



SKILLS NEEDS FOR BIOMEDICAL RESEARCH

CREATING THE POOLS OF TALENT
TO WIN THE INNOVATION RACE



FOREWORD

The pharma industry is Britain's top research sector, investing £3.9 billion a year. We account for a quarter of all business investment in R&D in the UK. Internationally we are among the leaders: Britain is fifth in the world GDP league but second in drug discovery, and one in five of the world's best selling medicines was developed here.

If we want to maintain the pharmaceutical industry's leading R&D position in the UK - and its strong position internationally, the key factor is the human factor. We need to find the best people and develop them.

In the ABPI, three years ago, we identified access to skills and knowledge as a critical factor in maintaining the flourishing R&D base needed for competitiveness. The work culminated in the report *Sustaining the skills pipeline in the pharmaceutical and biopharmaceutical industries*. This report was important because it exposed some of the most pressing needs in terms of skills for the pharma industry and led to action to start to address the issues.

This new report is based on a further survey of ABPI and BIA member companies to review the position three years on from our previous report. We had a very high level of response to the survey and that tells us how important education and skills are to this industry.

However, the data shows clearly that the UK is at a 'tipping point' with regard to skills supply. Business-as-usual will mean decline and we therefore need to do more. We need to dig deeper to find and develop the skills we need. In a world where competition is intensifying, technology is developing and potential compounds are becoming harder to find, skills are at a premium.

The pipeline of skills is not unlike the pipeline of compounds. We can't live forever on today's products. Neither can we live on today's skills – we need a healthy pipeline of people too. The recommendations of this report will start to create an appropriate climate for a UK pharmaceutical industry for the future.



Chris Brinsmead
ABPI President

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EXECUTIVE SUMMARY

The supply of high quality science skills is an essential element in attracting global pharmaceutical R&D investment. Historically the UK has been at the forefront of biomedical innovation, with a long history of leading the development of innovative medicines that have transformed healthcare and brought real benefits to patients.

In November 2005 the ABPI published a benchmark report: *Sustaining the skills pipeline in the pharmaceutical and biopharmaceutical industry*. This report highlighted a number of issues around the quality, number and supply of key scientific disciplines that have historically been a strength in the UK, especially skills associated with the discovery and development of new medicines.

The report included 13 recommendations and since 2005 there has been progress on many fronts, including the intent to establish a 14-19 Science Diploma. In particular we believe that the response of the Government to enhance and transform the skills and capabilities of students between 14-19 years of age has been very positive. While it will be a number of years before the impact of these changes becomes apparent, we believe that they could, if followed through, provide a sound foundation to re-establish the practical competence and in-depth scientific knowledge in students that is the essential foundation for university education or employment.

However, in terms of higher level skills the response from funders of Higher Education (HE) both at undergraduate and postgraduate level has been somewhat patchy. In particular we have been disappointed by the apparent disparity between the strategic priorities of the Government and the response of both the universities and HE funding mechanisms.

These higher level critical skills have not enjoyed the focus, incentives or funding initiatives concomitant with their pivotal importance to key UK initiatives such as translational medicine. If the UK wants to compete in a global environment for biomedical research it must take seriously the competition in skills supply that is emerging in countries such as China, Singapore and India.

In 2008 the ABPI, with the help of the BioIndustry Association, carried out a further skills survey to update our 2005 report. It is quite clear that there has been little progress with many disciplines of critical concern to the pharmaceutical and biopharmaceutical industry. While timelines are short between the two surveys, time is also running out.

Major issues in 2008

During the survey two areas of concern were identified, relating to core skills and core disciplines.

In terms of core skills – general capabilities that cut across all scientific disciplines – members were concerned about:

- Basic mathematical capability
- Practical skills
- Ability to apply scientific and mathematical knowledge

In terms of core disciplines it is quite clear that the UK has a substantive skills deficit in biomedical sciences, many of which are at the heart of translational medicine or are key to the commercialisation of research, namely:

- clinical pharmacology / experimental medicine;
- drug metabolism and ADME¹;
- pharmacokinetics, pharmacodynamics and modelling;
- *in vivo* sciences and supporting animal technologies;
- chemical and process engineering;
- statistics; and
- computational chemistry.

Recommendations

Recommendation 1: A Dialogue for Action – establishing a High Level STEM Strategy Group for Higher Education

The High Level Science, Technology, Engineering and Maths (STEM) Strategy Group in the Department for Children, Schools and Families has been key in galvanising and coordinating an action plan that has the potential to transform the science skills of 14-19 year old learners. The DCSF STEM Strategy Group used to encompass HE, however following the splitting of the Department for Education and Skills in 2007, its focus has, understandably, been on implementing the schools agenda and delivery of that potential.

Therefore a similar approach led by the HE Directorate in DIUS is essential to link employer needs to UK Government strategy and to coordinate across diverse stakeholders in research, postgraduate and undergraduate funding.

ACTION: DIUS should establish a High Level STEM Strategy Group for Higher Education by mid-2009, bringing together the key funders, industry, scientific institutes and academia to ensure a coordinated approach to developing a pool of UK talent to realise the Innovation Nation agenda. A National STEM Director for HE should be appointed to oversee and coordinate actions.

Recommendation 2: Transparency and Impact – improving the linkage between UK Government innovation strategy and the funding of STEM education and skills to support that agenda.

The UK Government has highlighted the importance of translational medicine underpinned by investments in biomedical research through such initiatives as OSCHR (the Office for the Strategic Coordination of Health Research) and NIHR (National Institute for Health Research). However, realising the value of this investment is dependent upon the supply of critical STEM skills and disciplines.

This report has highlighted critical shortages of a number of key underpinning skills, in particular *in vivo* sciences, clinical pharmacology and mathematical modelling. Although we highlighted this in 2005, there has only been modest progress and these needs have not been effectively addressed.

¹ ADME – absorption, distribution, metabolism and excretion of a medicine

Biopharmaceuticals will also play a key role in addressing priority health needs for the UK in the future, however this survey has shown that there is a need to enhance the supply of related skills especially in translating ideas into products and manufacturing.

We believe that the new Cabinet Committee on Science & Innovation, Chaired by the Science & Innovation Minister, Lord Drayson, should review the mechanisms by which Higher Education and research training courses are funded and incentivised in the UK. In particular they should consider whether they are fit for purpose to create the pools of STEM talent to allow the UK to win the global innovation race.

ACTION: The Cabinet Committee on Science & Innovation should review and take action to ensure the mechanism for reacting to and funding strategically important skills and disciplines is transparent and reactive to the needs of the scientific community in both the public and private sector. The proposed High Level STEM Strategy Group for HE should also play a substantive role in the review and in the subsequent identification of strategically important subjects.

Recommendation 3: Enhancing core skills and disciplines

This survey has reinforced the need for action to address the deficits in skills supply in terms of both core capabilities and essential skills. In terms of core skills for STEM graduates, employers believe that action needs to be taken to address:

- practical capability;
- the application of scientific knowledge; and
- mathematics across disciplines.

The survey has identified a continued need across a wider range of specialist disciplines. In particular skills that support:

- translational science; and
- high-value manufacturing (including biopharmaceuticals).

The solution to these problems must start in schools and feed through to higher education.

ACTIONS: A number of actions need to be taken.

- First, the mathematics capabilities of science students need to be enhanced through the implementation of both the 14-19 Science Diploma and free-standing maths courses in schools and colleges.
- Second, the funding formula for teaching practical science courses in universities needs to be augmented.
- Finally, provision of four year integrated Masters in biological sciences should be increased and appropriately funded. Accreditation schemes for strategically important disciplines, such as those for chemistry, physics and engineering, should be extended to include designated biological science courses.

1 INTRODUCTION

1.1 Context for this review

Global competition for pharmaceutical and biopharmaceutical R&D investment has never been greater. Pressures on prices, the need to improve R&D productivity and the expectation on industry to bring to market innovative medicines that transform the lives of patients, have created an environment where companies are seeking value for money in their research investment. Skills supply is a core element in attracting such investment – without this, it is impossible to compete.

Historically the UK led the world in the supply of skills that supports the discovery and development of new drugs, providing the foundation of the pharmaceutical industry. Indeed, the UK continues to attract around 9% of global pharmaceutical R&D investment and accounts for nearly 25% of all private sector R&D investment in this country².

But that leading position is under threat. Many countries, especially emerging ones, seek to attract high value added investment by providing enhanced skills supply and providing attractive regulatory and fiscal environments that support investment.

Since our report *Sustaining the Skills Pipeline in the Pharmaceutical and Biopharmaceutical Industry* was published in November 2005 the needs of science based industry in the UK and, indeed, of the academic science base, have been the subject of many reports and consultations and a substantial amount of activity has taken place. In some areas real progress has been made. However there are also areas where progress has been too slow or limited in scope to make a substantive indent in the problem. Actions to date have not, and are unlikely to, re-establish the UK as a global centre for biomedical investment.

There has been increased interaction between the industry and the Government in England, especially BERR and DCSF, with Sector Skills Councils and with Research Councils following publication of the 2005 report, however there are still organisations and areas of Government which are not engaging with industry. If the science based industry sector is to thrive in the UK, it is essential that their needs are articulated and those views taken into account.

Initiatives funded by the Higher Education Funding Councils for England and Wales (HEFCE and HEFCW) to nurture interest and demand for science and engineering such as 'moremathsgrads'³ and 'Chemistry for our Future'⁴ are having a very positive influence on young people and the additional funding provided by HEFCE for undergraduate teaching in very high cost laboratory based subjects which are particularly expensive to provide, including chemistry, physics and chemical engineering, are very welcome

One outcome of our 2005 report was the establishment of a taskforce to review provision of *in vivo* skills and develop an action plan to address any gaps identified. The review, taken forward by a secondee from DTI (now BERR) working closely with

² <http://www.abpi.org.uk/statistics/intro.asp>

³ <http://www.moremathsgrads.org.uk/home.cfm>

⁴ <http://www.rsc.org/Education/CFOF/>

ABPI and BSF, led to a report on *in vivo* sciences in the UK⁵ with a number of recommendations. Critical factors for success were identified as raising student interest in developing *in vivo* skills, development of employer focused taught Masters degrees which deliver 'hands on' learning, continued support for PhD level training and the Government providing protection for the sub-disciplines that include *in vivo* work through support for them as Strategically Important and Vulnerable Subjects (SIVS). There are major concerns both from industry and academia that the response to the recommendations of the report have not been sufficient or sustainable.

First recommended in the 2005 report, the ABPI has warmly welcomed the development of a 14 -19 Science Diploma to deliver employment related science education. The pharmaceutical industry is pleased to be fully engaged in development of the Diploma and anticipates that the Diploma, particularly at Level 3, will help to meet our needs for young people with high levels of practical skills and the ability to apply scientific and mathematical knowledge. The core programme of the Welsh Baccalaureate Qualification covers these key skills at all levels of study and its formal recognition by UCAS is very encouraging.

The creation of a High Level STEM Strategy Group, led by the National STEM Director has been a positive development. The Chair of the Science Forum Skills Working Group represents industry views on this group. This forum for joint industry/Government working is valued: work streams leading from it include consolidation and promotion of engagement and enrichment of STEM activities to enable all young people to benefit, and promotion of practical science activity in schools.

We strongly support Government action to make young people more aware of the opportunities that science, technology, engineering and maths qualifications can deliver. It is hoped that support being provided from DCSF for development of the 'FutureMorph' website⁶, developing a programme to improve the quality of advice and guidance about STEM careers to inform subject choice, development of a STEM careers awareness timeline, together with a promotional campaign to support and increase the number of students post 16 studying science technology, engineering and maths subjects - specifically physics, chemistry and maths A levels - will have a substantial impact on future supply of young people with the qualifications and skills for biomedical research. This action is vital in the light of findings from the CEM Centre, Durham University that "At A level, the STEM subjects are not just more difficult on average than the non-sciences, they are without exception among the hardest of A levels"⁷.

One recommendation of our 2005 skills report was for QCA to specify that information on careers in scientific subjects be included at Key Stage 3, GCSE and all post-16 courses. The science programme of study now encourages students to consider the varied career opportunities, both within science and in other areas that are provided by science qualifications, allowing students to see how they can contribute to the future success of the economy⁸. At Key Stage 3 students are required to 'consider career opportunities both within science and in other areas that are provided by science qualifications'. The QCA subject criteria for AS and A level

⁵ *In vivo* sciences in the UK: sustaining the supply of skills in the 21st century, ABPI and BSF, October 2007

⁶ <http://www.futuremorph.org/>

⁷ Relative difficulty of examinations in different subjects, Robert Coe et al, CEM Centre, Durham University, July 2008

⁸ <http://curriculum.qca.org.uk>

science subjects also demand that students should be encouraged to develop an interest in further study and careers in the subject.

