



Medicines Manufacturing Industry Partnership



About MMIP

MMIP is supported by The Association of the British Pharmaceutical Industry, the BioIndustry Association and the Knowledge Transfer Network. It includes leadership from Allergan Biologics, AstraZeneca, Eisai, FUJIFILM Diosynth Biotechnologies, GlaxoSmithKline, Pfizer and ReNeuron. MMIP works in partnership with Government organisations including the Medicines and Healthcare products Regulatory Agency, UK Trade and Investment, the Office for Life Sciences and Innovate UK.

Contact

For regular updates on the MMIP, sign up to our Newsletter by emailing MMIP@bioindustry.org or join the LinkedIn group <https://www.linkedin.com/groups/8476514>.



Medicines Manufacturing Industry Partnership: The journey so far



Introduction

The Medicines Manufacturing Industry Partnership (MMIP) represents the voice of medicines manufacturers in the UK. It was established jointly by the Government and the biopharmaceutical industry in 2014 to ensure that the UK is recognised by the global medicines industry as a world-class advanced centre for medicines manufacturing.

“The manufacture of modern medicines is one of our leading manufacturing sectors with exports worth over £20bn. MMIP is helping ensure we remain at the forefront of this highly competitive sector, building on the impressive work they have already led in areas like detailed innovation mapping and modern skills investment.”

George Freeman MP, Chair of Prime Minister's Policy Board



MMIP



Business Environment

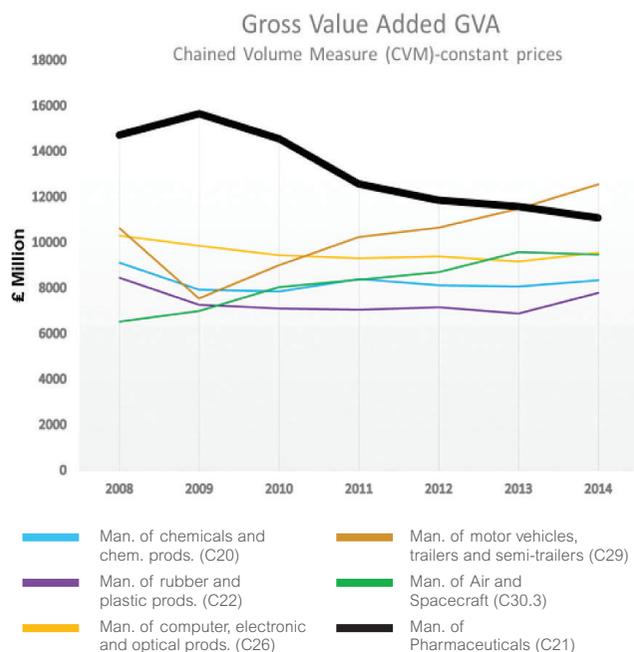


MMIP's work on the business environment seeks to develop the proposition of why the UK is a great place for medicines manufacturing and then identify and propose possible new interventions to improve international competitiveness.

Whilst recognised for its science and technology, the UK is not currently seen as a first choice location for medicines manufacturing and the value of the sector has declined as older small molecule

medicines were not replaced by new products. The current landscape of tax, patents, capital allowances and regulation is very complex. This has undoubtedly been a key factor in the manufacturing sector's decline in the UK. Following biopharmaceuticals, the next wave of innovation is in Advanced Therapy Medicinal Products (ATMPs) and MMIP wishes to ensure we articulate a clear proposition and secure a strong ATMP manufacturing sector.

Understanding how our industry compares with others in the UK



The productivity of each medicines manufacturing worker is higher than any other manufacturing sector. Our analysis (with OHE/ONS) highlighted that medicines manufacturing is not as large as it once was. In 2009 UK medicines manufacturing provided £16bn GVA to the UK economy. By 2014 this had declined to £11bn GVA, a 30% reduction.

Key work

1) Understanding the landscape

MMIP has been seeking to understand the changes in the UK landscape. This includes a trend of small molecule manufacturing moving to developing countries. However, the high-tech nature of biopharmaceutical manufacturing means that developed countries are more insulated from this competition.

