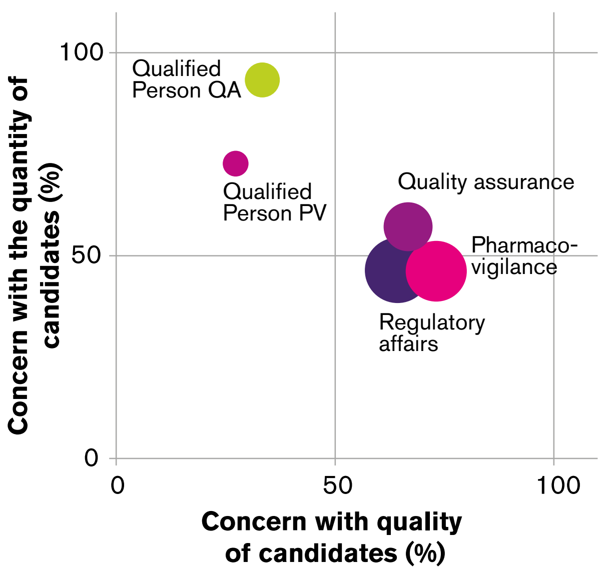


Figure 40: Percentage of respondents identifying a concern with the number vs. quality of candidates in each discipline. Size of bubbles represents the number of respondents in each area

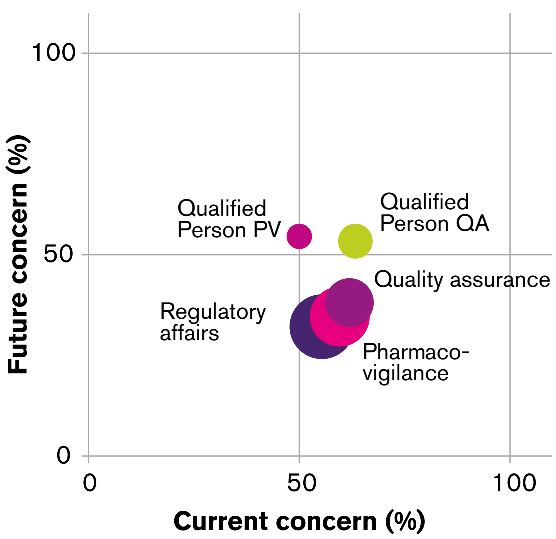


Figure 41: Percentage of respondents rating each discipline as a future concern vs. a current concern. Size of bubbles represents the number of respondents in each area

Table 11: Detailed regulatory areas results (including 2008 results and survey comments)

(green)	**Low priority** – an important area to watch
(amber)	**Medium priority** – requires action
(red)	**High priority** – requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

	2008			2014/15			
	Priority	Refer to key	Recruitment level	Priority	Refer to key	Recruitment level	Comments
Pharmaco-vigilance	Pharmacovigilance is the process of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, to ensure that drugs on the market are safe for patients, and to identify new hazards associated with the medication.						
	In 2008 this area was not rated.			(amber)	Q N F M	Non-graduate Graduate/ MSc PhD Post-doc Experienced staff	▪ Require people that have experience in handling additional risk minimisation materials. Skills lacking in the workplace. ▪ There don't appear to be many people with skills in these areas. If we advertise a job to get someone with say 2–3 years' experience, then we get very few applicants. ▪ Market offers very few experienced staff. ▪ It can be very difficult to recruit into pharmacovigilance – you need high quality people with high attention to detail – can sometimes be difficult to find.
Quality assurance	Quality needs to be built into the product. The information and knowledge gained from pharmaceutical development studies provide scientific understanding to support the establishment of specifications and manufacturing controls which will enable to ensure a pharmaceutical product's quality throughout its life-cycle. GLP, GCP and GMP guidelines ensure that appropriate standards are adhered to.						
	In 2008 this area was not rated.			(amber)	Q N F M	Non-graduate Graduate PhD Post-doc Experienced staff	▪ Practical experience in GMP Auditing is providing an issue. ▪ Very difficult to find experienced staff in GLP QA and new graduates are not very aware of GLP. Recruitment of GMP QA staff is easier with more applicants available.
Qualified Person (QA)	The primary legal responsibility of the Qualified Person is to certify batches of medicinal products prior to use in a clinical trial or prior to release for sale and placing on the market.						
	In 2008 this area was not rated.			(red)	Q N F M	Non-graduate Graduate PhD Post-doc Experienced staff	▪ No comments