The Ministerial Industry Strategy Group (MISG) which takes the Government-Industry relationship forward at a strategic level has also reviewed education and skills development following our 2005 report. Chaired jointly by the Department of Health and the CEO of AstraZeneca, with representation from the Treasury, DIUS and BERR, education and skills are seen as a vital part of the process to develop a long term strategy to secure the provision of safe and effective medicines for patients, maintain and strengthen the UK pharmaceutical industry within Europe, and to advance healthcare innovation with the NHS. However, in the light of the skills issues identified in the survey for this report, it is clear that dialogue must continue, and more effective engagement is required with some partners, in particular DIUS, HEFCE and the Medical Research Council.

A number of reports focussing on STEM Education and Skills have been published since 2005. Many of these reinforce our findings and concerns. The CBI⁹ found that six out of ten employers are having difficulty in recruiting enough STEM-skilled individuals to meet their needs, a third of firms were concerned by the shortage of STEM graduates and 42% consider that STEM graduates lack the right skills. These comments came from a cross section of companies across all sectors.

Progress against the objectives from 2005 is detailed in Appendix II.

1.2 Landscape for the industry in 2008

Development of new medicines is a lengthy, costly, high risk and uncertain process. In 2007 the number of new medicines approved for marketing in the US was the lowest for 24 years despite investment in research and development by the pharmaceutical industry being over five times that of the early 1980s.

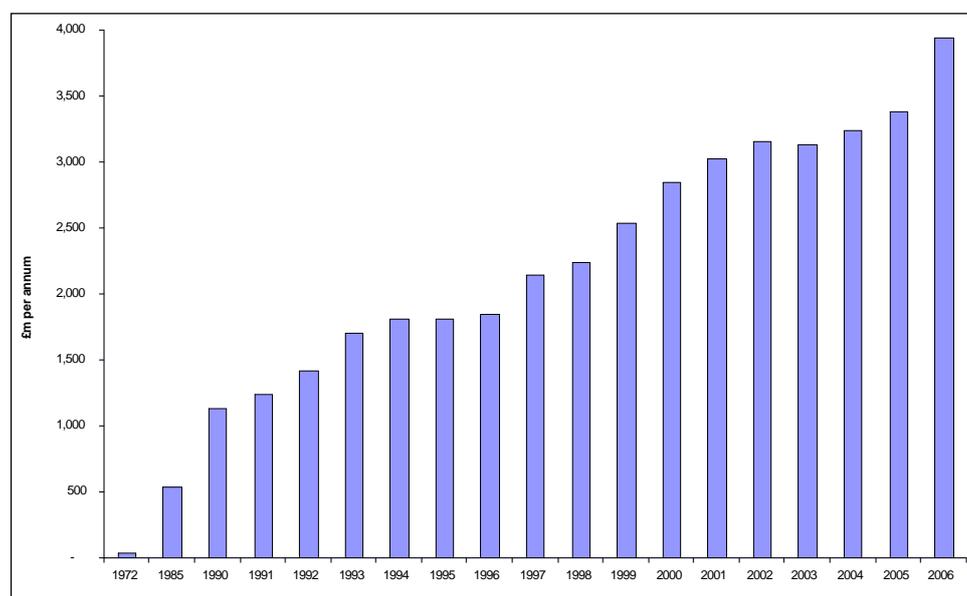


Figure 1: UK research and development expenditure by pharmaceutical companies

The sector is one of the most knowledge intensive in the UK. Around a quarter of UK research and development is undertaken by the industry and the UK attracted just

⁹ Taking stock: CBI education and skills survey 2008

under 8.9% of global investment in 2006 (slightly down from a peak of 10% in 2000) worth £3.9 billion.

A large, multinational pharmaceutical company will typically employ tens of thousands of people worldwide in research and development to create and progress a pipeline of potential new medicines across many different therapeutic areas. The latest, 2006, figures reveal that 28,000 people were employed in pharmaceutical R&D in the UK.

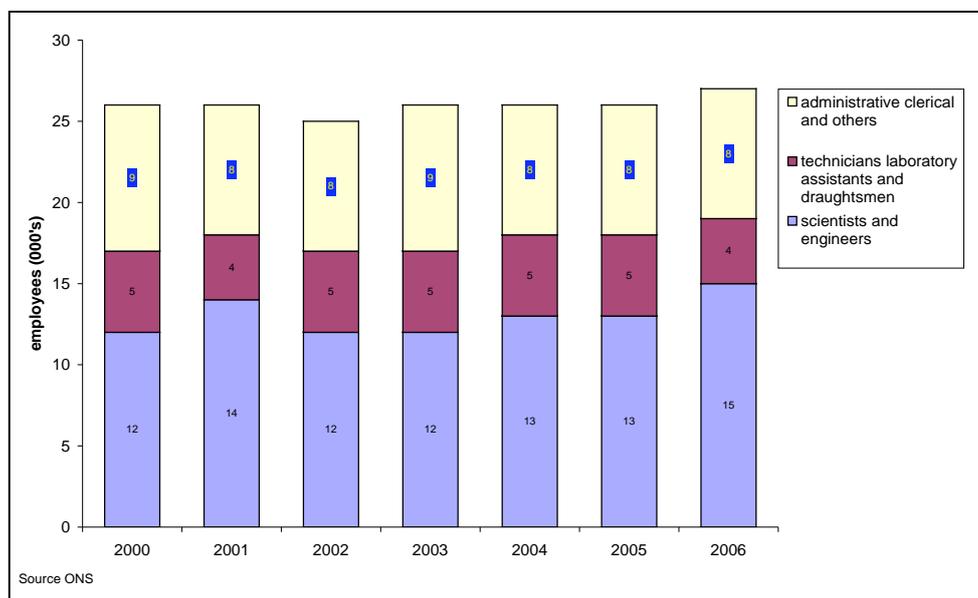


Figure 2: Employment in pharmaceutical industry research and development in the UK

Attrition affects all parts of the research and development process; over 95% of molecules evaluated as potential medicines fail to meet the requirements for safety or efficacy. Of those reaching the clinic, only 3 out of 10 ever recoup their R&D costs. The increased difficulty in creating a new medicine and the escalating associated cost has resulted in many companies reviewing their processes in order to speed up R&D and regulate spending. Part of this process has been a reduction in the numbers of R&D staff employed for many companies since 2006.

As a result of these changes there are many well qualified people, with backgrounds in some of the important disciplines, currently seeking employment in the UK. Our survey shows, however, that there are still areas with specific needs for specialists that are not readily available; this may partly be due to the changing nature of collaborations with biotech companies, and increased outsourcing of R&D. Company restructuring is a cyclical process and this report considers a wider and longer term view. In the longer term, all areas will be seeking to recruit individuals with appropriate knowledge and skills; hence capacity for these people to be educated must be maintained and, in some cases, expanded.

It is important to remember that for biomedical research / biotechnology to thrive in the UK pharmaceutical companies are only one part of the landscape, the bigger picture includes contract research organisations (CROs), small and medium-sized enterprises (SMEs) and academia, however in this area the skills needs are common to all. As companies change their operating procedures, more and more elements of the R&D pathway are being outsourced. The UK has a strong position with leading CROs attracting business from around the world; these companies are a vital element of the drug discovery pathway.

2 STUDY METHODOLOGY AND FINDINGS

2.1 Methodology and Respondents

The study questionnaire enabled respondents to address the following areas, with a combination of qualitative and quantitative responses. Companies were asked to comment on a wide range of skill areas, including all of the disciplines identified in 2005.

Quality, Number, and Future: Respondents were asked to score each discipline as either a “high priority, requires immediate action”, a “medium priority, requires action”, or a “low priority, area to watch” for each of the three categories: quality of applicants; number of applicants; and future prospects for the discipline.

Skill Level of Candidates: For each discipline, respondents were asked at which skill level the issues were by scoring each of non-graduate, graduate, PhD, and post-doctorate as either a high, medium, or low priority, or not applicable (due to no recruitment at that level).

Future Skills and Detailed Comments: Detailed comments were invited for each discipline. The questionnaire also included sections for comments on emerging skill needs identified in the 2005 report, and for comments on any other discipline the respondent felt to be a priority area not covered by the previous questions.

High Level Questions: Respondents were asked general questions about high level skills issues, such as numeracy and practical laboratory skills.

Respondents: Fifty seven responses were received from 30 companies. Questionnaires were sent to scientists involved in recruiting. Some companies collated their responses from all areas, others provided individual responses. The majority of responses were from companies based in England, with only a few from Scotland and Wales. The landscape could therefore differ in these nations and may have to be reviewed accordingly. The companies which responded to the survey that provided the data for this report are as follows:

| | |
|----------------------------|---------------------------------|
| Abbott Laboratories Ltd | Lonza Biologics Plc |
| Amgen Ltd | MedImmune Ltd |
| Ark Therapeutics Group Plc | Merck Sharp & Dohme Ltd |
| AstraZeneca Plc | Norgine Ltd |
| Boehringer Ingelheim Ltd | Novartis Pharmaceuticals UK Ltd |
| Charles River Laboratories | Organon (Schering Plough Ltd) |
| Chroma Therapeutics Ltd | Pfizer Ltd |
| Covance Laboratories Ltd | Pharmaceutical Profiles Ltd |
| Eisai Ltd | Piramed Pharma |
| Genzyme Therapeutics Ltd | Roche Products Ltd |
| Gilead | Sanofi-aventis |
| GlaxoSmithKline Plc | Servier |
| Huntingdon Life Sciences | UCB Pharma Ltd |
| Intercytex | Vernalis Plc |
| Lilly & Co | Xenova |

We would like to acknowledge the help of the BioIndustry Association with the data collection for this report.

The findings from the review were shared with stakeholder organisations at both a workshop and a high level dinner discussion for validation and comment (Appendix VII).

2.2 Core Skills

Respondents were asked whether the skills gaps which had been identified across new recruits in the 2005 survey were still problematical. The responses confirmed that in only a few instances had skills improved.

| Skills issue | a major concern | a concern | less of a concern now | not a problem | number of responses |
|---|-----------------|-----------|-----------------------|---------------|---------------------|
| Practical experience | 27 | 13 | 5 | 1 | 46 |
| Application of scientific and maths knowledge | 21 | 20 | 5 | 0 | 46 |
| High level maths knowledge | 13 | 21 | 4 | 4 | 42 |
| Scientific knowledge | 9 | 28 | 4 | 1 | 42 |
| Communication skills | 7 | 15 | 12 | 13 | 47 |
| Team-working skills | 4 | 9 | 18 | 13 | 44 |

2.2.1 Mathematics

Concerns over high level mathematical knowledge of new recruits was cited as a concern or major concern for 81% of responders to the survey. For 31% it was a major concern.

Many disciplines vital to research and development of new medicines rely on specific mathematical knowledge, statistics for clinical studies for example, or mathematical modelling for investigating the pharmacokinetics and pharmacodynamics of a potential new medicine. But, as well as these essential mathematical skills for the discipline, our survey revealed major concerns over the general mathematical competencies of job applicants.

“There is a lack of numerate biology graduates”

“Our demand is for science and maths qualifications to a reasonable standard at A level.”

There was general concern that too few students continue to study maths beyond school level, or even post-16. This leads to UK graduates lacking the quantitative skills necessary to analyse and interpret data and to have confidence in their analysis. Some candidates show a lack of even basic mathematical skills.

Higher education biological sciences courses rarely demand A level or equivalent maths for entry onto the course and undergraduates often avoid mathematically based modules. Even postgraduate courses may provide insufficient mathematical training.

“The general rigour of maths elements in postgraduate biochemistry courses is insufficient.”

2.2.2 Practical Skills

The level of concern over practical skills of new recruits was even higher with 59% of respondents stating that it was a major concern for them; in total 87% felt it was a concern or major concern.

“The major concern which is voiced by many recruiting managers within the organisation is the lack of lab skills which candidates now have, when previously they learned these skills as part of their course”

“Some candidates lack knowledge of very basic lab activities such as use of balances and pipettes.”

Companies look to employ people highly motivated by practical activity, this can often be encouraged through undergraduate industrial placements. In 2007 ABPI member companies hosted 530 industrial placement students, the vast majority of these for one year.

| | 2007 |
|-------------------------------------|-------------|
| School student work placements | 850 |
| Undergraduate industrial placements | 530 |
| PhD studentships | 606 |
| Post-doctoral grants | 327 |

“Practical experience is a real concern - a 3 year course does not provide enough practical experience. When we recruit students we only look at those who have at the very least a summer placement.”

