MMIP

Medicines Manufacturing in the UK 2017

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Medicines Manufacturing in the UK 2017

Welcome by Andy Evans

Chair, MMIP

Site Lead, AZ Macclesfield

Morning Agenda

10:00	Introduction	Steve Thompson ABPI Steve Bates BIA Sue Dunkerton KTN
10:30	Keynote Speech	Lord Prior of Brampton, Minister, BEIS
10:45	MMIP Achievements &	Ian McCubbin
11:00	MMIP Overview	Richard Turner Magda Papadaki Sean Bermingham Clive Badman Alex Felthouse Yvonne Stewart
12:00	Lunch & Tours	

Afternoon Agenda

14:00	How manufacturing might be evolving	Ian McCubbin Prof Lionel Clarke Steve Bagshaw Andy Evans Roger Kilburn
14:50	MMIP's Response to the Industrial Strategy	Andy Evans
15:30	Break-out Groups	Richard Turner Alex Felthouse Magda Papadaki Mike Sullivan Andy Evan
16:15	Feedback & Close Out	Andy Evans
17:00	Drinks Reception	Close out 18:00

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Medicines Manufacturing in the UK 2017

Introduction by ABPI, BIA, KTN

Mike Thompson, Chief Executive ABPI
Steve Bates, Chief Executive BIA
Sue Dunkerton, Director KTN

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Medicines Manufacturing in the UK 2017

KTN and MMIP

Connecting people to accelerate innovation

Sue Dunkerton OBE

Director

Knowledge Transfer Network

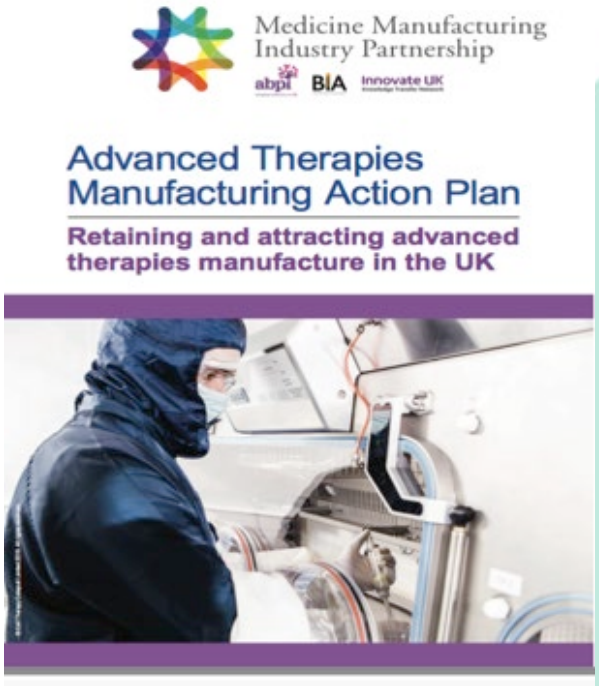
Knowledge Transfer Network (KTN)

- UK's Innovation Network
- Connecting the unusual suspects to accelerate innovation
- Seeking to ensure value is created from every great idea

Industrial Strategy

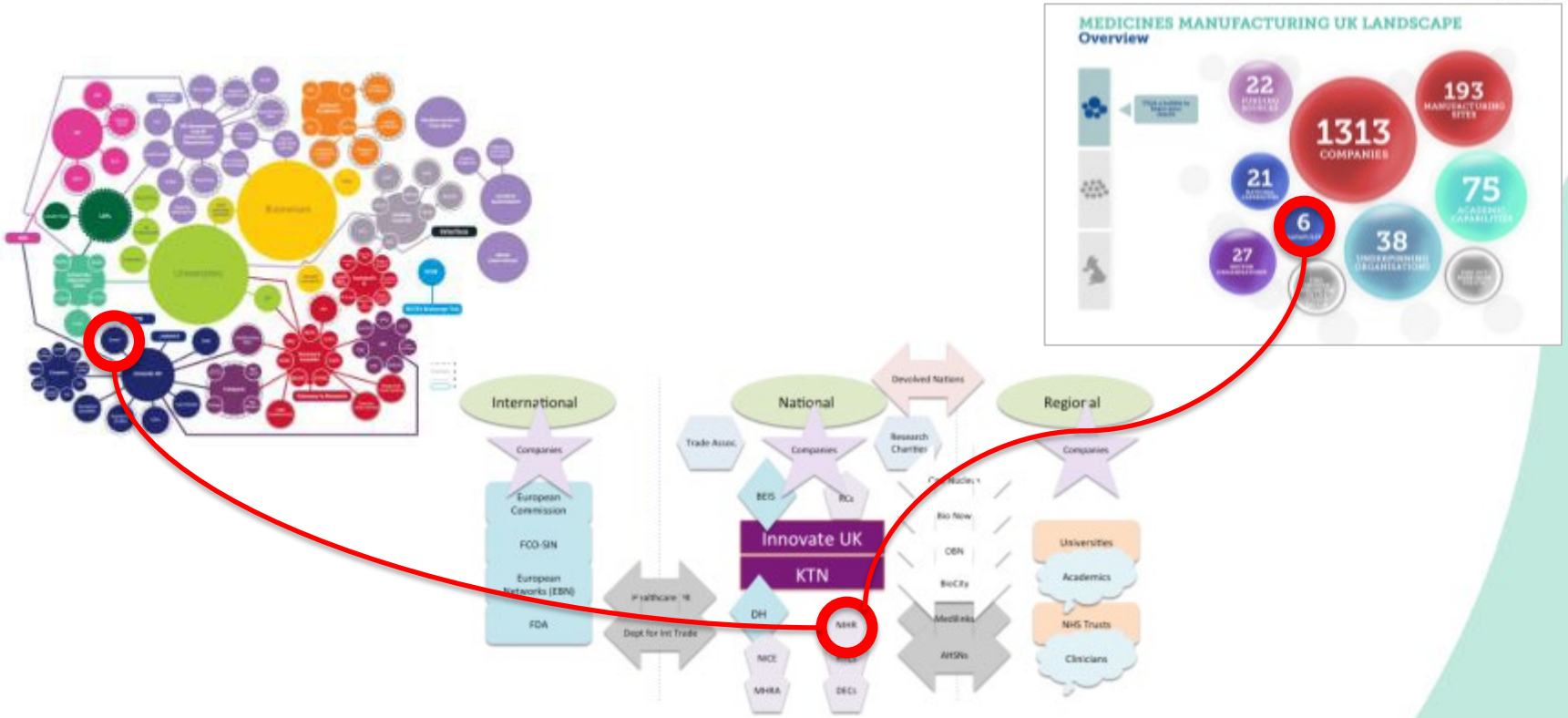
MMIP

- Industrial Strategy Challenge Fund workshops
  - 800 leaders in 9 workshops over 1 fortnight
- Leadership Councils
  - Medicines Manufacturing (MMIP)/Advanced Therapies (ATMTF), Industrial Biotechnology (IBLF), Advanced Materials (AMLC), Synthetic Biology (SBLC), Chemistry Growth Partnership (CGP) etc
- Reports and Roadmaps



