



# UK Medicines Manufacturing Industry Partnership

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NEPIC – 22 June 2016

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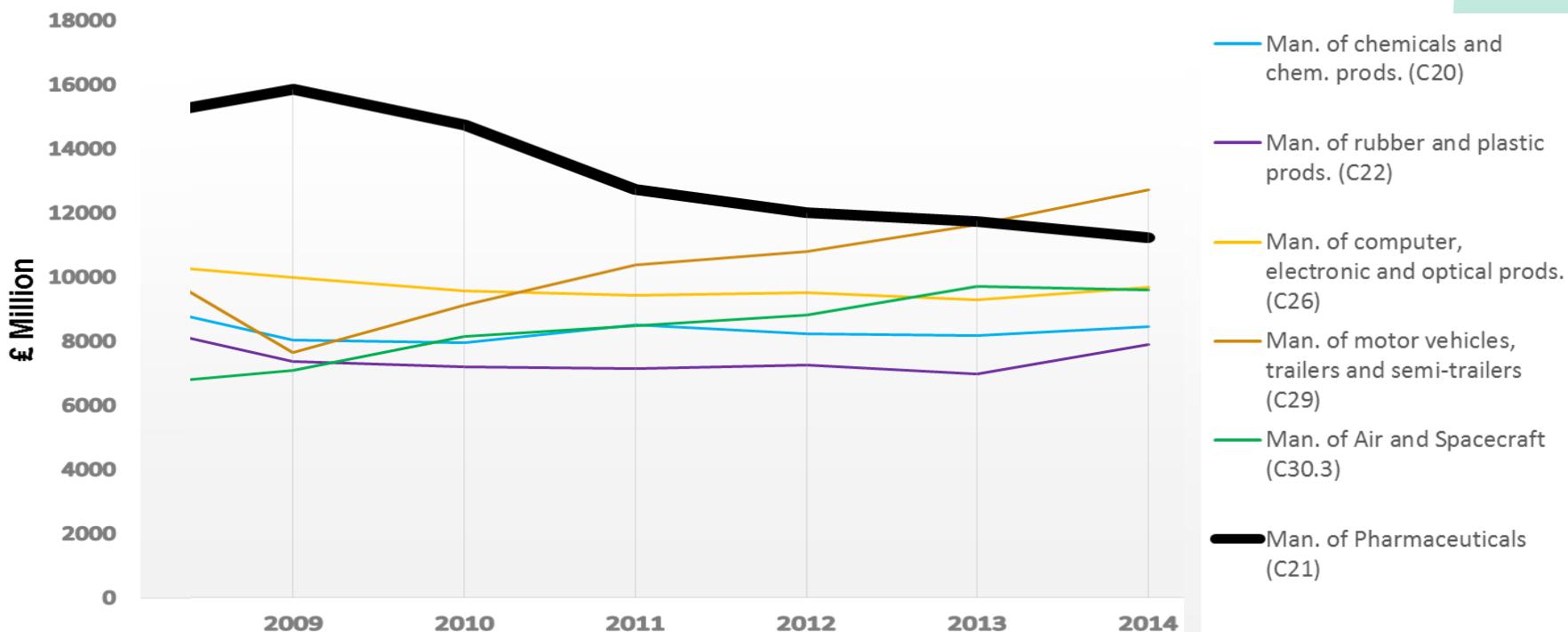


- Medicines Manufacturing
  - Challenges and Opportunities
- UK Medicines Manufacturing Industry Partnership
  - UK Landscape
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  - Future supply chain - Advanced Therapies Taskforce
- Conclusions and Acknowledgements

# GVA Trend in Manufacture of Pharmaceuticals



In 2009 the medicines manufacturing sector had the greatest economic contribution of any high technology research intensive industry providing some £16bn GVA. By 2014 this had declined to £11bn GVA, a 30% reduction. To reverse this decline the introduction of innovative technologies and a competitive fiscal environment are key.