Biological science courses in England and Wales, whatever their discipline, are almost all 3 year courses, whereas for chemistry and engineering students a wide choice of 4 year integrated masters courses are available. A number of responses cited the difficulty of including sufficient practical experience during a three year course.

A recommendation of the report *In vivo sciences in the UK*⁵ was to increase the number of biological science undergraduate industrial placements, particularly those involving *in vivo* work.

2.2.3 Application of knowledge

In addition to the practical skills and mathematical competency described above, a third area of concern was the ability of new recruits to bring aspects of an experiment together and to have sufficient understanding of their subject to make appropriate inferences about their experimental findings.

“There is a tendency to accept data at face value and the questioning and deeper understanding of data interpretation and application is missing. The lack of maths skills is worrying, as is the inability to estimate if a result is correct, or to have an idea of the answer before the computer generates one.”

Some candidates have “no understanding of the relevance of the knowledge and why they learnt it.”

Eighty nine percent of respondents said that the lack of candidates’ ability to apply scientific and maths knowledge was a concern for them.

Problem solving skills and a recruit’s abilities to convey their thinking logically were also cited as issues for some new recruits.

2.3 Core disciplines

The creation and testing of new medicines requires people with a variety of specialist skills and knowledge. Many of these will be people who have studied scientific subjects, engineering or maths at school, college and university. These are the core disciplines in demand within the pharmaceutical and biopharmaceutical industry.

Addressing problems with supply of appropriately skilled people within these specialist areas requires a more focused approach.

Recruitment issues for some of the disciplines are longstanding and worldwide. In other areas the issue may be around recruitment of people with the necessary skills at just one level, such as people with a PhD in a relevant area. Many of the issues identified have not changed in the three years since our last report. This is not surprising; decisions on curricula, funding and focus cannot be made in isolation and require careful review.

Although concerns were raised across many of the disciplines required for the research, development, manufacture and supply of medicines in the UK, some disciplines were found to be in a critical state.

The greatest concerns were around clinical pharmacology / experimental medicine, drug metabolism and ADME¹, *in vivo* sciences, animal technology, chemical and process engineering, statistics, computational chemistry and pharmacokinetics, pharmacodynamics and modelling.

Since 2005, improvements have been seen in the disciplines of pharmacy, analytical and physical chemistry, and synthetic organic / process chemistry. Much work has been focused on these areas, in particular chemistry, and this has resulted in an increase in the numbers for both A level and higher education chemistry courses.

Shown below is a comparison between the results of the surveys from 2005 and 2008. The detailed findings for 2008 can be found in Appendix IV.

Key

| Symbol | Description |
|---|--|
|  | Low Priority - Important area to watch |
|  | Medium Priority - Requires action |
|  | High Priority - Requires immediate action |
| Q | Quality - Candidate quality |
| N | Number - Candidate numbers |
| F | Future - Future of the discipline |
| M | Manufacturing - Priority for manufacturing disciplines |

In the results, Q, N, F and M are coloured to reflect their level of priority for each discipline. Any symbol shown in grey is not applicable to that discipline.

Translational and Biomedical Sciences

| DISCIPLINE | 2005 | 2008 |
|--|---|---|
| Clinical Pharmacology / Translational Medicine |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Molecular and Translational Toxicology | emerging discipline - not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Biomedical Imaging / Physics |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| "Omics" | emerging discipline - not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |

| DISCIPLINE | 2005 | 2008 |
|--------------------------------------|---|---|
| Drug Metabolism and ADME |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Biochemistry |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Bioscience and Molecular Biology |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| <i>In vitro</i> Pharmacology |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Pharmacy |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Medicine |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Biotechnology and Biopharmaceuticals |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| <i>In vivo</i> Physiology |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| <i>In vivo</i> Pharmacology |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |

| DISCIPLINE | 2005 | 2008 |
|--|---|--|
| Toxicology |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Pathology |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Veterinary Medicine and Veterinary Science |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Animal Technology | not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |

Chemical Sciences

| DISCIPLINE | 2005 | 2008 |
|---------------------------------------|---|--|
| Analytical and Physical Chemistry |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Synthetic Organic / Process Chemistry |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |

Engineering

| DISCIPLINE | 2005 | 2008 |
|----------------------------------|---|--|
| Chemical and Process Engineering |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |

| DISCIPLINE | 2005 | 2008 |
|--|---|---|
| Mechanical and Electrical Engineering |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Highly Complex Process Control and Instrumentation Engineering | emerging discipline - not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |

Mathematical Sciences and Statistics

| DISCIPLINE | 2005 | 2008 |
|--|---|---|
| Statistics |  Q N F M Non Graduate Graduate PhD Post-Doc |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Computational Science and Bioinformatics | emerging discipline - not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Computational Chemistry | emerging discipline - not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Pharmacokinetics, Pharmacodynamics and Modelling | emerging discipline - not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |
| Health Economics | not graded in 2005 |  Q N F M Non Graduate Graduate PhD Post-Doc |

3 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

3.1 Research and Development of Innovative Medicines

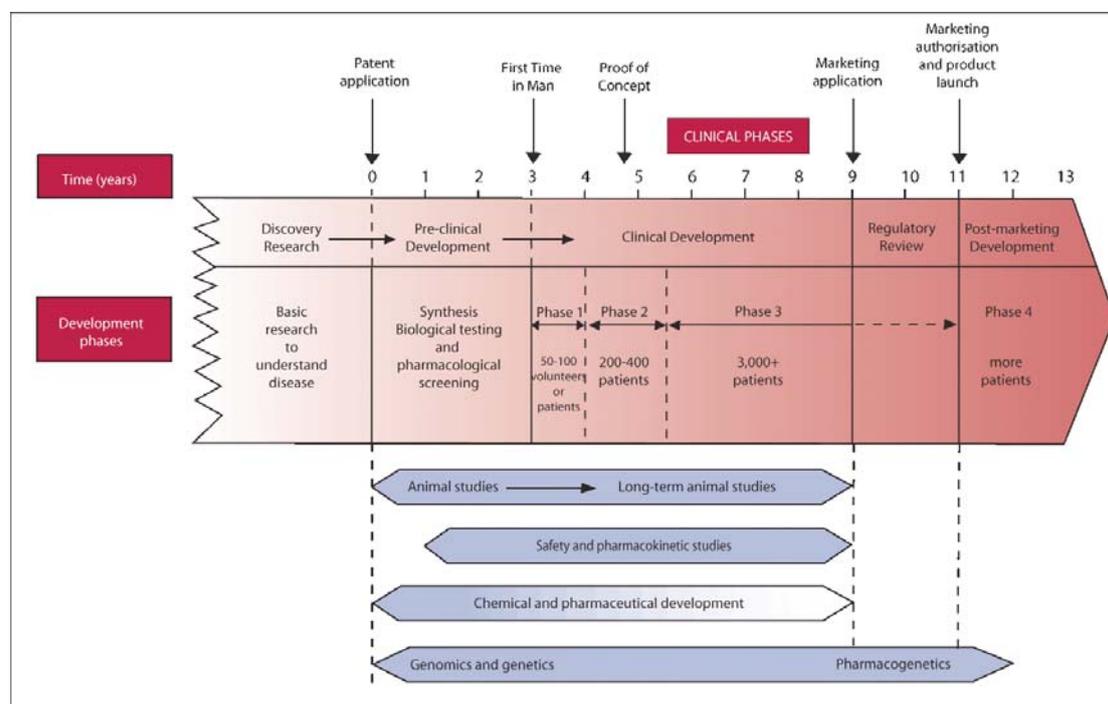


Figure 3: The drug development process

The transformation of a scientific hypothesis into a valued agent in the clinic is a long and complex process involving a variety of STEM skills, starting from fundamental research through translational medicine to manufacture and introduction into clinical practice. Detailed information on the research and development process is given in Appendix III.

3.2 Skills Needs for Biomedical Innovation

For many years the UK has been a leader in medical research, with particular strengths in preclinical research, pharmacology and early clinical pharmacology, and about a fifth of the top 100 medicines in use today originated from research in the UK – a record second only to the United States. The contribution of the pharmaceutical industry to this record has been highly significant, providing advances in both basic science and applied science.

Translational Medicine is a key step between basic scientific research and patient care, translating scientific discoveries into real therapies and medicines. This discipline is becoming increasingly significant in the industry as focus moves to a more patient-driven approach to drug development. The discipline encompasses specialists in both clinical pharmacology and experimental medicine. Major gaps in theoretical scientific understanding, a lack of focus on the skills required for translational medicine within medical and biomedical curricula and a lack of

understanding of drug development amongst academic clinical pharmacologists are all contributing factors to the problems seen in this discipline.

“Drug development and pharmacology are not sufficiently addressed in medical degrees.”

The recommendations of the 2005 ‘Walport’ report¹⁰ set out the training required for development of pathways necessary for a career in clinical research. Although some activity, led by the Wellcome Trust and the Medical Research Council, is ongoing to address this need through investment in clinical research infrastructure, there are immediate and severe concerns

over the recruitment of medically qualified individuals to direct translational medicine in industry. Pharmacological models are becoming increasingly important to predict accurately likely responses to biologicals and there is a need for a wide range of skills.

There is a lack of awareness of drug metabolism and pharmacokinetics amongst undergraduates. Candidates who have studied biochemistry have some awareness of the discipline, but their courses have often not provided appropriate practical experience and not all students have taken the necessary mathematically focused modules.

“They often do not have the minimum level of understanding of pharmacology to make appropriate inferences about the impact of pharmacokinetic differences on drug response.”

Biologics and biopharmaceuticals are now vitally important to the industry and there is an increasing need for skilled people with an understanding of biologics across a number of disciplines including the critical areas of drug metabolism and ADME¹, clinical pharmacology / experimental medicine and *in vivo* pharmacology.

The recently issued Subject Profiles for Biochemistry and Microbiology¹¹ map the trends in the student learning experience at a disciplinary level. They also meet a need across the sector for a contemporary baseline of trends within subjects, and provide a foundation which can be updated periodically, so enabling the continual enhancement of the student learning experience. However, although they identify concerns for the future of the discipline, there is no expectation that action will be taken to address these concerns.

3.3 Linking Higher Education Strategy to UK Needs

A strong message coming out of the survey was that scientific knowledge, practical skills, high level maths skills and, application of science and maths knowledge are critical concerns for employers. Most of the recruitment takes place at graduate level and above and it is the knowledge and skills of new graduates that is the major issue.

Within the UK higher education system, universities fulfil a number of different roles and have different priorities. Funding of universities comes from a variety of sources and individual universities have a greater or lesser reliance on income intended for its

¹⁰ Medically- and dentally-qualified academic staff: Recommendations for training the researchers and educators of the future, UKCRC March 2005

¹¹ National subject profiles for Biochemistry and Microbiology, Higher Education Academy for Bioscience, 2008

teaching activities. The Royal Society, in their 2006 report *A degree of concern?*¹², found that laboratory-based projects in the final year of BSc Honours courses are especially expensive, and that teaching of laboratory-based subjects have been inadequately funded in recent years.

The Higher Education Funding Councils for England has responded to pressure from Government and professional bodies to support subjects recognised as strategically important and vulnerable (including chemistry and physics) with additional funding for teaching for three years commencing 2007/8. Similar action has been replicated in Wales. However, despite concerns raised by the Biosciences Federation and ABPI⁵, and echoed by the Bioscience Higher Education Academy¹¹, there has not been any similar allowance for bioscience courses. As the Bioscience HEA comments “it is a misconception that the biosciences are not vulnerable to decline in student demand”.

Despite earlier calls from a variety of organisations, including The Royal Society¹³, Research and Development Society¹⁴ and others, for employers to have a mechanism to engage more closely with Higher Education institutions to encourage development of courses that more closely meet their needs, little progress has been made towards this goal. The Sector Skills Councils, whose central role is working closely with industry to identify skill needs and influence education and training policy, do not appear to have a common mechanism available to drive this engagement. The Bioscience Sector Skills Agreement¹⁵ brokered by Semta has, as a major recommendation, under ‘Top Quality Workforce’, actions to promote and develop a responsive system to address the emerging high level demand signals and to change metrics for undergraduates and university outputs to make higher education more responsive to employer needs. It is not clear what mechanism Semta could use to deliver on these recommendations, however, the creation of a higher education bioscience sub-group is a welcome start.