Navigating the landscapes

MMIP



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Working with the funders

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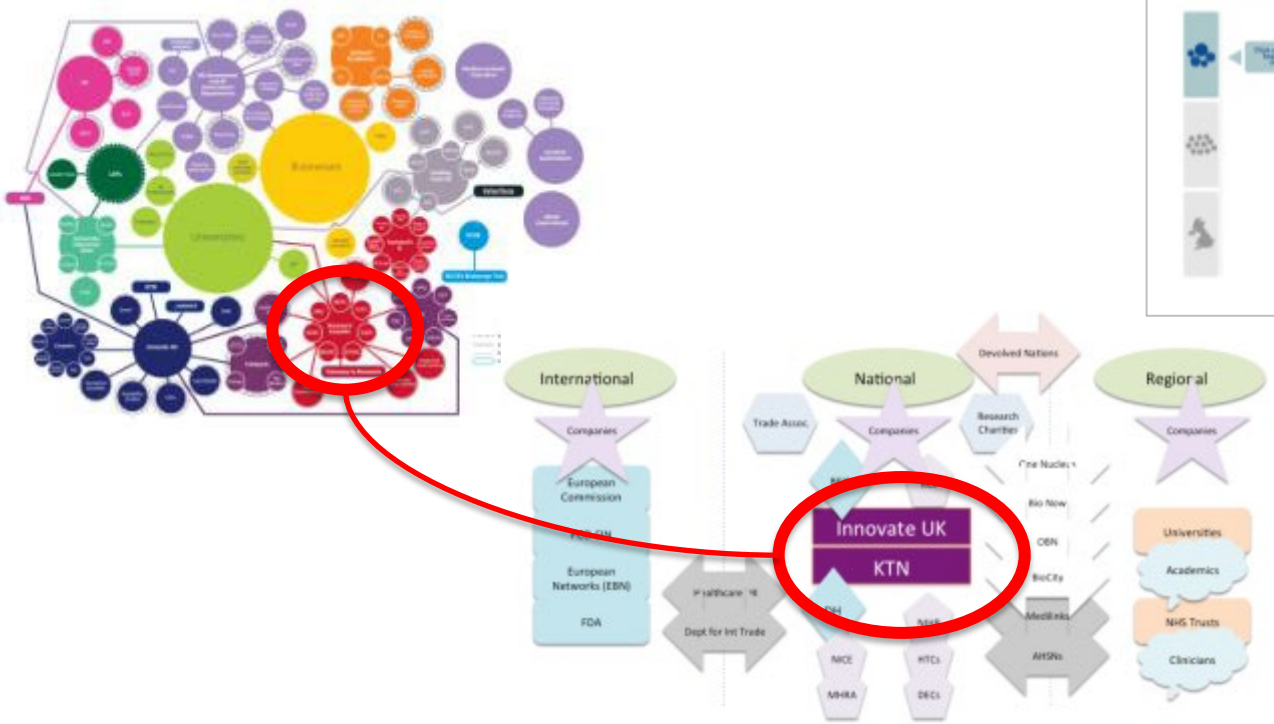

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Connecting communities

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SYNTHETIC BIOLOGY

IOT

PACKAGING

DIGITAL MANUFACTURING

ROBOTICS AND AI

FORMULATION

MEDTECH

DIGITAL HEALTH

MATHEMATICS

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Progress within MMIP

- Advanced Therapies Manufacturing Taskforce and Action Plan
- Initiated and supported AMSCI ADDOPT AMSCI - £20.4M Govt-industry-academia collaboration
- Delivered the Medicines Manufacturing Landscape Portal
- Ran the smart packaging scoping workshop for MMIP using cross KTN expertise
- Championed Technology Clubs such as BRIC for the biologics /bioprocessing community

Bioprocessing Research Industry Club (BRIC)

New areas of relevance

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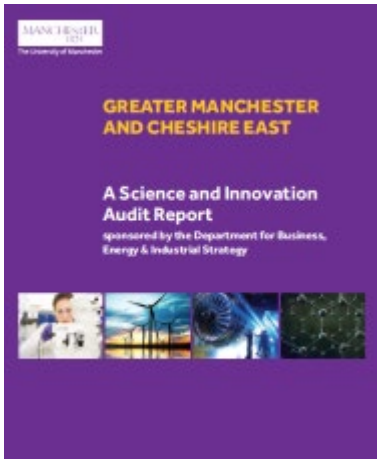
Innovation and Local



Science and Innovation Audits (SIAs)

SMART SPECIALISATION HUB

Diversity in Innovation

infocus
WOMEN IN INNOVATION

Connecting people
to accelerate innovation

The Future. Faster

sue.dunkerton@ktn-uk.org

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Medicines Manufacturing in the UK 2017

Keynote speech

Lord Prior of Brampton

Minister, Department for Business, Energy and Industrial Strategy

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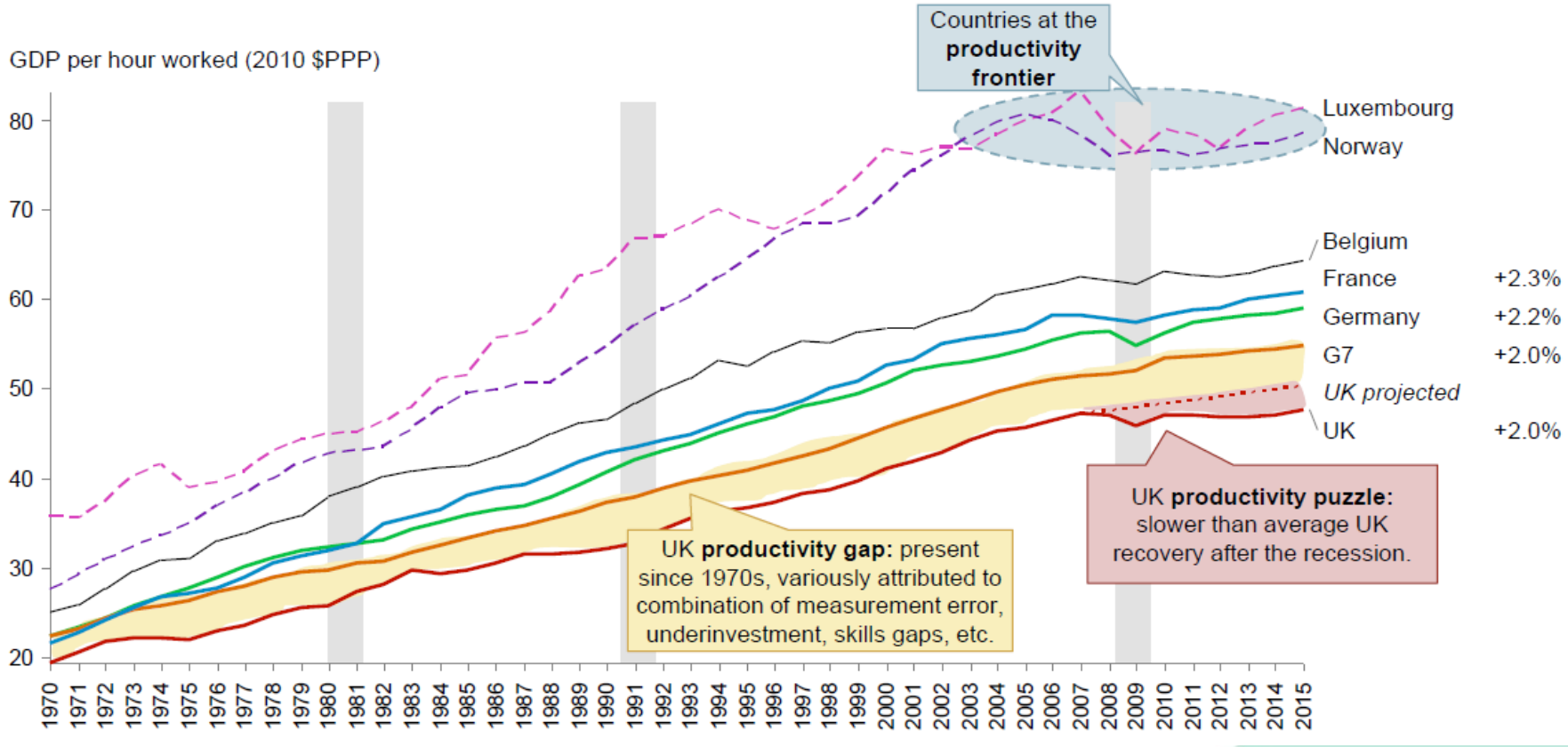
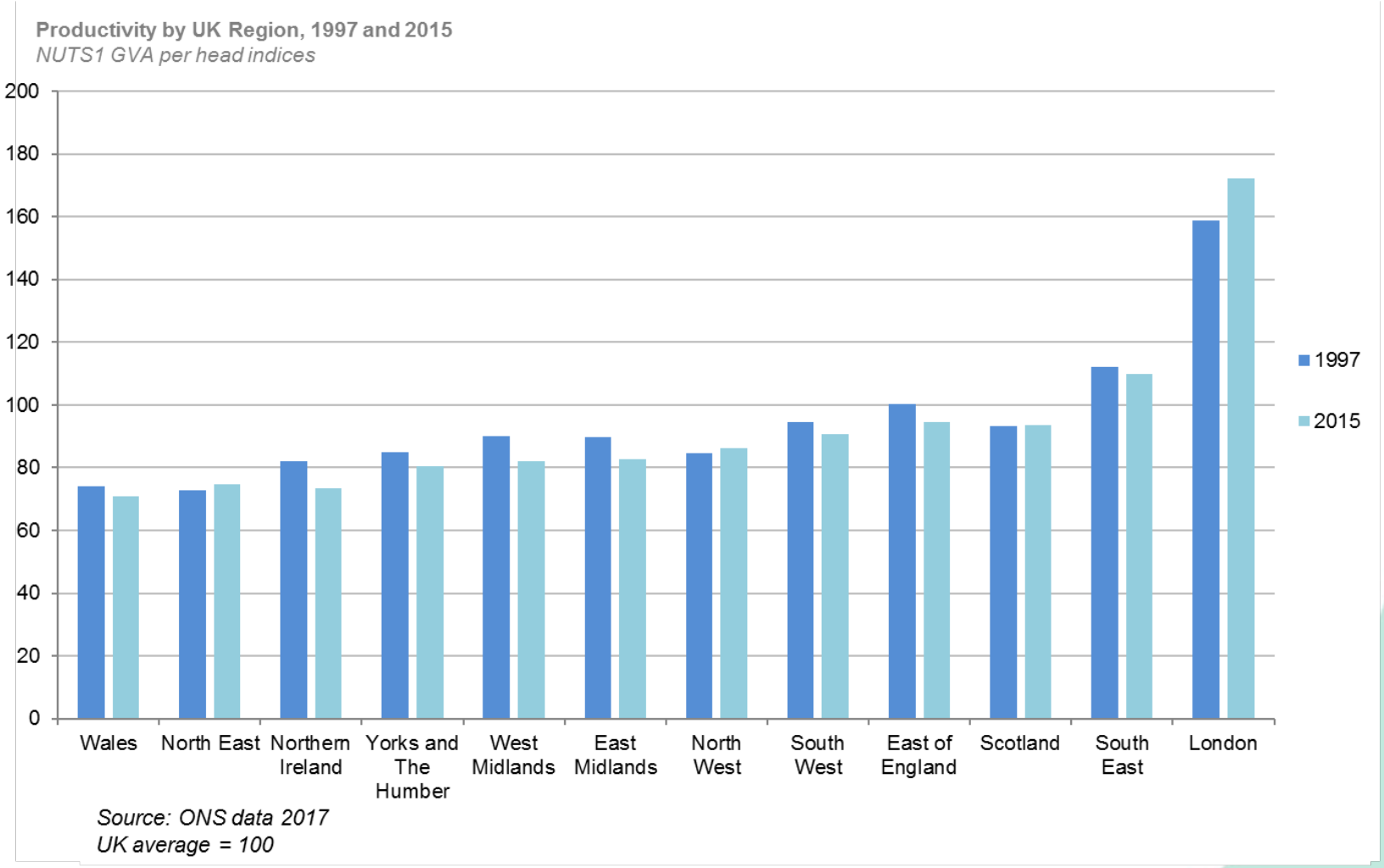
Challenge 1: the UK has lagging productivity at national level – and needs to transform productivity growth to catch up