Qualified Person (PV)	Under European pharmacovigilance regulations, each marketing authorisation holder (MAH) is required to appoint a QPPV. The QPPV is responsible for creating and maintaining the MAH's pharmacovigilance system. The system must fulfil the legal obligations regarding product safety and must be adequately resourced.				
	In 2008 this area was not rated.		Q N F M	Non-graduate Graduate PhD Post-doc Experienced staff	▪ No comments
Regulatory affairs	Regulatory affairs professionals ensure regulatory compliance and prepare submissions to regulatory authorities for new medicines and for any change to a marketed medicine.				
	In 2008 this area was not rated.		Q N F M	Non-graduate Graduate PhD Post-doc Experienced staff	▪ A significant decrease in high quality graduates looking to join RA has been seen in the last 3 years. Graduates are not aware of RA as a profession. ▪ Critical concern over the quality of experienced candidates applying for senior level regulatory roles. More experienced roles require a blend of RA expertise and commercial knowledge. Sometimes see very niched RA experience and the ability to cross over into a different area of regulatory has been challenging. Recruitment times to fill a position typically 6–12 months. ▪ No formal undergraduate degree course in RA, consequently all new to industry staff need training and we rely on the professional organisation, TOPRA, to provide courses to upskill employees. ▪ We struggle to recruit experienced regulatory staff with a focus on working in the UK. We have different areas and specialities, which creates a further narrowing of the pool of candidates that have both the skills for the speciality area and global experience. ▪ It appears that many undergraduates/ graduates are not aware of regulatory roles. ▪ Skills shortages are in general pharmaceutical regulatory affairs and PV. ▪ Easy to recruit graduates with no experience but it takes a long time to train them. Almost impossible to recruit staff with experience. ▪ Distinction between CTA and MAA experience required. Small molecule vs biological vs bio-similar vs device. Reflecting different experience levels. ▪ Can sometimes be difficult to find high quality staff with necessary attention to detail and motivation.

6.5 Manufacturing section summaries

6.5.1 Quality/ regulatory summary

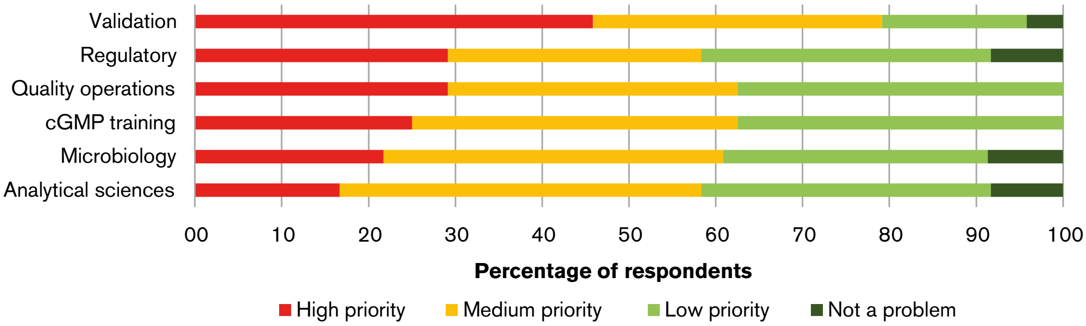


Figure 42: Percentage of respondents rating each quality/regulatory discipline as high, medium or low priority or identifying it as 'not a problem'

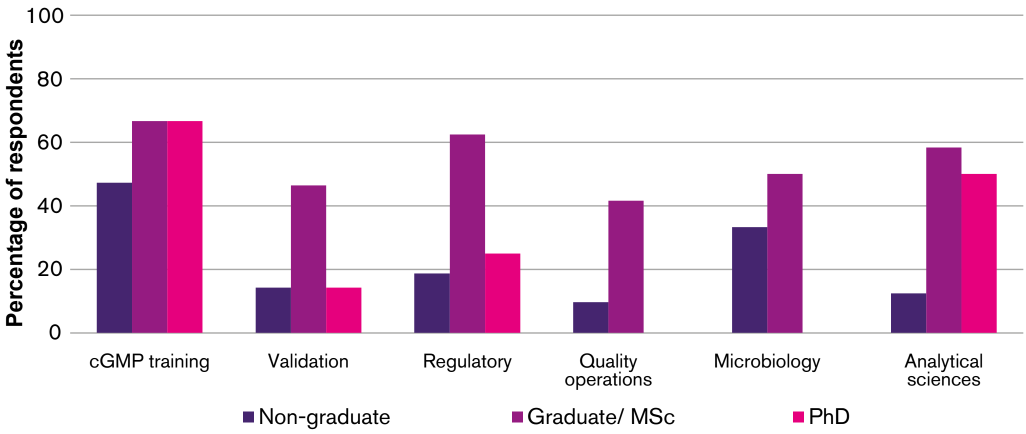


Figure 43: Percentage of respondents identifying each qualification level as an issue within the quality/ regulatory disciplines

Table 12: Detailed quality/regulatory manufacturing areas results (including survey comments)