At present there is no route for a meaningful dialogue between companies and universities collectively. Pharmaceutical companies employ graduates in a wide range of biological sciences, the variability in the content of individual disciplines is enormous and varies between institutions, thus creating a complex landscape of capabilities even within a single degree subject. A consequence of this complexity is reflected in the large number of PhDs and post-docs recruited by companies rather than first degree graduates.

Despite the promise in *World Class Skills*¹⁶ to ensure that “the supply of skills and qualifications is driven by employers” the required action does not seem to be happening.

To address these needs, and other specific needs identified for individual disciplines, dialogue with the Higher Education sector is essential. The most fruitful engagement between science based industry and Government in recent years has been the setting up of a High Level STEM Strategy Group, led by the National STEM Director. This provides a forum for science based industry to input directly into science policy and, through a working group chaired by the industry representative on the strategy group, a wide range of STEM employers are involved. However this group’s focus is

¹² A degree of concern? UK first degrees in science, technology and mathematics, The Royal Society, October 2006

¹³ A Higher Degree of Concern, The Royal Society, January 2008

¹⁴ Higher Education in 2015 and Beyond: will it meet our needs?, Research and Development Society, 2006

¹⁵ Bioscience Sector Skills Agreement: Stage 3 Gap Analysis: UK, Semta, December 2007

¹⁶ World Class Skills: Implementing the Leitch review of skills in England, July 2007

group, a wide range of STEM employers are involved. However this group's focus is almost exclusively on school education. A similar mechanism must be found to join up the needs of the biomedical research community, including the pharmaceutical industry, with the supply of graduates and postgraduates.

Recommendation 1

A Dialogue for Action – establishing a High Level STEM Strategy Group for Higher Education

The High Level Science, Technology, Engineering and Maths (STEM) Strategy Group in the Department for Children, Schools and Families has been key in galvanising and coordinating an action plan that has the potential to transform the science skills of 14-19 year old learners. The DCSF STEM Strategy Group used to encompass HE, however following the splitting of the Department for Education and Skills in 2007, its focus has, understandably, been on implementing the schools agenda and delivery of that potential.

Therefore a similar approach led by the HE Directorate in DIUS is essential to link employer needs to UK Government strategy and to coordinate across diverse stakeholders in research, postgraduate and undergraduate funding.

ACTION: DIUS should establish a High Level STEM Strategy Group for Higher Education by mid-2009, bringing together the key funders, industry, scientific institutes and academia to ensure a coordinated approach to developing a pool of UK talent to realise the Innovation Nation agenda. A National STEM Director for HE should be appointed to oversee and coordinate actions.

3.4 Priorities: Core skills and specialist disciplines

3.4.1 Mathematics

Specific issues have been identified for mathematics that need to be addressed in partnership with the maths community and higher education.

Mathematics is a core subject in the English National Curriculum, as it is in the curricula of the other UK nations. Although numbers studying maths beyond 16 are increasing, in 2008 there was a 7.4% increase in maths, and 15.75% increase in further maths A level entries, and maths remains the second highest subject for number of A level entries, our survey shows that we are not producing young people who can use their mathematical skills effectively.

“UK graduates are lacking the appropriate maths skills which are essential for transporter sciences and for the development of novel delivery methods.”

“Expertise in enzyme kinetics is currently lacking in some HE biochemistry departments.”

The need for people to apply mathematical skills within their discipline pervades the industry, and lack of mathematical skills is often a factor in rejecting applicants for a role in industry¹⁷.

Mathematics at Higher or A level is normally not required for biological science courses and many biological science graduates have not studied maths beyond 16. Hence their understanding of statistical techniques is low; understanding of statistics is vital to many areas of drug development – from animal studies to clinical trials – and a lack of knowledge and understanding in these areas is a barrier to recruitment. Demand for statistics skills will increase with moves towards stratified (personalised) medicines; it is an issue which must be addressed.

“Statistical concepts must be fully integrated into the medical curriculum.”

“Statistics needed to support pharmaceutical science skills.”

Quantitative analytical techniques are also vital in several areas of research, development and manufacturing, weak mathematical skills lead to poor candidates for roles in these areas.

There is also a critical need for individuals with expertise in engineering and maths to understand biology and drug development and be able to apply that knowledge to biopharmaceutical problems.

Mathematical modelling techniques are increasingly a core part of development of a new medicine, for instance within computational science, bioinformatics, medicinal chemistry, and pharmacokinetic/pharmacodynamic (PK/PD) modelling.

It is proposed that a taskforce be set up to identify the core mathematical capabilities for effective working in different scientific and technological areas, and communicate the need for these to be incorporated into undergraduate science courses to selected higher education institutions.

Clear messages on the need for applied mathematical skills should be relayed to students, at school, college and university.

Action to address the deficiencies should be reviewed through partnership working with curriculum setting bodies for school, further and higher education. The possibility of creating subject specific free-standing maths qualifications to meet the needs of students taking biology, chemistry or physics without studying maths should be explored. These could be designed to encourage students to apply their existing maths skills as well as learning those necessary to support their A level, Higher and Advanced Higher subjects.

3.4.2 Practical Skills

The majority of roles for graduates and postgraduates entering industry are laboratory based. For these roles the inadequate practical skills of new graduates was a common observation across the majority of disciplines in the survey. The issue appears to extend to really basic practical lab skills – ability to carry out serial dilutions, pipetting, using a balance and making up a molar solution.

¹⁷ A review of science-based skills requirements in R&D and manufacturing at Pfizer (Sandwich), Dr Mark Edwards, April 2007

A lack of basic practical skills was cited as an issue for graduates in most disciplines including molecular biology, clinical pharmacology, biochemistry, *in vivo* physiology and pharmacology and chemistry.

“The general quality of analytical and physical chemistry students is acceptable, they just lack practical experience.”

“Many courses don’t have the practical aspects, we will always hire a sandwich student as a preference.”

Some companies, in partnership with universities, are taking steps to improve the practical skills of their employees; one company, for instance, engages Bristol University to deliver intensive training in practical skills to the incoming cohort of chemistry industrial placement students at the start of their year placement.

For some disciplines there is also an issue with university laboratories not being able to offer undergraduate students experience with contemporary techniques or equipment.

“The practical component of pharmacology courses is no preparation for work.”

“We need to find ways to give bioscience and molecular biology students more hands-on experience with top level kit and assay technology.”

“It would help if biochemistry graduates had more opportunity to work with high level analytical equipment during their studies.”

There is a substantial amount of activity going on to improve the practical skills of school students and their teachers led by professional bodies, charities and industry itself. Further details can be found in Appendix V.

Employers could specify the core laboratory skills that are essential for scientific research in industry to supplement the subject based Student Employability Profiles. Examples of the types of skills that could be specified are included in Appendix VI.

There are opportunities to influence undergraduate teaching of practical skills through interaction with the Higher Education Academies for Bioscience and Physical sciences; however these organisations have no influence on funding of undergraduate courses.

Adequate and appropriate funding of universities is essential. Despite the sustained increase in public funding for science and innovation, funding for teaching of science and engineering subjects at universities has not received large increases. Changes made by HEFCE to subject weightings in 2004 have made laboratory based courses of importance to the economy, less viable. The reduction in the qualifier for laboratory based courses, from its previous level of 2 to 1.7, has resulted in the increase in funding for these courses in recent years being much less than that for clinical and lecture based courses. The data collected by the Higher Education Funding Council for England for 2006/7 using TRAC(T) does not demonstrate accurately the funding needs for laboratory subjects as it is based on current allocation of funding, rather than allocations to deliver high quality practically based courses.

3.4.3 Rigour of Degrees

The number of students studying chemistry, biology and maths at A level or equivalent has been rising over the last five years, and increased numbers are entering higher education. However, the percentages of students taking these subjects is low; in 2008 only 5% of total A level entries were for chemistry, 6.6% biology and 7.8% maths. Applications to study chemistry, biological sciences, physics and maths at Higher Education are increasing and 3,907 students were accepted on to undergraduate chemistry courses in 2007, 4,503 biology and 2,128 molecular biology, biophysics or biochemistry. When average figures are compared across 2000-2007 the percentage of students taking science A levels in Northern Ireland are higher than for England and in Wales they are lower. The figures for Highers in Scotland are not directly comparable however the percentages are much higher, particularly for maths where the number taking maths averages 22%¹⁸.

The new National Subject Profiles bring together a wide variety of information on Higher Education provision of a particular subject. To date only three have been published but these give useful information on content and delivery of Biochemistry, Microbiology and Materials Science. In line with our findings on the weak practical skills of new graduates, the Biochemistry profile¹¹ comments that all the Biochemistry graduates interviewed would have preferred more training in laboratory methods. This echoes a 2003 survey¹⁹ in which 21% of employed bioscience graduates said that they felt their university practical training had not prepared them sufficiently well for their occupation. The time allocated to practical work in the Biochemistry courses surveyed averaged only 3.4, 3.3 and 5.3 hours per week (excluding project work) in years 1, 2 and the final year of their course. Microbiology courses provided greater exposure to practical work 5.3, 5.0 and 3.0 hours per week (plus, on average 10.3 hours per week on project work in the final year), but some students still felt unprepared for their practical project.

Both biochemistry and microbiology courses generally allow students to select modules to study to achieve a fixed number of credits for each year of the course. It is rare for a fixed set of modules to be specified giving students no choice of what to study. Whilst enabling students to tailor the course to their interests, this could allow students to opt out of topics which provide essential skills for bioscience research. Experience from industry suggests that this is particularly prevalent where students have the option to not study course units with a higher mathematical content.

The flexibility and variability in the content of undergraduate courses is a real problem for industry, exacerbated by the lack of an effective mechanism to have a meaningful dialogue with universities collectively. A consequence of this situation can clearly be seen in many large pharmaceutical companies where new scientific positions are aimed more and more at PhDs and post-docs.

This view echoes that of the Council for Industry and Higher Education in their 2007 STEM Review²⁰: “Current discussion with some of the larger STEM employers reveals a view that there may be too much freedom for HEIs to modify the syllabus,

¹⁸ A ‘state of the nation report’: Science and mathematics education, 14-19, Royal Society, in press

¹⁹ Skills and Knowledge needs amongst recent bioscience graduates – how do our courses measure up? www.bioscience.heacademy.ac.uk/journal/vol6

²⁰ STEM Review the Science, Technology, Engineering and Maths Supply Chain, Hugh Smith, CIHE, March 2007

often in an attempt to create what they judge to be most appealing to students” and that this can lead to employers not having a clear picture of what the student has been taught.

Adoption of the model pioneered by the Royal Society of Chemistry to accredit degree courses would allow students and employers to recognise courses that provide depth of study in the discipline. A suitable body to carry out this function would be IOB/BSF.

3.4.4 Specialist Disciplines

The survey answered by member companies covered a broad range of disciplines that had been identified in the 2005 report (see Appendix IV). Although concerns were raised across many of the disciplines required for the research, development, manufacture and supply of medicines in the UK, some disciplines were found to be in a critical state.

Of particular concern were the subjects supporting biomedical translational science, and the subsequent transformation of ideas into products.

Many of the disciplines surveyed for our report work together to support the area of biomedical translational research: clinical pharmacology and translational medicine; pharmacokinetics, pharmacodynamics, modelling and the underpinning mathematical disciplines; the *in vivo* sciences - physiology, pharmacology and animal technicians; toxicology and biomarkers; imaging; drug metabolism and ADME; statistics; and “omics” and predictive, high throughput biology. Of the ten disciplines listed above, seven have a high priority grading.

Translational science is a key area of research within both the pharmaceutical industry and academia, forming the vital link between basic scientific research and patient care. Whilst we are aware that some work has begun since the 2005 report to address the issues within a few of the specific disciplines listed, it is of great concern that so many of the supporting disciplines for an area in which the UK sees itself to be a world leader are suffering from a shortage of skills.

Each of the disciplines above also has many applications outside of the translational science umbrella, and the importance of these should not be forgotten. Biologics and biopharmaceuticals are now vitally important to the industry, forming the basis of approximately 20% of all new molecular entities launched each year on the global market²¹. There is an increasing need for skilled people with an understanding of biologics across a number of disciplines including the critical areas of drug metabolism and ADME¹, clinical pharmacology and translational medicine, and *in vivo* pharmacology.

In the past the UK has had a strong track record in developing high-value manufacturing. One obvious need for these skills going forward is in the area of biopharmaceuticals, which requires a very different skills set in manufacturing. A priority for the biotechnology sector in the UK is the translation of scientific knowledge into valued products, which again requires access to the same skills base. The survey has shown that there are distinct gaps in expertise available in the

²¹ The Pharmaceutical Industry in Figures, EFPIA, 2008 Edition

UK to facilitate this process. Activity to address manufacturing needs is being considered through the manufacturing strategy²².

