



# Medicines Manufacturing in the UK 2017

**Moderator: Magda Papadaki, PhD**

Head of Manufacturing Innovation

The Association of the British Pharmaceutical Industry  
Medicines Manufacturing Industry Partnership (MMIP)



**25-26 April 2017**  
**Ricoh Arena, Coventry, UK**



**Innovate UK**  
Knowledge Transfer Network

# Medicines Manufacturing Industry Partnership (MMIP) led session



## Exhibitor Stand Number 228

09.15 - 09.35	Andy Evans, AZ, MMIP Chair	<b>The UK's Medicines Manufacturing Industry Partnership – <i>general intro</i></b>
09.35 – 09.55	Greg Anderson, GSK	<b>How to Plan a Future Proofed Technology Roadmap</b>
09.55 - 10.15	Andy Jones, AZ	<b>Implementing Next Generation Manufacturing</b>
<b>10.15 - 11.30</b>	<b>Break</b>	
11.30 - 11.50	Alex Felthouse, Eisai	<b>Building and Growing a Sustained Manufacturing Talent Pool</b>
11.50 -12.10	Greg Anderson, GSK	<b>Intelligent Design in Medicines Supply</b>
12.10 - 12.30	Andy Share, GSK	<b>Building New Platforms for Technology Development</b>
12.30 - 12.50	Clive Badman (OBE), GSK	<b>Collaborative research in Medicines Manufacturing</b>



MMIP

# The Medicines Manufacturing Industry Partnership

« 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,**  
Minister for Life Sciences