	Low priority – an important area to watch
	Medium priority – requires action
	High priority – requires immediate action
	Not applicable or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

Table 12: Detailed quality/regulatory manufacturing areas results (including survey comments)

	2014/15		
	Priority	Recruitment level	Comments
cGMP Training	Includes working in a GMP environment/ GMP awareness, deviation investigation and management, change control, technical writing (protocol/ report generation, SOPs), pharmaceutical auditing, risk management (ICH) and quality management systems.		
		Non-graduate Graduate/ MSc PhD	▪ Challenge with recruitment of people with suitable experience or willingness to learn. ▪ Technical writing is an increasingly seen weakness in new recruits (one of several similar comments). Literacy limitations are common. ▪ Main gap related to effective documentation and records related to in particular deviations and changes. ▪ Thought process to enable risk management and documentation of risks. ▪ Recruiting in this area is often difficult, consequently developing and training of these skills internally is an ongoing requirement. ▪ New graduates often lack structured writing skills.
Validation	Includes process validation, documentation writing (DQ, IQ, OQ, PQ), cleaning validation, analytical method validation, equipment qualification, computer systems validation.		
		Non-graduate Graduate/ MSc PhD	▪ Challenge with recruitment of people with suitable experience or willingness to learn. ▪ General lack of experience in Quality By Design based development and validation. ▪ It takes a long time to train people and it is difficult to find the right skills. ▪ Getting skilled and experienced permanent employees. Most skilled people are contractors. ▪ Issues in all areas – computer systems and cleaning validation are major problems within this area. ▪ Analytical method validation skill gap. ▪ Whilst there is a sizeable contract workforce working in this area the level of scientific and engineering competency amongst the contract workforce is generally low. Improvements to or specific university modules in these areas would improve the skills of new graduates.
Regulatory	Includes health authority inspections/ audits, regulatory framework understanding, regulatory filings and variations (EU/ FDA)/dossier preparation, regulatory report writing, chemistry, manufacturing and control (CMC) regulations, regulatory aspects (e.g. USP/ ISO14644).		
		Non-graduate Graduate/ MSc PhD	▪ Challenge with recruitment of people with suitable experience or willingness to learn. ▪ Researchers would benefit from understanding how their work must be complemented by regulatory input in practice. ▪ Required skills/knowledge are usually provided by a central regulatory function for many of these areas. ▪ Background in regulatory understanding is a gap.
Quality operations	Includes batch record review/batch disposition, QP release process and regulations, raw materials/component sampling, vendor management, responsible persons/warehousing, auditing of suppliers/vendors, stability testing, manufacturing unit operations understanding, quality management systems.		
		Non-graduate Graduate/ MSc PhD	▪ Not seen as attractive by many or a viable career path. Not generally valued by many 'bosses' as much as it should be. ▪ Gap is more in Quality Assurance than QC testing. QPs are leaving frequently and are hard to find. ▪ Gaps in the level of capability of QPs in particular for batch release and stability. ▪ Lack of QP/ Quality Operations resource across the UK rather than a skill gap in those working in this area. ▪ Need for more manufacturing experience within the Quality Operations function. ▪ QPs: The size of the skills gap is mitigated by a rolling programme of QP development. However, retention once qualified is low due to the high contract rates available.

Microbiology	Includes basic microbiology, hands-on lab experience with various instruments, facility environmental monitoring.	
	Non-graduate Graduate/ MSc PhD	▪ Tough to recruit – definite skills shortage. ▪ It takes a long time to develop experts. ▪ Skills in new technology progression in microbiological testing. ▪ Skill gap especially within operation team staff.
Analytical sciences	Includes knowledge of analytical tools and techniques, analytical method development, analytical method validation, stability testing, environmental monitoring, hands-on lab experience with various instruments.	
	Non-graduate Graduate/ MSc PhD	▪ Tough to recruit – definite skills shortage. ▪ PAT and calibration are important areas. Critical analysis of results and supporting statistical tools. ▪ Expertise on analytical methods/techniques harder to find. ▪ EU country applicants generally outshine UK educated graduates.

6.5.2 Technical summary

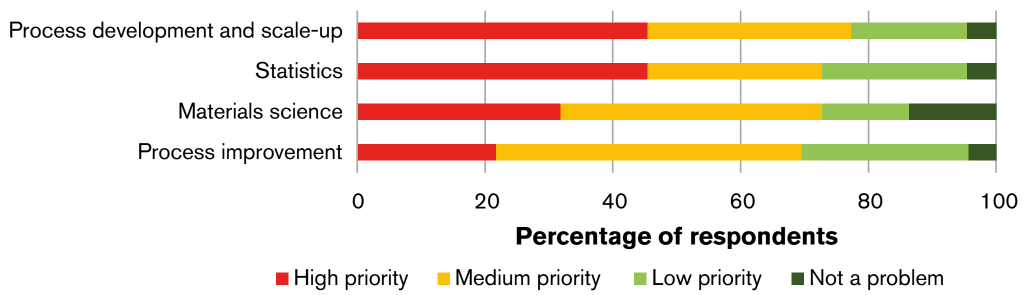


Figure 44: Percentage of respondents rating each technical discipline as high, medium or low priority or identifying it as 'not a problem'