Source: BCG, OECD

Challenge 2: significant unevenness in productivity in different places and sectors



Response: Our green paper leading to an Industrial Strategy

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Science, Research and Innovation

Skills

Infrastructure

Business Formation, Growth and Investment

Procurement

Trade and Inward Investment

Affordable Energy and Clean Growth

Sectors

Spreading Growth Across the Country

Sectors and Places: Linking Institutions

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Life science investment is globally competitive – multiple established and emerging hubs

1b Bay Area

- ✚ **Entrepreneurial culture and talent base,** incl. venture capital (VC) fund presence at Stanford and UCSF
- ✚ Extensive **through-cycle funding driven by major VCs**

1a Boston

- ✚ **1 square mile** of talent, skills and funding (Kendall Square)
- ✚ **Organic growth of start-ups and corporates** around Harvard and MIT, e.g., Sanofi
- ✚ **Basic science expertise** (e.g., CRISPR-Cas9)

2 UK Southeast

- ✚ **4 out of the top 10** global universities incl. **13 Nobel Prize winners from 1 lab** in Cambridge
- ➖ **Uncertainty as a result of Brexit**
- ✚ **Incubators** located around universities, e.g., Babraham in Cambridge

3 Israel

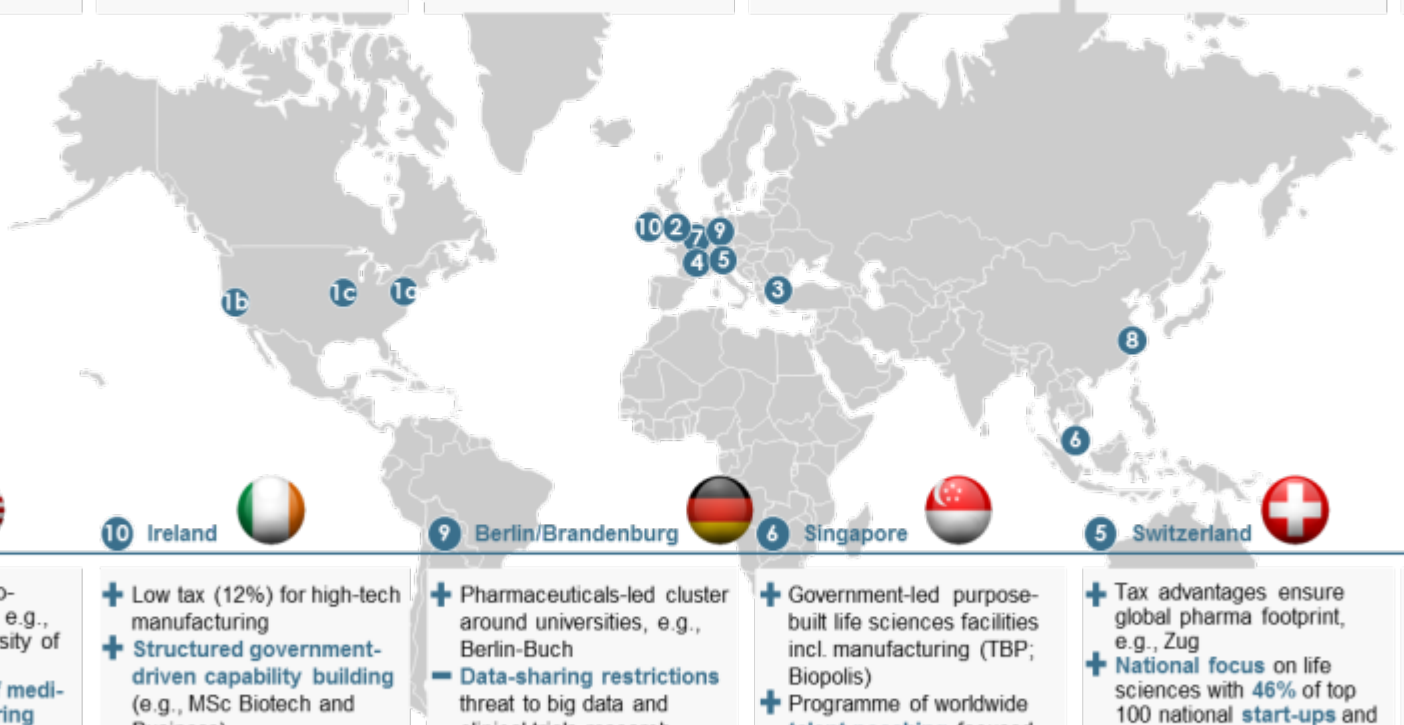
- ✚ Government support built around **military and engineering expertise** and **focused on devices and medtech**
- ✚ **Highest start-up funding per capita,** 3x that of the US

8 Shanghai

- ✚ Co-ordinated government policies to attract global brands into R&D/ manufacturing hub (e.g. **requirement for market access**)
- ✚ Large population and **low export costs**

4 Paris

- ✚ INSERM **national level tech transfer**
- ✚ **Grand Paris project infrastructure** to link tech and biosciences clusters
- ➖ **Regulation burden** (121st worldwide)



1c Minneapolis

- ✚ Historic basis in cardio-thoracic implantables, e.g., Medtronic from University of Minnesota
- ✚ **Talent at interface of medicine and bioengineering** incl. University of Minnesota's Biomedical Engineering programme
- ➖ **New stricter FDA regulation** is disproportionally affecting complex implantables and threatening future growth

10 Ireland

- ✚ Low tax (12%) for high-tech manufacturing
- ✚ **Structured government-driven capability building** (e.g., MSc Biotech and Business)
- ✚ Coordinated industry policy, e.g., IDA and Enterprise Ireland

9 Berlin/Brandenburg

- ✚ Pharmaceuticals-led cluster around universities, e.g., Berlin-Buch
- ➖ **Data-sharing restrictions** threat to big data and clinical trials research

6 Singapore

- ✚ Government-led purpose-built life sciences facilities incl. manufacturing (TBP; Biopolis)
- ✚ Programme of worldwide **talent poaching** focused on leading bio-scientists