**Andy Evans, MMIP Chair**  
AZ Site Lead (VP), Macclesfield Multi Format Facility



# UK life science exports lower than those of Germany and the US – we can do better

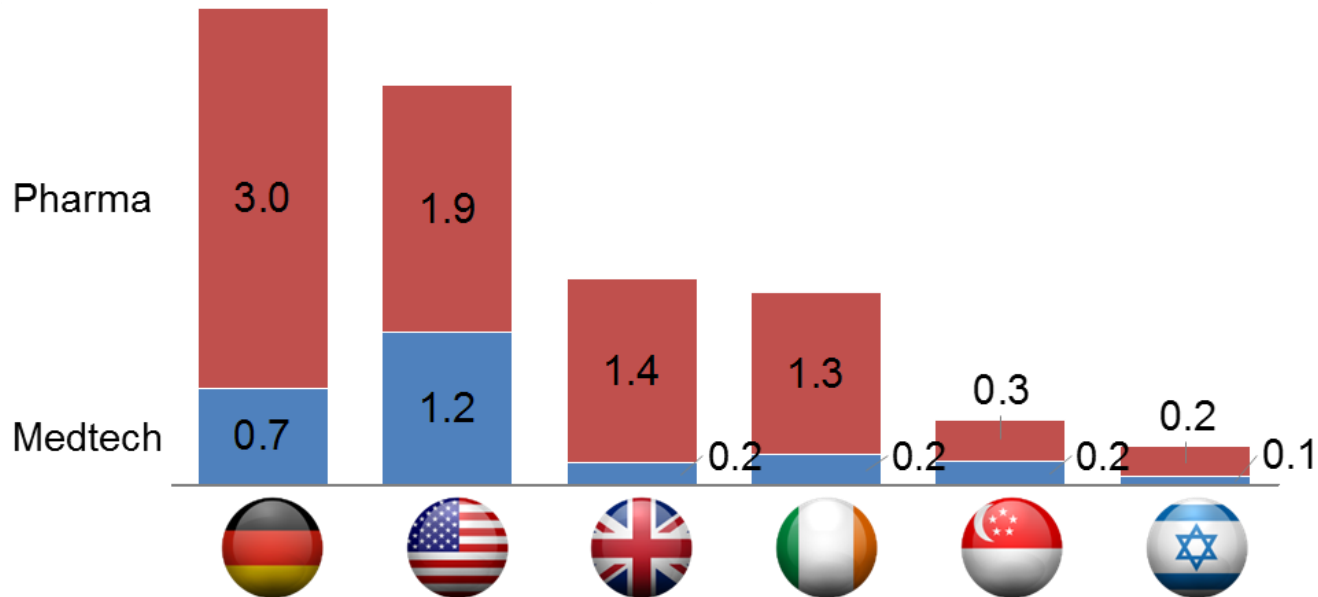
**Total exports**  
USDbn  
Avg 2010-15



**Avg as %**  
**GDP 2010-15**



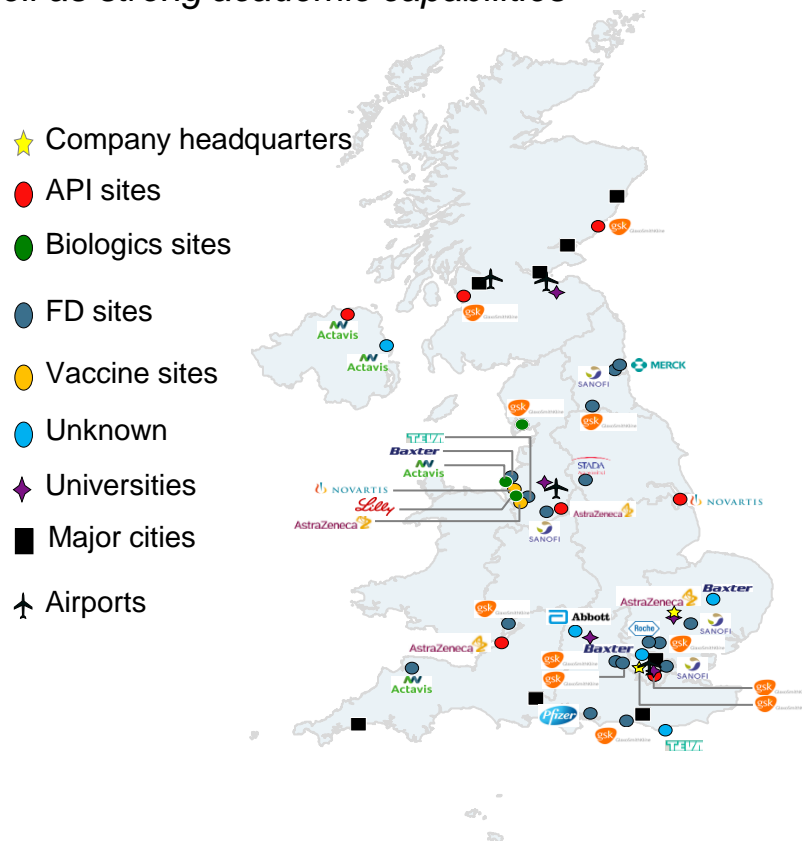
Health and life sciences product exports  
% of GDP



# We need to take the opportunity to increase the amount of Medicines Manufacturing in the UK.

## Current UK position

*Critical mass of manufacturing in this area as well as strong academic capabilities*



**Opportunities to become world leaders**  
*scale of manufacture required is reducing and product potency is increasing leading to worldwide gaps in capabilities*

- Improved productivity through continuous processing and processing analytical technology offer opportunities
- New modalities (e.g., Antibody Drug Conjugates, oligonucleotides and the potential for synthetic biology toolkits)
- Technology improvement opportunity through use of digital manufacturing, AI and the Internet of Things to develop the next generation of pharma manufacturing and recapture manufacturing that has been offshored

# Pharma Industry 2017: Change drivers and impact



MMIP



Trends

- Healthcare costs rising
- Rising utility costs
- Globalisation – shift in wealth
- Resource constraints
- Patient specific treatment
- Widespread data access
- Aging population
- More informed patient population



Response

- *Fast to patient*
- *Globally available*
- *Individualized to meet patients specific needs*
- *Carbon neutral*
- *Lower cost products*
- *Higher quality*
- *Information available (data transparency)*



Impact

- *Access to the correct medicines when needed*
- *More sustainable product*
- *Confident of quality of medicine*
- *Medicine more affordable*
- *Access to right information*
- *Continued innovation to the patients benefit*

# MMIP: STARTING WITH THE END IN MIND



GVA

EXPORTS

JOBS

OUTCOMES

NOVEL  
Facilities

FOCUS AREAS

COMPLEX  
MEDICINES

ATMPs

PACKING  
AND  
DEVICES

VIRAL  
VECTORS  
AND  
VACCINES

- Large Pharma
- SME
- CMO's

CRITICAL SUCCESS  
FACTORS

TAX

SKILLS

FISCAL  
INCENTIVES

REGULATION

INNOVATIVE  
FUNDING





# MMIP action pillars



MMIP

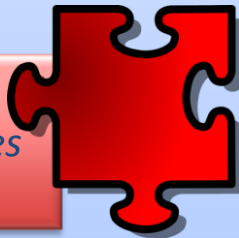
Drive Growth in all areas of Medicines Manufacturing  
Ensure the UK is globally recognised as an attractive and thriving environment for manufacturing investments