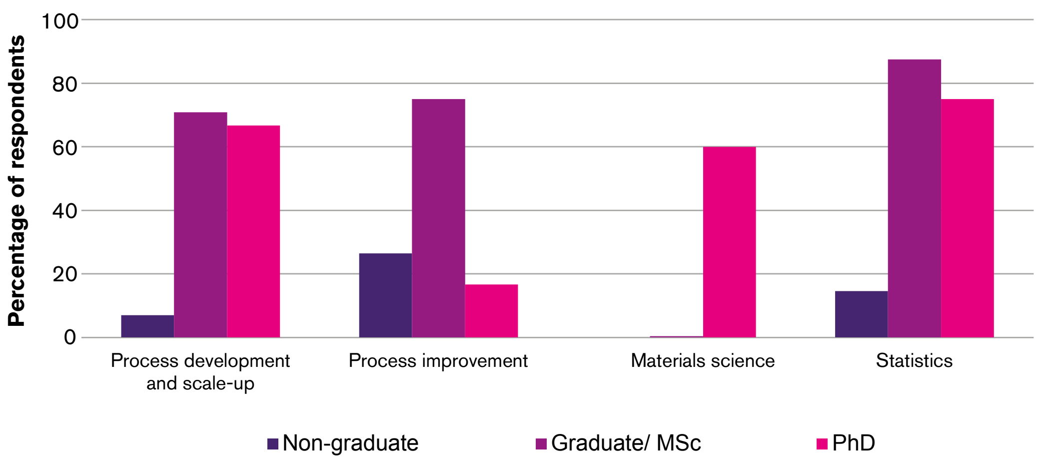


Figure 45: Percentage of respondents identifying each qualification level as an issue within the technical disciplines

Table 13: Detailed technical manufacturing areas results (including survey comments)

(green)	**Low priority –** an important area to watch
(amber)	**Medium priority –** requires action
(red)	**High priority –** requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

	2014/15		
	Priority	Recruitment level	Comments
Process development and scale-up – laboratory/ pilot plant scale	Includes Process development and scale up, Process development and optimisation, Quality by Design – approaches and terminologies, Process analytical technology, Green chemistry, Process safety, Biotechnology/upstream and downstream processes, Technical transfer of processes, Drug product formulation, Drug delivery systems, Scale-down modelling.		
	(red)	Non-graduate (green) Graduate/ MSc (red) PhD (red)	▪ Multidisciplinary training often required e.g. use of automation, informatics, modelling and prediction needs to be improved. ▪ Recruitment and retention of process /chemical engineers with 5 years = experience of API process development is an issue. ▪ Translation of R&D ideas to a manufacturing process is an issue; also how we build in manufacturability from day 1. ▪ Few people out there with broad overview /trouble shooting / 'how to move forward' / design skills – we advertised a role 3 times before appointing.
Statistics	Includes Fundamental knowledge of statistics tools and techniques, DoE and statistical multivariate approaches, Scientific computational skills (in silico/ prediction/ modelling), Retrospective informatics analytical approaches.		
	(red)	Non-graduate (green) Graduate/ MSc (red) PhD (green)	▪ Very important area, tools exist but need to be developed and implemented in user-friendly, intuitive way to maximise usage and benefit. ▪ Difficult to recruit statisticians with experience in API/pharma manufacture. ▪ More stats expertise needed as we move to Continuous Process Verification and Quality By Design.
Materials science	Includes Material characterisation (particle size, flow, physical properties), Knowledge of analytical tools and techniques.		
	(amber)	Non-graduate (green) Graduate/ MSc (green) PhD (red)	▪ Nano scale technologies are a problem for analytics.

Process improvement	Includes LEAN/Six Sigma/ Continuous improvement tools and techniques, Process trouble shooting/diagnosis, Offline analysis and characterisation, Process control technologies/automation, Unit operations understanding.		
		Non-graduate Graduate/ MSc PhD	▪ As products become more complex, understanding, measuring and controlling attributes and performance through process parameters is key. Need stronger/ more skills to link materials attributes with process parameters. ▪ Developing skills in-house with dedicated Lean / Six Sigma team.