The effects of the skills shortages are not limited to the pharmaceutical industry. Many of the disciplines are also experiencing problems within academia, other industry sectors, and the NHS and actions to address the problems must take this into account. A concerted effort is needed across all disciplines and on behalf of all stakeholders in order to sustain these important subjects.

Recommendation 2

Transparency and Impact – improving the linkage between UK Government innovation strategy and the funding of STEM education and skills to support that agenda.

The UK Government has highlighted the importance of translational medicine underpinned by investments in biomedical research through such initiatives as OSCHR (the Office for the Strategic Coordination of Health Research) and NIHR (National Institute for Health Research). However realising the value of this investment is dependent upon the supply of critical STEM skills and disciplines.

This report has highlighted critical shortage of a number of key underpinning skills, in particular *in vivo* sciences, clinical pharmacology and mathematical modelling. Although we highlighted this in 2005, there has only been modest progress and these needs have not been effectively addressed.

Biopharmaceuticals will also play a key role in addressing priority health needs for the UK in the future, however this survey has shown that there is a need to enhance the supply of related skills especially in translating ideas into products and manufacturing.

We believe that the new Cabinet Committee on Science & Innovation, Chaired by the Science & Innovation Minister, Lord Drayson, should review the mechanisms by which Higher Education and research training courses are funded and incentivised in the UK. In particular they should consider whether they are fit for purpose to create the pools of STEM talent to allow the UK to win the global innovation race.

ACTION: The Cabinet Committee on Science & Innovation should review and take action to ensure the mechanism for reacting and funding strategically important skills and disciplines is transparent and reactive to the needs of the scientific community in both the public and private sector. The proposed High Level STEM Strategy Group for HE should also play a substantive role in the review and in the subsequent identification of strategically important subjects.

²² Manufacturing: New Challenges, New Opportunities, BERR and DIUS, September 2008

Recommendation 3

Enhancing core skills and disciplines

This survey has reinforced the need for action to address the deficits in skills supply in terms of both core capabilities and essential skills. In terms of core skills for STEM graduates employers believe that action needs to be taken to address:

- practical capability;
- the application of scientific knowledge; and
- mathematics across disciplines.

The survey has identified a continued need across a wider range of specialist disciplines. In particular skills that support:

- translational science; and
- high-value manufacturing (including biopharmaceuticals).

The solution to these problems start must in schools and feed through to higher education.

ACTIONS: A number of actions need to be taken.

- First, the mathematics capabilities of science students need to be enhanced both through the implementation of the 14-19 Science Diploma and free-standing maths courses in schools and colleges.
- Second, the funding formula for teaching practical science courses in universities needs to be augmented.
- Finally, provision of four year integrated Masters in biological sciences should be increased and appropriately funded. Accreditation schemes for strategically important disciplines, such as those for chemistry, physics and engineering, should be extended to include designated biological science courses.

3.5 Industry's Contribution

UK pharmaceutical companies invest over £1.75 million annually in supporting education activities. This includes outreach activities to local schools and colleges, curriculum enhancement and training for teachers. This is the tip of the iceberg as pharmaceutical company employees contribute a lot of time engaging with schools as Science and Engineering Ambassadors, Business Ambassadors, or as volunteers outside of a formal programme. Industry mentors work with students through Young Enterprise, CREST Awards and Young Foresight, as well as providing direct mentoring to students studying for advanced level science qualifications.

“Work experience at school level and participating in industry visits with universities are crucial for us to participate in, in order to forge links with schools and universities and raise awareness of the industry job opportunities.”

The lack of a clear career pathway in industry may be a deterrent for some young people, and poor perceptions of the industry could mean we are not attracting the best candidates. In emerging areas, such as biomedical imaging and biomarkers, low awareness of industrial opportunities may be an issue. Some survey responses

indicated unexpectedly low numbers of candidates for some disciplines. This could be due to a lack of awareness rather than a small overall candidate pool. To overcome this, some companies collaborate with universities to try to encourage graduates from the required disciplines to consider a career with them.

Employers within the pharmaceutical industry are very keen to engage with young people to promote the opportunities that exist, particularly for those with science or engineering qualifications, in the industry. Companies offer information on careers in the industry on their own websites, and the ABPI has a comprehensive website, www.abpicareers.org.uk dedicated to providing information to young people and to their career advisors, teachers and parents. The ABPI and pharmaceutical employers are already engaging closely with initiatives such as the Science Council Futuremorph⁶ website and the projects being taken forward by the National STEM Careers Coordinator.

3.5.1 Case Studies

WORK PLACEMENTS: Pharmaceutical companies also provide work experience placements; over 850 for school students in the UK, and, in 2007, 514 year long industrial placements for UK undergraduates and 606 PhD studentships. Through experiences such as these, students can find out at first hand what different jobs are like, and what opportunities there would be for them in industry.

OUTREACH: Companies carry out other outreach activities with local schools such as attendance at career fairs, providing speakers at career events, and by providing tours of their facilities, including virtual tours for school students who would not have the opportunity to visit a site.

PROJECT ENTHUSE: Three pharmaceutical companies, GlaxoSmithKline, GE Healthcare and AstraZeneca are each providing £1million funding over 5 years to Project Enthuse, a major new partnership between industry, government and the Wellcome Trust to enable 2,200 teachers each year to take part in courses at the National Science Learning Centre.

CHEMISTRY FOR NON-SPECIALISTS: High quality science education relies on enthusiastic, knowledgeable teachers, and the pharmaceutical industry is also playing a part in supporting initial teacher training. GSK is providing £450,000 funding for training of 2,700 non-specialists to teach chemistry in a partnership with the Royal Society of Chemistry.

ACADEMIC-INDUSTRY RESEARCH COLLABORATIONS: Pharmaceutical companies collaborate with universities on research in many ways – from funding PhD students, to large scale grants. These totalled around £60-80 million in 2005, Specific funding has also been provided to catalyse capacity building in critical areas such as integrative mammalian biology²³

ENGAGEMENT WITH OTHER ORGANISATIONS: Support for education and skills delivery is also supported through companies enabling their staff to sit on Research Council and university boards, Sector Skills Council boards and supporting strategy groups.

²³ Integrative Mammalian Biology Initiative (IMBI)

3.6 Effective Implementation

During the consultation with diverse stakeholders it has become clear that since the publication of our first skills report in 2005, there has been much activity that will help to create the foundation for the future (Figure 4). However, the Government and stakeholders must continue to monitor the impact of these initiatives: but they must be given time to create an impact on the skills and capabilities of students.

The recommendations laid out in this report are not meant to duplicate, replace or impede the existing activity. Rather they are meant to close gaps, the most critical being the need to link more closely UK Government strategy on science and innovation to the funding of higher education and research training in a coordinated, rather than piecemeal, way.

The High-Level STEM Strategy Group in DCSF has been a particular success focusing mostly on STEM education in schools; an approach that could be adopted in Higher Education with the Secretariat provided by the relevant Directorate in the Department for Innovation, Universities and Skills.

A coordinated approach, monitored for impact, is essential. While the UK has a more mature and complex education sector, emerging countries such as China, Singapore and India are now able to provide the essential skills on which industry depends to develop innovative medicines. Without this the UK is unlikely to sustain its global competitive position as a centre for biomedical research investment.

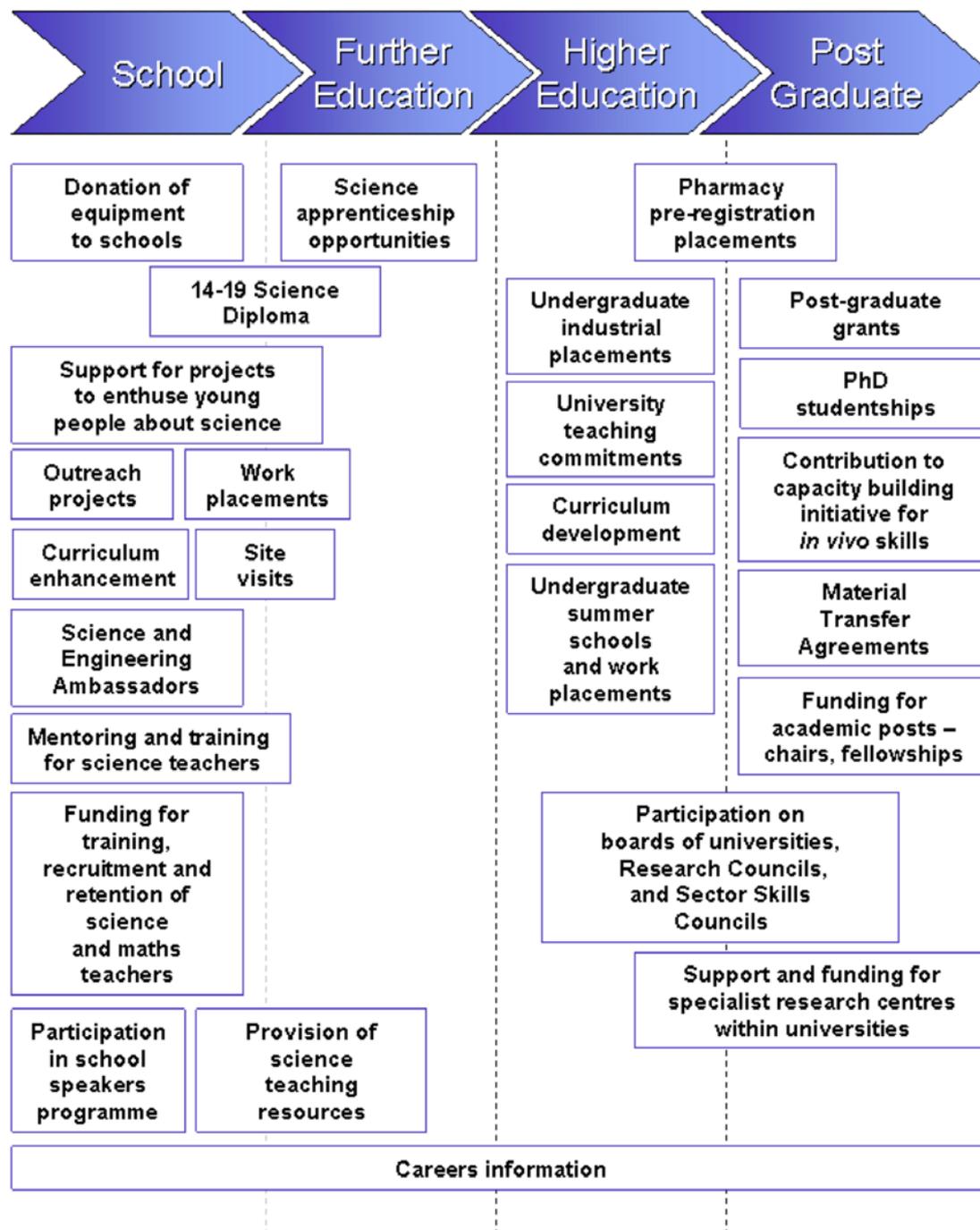


Figure 4: Industry activities within science education

4 APPENDICES

Appendix I Members of the Taskforce

| | |
|-------------------------------|--|
| Dr Aileen Allsop | AstraZeneca Plc (Chair) |
| Dr Tony Bradshaw | BioIndustry Association |
| Dr Paul Brooker | Huntingdon Life Sciences |
| Mr Mark Edwards | Pfizer Ltd |
| Dr Pablo Fernandez | PharmaNet Ltd |
| Mr James Graham | Pfizer Ltd |
| Miss Janet Kelly | Covance Laboratories Ltd |
| Dr Jeff Kipling | GlaxoSmithKline Plc |
| Dr Tim Mant | Quintiles GDRU |
| Ms Carolyn Mason | GlaxoSmithKline Plc |
| Mrs Kay Roberts | GlaxoSmithKline Plc |
| Dr David Sciberras | Amgen Ltd |
| Mr David Strickland | Norgine Ltd |
| Dr Kay Wardle | The RSA Group |
| Mrs Jackie Wilbraham | AstraZeneca Plc |
| Mr Stephen Stanton (Observer) | Department for Children, Schools and Families (DCSF) |
| Dr Hannah Gilbert | ABPI (R&D Policy Officer) |
| Mrs Sarah Jones | ABPI (Head of Education) |
| Dr Philip Wright | ABPI (Director of Science and Technology) |

Appendix II Progress Since 2005

Progress against the objectives from our 2005 report *Sustaining the Skills Pipeline in the pharmaceutical and biopharmaceutical industries* is detailed below:

RECOMMENDATION 1

In vivo taskforce

Objective: Government to facilitate the establishment of a UK *in vivo* sciences taskforce to consolidate information on current provision of *in vivo* skills, identify gaps and develop an action plan for a 5 – 10 year programme

Progress: A detailed review was carried out to test the findings of the 2005 report, to provide more detail of the issues and to consider action to sustain education and training in the *in vivo* sciences in the UK. Positive interaction with the Biosciences Federation during the review culminated in a report *In vivo Sciences in the UK: sustaining the supply of skills in the 21st century*, with a number of recommendations for action by the pharmaceutical industry, Biosciences Federation, research funders and the Home Office.