5 Switzerland

- ✚ Tax advantages ensure global pharma footprint, e.g., Zug
- ✚ **National focus** on life sciences with **46%** of top 100 national **start-ups** and 30% of **publications** from ETH Zurich, Basel and Geneva
- ➖ **Strict regulation** is cumbersome for start-ups

7 Belgium

- ✚ **Flagship institutions,** e.g, Janssen Pharmaceutica, UCB
- ✚ **Proof-of-concept trials** for early-stage drugs, e.g., Novadeep
- ✚ **Regional funds,** e.g., IWT (Flanders), Innoviris (Brussels), and DGO6 (Wallonia) bridge early stage growth to mid-caps

The UK has world-leading universities and a strong, well-distributed research base

Total number of life sciences employees by region

Southeast	49,548
East of England	33,797
Northwest	25,712
London	20,650
West Midlands	16,683
Yorkshire	13,262
East Midlands	15,958
Scotland	11,696
Wales	13,882
Southwest	8,577
Northeast	6,206
Northern Ireland	5,932

4 out of the **top 10** global universities

13 Nobel prize winners from one laboratory in Cambridge

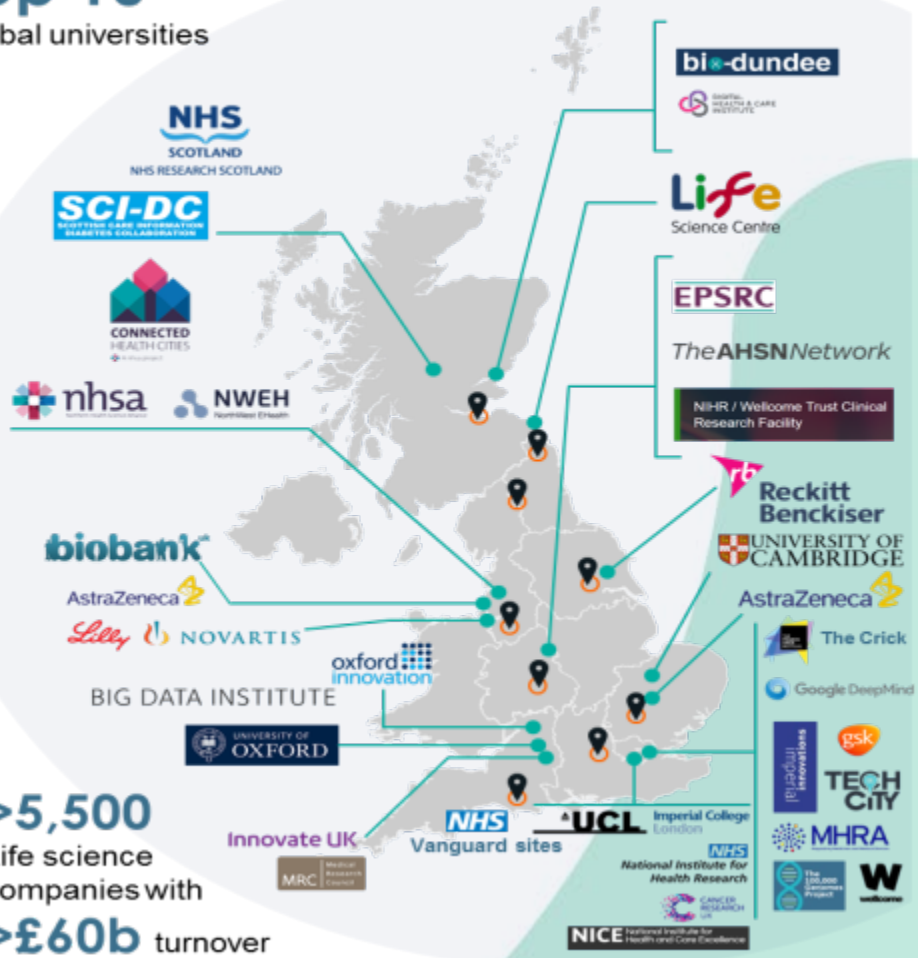
600,000 patients in clinical trials

The most **productive** sector in the UK

£6bn industry R&D spend

£3bn public R&D spend

>5,500 Life science companies with **>£60b** turnover



Source: HMG Strength and Opportunity 2015: the data behind the charts; OECD; Government of the UK; NIHR; ONS

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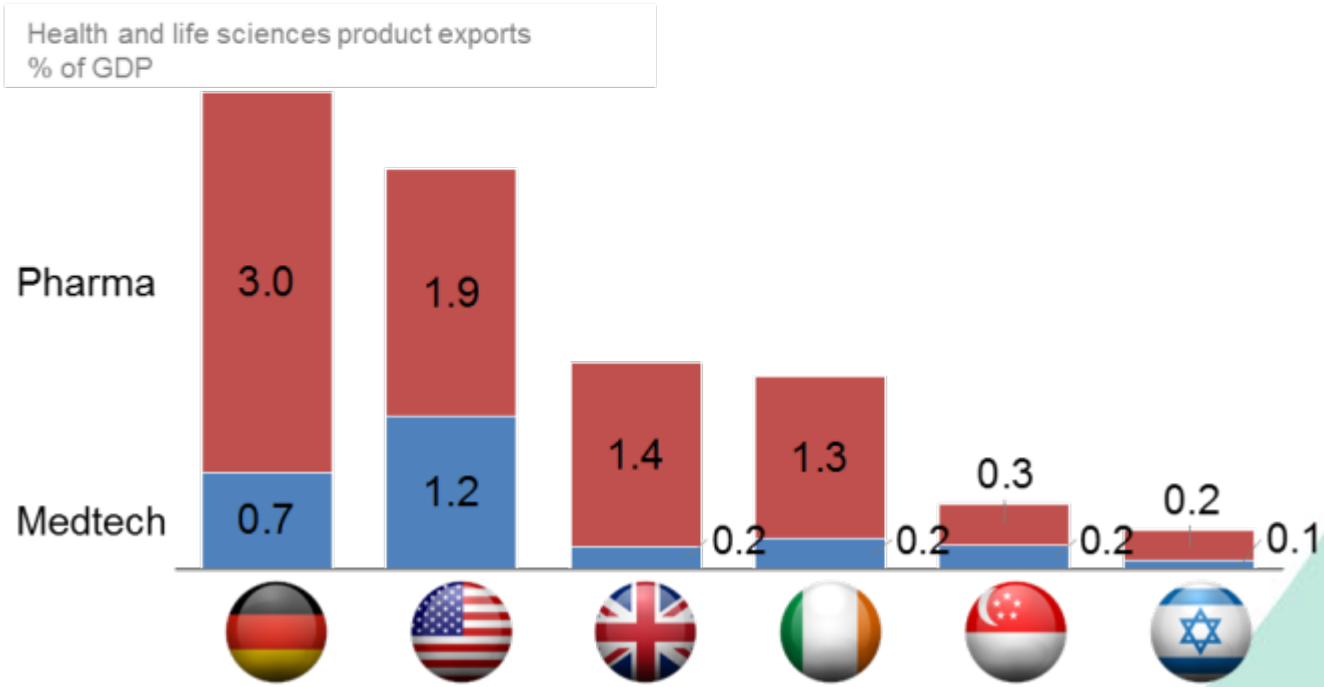
UK life science exports lower than those of Germany and the US – we can do better

Total exports USDbn Avg 2010-15	90	80	40	35	10	8
Avg as % GDP 2010-15	3.7	3.1	1.6	1.5	0.5	0.3



Source: ONS UNCTAD STAT Data, World Bank

Small molecule manufacturing is an example where the UK capabilities can become world leading

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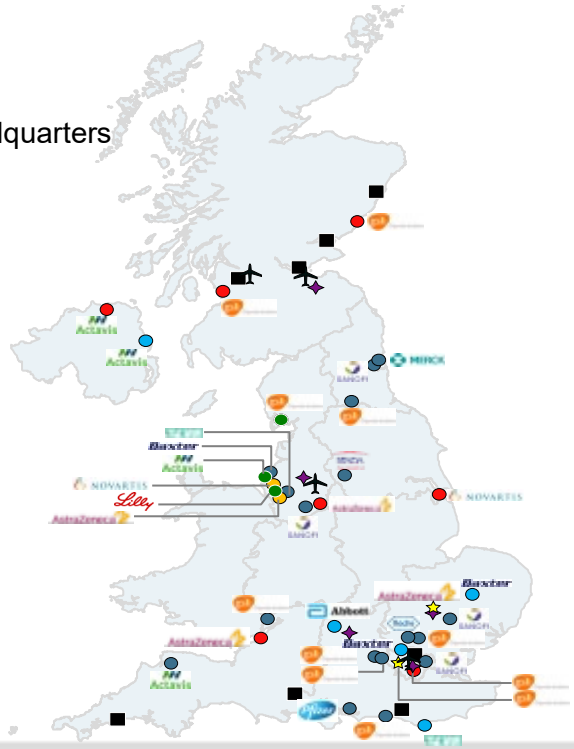
Current UK position