*Workforce with relevant **SKILLS***



- ✓ Setting frameworks and solutions to meet industry needs and secure a rich talent pool for growth and succession

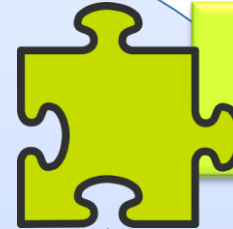
***Business Environment**  
Investment friendly policies  
& robust metrics*



- ✓ Assessment of the fiscal tools to sustain and grow inward investment.

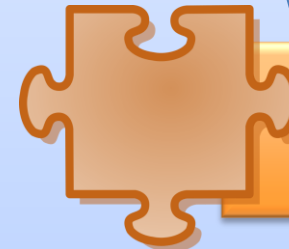
*Aligned medicines manufacturing voice in shared challenges (Brexit) and opportunity areas, ie. the UK industrial Strategy*

***REGULATORY**  
Adaptive and flexible regulation*



- ✓ Shape a future-proofed regulatory framework for Medicines Manufacturing

***ATMP**  
Manufacturing Taskforce*



- ✓ Design and implement an integrated roadmap to make the UK a global hub for ATMP discovery, development and adoption

***Technology & Innovation**  
Connected infrastructure and advanced technologies to meet evolving patient needs*





# 2016 ATMP Manufacturing Taskforce

Co-chaired by **Minister for Life Sciences George Freeman** and  
**Ian McCubbin, SVP GSK**



Medicine Manufacturing  
Industry Partnership

abpi **BiA** Innovate UK  
Knowledge Transfer Network

## Advanced Therapies Manufacturing Action Plan

Retaining and attracting advanced  
therapies manufacture in the UK



Recommended actions to make the UK a global hub  
for manufacturing advanced therapies

1. Strengthen and secure an internationally competitive fiscal landscape to attract investment
2. Target and capture internationally mobile investments through a proactive and simplified process of engagement
3. Maintain science and innovation funding to support industry developing cutting-edge technologies
  - 3.1 Securing investment in manufacturing capacity through flexible funding
  - 3.2 Invest in viral vector manufacturing capacity in the UK
  - 3.3 Sustain the range of funding mechanisms to grow advanced therapies manufacturing technologies
4. Set out an end-to-end talent management plan to secure the relevant skills for emerging manufacturing technologies
5. Clearly set out a swift, predictable and viable route to market for these innovative products and give industry confidence that the UK is a progressive global hub
6. Develop a long-term regulatory strategy and plan for the MHRA to lead in global standards, supporting the scientific activities and international outreach of NIBSC

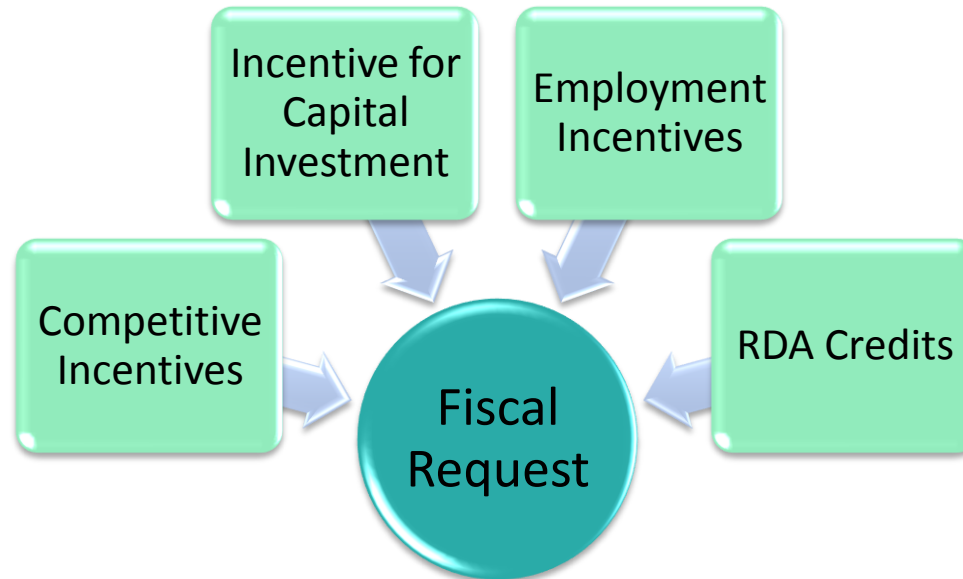
# Adopting The Recommendations of the ATMP Manufacturing Taskforce