Progress following publication of the *in vivo* sciences report has been limited. In particular we are extremely disappointed that the HEFCE advisory group for Strategically Important and Vulnerable Subjects (SIVS) has recommended against *in vivo* sciences being included as a strategically important and vulnerable subject. We are also disappointed with the very limited response from the Research Councils to addressing the needs identified in areas of importance to industry, including *in vivo* areas. The introduction of a relatively small number of taught Masters courses has stalled due to lack of funding, despite industry and academia having developed a curriculum for a Masters in Safety Sciences.

RECOMMENDATION 2

Raising the practical skills of science teachers

Objective: Increase the opportunities for young people to carry out meaningful practical work in schools, especially that relevant to the skills needs of industry

Progress: This recommendation led to the Sector Skills Agreement for Bioscience having as a focus 'Raise practical skills as an integrated component of the education system at all levels'.

Courses for science teachers are being delivered through the Science Learning Centre network, IOB, RSC and other organisations.

RECOMMENDATION 3

14-19 Diploma in Science

Objective: To develop a 14-19 Science Diploma, promoting both vocational and 'academic' study of science

Progress: A Science Diploma is to be introduced for first teaching in 2011. The pharmaceutical industry is represented on the Diploma Development Partnership steering group and Philip Wright is chairing the Employer Working Group.

RECOMMENDATION 4

Developing Profiles of skills needs in priority areas to ensure the gaps are addressed

Objective: Improve the skills of first degree graduates to make them more 'work ready'

Progress: A new ABPI careers website has been created. The site communicates key messages to students, career advisors, teachers and parents on the skills and education that are valued by the pharmaceutical industry. Case studies of people working in the industry provide examples of routes in to working in the industry including the skills needed to carry out each role.

Whilst this has had some impact in raising the profile of careers in the industry and feedback on the site has been good, it is recognised that further activity is required to raise the profile of the pharmaceutical and biopharmaceutical industries.

RECOMMENDATION 5

Supporting RSC to promote understanding of needs of industry to university chemistry departments

Objective: Improve awareness of industry's needs in HE chemistry departments to ensure that undergraduate study provides the skills industry seeks.

Progress: Outcomes of workshops held with both industry and academic participants have fed in to the SEMTA Sector Skills Agreement (SSA) for Bioscience. Development of a top quality workforce is a priority area within the SSA.

Activity, such as that led by the Royal Society of Chemistry with funding from HEFCE, has led to increased numbers of students studying chemistry at A level and at university.

RECOMMENDATION 6

Liaison with Research Councils to target awards to areas of importance to industry.

Objective: Increase the relevance of postgraduate funding by Research Councils to the needs of industry

Progress: An ABPI/Research Council Framework for Priorities in strategic science including translational medicine has been agreed. Activity under this framework is ongoing but a positive outcome has been the opportunity to influence Research Council priorities.

RECOMMENDATION 7

Government to set targets for HE Funding Councils to expand physics and chemistry courses in line with UK strategy on science and innovation.

Objective: Increased funding for teaching of science courses within HE through an increase in HEFCE's funding multiplier for teaching, and an increase in student demand for these courses.

Progress: The Higher Education Funding Council has provided funding for Strategically Important and Vulnerable Subjects including physics and chemistry through initiatives to drive up demand for these subjects at Higher Education. Funded

projects include Chemistry for our Future, Stimulating Physics and More Maths Grads.

It is very disappointing that no change has been made to the funding multiplier for teaching for laboratory based subjects to differentiate those with a greater practical component, and that no targets have been set for expansion of these courses. However increasing numbers of students are taking these subjects at A level and acceptances into chemistry and physics degree courses are increasing.

RECOMMENDATIONS 8 AND 9

Industry/school liaison

Objective: Increase the effectiveness of industry engagement with schools

Progress: ABPI Education and Schools Liaison Advisory group provides a forum for companies to share information on activities. The National STEM director, John Holman, is leading activity set out in the STEM Programme Report which focused on how best to support science, technology, engineering and mathematics through school, post-16 education and university and how to streamline the current numerous STEM initiatives and implement them more effectively in schools and colleges. An ABPI workshop is planned to promote effective engagement between schools and the pharmaceutical industry.

RECOMMENDATION 10

Linking study of science in school to career information

Objective: QCA to specify that information on careers in scientific subjects should be included at Key Stage 3, GCSE and in all post-16 courses

Progress: The new Key Stage 3 programme of study for science in England states that opportunities must be provided for pupils to consider the career opportunities that science qualifications can lead to, both within science and in other areas. There is now an expectation that links will be made between the science curriculum and career opportunities throughout secondary education.

RECOMMENDATION 11

Co-ordinate and enhance delivery of careers information in schools

Objective: Increase student, teacher and career advisor knowledge of careers in science to increase demand for science degree education.

Progress: The ABPI career website was re-launched in October 2007 with information targeted at specific audiences, school and university students, career advisors, teachers and parents.

The DCSF supported Science Council 'FutureMorph' web portal is due for launch in November 2008. Delivery of information on STEM careers to school students is being taken forward as a project by Sheffield Hallam University and the National STEM Careers Coordinator. ABPI represents the pharmaceutical industry on the STEM Careers Stakeholder Advisory Board.

RECOMMENDATION 12

Establish technical and vocational university funding streams

Objective: Provide high quality local delivery of vocational courses to meet industry needs

Progress: The Sector Skills Agreement for Bioscience identifies 'Change metrics for undergraduate and university outputs to make the system more responsive to employer needs' as a key objective within the area of 'Creating a Top Quality Workforce'. Response to our recommendation has been slow and action against the SSA objectives has yet to have any impact.

RECOMMENDATION 13

Move towards a full economic cost model for teaching in Higher Education

Objective: Sustainable, well resourced, science teaching in UK universities

Progress: The Sector Skills Agreement for Bioscience identifies 'Change metrics for undergraduate and university outputs to make the system more responsive to employer needs' as a key objective within the area of 'Creating a Top Quality Workforce'. Response to this recommendation has been slow and no change has been implemented.

Appendix III Development of Innovative Medicines

The R&D process starts with a company deciding which areas of medicines research it wants to focus on. Once a disease has been identified where good therapies don't already exist and where the cause of the disease is sufficiently well understood, biologists will work to determine the biological basis of the disease. This vital "basic research" may be conducted by industry scientists, scientists in universities or increasingly, as a partnership between the two. It's also an area where well-conducted animal research is vital to ensure medical progress.

Many diseases occur due to the action of a specific protein. Biologists would call this protein a "target". However, before trying to find a drug that could work against this target it's essential to "validate" it i.e. conduct further research, again often involving animal models, to ensure that a change in the target is reflected by a change in the disease of interest.

Once the target has been validated, chemists can start work to find a drug that could interact with it. Compounds can be identified through screening large compound libraries or by rational design if the structure of the target binding site has been determined. Most compounds are created through synthetic techniques, in which chemists create compounds based on established pharmacophores. They might also use combinatorial chemistry, in which they create molecules in complex mixtures and test them rapidly for desirable properties.

Testing the expanding number of available biological targets against hundreds of thousands of chemical entities requires some highly sophisticated screening methods. If a prototype compound shows activity against the target, it's called a "hit". The chemists will then work to determine which of these hits is most likely to have the best fit of overall properties to be developed into a future medicine. Once identified, the chosen "lead" compound must be refined or "optimised". Sometimes many hundreds of related compounds may be tested for greater effectiveness or less toxicity. They can also be tested for improved pharmacological behaviour, such as better absorption.

To optimise these molecules, scientists use virtual modelling to understand how lead compounds interact with the target protein or enzyme. This kind of structural information gives chemists a chance to modify the selected molecules or compounds in a more rational way. This "lead optimisation" process produces a "drug candidate" that has promising biological and chemical properties to treat a disease.

Using additional animal and computer models, the drug candidate is then tested for its pharmacokinetic behaviour – that is – how the body will be expected to handle the drug. This involves assessments of its intestinal absorption, distribution throughout the body, metabolism, and excretion. It is also tested for its pharmacodynamic properties – that is – what it will be expected to do to the body in terms of effect.

Throughout lead optimisation compounds are evaluated for safety, efficacy and toxicity in animal models.

As a patient's ability to excrete a drug can be just as important as his or her ability to absorb it, both of these factors are also studied at this pre-clinical stage. These pre-clinical "safety pharmacology" studies also help researchers to design the first human studies. For example, the pre-clinical studies help to predict the initial clinical trial

dose, along with safety evaluation criteria – factors like patient signs and symptoms – that should be monitored closely during clinical trials.

Before a drug candidate can actually enter clinical testing, we also have to develop a way to “scale up” the manufacture of the compound. The manufacturing process involves a broad range of activities, such as formulating, blending, and assembling drugs and medications, and then preparing them in capsules, inhalers or other forms for delivery to patients. The challenge is to produce larger amounts of the compound while ensuring that it’s safe for humans. This work is the domain of “pharmaceutical sciences” who essentially convert the “molecule” into a high quality “medicine”.

Once all this is done, then, at long last (maybe after up to 10 years of pre-clinical work), the drug is ready for testing in humans.

Clinical trials are designed, conducted and reported in accordance with the highest ethical standards, which are recognised internationally, as well as with all local laws and regulations.

First in Man studies are the first time a drug is tested in humans. Generally, these are trials of short duration (e.g. from 1-14 days duration) and for any one drug involve a total of about 20-100 healthy volunteers.

They test the overall safety and tolerability (side effects) of the new drug in a population that does not have the target condition or disease.

In Phase II clinical trials the study drug is tested for the first time in patients with the disease or condition targeted by the medication. These studies may have up to several hundred patients and may last several months to a few years. Fundamentally these clinical trials explore whether the drug will have the desired effects in patients. They also help to determine correct dosage, common short-term side effects and the best regimen for proceeding to larger clinical trials. Increasingly such studies will make use of early biomarkers which are indicative of the desired biological response.

Phase III clinical trials are where candidate drugs prove their benefit to the patient population. Here, the study drug or treatment is given to large groups of patients. The trials confirm efficacy, monitor side effects, and may compare the drug candidate to other commonly used treatments.

Clinical researchers also use these trials to collect additional information on the overall risk-benefit relationship of the drug and to provide a firm basis for the product information provided to physicians, pharmacists and patients when the drug is prescribed in clinical practice. These studies are conducted in a large patient population consisting of several hundred to several thousand patients with the disease or condition of interest. They typically take place over several years and at multiple centres world-wide.

The data from phase III trials provide the basis for the drug’s evaluation for approval by regulatory authorities. If the regulatory agencies decide that there is a sufficient balance of benefit to risk for a new drug then they will authorise its use.

Phase IV trials are those studies that are performed following the approval of the drug. They help gain additional information on a drug’s long-term safety and efficacy, including its risks, benefits, and optimal use. Some serious side effects are very rare

and will only become apparent once tens of thousand of patients have received the drug.

These trials are also designed to further development of the drug, by exploring its potential to bring benefit to additional patient populations with the disease and/or deliver it in new dosage forms.

Appendix IV Survey Responses

Questions in the 2008 survey of member companies were based on the format of the 2005 report. Respondents were asked to complete the survey for only those disciplines they were familiar with, rating Quality, Number, Future, and Skill Level as either a high, medium, or low priority (defined in the key below), and adding comments were necessary.

The overall priority rating for each discipline is based on a combination of the quantitative and qualitative responses received. Where there was variation in the responses, the overall priority level allocated to the discipline represents the average rating, with opposing views being brought out in the detailed comments to reflect the differing experiences across the industry. The individual priority ratings for Quality, Number, Future and Skill Level are based only on the quantitative responses received.

Key

| Symbol | Description | |
|---|-----------------|--|
|  | Low Priority | - Important area to watch |
|  | Medium Priority | - Requires action |
|  | High Priority | - Requires immediate action |
| Q | Quality | - Candidate quality |
| N | Number | - Candidate numbers |
| F | Future | - Future of the discipline |
| M | Manufacturing | - Priority for manufacturing disciplines |

In the results, Q, N, F and M are coloured to reflect their level of priority for each discipline. Any symbol shown in grey is not applicable to that discipline.