6.5.3 Manufacturing summary

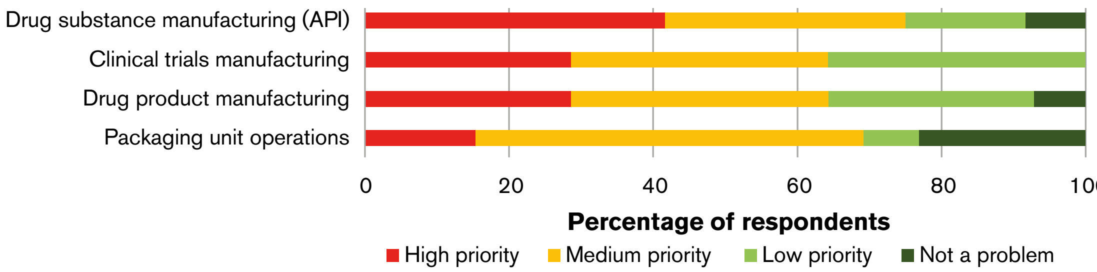


Figure 46: Percentage of respondents rating each manufacturing discipline as high, medium or low priority or identifying it as 'not a problem'

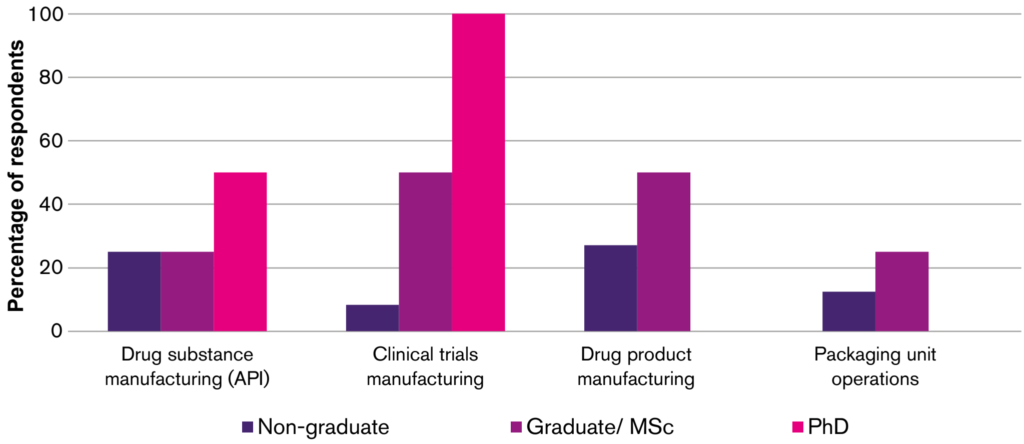


Figure 47: Percentage of respondents identifying each qualification level as an issue within the manufacturing disciplines

Table 14: Detailed manufacturing areas results (including survey comments)

Green	**Low priority** – an important area to watch
Amber	**Medium priority** – requires action
Red	**High priority** – requires immediate action
Grey	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

	2014/15		
	Priority	Recruitment level	Comments
Drug substance manufa-cturing	Includes Understanding of fundamental science, In-process control sampling and testing, Unit operations understanding, Environmental Health and Safety, Commercial scale manufacturing technology, Continuous manufacturing – synthesis, work up, crystallisation.		
	(red)	Non-graduate (amber) Graduate/ MSc (amber) PhD (red)	▪ Fundamental science and engineering principles are key. ▪ Integrating operations, control strategies and analysis are all important to opportunities for continuous manufacturing to be more widely used. Lack of sterile technical skills and aseptic manufacturing experts.
Clinical trial manufa-cturing	Includes Pre-clinical manufacturing requirements/regulations, Clinical trials manufacturing requirements/regulations, Drug product formulation, Drug delivery systems.		
	(amber/green)	Non-graduate (green) Graduate/ MSc (amber) PhD (red)	▪ Shortage of formulation scientists to deliver rapid formulation development and scale-up.
Drug product manufa-cturing	Includes Dispensary, Granulation (wet, dry, roller compaction), Milling, Bulk blending, Tablet compression, Tablet film coating, Encapsulation (hard shell and soft shell), In-process control sampling and testing, Formulation – integration of primary to secondary formulation, Continuous formulation, Unit operations understanding, Other unit operations.		
	(green)	Non-graduate (amber) Graduate/ MSc (amber) PhD (green)	▪ Skill gaps in scientific basis and technical understanding of more complex processes. ▪ The workforce in this area is ageing with few new entrants/developing candidates in the workplace. ▪ Building fundamental knowledge of materials, formulation science and process parameters and control into these areas is important.
Packaging unit operations	Includes Primary packaging (blister packaging, bottling), Cartoning (secondary packaging), Labelling, Pack serialisation, Pack collation (tertiary packaging), Artwork generation and approval, Distribution/ supply chain/ operations management, Pack development, Cold chain management, Continuous packaging operations.		
	(green)	Non-graduate (green) Graduate/ MSc (amber) PhD (green)	▪ Not seen as 'sexy'; as process/technical areas – hard to attract people to this area. ▪ New technology causes issues.