# Change Brings Opportunities

- We have arrived at a Crossroads



- Patients becoming partners in their own healthcare
- Continued shift towards personalised medicines
- Regulatory requirements adapting to new technologies
- Impact of “digital” on factory design and operation
- Impact of Intelligent Products (and how we supply)
- Manufacturing technologies and effective supply chains for new product types (ATMPs)
- Availability of skilled people
- Availability of funding (govt and private)
- Infrastructure of national facilities and capabilities to support product and technology development
- Attractiveness of UK tax structure



# 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. ”

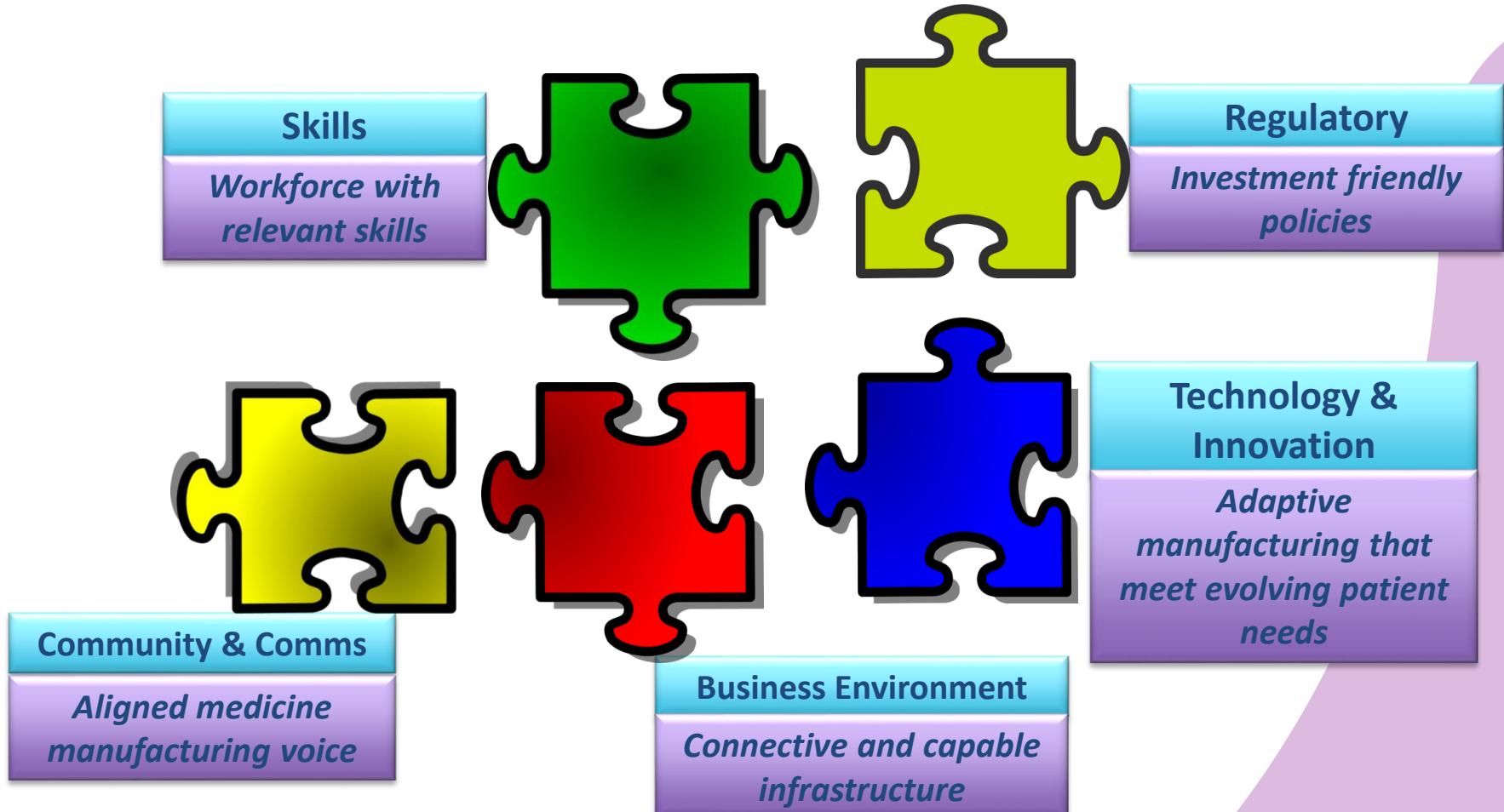
**George Freeman MP,**  
Minister for Life Sciences