Critical mass of manufacturing in this area as well as strong academic capabilities especially in chemical engineering

- Company headquarters
- API sites
- Biologics sites
- FD sites
- Vaccine sites
- Unknown
- Universities
- Major cities
- Airports



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

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Medicines Manufacturing in the UK 2017

MMIP Overview & Achievements

by Ian McCubbin

Senior Vice President for Global Supply and Manufacturing,
GSK & Former Chair MMIP

Medicines Manufacturing in the UK 2017

The Tax Environment

by Richard Turner

Managing Director, FTI Consulting

Benefits of the UK for EMEA medicines manufacture

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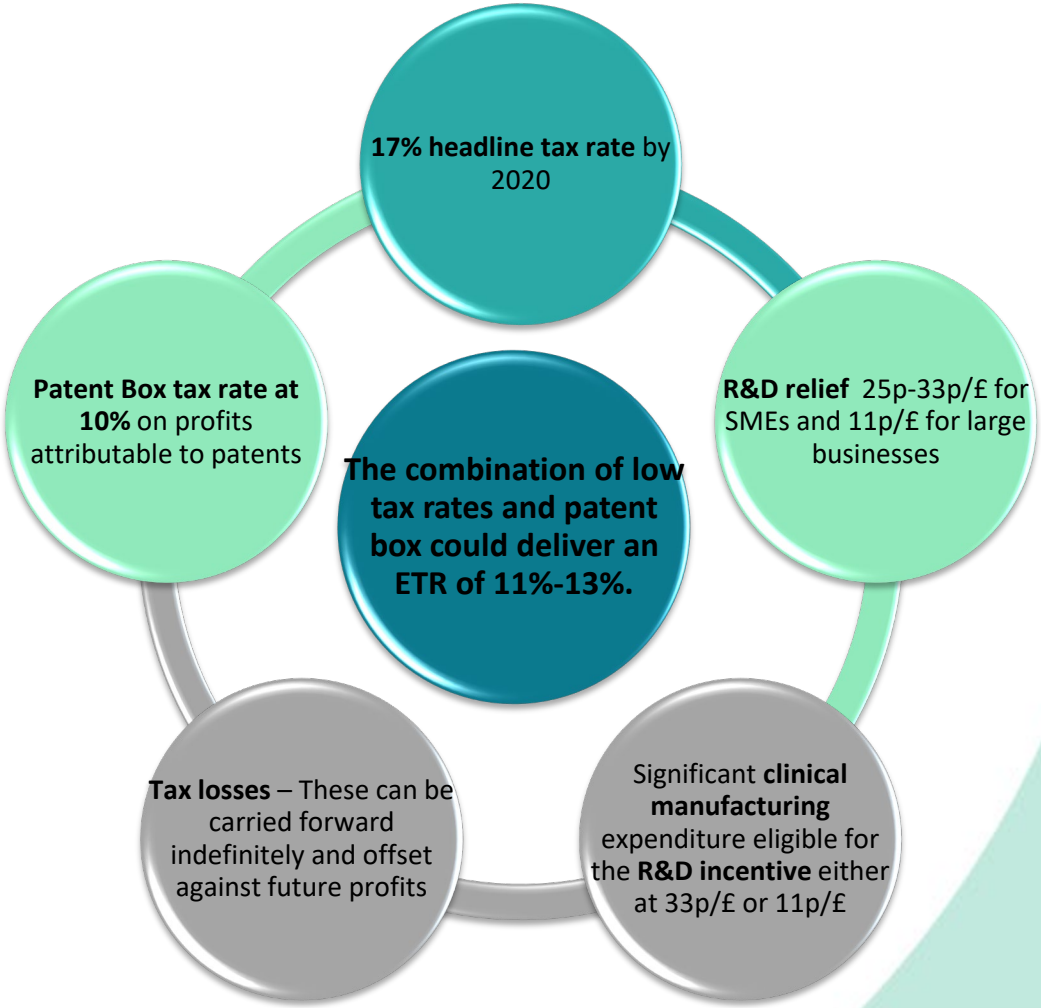
The UK provides a very attractive tax regime for a regional manufacturing.

It combines low rates of tax, innovation incentives (R&D tax relief and Patent Box), other significant tax benefits (below) and one of the most comprehensive global treaty networks.



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Medicines Manufacturing in the UK 2017

Technology and Innovation
by Magda Papadaki
Head of Manufacturing Innovation, ABPI

Apologies from Gregor Anderson, feel free to contact him on:
Gregor.jm.anderson@gsk.com

Technology & Innovation 2017

Technology and Innovation

- Identify opportunities for innovations and technologies that will drive UK growth - **align with** technology roadmap.
- Selectively deliver Technology **events** to disseminate sector knowledge on disruptive technologies and source ideas.
- Work across MMIP-supported projects to expand the existing UK capability and infrastructure – look beyond MMIP

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Main Drivers

- **Building on and expanding the UK's strong knowledge, technology and innovation base**
- **Emerging science and modalities pose new manufacturing and process challenges**
- **Industry also faced with growing pressures for higher efficiency and patient centric value**
- **New technology and more effective and agile end-to-end supply chains are essential to achieving this**

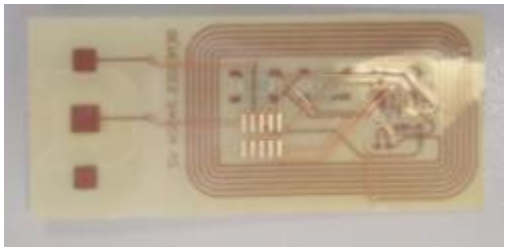
Specific Deliverables and Outputs	TARGET
Grow and maintain links across manufacturing ecosystem to promote and enrich project portfolio: • Advisory group to include/ link small innovators and bio-cohorts; partnerships with existing groups such • Include academia, ISPE, MHRA, Innovate UK, research councils and the Catapults (HVM, Cell & Gene Therapy and in the future Precision medicine and Medicines Discovery ,MedTech). **Collaborate across sectors**	**Through 2017**
Maintain and promote Technology 2017 roadmaps, through targeted community building actions	**Q3/2017**
Sponsor aligned project proposals (MMIC) and continue to coordinate existing portfolio (ADDoPT, REMEDIES)	**Q3/2017**
Connect to investigate and progress new opportunities such as: ATMP manufacturing, supply digitalization and electronic labelling, advanced analytics, redistributed manufacturing, Collaborate with enabling suppliers	**Through 2017**

Technology & Innovation 2017

MMIP

Q1 Update – where are we with specific initiatives

- Road map – Highlighted technology opportunities – to be published end Q1 17
- Electronic Leaflets –Project transferred to REMEDIES Q1 2017
- Smart Labels – Offers increased security/tracking in supply chain – trials Q1 17
- NHSE Partnership – MMIP supporting two projects (Prof Liz Kay /ABPI)
  - Simplified pack sizes for blister packs
  - Chemotherapy banding – technology and standard potential
- ISPE/MMIP Technology seminar held Feb 17 – more sessions planned through 17