6.5.4 Engineering/ Health and Safety summary

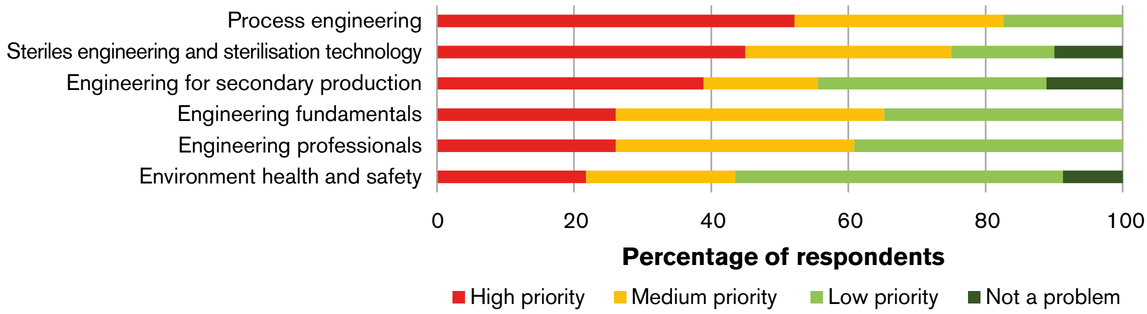


Figure 48: Percentage of respondents rating each engineering/ health and safety discipline as high, medium or low priority or identifying it as 'not a problem'

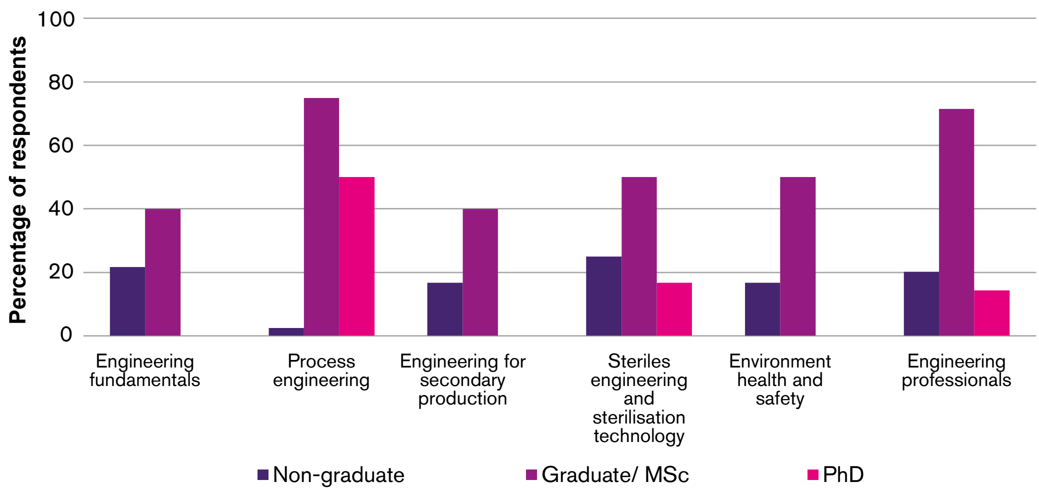


Figure 49: Percentage of respondents identifying each qualification level as an issue within the engineering/ health and safety disciplines

Table 15: Detailed engineering/ health and safety manufacturing areas results (including survey comments)

(green)	**Low priority –** an important area to watch
(amber)	**Medium priority –** requires action
(red)	**High priority –** requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

Table 15: Detailed engineering/ health and safety manufacturing areas results (including survey comments)