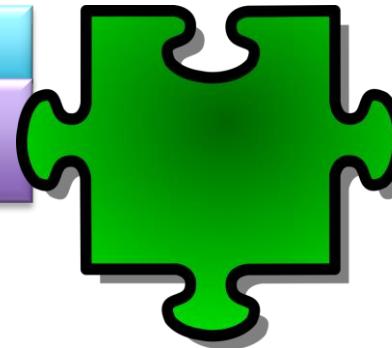
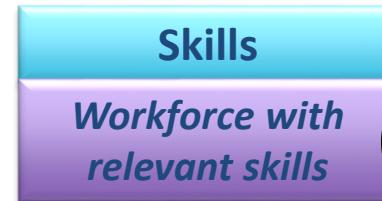


# MMIP Objectives & areas of focus



**To drive Growth** in all areas of the Medicine Manufacturing sector and  
**ensure the UK is recognised as an attractive and thriving environment**  
**for medicines manufacturing.**





- ✓ **MMIP Conducted an Industry Skills Survey and ABPI skills review**
- ✓ **Science Industry Partnership Skills Strategy**
  - ✓ MMIP has contributed to the SIP Futures Group and Skills Strategy (now issued)



⇒ Ensuring skills development frameworks and solutions are in place to meet industry needs

⇒ Ensuring we have a rich candidate pool for growth and succession

## Published Innovation Office case studies



### Innovation

Early and flexible input from MHRA facilitates successful pharmaceutical site in UK

#### The issue

In 2007 Eisai, a Japanese pharmaceutical company with no prior manufacturing or packaging capability within Europe, embarked on an aggressive £100M investment plan to develop a European headquarters, research and production site.

The design of the production facility had been undertaken in the UK and involved a cross-functional team including Japanese expatriates, professional services organisations and a newly appointed local team.

Before construction of the site commenced, Eisai wanted to be sure that its concepts and design philosophies would meet the requirements of regulatory authorities.

Making changes later on in the process could cost them both time and money.



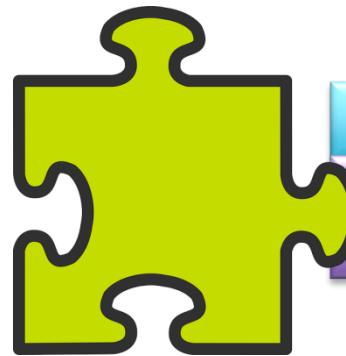
The completed facility.



The completed facility.

#### How can we help you?

Is your organisation developing innovative products or technologies? Get in touch with us at the beginning of your project – we provide access to knowledge, guidance and experience that could help your organisation progress its innovation: [innovationoffice@mhra.gov.uk](mailto:innovationoffice@mhra.gov.uk) [www.gov.uk/government/groups/mhra-innovation-office](http://www.gov.uk/government/groups/mhra-innovation-office)



Regulatory  
*Investment friendly*  
policies



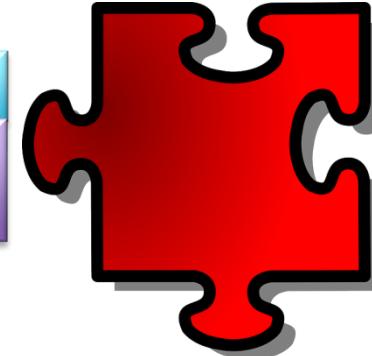
✓ **The MHRA, as a progressive regulator, is recognised as an asset for the UK.**

✓ **The value of the unique MHRA Innovation Office is early collaboration and engagement between Industry and MHRA, this has been actively promoted via multiple case studies.**

⇒ **To promote the role of the MHRA Innovation Office and to maximise utilisation of existing flexibility within the current UK regulatory framework.**

⇒ **To understand the long term strategy for Medicines Manufacturing in the UK and to proactively shape the future regulatory framework.**

Business Environment  
*Connective and capable infrastructure*



- ✓ **Fiscal assessment of the tax treatment of costs to support existing UK manufacturers and enhance the attractiveness of the UK to inward investment.**
  
- ✓ **MMIP, Office of Health Economics (OHE) and Office of Life Sciences** jointly outlined UK medicine manufacturing measures.