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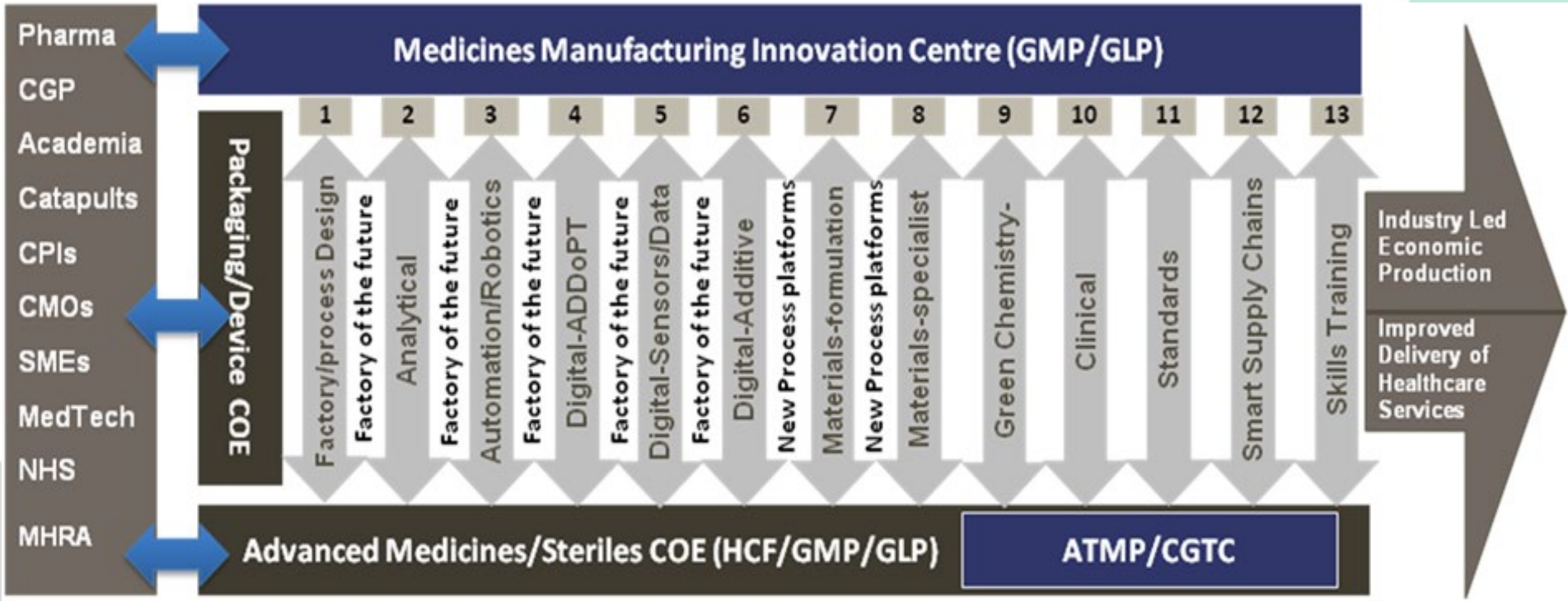
Technology & Innovation road map

- Road map has clear outputs built on a 2 pronged end goal – economic growth and enhanced healthcare
- Focus is on GMP clinical manufacturing and enables new medicines supply into the clinic early
- Builds on and complements existing requests (CGTC) and on-going programs (ATMP/MMIC)
- Encourages sharing of core technologies – leans and focuses to remove any gaps in journey from bench to clinic
- Sets the UK up as a research and development AND manufacturer for all medicines platforms
- Enhances current capabilities and academia/SMEs/CGP in the UK – and future proofs
- Packaging and Device CoE will serve whole supply chain and future device opportunities



From molecule to drug product to patient: increasing R&D efficiency, reliability of supply chains and robustness of drug product performance

Dr Clive Badman
Director, Project Remedies

Dr Sean Bermingham
Director, Project ADDoPT

Macclesfield, 20 March 2017

Outline

- ADDoPT project overview

- REMEDIES project overview

- Industrial Strategy Challenge Fund considerations

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Industrial Strategy Challenge Fund considerations

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Medicines Manufacturing Innovation Centre

Accelerating the translation of promising research into commercial adoption in small molecule pharmaceutical manufacturing.

Date: 06-March-2017

File: MMIC_Overview_Rev 4.ppt

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ADDOPT

ReMediES RE-configuring MEDIcines End-to-end Supply

MMIC - OVERVIEW

MMIP

DEFINITION

Open access innovation centre dedicated to small molecule pharmaceutical medicines manufacturing

GMP Facility
Primary and Secondary Manufacturing
Novel Technology Platforms
Novel Building/Facility
Regulatory Interface
Research Translation
Proof of Concept

OBJECTIVES

Accelerate adoption of emerging & novel manufacturing technologies and transform fine chemical /pharmaceutical manufacturing by:

Creating a physical infrastructure and capability for radical and disruptive innovation in fine chemical/pharmaceutical manufacturing.

De-risking investment in new technologies

Creating a focal point to coordinate and drive fine chemical/pharmaceutical manufacturing innovation.

Providing a support structure for SMEs and start-ups to innovate and grow.

Providing thought leadership to the fine chemical/pharmaceutical innovation community.

INDUSTRY SECTORS SERVED

R&D and Manufacturing:
Pharmaceutical
Fine Chemical

BENEFITS TO INDUSTRY

Cost savings and income generation via:

Capital efficiencies

Risk reduction

Demonstration of benefits of new technologies and innovation in an external environment

Enabling collaboration Platform for engaging with regulators

Increased productivity

Deepening the skills base

CURRENT INDUSTRY ENGAGEMENT & SUPPORT

LARGE COMPANIES
GSK, Pfizer, AstraZeneca, Johnson Matthey Bayer, Lilly, Merck, Patheon, Sanofi, Siemens, GEA, GE, Morgan Sindall

SMEs
Shasun, Chemtrix, Nitech, Pharma Solutions, Robinson Bros, Thomas Swan & Co. Ltd. Range of technology companies

FUNDING

The total ask from the Government and Industry is £55.8m over a 5 year period to cover capital spend for physical infrastructure and equipment (£35.2m) and operating costs (£20.6m). Anticipated funding from government includes up to £15m via Scottish Enterprise and £13m via IUK.

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ADDOPT

ReMediES
RE-configuring MEDIcines End-to-end Supply

CURRENT AREAS OF INTEREST

# Companies	Area of Interest
(9)	Showcase emerging technologies
(6)	Primary manufacturing processes (synthesis, API, drug substance)
(4)	Bring continuous manufacturing into manuf supply chain
(4)	Secondary manufacturing processes (formulation, drug product)
(2)	Emerging sterile technologies
(2)	Develop and explore new analytical, IT, control systems
(2)	Supply chain optimisation
(1)	Contract development and manufacture using new technologies

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The following is a high level summary of the most common themes indicated by potential MMIC users/collaborators:

- De-risk the introduction of new technologies into current supply chains (clinical and commercial)
- GMP demonstrator of emerging technologies (to ensure data can be used for regulatory filings, potential use of clinical materials)
- Supply chain optimisation

Several companies have indicated a desire to be able to make commercial materials, this will be investigated further for state aid implications.

Several companies have indicated a desire to be able to make clinical materials, this will be investigated further as this is primary driver for MMIC to be a GMP facility.

Note: The scope of MMIC is flexible and has not been fixed. Scope will be determined through industry demand, which will be identified through dialogue with potential contributors and collaborators in MMIC via future workshops and discussions.

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Further development and adoption by practitioners of Digital Design tools

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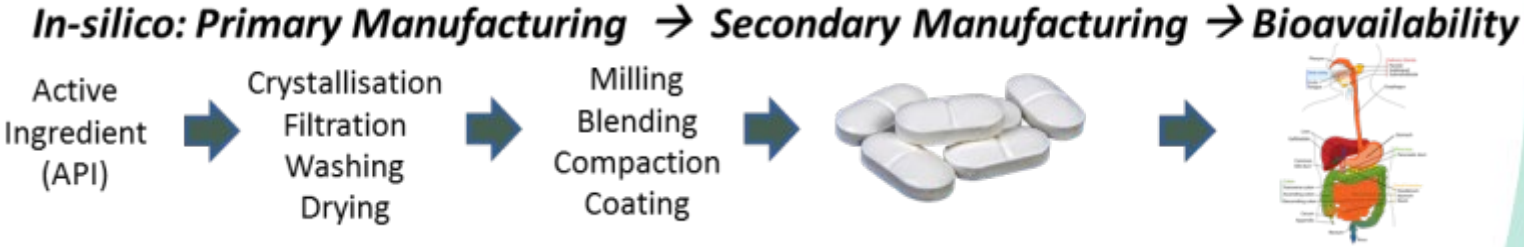
- Efficient R&D → capacity to bring more products to the market



- QbD 2.0 to ensure robust manufacturing using order of magnitude less experimentation
- High TRL activity ('AMSCI' like)

Medicines Manufacturing in the UK 2017

Skills

by Alex Felthouse

General Manager, Eisai Manufacturing Ltd.

Workforce in Numbers…

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107,000 — Medicines Manufacturing Labour Force*1

New Staff Required by 2025 to Meet Demand*2 — 32,000.