Translational and Biomedical Sciences

| DISCIPLINE | KEY COMMENTS | SKILL LEVELS |
|--|--|--|
| Clinical Pharmacology / Translational Medicine  Q N F M | <p>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”). This discipline is becoming increasingly significant in the industry as focus moves to a more patient-driven approach to drug development.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - A critical, global, longstanding problem across the industry in an area where demand is increasing; - No real change since 2005; numbers of candidates are low and recruitment of high quality staff is difficult; difficult to find appropriate candidates; few people with knowledge or experience - Major gaps in theoretical understanding; medical and biomedical curricula not focussing on the skills required for translational or experimental medical research; lack of academic clinical pharmacologists with an understanding of drug development; the subject is not being addressed in medical degrees or academic training - clinical pharmacology is not seen as a prestigious specialism - May be seen as less attractive than either later phase clinical development or biotech - Candidates require knowledge of clinical trials; MD PhD combination is sought after | |
| Molecular and Translational Toxicology  Q N F M | <p>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, see <i>in vivo</i> toxicology for this.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - This is an increasingly important area in pharmaceutical companies and CROs; numbers recruited are presently low, but likely to increase in the future - The technical needs are high, so there is little graduate level recruitment and in-house training is often necessary - Candidates need multidisciplinary skills and knowledge (toxicology, PK, ADME, immunology, genomics, toxicokinetics) and this is rare, even amongst the best candidates | |

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| <p>Biomedical Imaging / Physics</p>  <p>Q N F M</p> | <p>Biomedical Imaging is increasingly used in the pharmaceutical industry as a non-invasive technique during the clinical trials phase of development. 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.</p> <ul style="list-style-type: none"> - A growth area, but demand is not high at the moment - Mixed responses received for graduate level - many companies collaborate with e.g. academic groups, but for others recruitment at this level is a high priority - Quality is generally good, although some candidates do not have experience of non-invasive imaging or “real-world” application of their knowledge and skills - There is no obvious route into the pharmaceutical sector; there is strong competition from both the health service and academia - Interdisciplinary skills are needed - <i>in vivo</i> physiology skills can be lacking - Recent Research Council initiatives will hopefully work to improve things for the future | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>“Omics”</p>  <p>Q N F M</p> | <p>“Omics” includes areas such as proteomics and metabonomics. Proteomics is the large-scale study of the structure and function of proteins and can be used to identify new biomarkers of disease as well as potential new drugs and drug targets. 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.</p> <ul style="list-style-type: none"> - Needs in this area are small but specific; a rapid growth area in some CROs - Increasingly work in this area is outsourced - candidates need to be experienced, preferably PhD level and above, and able make decisions on whether or not the work is necessary - Computational maths skills are important; some candidates still lack basic arithmetic skills - Awareness of the role of “omics” in industry is low | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Drug metabolism and ADME</p>  <p>Q N F M</p> | <p>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 required (see Mathematical Sciences section below). This information is crucial to the understanding of whether or not a drug will be safe for use in humans and gives information about dose and possible side effects.</p> <ul style="list-style-type: none"> - Recruiting is very difficult, quality is an issue; number of candidates is low; candidates often lack appropriate experience and core skills, as well as knowledge of basic pharmacology, physical chemistry and maths - This is a particular concern given the increase in biologics - There are no focused university courses for PK and ADME; if offered within a degree they seem to be unpopular option choices, if offered at all; there is a need for more good quality post-graduate courses; lack of investment and grants for the discipline in the UK | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |

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| <p>Biochemistry</p>  <p>Q N F M</p> | <p>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 to go into development.</p> <ul style="list-style-type: none"> - “Old fashioned” biochemistry is being overlooked in favour of “trendier” subjects; the general rigour of academic courses at all levels is poor - Basic skills often lacking include: enzyme kinetics, physiology and numeracy - Practical skills and knowledge of regulation (e.g. GLP) and quantitative analytical techniques often lacking - Some graduates cannot apply their knowledge | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Bioscience and Molecular Biology</p>  <p>Q N F M</p> | <p>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 bioscientists 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.</p> <ul style="list-style-type: none"> - Large recruitment pool - on the whole a reasonable number of suitable candidates, although graduates may lack basic grounding in quantitative analytical techniques and lab skills - The issue is quality, not quantity - industrial placements and links with university departments improves access to quality candidates - There are few PhD and Post Doc level candidates with advanced, specialist disease molecular biology skills and experience: increased recruiting from overseas in this area | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p><i>In vitro</i> Pharmacology</p>  <p>Q N F M</p> | <p><i>In vitro</i> 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 of the experiments are done 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.</p> <ul style="list-style-type: none"> - Quality and number are a concern; this is a critical area for drug development - Becoming an “unfashionable” subject; more undergraduate degree and MSc courses are needed with a strong practical element - Practical laboratory skills are of particular concern - Increasing recruitment from continental Europe, especially France and Germany | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |

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| <p>Pharmacy</p>  <p>Q N F M</p> | <p>Pharmacists work across the industry in areas such as the assessment of safety and efficacy of new medicines, the formulation of medicines (e.g. skin patches, pills, targeted release), and could be responsible for the release of medicines to the market.</p> <ul style="list-style-type: none"> - There is a pool of good graduates, but this is diminishing as pharmacy degrees reduce their industry focus and basic science content - Bringing pharmacists in to the industry is hard; retail and hospital pharmacy may be more attractive - Recruiting people with experience is difficult; there is increasing recruitment from the EU - Formulation is still a particular problem; pharmaceutics and pharmaceutical technology skills are weak - There is some demand from CROs for non-graduate candidates at the technician level, but awareness of this entry route is low | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Medicine</p>  <p>Q N F M</p> | <p>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.</p> <ul style="list-style-type: none"> - Difficult to attract talented graduates into the Pharma sector; this is a particular problem for early stage research - “Big Pharma” seems to be more attractive than biotech or smaller companies - Medical school curricula not focusing on skills required for drug development; major skills gaps created through exclusion of quantitative, integrated disciplines from medical training - More interchange between academia and industry through partnerships and placements may help to raise awareness and skill levels | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Biotechnology and Bio-pharmaceuticals</p>  <p>Q N F M</p> | <ul style="list-style-type: none"> - Biotechnology is the combination of biological sciences and engineering to enable the use of microorganisms and biological molecules to perform specific processes, such as the production of medicinal compounds (known as biopharmaceuticals). Biopharmaceuticals are growing rapidly in importance in the pharmaceutical industry and include vaccines, medicines and diagnostic tests. - Growing importance of biopharmaceuticals in industry; many companies increasing their bio pharmaceutical activities in the UK; rapidly changing discipline, many new advances - Hard to find graduates with up to date skills and experience; industrial placements and an increased involvement of the industry in HE education should be encouraged; universities may struggle to keep up to date with new developments in these areas - Skills shortage in: fermentation; separation sciences; analytical protein chemistry; and pharmacy; need more people with expertise in engineering and maths together with an understanding of biology | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |

In vivo Sciences

| DISCIPLINE | KEY COMMENTS | SKILL LEVELS |
|---|---|---|
| <p>In vivo Physiology</p> <p></p> <p>Q N F M</p> | <p><i>In vivo</i> Physiology is the study of the physical, chemical and biochemical properties of the functions of living organisms. In the pharmaceutical industry <i>in vivo</i> 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.</p> <ul style="list-style-type: none"> - This remains a high priority discipline; recruitment is still very difficult - the candidate pool is small - but numbers needed at present are low - Still a lack of clarity around <i>in vivo</i> careers within the industry; minimal exposure to <i>in vivo</i> work throughout the education system means that there is a lack of interest and experience - Higher level educational courses are few and far between; more must be done to encourage HEIs and RCs to maintain their courses; Animal Rights Extremism is still a deterrent, but less so than in 2005 | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>In vivo Pharmacology</p> <p></p> <p>Q N F M</p> | <p><i>In vivo</i> Pharmacology is the study of how medicines interact with living organisms, with the aim of predicting what effects a medicine might have in humans. <i>In vivo</i> 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).</p> <ul style="list-style-type: none"> - Still a high priority; recruitment remains difficult; candidates are of poor quality and are low in number - Unknown as a career; declining interest in the subject as a whole; no understanding of the importance of <i>in vivo</i> work to the pharmaceutical industry - Graduates lack <i>in vivo</i> practical skills; new starters lack the ability to put their skills into practice - The increase in biologics may increase the demand for this discipline | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Toxicology</p> <p></p> <p>Q N F M</p> | <p>Toxicologists study the adverse effects of chemicals on living organisms. Compounds that have the potential to become medicines are assessed for toxicity in both <i>in vitro</i> and <i>in vivo</i> experiments that are required by law for preclinical studies.</p> <ul style="list-style-type: none"> - The need for good toxicologists remains very high, but recruitment is in smaller numbers - Lack of knowledge around the design of animal studies; this is a concern for the longer term 3Rs programme (reduce, refine, replace) - Problems recruiting at all levels; candidates often have too narrow a field of experience, although increased breadth of a few MSc courses has gone some way to improving quality | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |

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| <p>Pathology</p>  <p>Q N F M</p> | <p>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.</p> <ul style="list-style-type: none"> - Recruiting experienced (PhD level and above) clinical, veterinary and toxicological pathologists is a particular problem; small candidate pool; global problem - Demand is increasing - this is a key priority for the industry - but supply is likely to decrease due to an ageing population nearing retirement - Need to do more to train, retain and attract pathologists within the UK, especially the post graduate study of clinical and veterinary pathology; awareness of opportunities in the industry is low | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Veterinary Medicine and Veterinary Science</p>  <p>Q N F M</p> | <p>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.</p> <ul style="list-style-type: none"> - Global recruitment necessary for high quality candidates; quality of applicants mixed - Hard to attract vets into the sector; however, only small numbers needed as much specialist vet knowledge is outsourced by pharmaceutical companies and SMEs to CROs - Mixed responses received for graduate level - many companies outsource, but for others recruitment at this level is a medium priority - Lack of awareness of the industry careers - Lack of training in relevant, routine lab species | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Animal Technology</p>  <p>Q N F M</p> | <p>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.</p> <ul style="list-style-type: none"> - A current and a future concern; qualified, licensed technicians are scarce, especially those with surgical skills - Companies based in some areas of the UK experience more of a problem recruiting than others - The industry is not recognised as a career option; minimal exposure to in vivo work throughout the education system exacerbates the lack of interest - Links between individual companies and FE colleges improve training and recruiting, but these links are rare; training provision needs to be improved; more must be done to encourage HEIs and RCs to maintain their courses | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |

Chemical Sciences

| DISCIPLINE | KEY COMMENTS | SKILL LEVELS |
|---|--|---|
| Analytical and Physical Chemistry  Q N F M | <p>Analytical Chemistry is the study of the chemical composition of materials. Analytical chemists work at every stage of development of a medicine, from identifying 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.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - High priority for manufacturing; quality is an issue; increasing recruitment from outside the UK - Relatively small candidate pool; general lack of practical experience, analytical and method development skills - Very few specific courses available in academia; courses do not go into enough depth; universities may struggle to keep up to date with new developments in these areas | |
| Synthetic Organic / Process Chemistry  Q N F M | <p>Medicinal or Synthetic Organic Chemists are involved in designing and making chemical compounds, which are then tested for their potential as new medicines.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - Particular problem for manufacturing; hard to recruit experienced people; poor understanding of the role of chemistry in manufacturing, awareness of this career lacking; more engagement with needed with universities - A growth area due to increase in biotechnology, although demand is low at present; increasing recruitment from outside the UK - Experience lacking; quality generally acceptable - Industrial placement schemes and relationships with universities aids recruiting and quality of recruits | |

Engineering

| DISCIPLINE | KEY COMMENTS | SKILL LEVELS |
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| Chemical and Process Engineering  Q N F M | <p>Chemical engineering deals with the ways in which raw materials are changed into useful and commercial end products. In the pharmaceutical industry chemical and process engineers work to devise methods to scale up the production of potential medicines identified in research to levels for full scale manufacture. They also try to improve the processes of manufacture for existing products by implementing alternative chemical routes or novel technologies.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - Priority area across the sector, both R&D and manufacturing; quality and experience lacking; numbers decreasing - Strong competition from non-scientific careers as well as oil and gas sectors; the pharmaceutical industry is not the destination of choice for engineers; no focus on the pharmaceutical industry in university courses - An increasing number of applicants require UK work permits; more recruitment from the far east | |