It is also critical that funds are also geared towards meeting the recommendations of the [ATMP Taskforce report](#):

- [Support advanced therapies manufacturing investments in 2016/17](#), providing a level of competitive or loan/grant funding in the range of £30m p.a. over three years to attract and anchor a calculated £350m in ATMP manufacturing investment.
- [Establish a network Gene Therapy Treatment Centres](#), with public funding (£30m) delivered through a competitive process.
- [Establish competitive Government funding to support viral vector capability within two years](#), through the development of a specialist manufacturing operation that will also leverage existing infrastructure.
- [ATMP end-to-end talent plan \(£1.5m\)](#): support the creation and implementation of an end-to-end talent plan covering multiple entry-points, from manufacturing technicians to post-doctoral and professional levels.

# Life Sciences Industrial Strategy Examples: The Fiscal Request



Posted in category [Opinion](#) by [Medicines Manufacturing Industry Partnership](#) on 13/03/2017



## Facing the challenge of STEM skills in the UK

Looking back at National Apprenticeship Week and National Careers Week (6 – 12 March), Alex Felthouse from Eisai, and MMIP Skills Chair, discusses what we need to do next to ensure the UK has the STEM skills it needs. [Read more](#)

Tags [Education](#) [Manufacturing](#) [R&D](#) [Skills](#)

Posted in category [News Release](#) by [Medicines Manufacturing Industry Partnership](#) on 10/03/2017



## Medicines Manufacturing Industry Partnership Chair responds to Budget

Andy Evans, Macclesfield Site Manager at AstraZeneca and Chair of the Medicines Manufacturing Industry Partnership has responded to the proposal in the Budget for investment in medicine manufacturing technologies. [Read more](#)

Tags [ABPI news](#) [Manufacturing](#) [Politics](#) [R&D](#)

Posted in category [Opinion](#) by [Medicines Manufacturing Industry Partnership](#) on 10/03/2017



## Motivating the future medicine manufacturing workforce

For National Apprenticeship Week and National Careers Week (6 – 12 March), Simon Mowat from AstraZeneca is putting the spotlight on how companies are working with schools to open up opportunities for students. [Read more](#)

Tags [Education](#) [Manufacturing](#) [R&D](#) [Skills](#)

Posted in category [Opinion](#) by [Medicines Manufacturing Industry Partnership](#) on 09/03/2017



## Apprenticeships: the career step for you?

For National Apprenticeship Week and National Careers Week (6 – 12 March), Kate

## Skills Environment

As part of its programme of work, the Medicines Manufacturing Industry Partnership (MMIP) seeks to ensure that the UK has an adaptive workforce with relevant skills to sustain the future requirements of the UK medicines manufacturing industry.

MMIP has identified **six objectives** for medicines manufacturing skills in the UK:

1. Promote the Medicines Manufacturing Industry and careers within it
2. Create apprenticeships standards to enable companies to use the Apprenticeship Levy
3. Share and promote good practice for training and skills development
4. Address the low level of practical skills in graduates and other new-starters
5. Address the issues arising from there being relatively small national cohorts for education and training in a number of critical skills areas
6. As part of the [ATMP Taskforce recommendations](#), deliver an End to End Talent Management Plan for the sector and establish a Skills and Training Academy for the UK

## Progress and activity

During 2015 and early 2016, MMIP was a major contributor to the [Science Industry Partnership's \(SIP\) Skills Strategy](#). This Strategy was published in April 2016 and identifies the key skills issues and gaps that need to be addressed across the science industries, including small and large molecule pharmaceuticals and advanced therapies.

The SIP Skills Strategy provided further reinforcement of many of the skills issues identified in the ABPI's 2015 Report "[Bridging the Skills Gap in the Biopharmaceutical Industry](#)".

In addition the MMIP has been working with the Department for Education and The Life and Industrial Science Trailblazer Group to develop [new apprenticeship standards for medicines manufacturing](#).

MMIP also supports the SIP [Ambassador Programme](#).