54% — Technical Level Jobs*2

*1 – Strength and opportunities report 2015
*2 – SIP Skills Strategy 2016

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Medicines Manufacturing Skills

Ensure the education system and curricula can meet the demands of our industry

- Input into the Government's Industrial Strategy.
- Support the Life Science and Industrial Trailblazer Group in the development of new apprenticeship standards.
- Map the current HE offering in relation to industry specific courses and determine gaps.

Ensure suitable facilities are available to develop a skilled workforce in current and emerging technologies

- Deliver on the Advance Therapy Manufacturing Taskforce Report recommendations.
- Establish if there is a roll for Technical Colleges to support manufacturing clusters and local colleges to support businesses.

Attract, retain and develop the Medicines Manufacturing workforce of the future.

- Inspire the young to follow STEM subjects , inform children and teachers of career paths and expose student to the workplace – STEM and SIP Ambassador
- Attract the next generation of technicians and graduates into the industry.
- Support the development of networks or clubs, where national cohorts are small.

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The Medicines Manufacturing Industry needs to attract 3 new people for every 100 it employs each year from now till 2025!

Medicines Manufacturing in the UK 2017

Regulatory

by Yvonne Stewart

Head of Advocacy,

Global Product Quality, GSK

REGULATORY

- Connect and promote UK's regulatory environment as a core asset for medicine manufacturing investment.
- Support the UK's regulatory negotiations for Brexit.
- Provide industry's views and objectives in opportunity areas like ATMPs and innovative manufacturing technologies.

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Main Drivers

- **Support an effective regulatory environment and optimise UK framework for implementing established licensing and inspection legislation.**
- **Understand new challenges and shape the future regulatory framework for emerging products and technologies, e.g. ATMPs, digitalized, distributed and continuous processes and supply chains**

Specific Deliverables TBD – Key action pillars:	TARGET
Future proof the UK's regulatory environment and enable a long term medicines manufacturing strategy for the UK - Finalize and promote the regulatory optimisation paper - Continue close work with MHRA to understand their priorities for support – e.g. EU/UK transition.	Throughout 2017
Canvass existing and emerging regulatory challenges / opportunities across innovation areas: - Support MHRA in delivering the ATMT recommendations and set up technical workshops with industry - Liaise closely with the work of the ATMP Task Force and Technology Work Stream. - Leverage ABPI'/ BIA global outreach and ensure visibility of and alignment on technical and legal issues at the European and global level.	Q1-Q2 2017
Grow stakeholder engagement - Maintain effective connection across industry regulatory forums, including ABPI- PQEN, BIA-MAC	Throughout 2017

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Medicines Manufacturing in the UK 2017

MMIP Close Out

by Ian McCubbin

Senior Vice President for Global Supply and Manufacturing,
GSK & Former Chair MMIP

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.

Lunch & Site Tours

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Group	Agenda
Group 1 (Tax - Red)	12:00 – Zoladex Tour followed by Lunch
Group 2 (Skills - Green)	12:00 – Packing Tour followed by Lunch
Group 3 (Technology - Yellow)	Lunch followed by Zoladex Tour @ 12:45
Group 4 (Financial incentives - Blue)	Lunch followed by Packing Tour @ 12:45
All back in the Saffron Rooms by 14:00	

Review of 2017 MMIP activity will be showcased at BIA's

Annual bioProcessUK Conference

29-30 November, Cardiff

For further details please contact:
aengland@bioindustry.org

save, connect, influence

UK BioIndustry Association

For further details please contact

aengland@bioindustry.org

save, connect, influence

Taxis

- We have notified local companies, however, to avoid delays leaving site, you are best to pre-book your taxi to the station
  - Options include:
    - Macclesfield Radio Cars
    - **01625 421 111 or 01625 421 112**
    - Pronto Taxi - 07818991663

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Medicines Manufacturing in the UK 2017

How manufacturing might be evolving: current thinking on Advanced therapies and Advanced Manufacturing

Introduced by: Ian McCubbin

Supported by: Prof Lionel Clarke

Steve Bagshaw

Andy Evans

Roger Kilburn

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MMIP's Response to the Industrial Strategy

MMIP Response to the Industrial Strategy

by Andy Evans

Key asks from MMIP in letter to Sir John Bell

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Focus on Advanced Therapies and Advanced Manufacturing underpinned by 6 enablers:

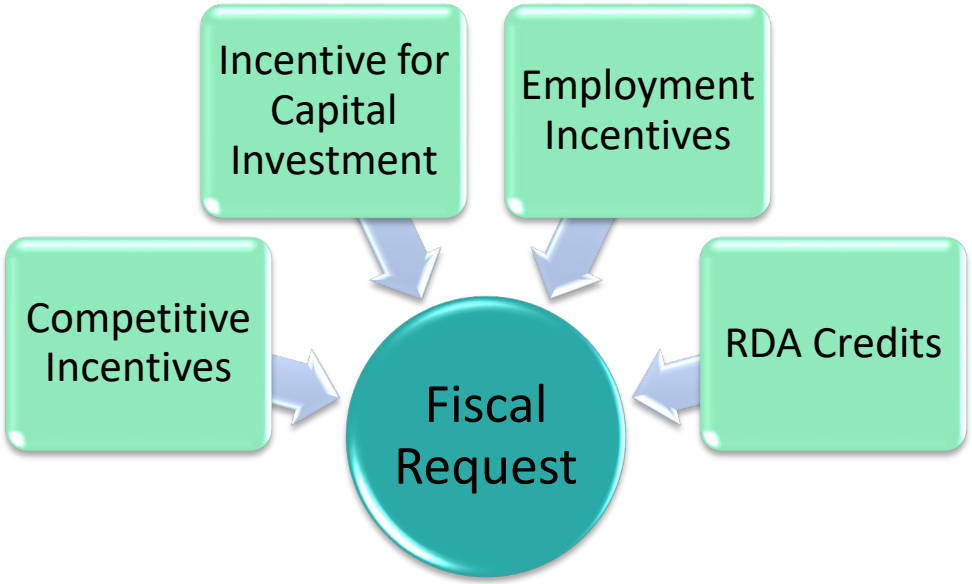
1. Further improvements to Tax and Capital Allowances
2. Skills Support
3. Financial Support and Incentives
4. Innovation Support
5. Strong Account Management
6. Market Access Improvements

MMIP's Response to the Industrial Strategy

Tax & Capital Allowances

By Richard Turner

Industrial Strategy – The Fiscal Request



MMIP's submission to Sir John Bell

Tax is a key issue in making manufacturing decisions. The UK situation has improved with a lower rate, targeted incentives such as the patent box and R and D credits but needs to remain competitive. An area that has lagged behind is improvements to the environment for encouraging high tech manufacturing and associated jobs and we strongly recommend targeted tax relief on incremental capital investment in order to improve the UK's position of 17th in the G20. This would cover incremental high tech buildings, and plant and machinery at rates similar to R&D incentives and would set the UK apart. Tax credits for incremental high tech jobs would also encourage investment and associated employment. When SMEs critically need to invest in GMP capability they would benefit greatly from tax credits, and we have recently submitted a proposal for an R&D allowance credit for capital investment as part of HMT's current review of research incentives.

Industrial Strategy – The Fiscal Request

Tax Breakout – Discussion

1 Is the UK competitive?

2 Which territories offer the greatest competition?

3 Has the fiscal environment (UK and International) influenced investment decisions?

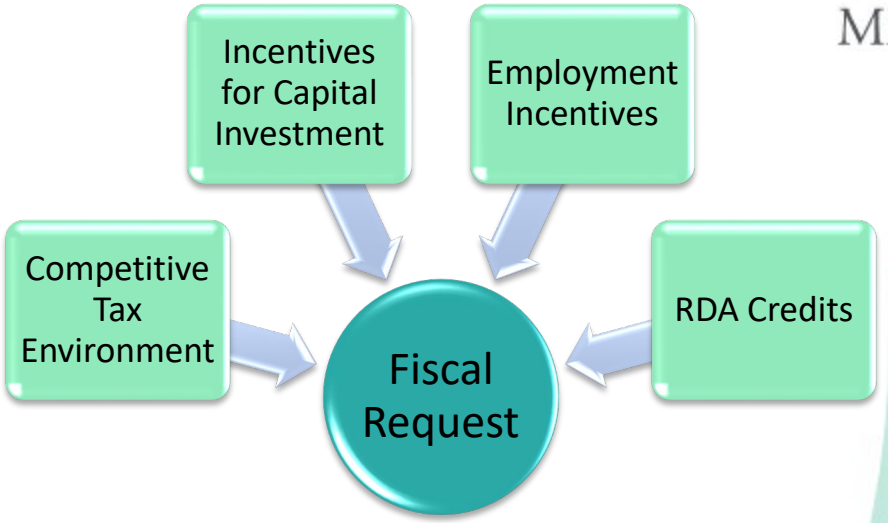
4 What should be preserved in the UK?