2) Learning lessons from biopharmaceuticals

The major growth sector in the past 20 years has been biopharmaceuticals which now represent a high proportion of the world's best selling medicines. Unfortunately very few are made in the UK. MMIP has interviewed a cross section of key industry experts to understand their views on why the UK missed out. The failure of the UK to grasp the potential of biopharmaceutical manufacturing and powerfully market the UK as a manufacturing centre were key. By comparison Ireland and Singapore have become global biopharmaceutical manufacturing hubs.

3) Highlighting the UK's competitive fiscal environment

Interviews with companies and the Department for International Trade have confirmed that the fiscal environment is the number one consideration for manufacturing companies considering investments.

However the UK's offer is hard to demystify which is a fundamental pre-requisite to effective marketing. It is now clear that the UK's current fiscal offer is very competitive but hard to grasp. Led by Richard Turner from FTI Consulting and BIA's Finance and Tax Advisory Committee, MMIP has produced documents detailing and simplifying the UK's current fiscal offer.

Future work

It is now clear that the UK has a strong proposition to companies considering medicines manufacturing investments, both fiscal and the 'soft' drivers of regulation, technology and skills. However the UK has not made this offer sufficiently clear. MMIP intends to promote the work it has done to highlight the UK's fiscal offer, this includes supporting UKTI in its efforts to attract new medicines manufacturing investment into the UK.

In future a large part of MMIP's focus will be on the next generation of ATMPs through the Advanced Therapies Manufacturing Taskforce. The goal is to ensure the UK builds on the work done and does not miss out on the opportunity to manufacture these innovative medicines.

Skills

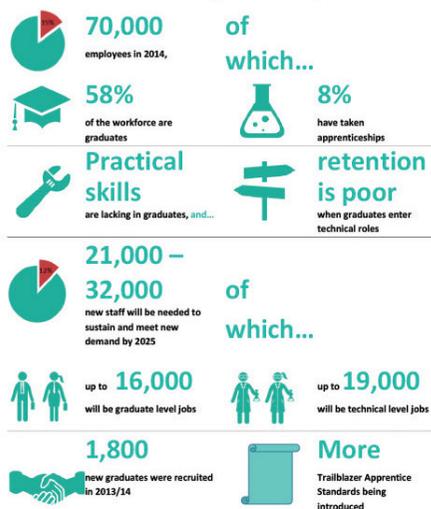


The need for a skilled and capable workforce in medicines manufacturing and the supporting advanced manufacturing sectors is self-evident. This need has been well articulated and illustrated in existing reports, particularly in the Science Industry Partnership (SIP) Skills Strategy 2025, the ABPI's report "Bridging the skills gap in the biopharmaceutical industry" and the Semta Skills Vision. These reports – and others –

have utilised available statistics, specific skills surveys and consultation discussions with training providers and industry to describe the skills landscape and issues for the sector and identify the strategic actions required. MMIP have ensured that issues concerning skills and capabilities for medicines manufacturing are specifically included in the SIP and ABPI reports.

Key findings from the SIP Skills Strategy 2025

The Medicines Manufacturing Skills Landscape



Employment is concentrated in the South East, East of England and London



Sources: Employment figures: HMG Strength & Opportunity (2014). Qualifications profile of the workforce: Labour Force Survey 4 Quarterly Average (2014). Graduate Recruitment: The HESA Destinations of Leavers of Higher Education Survey (2013/14). Staff demand forecasts: SIP Skills Strategy 2025 (2016)

Key work

1) Promoting the medicines manufacturing industry and careers within it

MMIP is encouraging companies to get involved with existing careers programmes such as the STEM Ambassadors, SIP Ambassadors and Women in Science, Technology and Engineering (WISE).

2) Promoting apprenticeships and ensuring effective implementation of the Apprenticeship Levy

MMIP is ensuring that the content of new 'Trailblazer' Apprenticeship Standards fully incorporate the needs of medicines manufacturers.