## Further information

Kate Barclay, Pfizer, contributed a guest blog to the ABPI for National Apprenticeship Week (6-12 March 2017) on [Apprenticeships: the career step for you?](#)

Simon Mowat, AstraZeneca, contributed a guest blog to the ABPI for National Careers Week (6-12 March 2017) on [Motivating the future medicine manufacturing workforce](#).

# Revolutionizing Medicines Through Advanced Manufacturing Technologies



**Design and launch of specialized capacity facilities**, aligning technology development and commercialization, to support the generation and application of advanced manufacturing technologies, specifically:

- **New Modalities' Centre of Excellence**, focused on the production of highly potent assets, as well as sterile capability development.
- **Medicines Manufacturing Innovation Centre (MMIC)** – Building on current MMIP proposal on continuous manufacturing further developed to include: digital capabilities and potentially complex chemistry/enzymes and additive technologies (3D printing).
- **Packaging and Device Centres of Excellence**, designed to develop and produce optimised packaging solutions for medicines and the medicines supply chain.



# Ambitious manufacturing technology vision



MMIP

In our vision of the **Future State**, UK Pharma will have a more agile and responsive supply chain that delivers higher quality medicines to patients at the point of need

- Small high-tech facilities
- Interconnected
- Flexible and responsive
- Accelerated development
- Build on existing capabilities
  - Fill identified tech gaps
- High Quality – GMP
- Shared with partners
- Low Carbon consideration



Flexible spaces that can evolve rapidly as manufacturing technology advances



Modular (continuous) manufacture



Smart intensive standard platforms

# Propelling technology implementation through collaboration



Drivers	Opportunity	Benefit
Cost of Exploration (almost prohibitively)	Changing industry culture and focus fast to clinic for Advanced Therapies (ATMPs) and Complex Medicines	Sharing cost of exploration and facilities Anchoring early and growing UK capabilities
Scale of opportunity	Supportive Governments Supportive Regulators	Shared risks in early dev (especially with SMEs) UKs potential fully realised
Healthcare is changing	Partnership with Government and NHS	Increase in knowledge and capability
Sharing lessons from other industries	Build on experience from Automotive	Successful model of collaboration and step change in technology challenges



# UK Medicines Manufacturing Landscape



## MEDICINES MANUFACTURING UK LANDSCAPE Overview



- ✓ Medicines Manufacturing Landscape portal: [mmlandscape.ktn-uk.org](http://mmlandscape.ktn-uk.org)
- ✓ “One stop shop” to understanding type of businesses and where located / clustered.
- ✓ Outline the UK capability, funding and infrastructure available to medicines manufacturers and identify **capability clusters across the value chain.**

## ATMP TASKFORCE

Completed 6 months of Task force engagement activities – Skills, International Competitiveness and Manufacturing/ Technology

ABPI/PWC delivered project to define the ‘size of the prize’.

End of November: Final report presentation at MISG/ Bioprocess

## FISCAL & BUSINESS ENVIRONMENT

- Concluded GVA demystification work and developed Fiscal guide and webinar
- Continued work with UKTI to market UK’s fiscal and manufacturing offers.

## TECHNOLOGY AND INNOVATION

- Refresh of the T&I roadmap nearing completion for future theme selection.
- Built portfolio of projects: ADDoPT, REMEDIES
- Letters of support for MMIC and UCL manufacturing hub bid
- Ongoing project scouting: NHS batch optimization, electronic leaflets, analytics, among others

## SKILLS

- Supported SIP report providing industry’s angle and developed MMIP skills plan
- Published MMIP Skills Solutions / Actions document to define industry objectives
- Commencing implementation of action plan

## REGULATORY

- Established links across other regulatory groups and UK Industry Associations
- Developing concept paper with MHRA to explain existing regulatory flexibilities
- Promoted MHRA’s Innovation Office and ‘one-stop-shop’, including case studies.



MMIP

## And the journey continues...

### To contact us:

<http://www.abpi.org.uk/our-work/mmip/Pages/default.aspx>  
or [MMIP@Bioindustry.org](mailto:MMIP@Bioindustry.org)

### Acknowledgements

MMIP is supported by the ABPI, the BioIndustry Association (BIA) and the Knowledge Transfer Network, and includes leadership from AstraZeneca, Eisai, FUJIFILM Diosynth Biotechnologies, GlaxoSmithKline, Pfizer and ReNeuron.