	2014/15		
	Priority	Recruitment level	Comments
Engineering fundam-entals	Includes Commissioning and qualification of equipment, First line maintenance (preventative maintenance), Routine calibration.		
	(amber)	Non-graduate Graduate/ MSc PhD	▪ Shortage specifically around steriles. ▪ Technician level engineers are few and far between. Recruitment in the South East is very difficult as a result of so few apprenticeships over the last two decades. ▪ Not seen as an attractive career by many, hence skills/knowledge shortage. ▪ Depth of fundamental understanding of equipment and utilities is an issue. Need to retain internal expertise in these areas to be able to then also appropriately use contractors.
Process engineering – commercial scale/ plant level	Includes Continuous processing and formulation, Process development and scale up, Process development and optimisation, Quality by Design – approaches and terminologies, Process analytical technology, Green chemistry, Process safety, Offline analysis and characterisation, Process control technologies/automation.		
	(red)	Non-graduate Graduate/ MSc PhD	▪ Difficult to find process engineers particularly with sterile manufacturing knowledge. ▪ Attracting the most highly skilled and capable engineers into industry is difficult due to the general perception of engineering in the UK. More specific courses at A- and degree-level would support a more obvious and specific career path. This would also provide specific channels/faculties that the industry may tap into. ▪ Seen as quite 'trendy' by many (e.g. quality by design, green), so recruitment pool is larger. ▪ Need 'hands-on' graduate process engineers. ▪ Ability to hire process engineers to fulfil these activities is a major problem. ▪ Shortage of suitable candidates in the labour market.
Engineering for secondary production	Includes Packaging engineering, Packaging technology, Device engineering, Automation engineers, Maintenance engineers		
	(green)	Non-graduate Graduate/ MSc PhD	▪ Automation skills hard to fill in UK. ▪ Attracting the most highly skilled and capable engineers into industry is difficult due to the general perception of Engineering in the UK. More specific courses at A- and degree-level would support a more obvious and specific career path. This would also provide specific channels/faculties that the industry may tap into. ▪ Specialised – tough to get the right people. ▪ Difficult to get good 'hands-on' automation engineers and device engineers.
Steriles engineering and sterilisation technology	Includes CIP (cleaning in place) and SIP (sterilisation in place) technologies, Aseptic technique: theory and practice, Hands-on experience of Aseptic manufacturing, Barrier technology (Isolators: RABS), Glove integrity testing, Decontamination (vaporised hydrogen peroxide, fumigation, gradiation), Adjuvant preparation.		
	(red)	Non-graduate Graduate/ MSc PhD	▪ Scarce resource difficult to attract as direct employees rather than contractors. ▪ Attracting the most highly skilled and capable engineers into industry is difficult due to the general perception of Engineering in the UK. More specific courses at A- and degree-level would support a more obvious and specific career path. This would also provide specific channels/faculties that the industry may tap into. ▪ Extremely difficult to find skilled people in this area. ▪ This could be a significant area of growth as drug delivery moves towards long-acting parenterals. ▪ Need good hands-on aseptic /process engineers especially to support GCP (very hard to find /attract), hence our policy is to train our own. ▪ Hard to recruit experienced personnel in this area.
Environment Health and Safety	Includes Knowledge of safety regulations, Risk assessments (HAZOP, GMP reviews, etc), Safe systems of work (e.g. Pressure systems), COSHH assessments, Environmental.		
	(green)	Non-graduate Graduate/ MSc PhD	▪ Lots of interest in this area and seen as satisfying career = larger recruitment pool. ▪ Main areas where skills are lacking is in process safety/HAZOP & COSHH. ▪ Reflects lack of previous investment.

Engineering professionals	Includes Mechanical engineers, Electrical engineers, Capital Project engineers/managers, New, Technology, Utility engineers, Energy engineers.		
		Non-graduate Graduate/ MSc PhD	▪ Difficult to find candidates with steriles knowledge and experience. ▪ Electrical area most difficult to find of the engineering disciplines. ▪ Professional engineers in short supply especially controls, process, electrical. ▪ Shortage of suitable candidates in the labour market.

6.5.5 Biologics/ ATMP summary

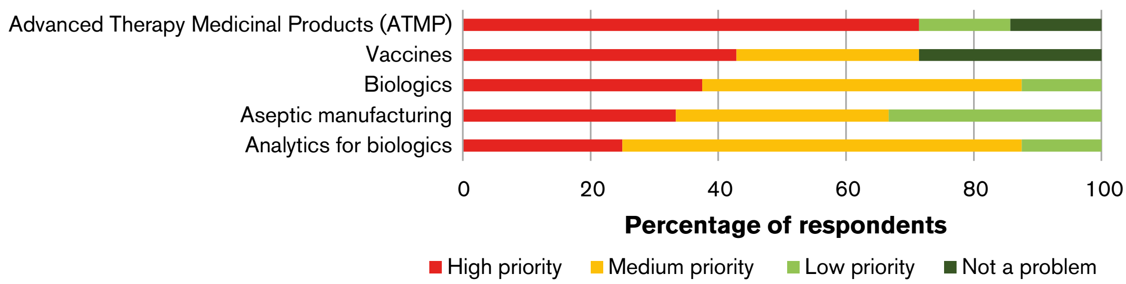


Figure 50: Percentage of respondents rating each biologics/ ATMP discipline as high, medium or low priority or identifying it as 'not a problem'