⇒ Clarify the landscape of tax, patents, capital allowances and regulation

⇒ Seeking ways to differentiate the UK and improve attractiveness for investment decisions

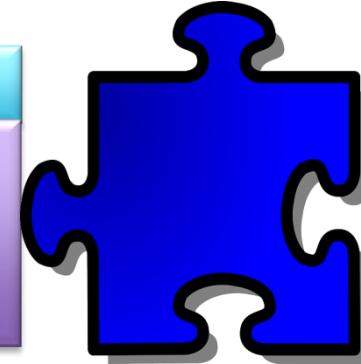


## MEDICINES MANUFACTURING UK LANDSCAPE Overview



### Technology

*Adaptive manufacturing that meet evolving patient needs*



## A Strong Base: UK Medicines Manufacture Landscape

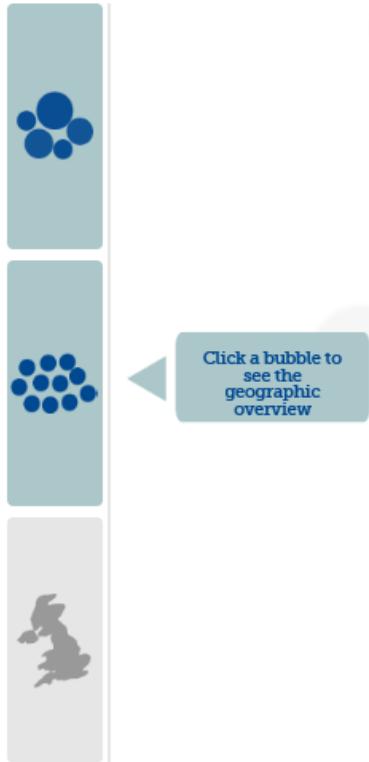
- ✓ Medicines Manufacturing Landscape portal: [mmlandscape.ktn-uk.org](http://mmlandscape.ktn-uk.org)
- ✓ Delivered by the Knowledge Transfer Network – the UKs Innovation Organisation
  - outlining the UK capability, funding and infrastructure available to medicines manufacturers to support innovation and identify capability clusters across the value chain for companies.
- ✓ “One stop shop” approach to understanding the capabilities, type of businesses and where located / clustered.
  - The tool is not only for UK based business but those international companies that currently operate off-shore and are considering re-shoring/investment to the UK.

## MEDICINES MANUFACTURING UK LANDSCAPE Overview



# MEDICINES MANUFACTURING UK LANDSCAPE

## Overview



Click a bubble to  
see the  
geographic  
overview



## Detailed search

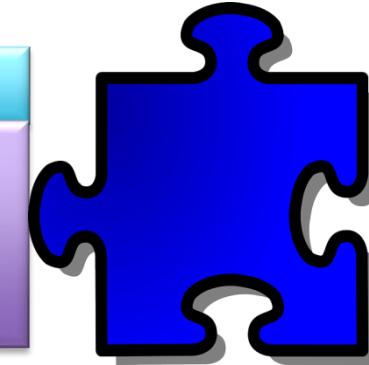
All	Academic capabilities	Funding sources	Underpinning organisations	Catapults	National capabilities
Sector organisations	Manufacturing sites	Companies			

There are **6** entries that match your search.

LIST VIEW
MAP VIEW

Sort by name A-Z
Show all regions
Reset

Catapults	Cell Therapy Catapult	 Visit website	 London
Catapults	Digital Catapult	 Visit website	 London
Catapults	High Value Manufacturing Catapult	 Visit website	 West Midlands
Catapults	Medicines Technologies Catapult	 Visit website	 North West England
Catapults	Precision Medicine Catapult	 Visit website	 East of England
Catapults	Transport Catapult	 Visit website	 South East England



- ✓ **MMIP supported ADoPT** - advanced digital design of pharmaceutical therapies.
  - Key component of the UK Ecosystem will add world leading capability in the design of and optimisation of small molecules. AMSCI funding December 2015, project will run through 2016/17.
- ✓ **The MMIP supported business case for the Medicines Manufacturing Innovation Centre**

⇒ Grow a strong knowledge, technology and innovation base

⇒ Industry needs to move towards higher efficiency with reduced cost of goods. New technology and the drive for more effective and agile supply chains are essential to achieving this.