3) Sharing and promoting good practice for training and skills development

MMIP is facilitating the use of a structured programme of one week work experience placements for school pupils to encourage their interest in getting involved in life sciences.

4) Actions to address the low level of practical skills in graduates and other new staff

MMIP is working to encourage companies to offer placements for learners and students, ranging from shorter internships to whole year sandwich placements.

5) Address the small national cohorts for education and training relative to demand

MMIP is coordinating with companies and education and training providers to begin to scope out how best to balance supply and demand.

Future work

Key work will continue throughout 2017. To support implementation, MMIP intends to establish a network of companies who wish to actively contribute to action delivery in one or more of the themes.

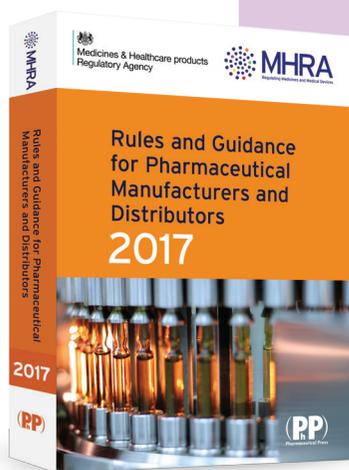
In addition, MMIP has supported the skills work carried out by the Advanced Therapies Manufacturing Taskforce during 2016 and will ensure alignment of their actions with the above through 2017.

Regulatory



The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. It is recognised as one of the most forward thinking agencies of its type in the world and through its Innovation Office encourages an open and proactive dialogue with industry in supporting innovation for medicines manufacturing in the UK.

MHRA inspectors have been involved in the work of MMIP and together with the MMIP constituent associations and other interested stakeholders, have discussed how the UK manufacturing sector might best leverage the technical and regulatory excellence of the MHRA to maximise the attractiveness of the UK as a manufacturing location.



Medicines are manufactured in accordance with Good Manufacturing Practice (GMP) rules and guidance developed by regulatory authorities. In the EU these requirements are issued by the European Commission. In the UK this guidance is published in Rules and Guidance for Pharmaceutical Manufacturers and Distributors ('the Orange Guide'). This EU GMP guidance sets out what standards a manufacturer must achieve in its operations but within these there are acceptable alternative ways in which those standards might be achieved.

Key work

1) Optimising use of the existing regulatory framework

MMIP recognises the strength of the MHRA as one of the key global regulators with a strong reputation for regulatory and technical expertise. Industry and government consider that the UK has a good story to tell on regulation and recognize that there are further opportunities to work together to stimulate optimal use of existing regulatory processes. Awareness of this regulatory interaction is essential in optimising the benefits of new technologies in manufacturing.

MMIP, in conjunction with MHRA, has developed a paper to establish greater awareness of the opportunities provided by existing regulatory processes and 'to bust' some potential 'myths' that surround the perceived requirements of GMP. It is hoped that this work will encourage companies to be more willing to seek advice from MHRA at an early stage to obviate some of issues that can arise at the later stages of developing manufacturing capability and which can cause delays in commissioning such capability.

2) Publicising the work of the Innovation Office

Since the inception of MMIP, companies who have benefitted from interaction with the Innovation Office have shown a willingness to share the outcomes and benefits of such collaboration. This has resulted in a series of case studies that give details of projects where timely interaction with the Innovation Office has

resulted in a smoother progress to manufacturing capability and output. The MMIP works with the MHRA to publicise these case studies and the work of the Innovation Office, to encourage companies to reach out to the Innovation Office and to promote the regulatory support available to companies in the UK.

Future work

The prime focus of the work of the MMIP this year has been around the question of advanced therapy medicinal products (ATMPs) and the opportunity for manufacture that the UK preeminence in the research aspects of these products presents.

Due to their nature, these products present new regulatory challenges where some of the established manufacturing guidance and regulatory control philosophy may not be entirely appropriate and some new thinking is may be needed on the best ways of handling them.