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| <p>Mechanical and Electrical Engineering</p>  <p>Q N F M</p> | <p>Mechanical and electrical engineers design, develop, manufacture and commission special purpose equipment for the pharmaceutical industry. They also develop and design documentation including engineering calculations and drawings for plant utilities. Mechanical engineers may also supply feasibility studies, concept development, safety/risk analysis, equipment/utilities capacity analysis and sizing.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| <p>Highly Complex Process Control and Instrumentation Engineering</p>  <p>Q N F M</p> | <p>Process Control Engineers are concerned with creating and maintaining the computer software and systems designed to control the quantity and quality of products when during manufacture. Computers are used throughout manufacturing plants to control things such as pressure, temperature and liquid levels in tanks.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |

Mathematical Science and Statistics

| DISCIPLINE | KEY COMMENTS | SKILL LEVELS |
|--|---|--|
| <p>Statistics</p>  <p>Q N F M</p> | <p>Statisticians are a fundamental part of a drug development project team across the whole lifecycle 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.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - Critical discipline throughout the industry; demand increasing - Shortage of high quality, experienced statisticians with knowledge of clinical research and science; it is still hard to recruit and retain good quality candidates - Some knowledge often lacking, e.g. Bayesian statistics and adaptive design; courses too broad, candidates have no depth of knowledge; communication and team-working skills often poor - Paucity of funding in the UK for high level qualifications | |

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| <p>Computational Science and Bioinformatics</p>  <p>Q N F M</p> | <p>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.</p> <ul style="list-style-type: none"> - Growing demand for candidates with modelling skills and ability to analyse large, increasingly complex biological and chemical data sets - Skills need is multidisciplinary; few candidates with skills across computational science, mathematics and biological sciences - Recruiting is mostly at PhD level and above; if graduate level recruiting, life sciences graduates who can be trained in IT are preferred; mixed responses received for graduate level - some companies do not recruit at this level, but for others this is a medium priority | <p>Non Graduate Graduate PhD Post-Doc</p> |
| <p>Computational / Structural Chemistry</p>  <p>Q N F M</p> | <p>Computational Chemistry is part of computer aided drug design and involves modelling the chemical properties of molecules to predict how they might interact with a target. Computational Chemists work with Structural Chemists, who try to elucidate the structures and shapes of molecules. This approach is widely used in the design of new medicines.</p> <ul style="list-style-type: none"> - Recruitment is very challenging; number of applicants is low; increasing recruitment from abroad - Set to be a high priority area in the future - Need to increase relationships with academia in this area - Molecular modelling experience often lacking | <p>Non Graduate Graduate PhD Post-Doc</p> |
| <p>Pharmacokinetics Pharmacodynamics and Modelling</p>  <p>Q N F M</p> | <p>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, pharmaceutical scientists acquire an earlier understanding of the link between drug and response, and can better characterize a drug's absorption, distribution, and elimination properties (ADME - see Biological Sciences section above).</p> <ul style="list-style-type: none"> - Increasingly difficult to recruit in this area; worldwide problem - Shortage of both newly qualified and experience candidates - Very few courses available; MSc is generally minimum entry level; mixed responses received for graduate level - many companies do not recruit at this level, but for others this is a high priority - Skills required include chemistry, pharmacology, pharmacokinetics, and maths some of these are transferable; lack of numerate biological sciences graduates | <p>Non Graduate Graduate PhD Post-Doc</p> |

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| <p>Health Economics</p>  <p>Q N F M</p> | <p>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.</p> | <p>Non Graduate</p> <p>Graduate</p> <p>PhD</p> <p>Post-Doc</p> |
| | <ul style="list-style-type: none"> - Health economists are currently in high demand; competition will increase with the projected expansion of NICE and other HTA organisations - Few candidates for industry; many different career options for economists; strong competition for health economists from the NHS; credibility and perception of industry is low - MSc level is generally minimum requirement and workplace experience is desirable; PhD level candidates are scarce | |

Appendix V Activity to Improve Practical Skills

The Royal Society of Chemistry and GlaxoSmithKline have created courses to give non-specialist chemistry teachers the confidence and skills to teach chemistry to Key Stage 3 and 4 students, and DCSF are funding pre-initial teacher training courses for graduates who want to teach physics or chemistry but whose subject knowledge needs deepening before they can begin their teacher training. Websites focusing on 'Practical physics', 'Practical chemistry' and 'Practical biology' have been developed by the professional bodies for these subjects in collaboration with the Nuffield Curriculum Centre to encourage teachers to include more practical activities in their lessons. Many of these are 'traditional' experiments which are no longer routinely used in schools.

At Masters' level, the Integrated Mammalian Biology Initiative, created with funding from pharmaceutical companies, Research Councils and Government has proved successful at raising the amount of translational medicine being taught and in raising capacity in *in vivo* skills, and BBSRC have allocated funding for small numbers of students to follow *in vivo* masters courses. *In vivo* science is also one of four priority areas for funding of 60 masters studentships per year for 3 years from MRC. However further action needs to be taken to address this particular critical need. Many of the actions identified in the 2007 ABPI/BSF report *In vivo sciences in the UK: sustaining the supply of skills in the 21st century*⁵ have yet to be addressed. It is disappointing that, following a substantial amount of work led by the Biosciences Federation, to create an MSc course in safety sciences, progress has stalled as funding for it has not been found.

Postgraduate doctoral training is also being strongly supported by industry and Research Councils. A 2007 ABPI survey of member companies found that over 600 PhD students were being supported by pharmaceutical companies and nearly 330 postdoctoral grants were active at the time of the survey. Although the level of support had dropped since our previous survey was carried out in 2005, this is still a substantial contribution to the training of young scientists. The majority of these studentships were funded in partnership with one of three Research Councils, 181 with BBSRC, 112 with ERSRC and 21 with MRC. We are pleased to note that MRC are to fund additional studentships in 2009 and that, through the Integrative Toxicology Training partnership, PhD studentships and career development fellowships in toxicology are being supported.

Less activity to promote practical skills is taking place at undergraduate level. Summer schools are organised by the British Pharmacological Society and funded by the Wellcome Trust, industry and BBSRC to provide pharmacology undergraduates with training in *in vivo* techniques, but, in general university summer schools are focused at outreach to school and college students as part of their widening participation agenda.

Appendix VI Practical Skills and Capabilities

Examples of the skills and capabilities that are expected of new recruits:

- Understanding of basic experimental design, observation, recording, and testing hypotheses.
- Ability to plan and conduct a scientific experiment with appropriate controls and analysis of data
- Demonstration of good, safe laboratory practice, including an understanding of Good Laboratory Practice, standard operating procedures and the impact of health and safety in the laboratory environment (and environmental issues).
- Basic practical laboratory procedures (setting up equipment, use of pipettes, serial dilutions, basic chromatography and basic chemistry skills)
- Exposure to molecular biology procedures (such as tissue culture and collection, aseptic techniques)
- Experience of the handling of live organisms and dissection of organs.
- Ability to accurately observe and record data (including understanding of the importance of accuracy over speed)
- Recognition of the integrity of data gathered.
- Ability to bring aspects of an experiment together
- Understanding of how errors arise (including use of error bars).
- Critical analysis of their results
- Independent and confident interpretation and assessment of scientific experiments
- Problem solving skills, for example independently solving difficulties encountered in the lab.
- Application of scientific and mathematical knowledge in designing experiments and interpreting results
- Critical thinking skills and being able to dispute scientific procedures, data sets and other people's work
- Basic report writing and accurate record keeping
- Ability to develop a project plan and be able to use it as a communication tool
- Know how and when to use IT; including Word, Excel (use of spreadsheets for computer modelling), data capture devices, search engines (to effectively research scientific literature).
- Communication and interpersonal skills
- Team working, collaboration and problem solving
- Independent working
- Data and text mining skills

Appendix VII Stakeholders Consulted

Stakeholder Dinner Discussion

The key findings from the survey were presented and discussion focused on existing and future activity that might help to address the issues identified.

It was agreed that the key focus should be on working in partnership with other bodies and, where appropriate, across other sectors, to:

- Develop maths content of biological science undergraduate degrees
- Increase practical content of undergraduate degrees
- Promote the need for clinical pharmacology within medical degrees
- Take forward proposals from the In vivo report

Attendees:

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|-----------------|--|
| David Abrahams | President, Institute of Mathematics and its Applications, Department of Mathematics, University of Manchester |
| Aisling Burnand | Chief Executive, BioIndustry Association |
| Celia Caulcott | Director of Innovation and Skills, BBSRC |
| Richard Dyer | Chief Executive, Biosciences Federation |
| Judith Howard | Chair, Royal Society Higher Education Working Group, Department of Chemistry, University of Durham |
| Alan Malcolm | Chief Executive, Institute of Biology |
| Gordon Mizner | CEO, Engineering Development Trust |
| Declan Mulkeen | Research Management Group Director, MRC |
| John Neilson | Head of Research Base Directorate, DIUS |
| Liam O'Toole | Chief Executive, UKCRC |
| Peter Ringrose | Chairman, Biotechnology and Biological Sciences Research Council |
| Tina Sawyer | Head of Pharma, BERR |
| David Sweeney | Director for Research, Innovation and Skills, HEFCE |
| Helen Williams | Director, School Curriculum and Well-being, DCSF |

Stakeholder Workshop

The key findings from the survey were presented. These were discussed in small groups focussing on mathematics, *in vivo* sciences, biological and medical sciences, chemical sciences and engineering. Groups were tasked with identifying existing activity which might impact on the issues identified and noting gaps where additional activity is required.

Substantial action was found to be in progress and planned at school level in England to provide a high quality, engaging learning experience for all students in mathematics and science, with options for applied learning. Action is also taking place to improve career information and guidance on STEM related careers. The planned activity could be supplemented with industry related enrichment and enhancement activities and promotion of careers in the sector.

At Higher Education the challenge of increasing practical activities within undergraduate degrees with the current funding arrangements were a major issue. The Government focus on quantity of learners, over quality of experience and

outcome, was also identified as a barrier. Accreditation of degrees was proposed as a possible way forward to encourage universities to address the concerns identified.

Identification of chemistry and physics as strategically important and vulnerable subjects has led to substantial HEFCE funded activity to raise awareness, interest and enthusiasm for these subjects. Biological and medical sciences, of equal importance to the bioscience sector are not being promoted through this mechanism. This is a key concern for *in vivo* science subjects and clinical pharmacology where capacity building is vital.

Attendees:

Advisory Committee on Mathematics Education (ACME)
Biosciences Federation (BSF)
Biotechnology and Biological Sciences Research Council (BBSRC)
British Association of Pharmaceutical Physicians
British Pharmacological Society (BPS)
British Society of Toxicological Pathologists
Cogent (Sector Skills Council for Chemicals, Nuclear, Oil and Gas, Petroleum and Polymers)
Council for Mathematical Sciences
Department for Business, Enterprise and Regulatory Reform (BERR)
Department of Health (DH)
Eastern Region Biotechnology Initiative (ERBI)
Engineering and Physical Sciences Research Council (EPSRC)
Faculty of Pharmaceutical Medicine
Higher Education Funding Council for England (HEFCE)
Institute of Animal Technology (IAT)
Institute of Biology (IoB)
Institute of Clinical Research (ICR)
Institute of Physics (IoP)
Institution of Chemical Engineers (IChemE)
Institution of Engineering Technology
Lantra (Sector Skills Council for the Environmental and Land-Based Sector)
Medical Research Council (MRC)
National Centre for Excellence in the Teaching of Mathematics
National Skills Academy for the Process Industries
Royal Society of Chemistry (RSC)
Science Council
Scottish Enterprise
Semta (Sector Skills Council for Science, Engineering and Manufacturing Technologies)
Specialist Schools and Academies Trust
TOPRA (The Organisation for Professionals in Regulatory Affairs)
VETNET LLN (The National Lifelong Learning Network for Veterinary and Allied Professionals)
Vitae (incorporating the UK GRAD Programme and UKHERD)
Wellcome Trust

Appendix VIII Bibliography

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The Association of the British Pharmaceutical Industry represents more than 70 companies in the United Kingdom producing prescription medicines. Its member companies are involved in all aspects of research, development and manufacture, supplying more than 80 per cent of the medicines prescribed through the National Health Service. The ABPI also represents companies engaged solely in the research and/or development of medicines for human use. In addition, there is general affiliate membership for all other organisations with an interest in the pharmaceutical industry in the United Kingdom.

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Association of the British Pharmaceutical Industry

12 Whitehall, London SW1A 2DY
T: +44 (0)870 890 4333 F: +44 (0)20 7747 1411
www.abpi.org.uk