# Medicines Manufacturing Innovation Centre



# Medicines Manufacturing Innovation Centre

End to End Technology Thinking



*Knowledge , technology  
industry and academia*



*Knowledge  
Construction Industry*



**TECHNOLOGY  
DEVELOPMENT**

**PROCESS  
DEVELOPMENT**

**DEPLOYMENT**



*PAT, Control, Training, Regulatory, Business Case, Stabilisation*



*Knowledge , Molecule  
Industry*



*MMIC Joint venture between CPI, University of Strathclyde supported by*



*Scottish Enterprise and Innovate UK*

Input into the URS development, cost estimate and economic case:

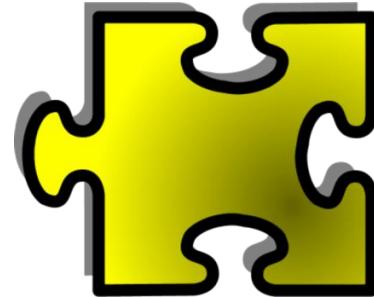


Letters of Support



Community & Comms

*Aligned medicine  
manufacturing voice*



- ✓ **Joint Government / industry approach to strategy** to invest and utilise the UK's rich technological landscape for medicines, leveraging opportunities available to support translation of innovation to commercialisation.
- ✓ MMIP community outreach - MMIP initiatives - work-shops, roundtables and face to face meetings with the medicines manufacturing building "the VOICE of the sector"
- ✓ Strong interest from George Freeman (Minister for Life Sciences) to be personally involved → **Advanced Therapy sector Task Force**

⇒ Promote existing strong base of medicines manufacturing in the UK.

⇒ Potential for inward investments

⇒ There is a strong political interest in the potential to expand Medicines Manufacturing and to create more exports.

# Future Supply Chains and MMIP



- PRODUCT RESEARCH
- TECHNOLOGY



**Advanced Therapy Medicinal Products**



SMALL MOLECULE

LARGE MOLECULE and Vaccines

Technology



Business Environment



Regulatory



Skills



MEDICINES  
for Human  
Health

Community &  
Comms



# Government/Industry Taskforce launched - Manufacturing Advanced Therapy medicines in the UK



- Co-chaired by **Minister for Life Sciences George Freeman** and **Ian McCubbin, SVP North America, Japan & Global Pharma Supply, GlaxoSmithKline**,
  - Work to anchor advanced therapy manufacturing and the associated supply chain in the UK
  - Complement the work of the Regenerative Medicine Expert Group (RMEG) that is developing an NHS regenerative medicine strategy so that the NHS is fully prepared to deliver these innovative treatments.
- UK leading in development of Advanced Therapies
- Investment in national facilities – Cell and Gene Therapy Manufacturing centre opens 2017
- MHRA and EMA based in London (MHRA Innovation office)
- Licensed 22 GMP facilities

# Conclusions



- ⇒ UK has strong technology base in academia, industry and the emergent national centres
- ⇒ The MHRA is seen and valued as an asset
- ⇒ Recognition of the importance of design and manufacture of medicines in UK policy
- ⇒ Significant ongoing change brings opportunity across a number of therapeutic modalities
  - ⇒ It is an opportunity to build recognising competition in a global model
  - ⇒ Advanced technology will be the driver supported by policy enablers
- ⇒ Further strengthening our industry connectivity, alignment and partnership with government via MMIP
- ⇒ There is a strong foundation in the UK for turning challenges into opportunities for the pharmaceutical development and manufacturing sector

# Thank you



## Acknowledgements

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

With additional thanks to Tommy Dolan Pfizer/MMIP, Sean Birmingham PSE/ADDOPT, Clive Badman GSK/MMIC, Ian McCubbin GSK/MMIP, Mark Bustard KTN, Greg Anderson GSK/MMIP and David Garton AZ/MMIP