The MMIP's regulatory work will be turning its attention to helping shape and optimise the regulatory environment surrounding these products.

Technology and Innovation

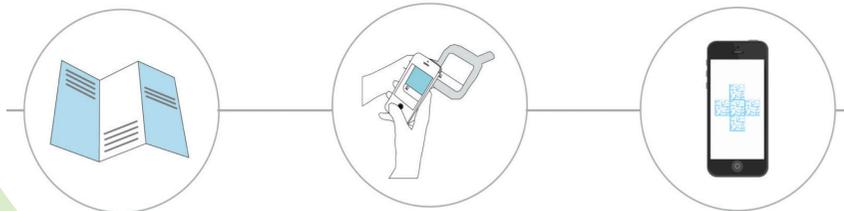


It is essential for future success that the medicines manufacturing sector continues to build on the Technology and Innovation foundations that the UK is renowned for – leveraged by close collaboration between industry and academia. Over the last few years there have been many successful technology platforms set up in the UK including the Genomic Medicine Centres, Catapult Centres and crucial funding mechanisms such as the Industrial Biotechnology and Biomedical Catalysts.

The ongoing challenge is continuing to identify and improve innovative tools and technologies to optimise manufacturing processes and drive down the cost of goods. The MMIP's work on technology and innovation has had several areas of focus that have been shared across the community and these are driven by this constant need to improve manufacturing efficiencies and develop agile supply chains that meet patient needs.

Smart packs and electronic leaflets

Smart packs that can enhance compliance through communication devices are an opportunity as is the development of tracking labels that can help improve efficiencies within the supply chain. The use of packs that can connect with devices to provide more product information for patients is being further evaluated by MMIP.”



Key work

In 2016 there have been some key areas that the MMIP T&I Team have supported and these include:

1) Continuous Manufacturing

Continuous Manufacturing Technology is being developed through partnerships that will enable improved processing, analytics and optimised yields. MMIP has supported the strategy for the delivery of this capability. This includes the creation of the Medicines Manufacturing Innovation Centre which will bring stakeholders together to test innovative manufacturing technologies.

2) Agile Supply Chains

With the advent of personalised medicines the traditional 'Pharma' supply chain model is being challenged. Tracking technologies and new materials are being developed to extend shelf life and reduce waste whilst at the same time improve inventory management – which is critical with small batch production. This is a collaboration with the REMEDIES project which was initiated in 2015 and our development partner is the Centre for Process Innovation.

3) Digital Technology

Opportunities for 'Industry 4.0' is being investigated and experimented with and this includes: big data management, impact on integrated processing and inspection, intelligent automation and even the use electronic patient instruction leaflets. The T&I team are linked to the MHRA Innovation Office as a forum to discuss these opportunities and are continuing to build this collaborative relationship with the regulator.

4) ADDoPT

MMIP supported the Advanced Digital Design of Pharmaceutical Therapeutics (ADDoPT) funding proposal and this programme is now in full development.

5) Medicines Manufacturing Landscape

The Knowledge Transfer Network (KTN) on behalf of MMIP successfully delivered the Medicines Manufacturing UK Landscape (www.mmlandscape.ktn-uk.org), which is the first map of the UK medicines manufacturing landscape.

Future work

The MMIP is refreshing the Innovate UK and KTN 'technology roadmap' which highlights the enabling technologies in medicines manufacturing, especially in the advanced therapy area. This will help MMIP and all stakeholders to better understand the current medicines manufacturing landscape, its direction of travel and the opportunities available to companies.

2017 will be an important year for the Medicines Manufacturing Innovation Centre and the ongoing supply chain initiatives well under way with the REMEDIES program (<https://remediesproject.com/>).

2017 will also include more detailed understanding on the impact of digital technology coupled with packaging solutions to enable improved compliance. MMIP will be partnering with the NHS to understand how to improve pack design to enable more efficient dispensing with a focus on personalised medicine. This will see medicines packets produced in a way that is more helpful to pharmacists and will reduce medicines wastage.