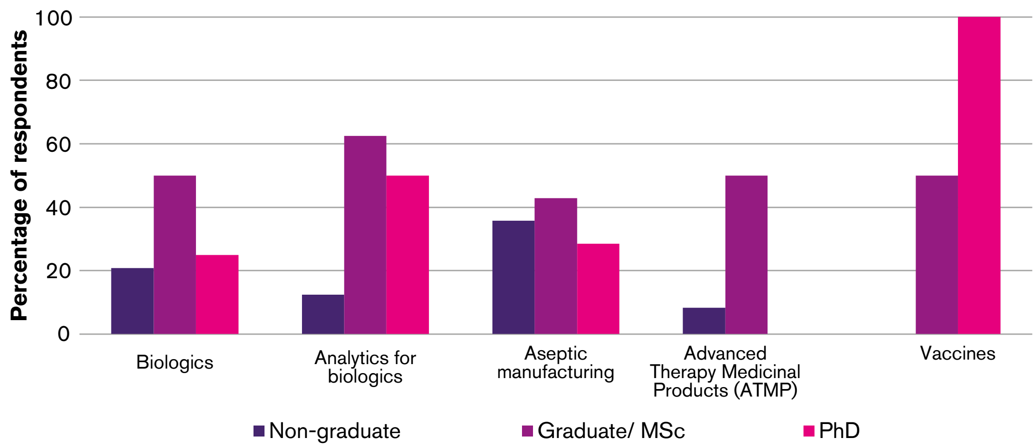


Figure 51: Percentage of respondents identifying each qualification level as an issue within the biologics/ATMP disciplines

Table 16: Detailed biologics/ ATMP manufacturing areas results (including survey comments)

(green)	**Low priority** – an important area to watch
(amber)	**Medium priority** – requires action
(red)	**High priority** – requires immediate action
(grey)	**Not applicable** or not rated

Q = Quality of candidates, N = Number of candidates, F = Future problem, M = Manufacturing

- Q, N, F, M and recruitment level colour-coded according to the percentage of respondents identifying it as a concern (0 – 30% respondents considered low priority, 30 – 60% respondents considered medium priority and 60 – 100% respondents considered high priority)
- Overall priority band colour-coded according to the priority level with the greatest percentage of respondents

Table 16: Detailed biologics/ATMP manufacturing areas results (including survey comments)

	2014/15		
	Priority	Recruitment level	Comments
Biologics	Includes Biotechnology overview and knowledge/experience, Microbial fermentation, Biotechnology/upstream and downstream processes, Mammalian Cell Culture, Separation techniques (centrifugation, microfiltration, homogenisation), Bioreactors – technology, Development and manufacture in disposables, Purification techniques (chromatography, tangential flow filtration), Final fill, Formulation/lyophilisation, Virus inactivation, Biopharmaceutics (e.g. biopharmaceutics classification system (BCS) and drug delivery, Process characterisation, Filter integrity testing, Viral inactivation/removal – (filtration/pH), Aseptic/hygienic engineering basics, Product process qualification (PPQ)/ validation (PV) and licensing.		
		Non-graduate Graduate/ MSc PhD	▪ Above list all important; there are gaps at various levels – quite often senior people are having to take more decisions than ideal to cover – main gap is experience rather than training. ▪ Difficult to find skills in industrial fermentation. ▪ Difficult to find these skills in North East England, particularly in manufacturing.
Analytics for biologics	Includes Product characterisation, Potency assay development, Analytics methods for vaccines.		
		Non-graduate Graduate/ MSc PhD	▪ No comments
Aseptic manufact-uring	Includes Unit operations understanding, Cleanroom working, Aseptic techniques, Basic microbiology, Environmental monitoring, Cleanroom working.		
		Non-graduate Graduate/ MSc PhD	▪ No comments
Advanced Therapy Medicinal Products (ATMP)	Includes Expansion of stem cells, somatic cells, immune cells, Growth of 3D organ, Autologous and Allogeneic cell growth, Controlled cell differentiation, Manual and enclosed processing, Cell selection and purification technology, Expansion of stem cells, somatic cells, immune cells, Potency assay development, Cell transduction and transfection, 2D and 3D sterile culture processing, Sterile volume reduction and fill finish, Cell therapy cultivation.		
		Non-graduate Graduate/ MSc PhD	▪ Skills gaps in Validation methods for totally enclosed sterile manufacturing (upstream and downstream) where final filtration or sterilisation not possible.
Vaccines	Includes Live virus, Viral subunit, Bacterial vaccines, Bacterial subunit, Toxoid, Conjugate, Facility design – containment levels (cleanrooms, labs), Facility fumigation, Virology, Protein engineering and aggregation, Viral inactivation, DSP – ultracentrifuges, Stability and formulation, Analytical methods for vaccines – current and alternatives, Adventitious agents, Carrier molecule technology and manufacture (e.g. CRM197), Conjugation technology, Emerging technologies for vaccines – mammalian cell culture, insect cells, Filling of suspension products (fluid path).		
		Non-graduate Graduate/ MSc PhD	▪ No comments

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