5 What are the principal disincentives?

6 What fiscal improvements would make most difference?

7 Tax incentives or Government grants?

Request – Case studies and representation



MMIP's Response to the Industrial Strategy

Skills

By Alex Felthouse

Skills Discussion Points

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- We are faced with challenges in attracting skilled people to our industry
- A strategy is required to enhance the focus on STEM subjects
- The need for an improved HE offering in practical skills for undergraduate, masters and doctoral levels.
- Provision of regional technical training centres

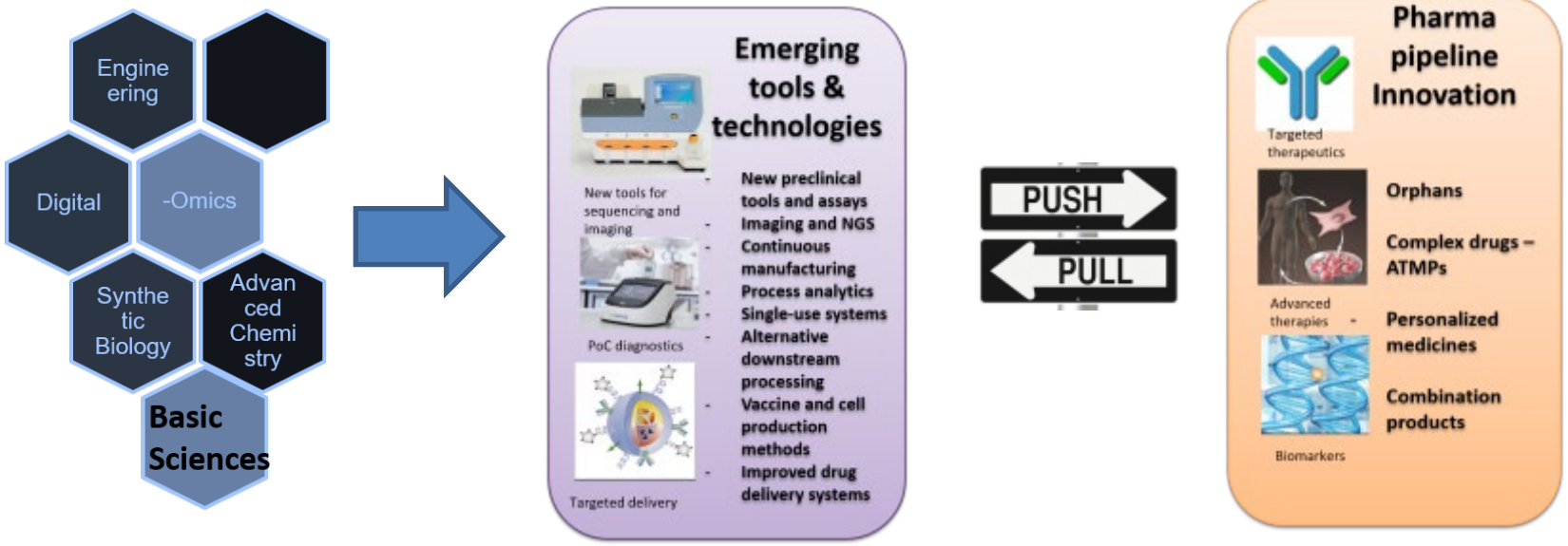
MMIP's Response to the Industrial Strategy

Technology & Innovation

By Magda Papadaki & Mike Sullivan

Sustain investment in the UK's science and manufacturing infrastructure

- Strengthen the UK research base by creating unique opportunities in the areas of personalised medicines, cell and gene therapies, genomics, diagnostics and digital technologies, as well as the underpinning tools, technologies and processes



To achieve this it will be important that funding is directed across a number of enabling areas, beyond the ongoing funding for basic science, that cover:

1. Cross-disciplinarity and collaboration across sectors and stakeholders
2. Measures to improve UK commercialisation and industrialisation of research
3. Skilled workforce and sustained talent pool
4. An enabling and future-proofed regulatory framework

1. REVOLUTIONIZING MEDICINES THROUGH ADVANCED MANUFACTURING TECHNOLOGIES

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A portion of funding should be devoted to the **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 (£28m), 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.

2. ADOPTING THE RECCOMENDATIONS OF THE ATMP MANUFACTURING TASKFORCE

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It is also critical that part of the £2b Fund is 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.

MMIP's Response to the Industrial Strategy

Financial incentives

By Andy Evans

MMIP's Response to the Industrial Strategy

Focus Groups

Focus Groups

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Group	Topic	Location	Facilitators
1	Tax	JC Ryle (2nd Floor)	Richard Turner Sarah Golding
2	Skills	Thomas Wardle (2nd Floor)	Alex Felthouse Tim Windle
3	Tech & Innovation	Saffron Rooms (1st Floor, here)	Magda Papadaki Mike Sullivan Andy Jones
4	Financial Incentives	Charles Roe (2nd Floor)	Andy Evans Matt Doherty

Medicines Manufacturing in the UK 2017

Focus Group Feedback & Open Discussion

Chaired by:	Andy Evans
Supported by:	Richard Turner
	Alex Felthouse
	Mike Sullivan
	Magda Papadaki

MMIP's Response to the Industrial Strategy

Closing Remarks by Andy Evans

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Drinks Reception

Security are on call until 18:30.

Please leave the building before this time

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Medicines Manufacturing
The Tax Environment

Richard Turner

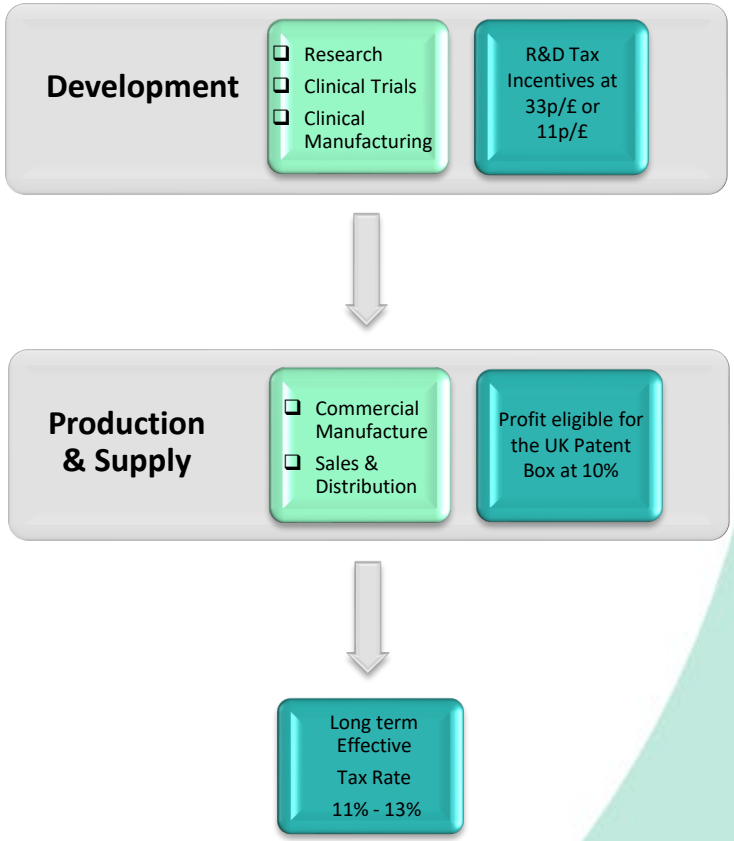
FTI CONSULTING

abpi BIA Innovate UK Knowledge Transfer Network

Benefits of retaining medicine manufacture in the UK

The UK has created a very favourable tax environment for innovation and commercialisation. In the past, UK companies would locate elements of the supply chain across two or more territories in order to optimise the tax position. The UK tax landscape has changed in recent years to present a much more compelling case for retaining the entire supply chain from development through to manufacture in the UK. The tax benefits of this are set out below with further efficiency through the lower cost of compliance with reduced cross border transactions and product flow.

- **Tax rates** – The current corporation tax rate is 20% regardless of the size of the business and will reduce to 17% by 2020. This is one of the lowest rates of tax among the developed economies, such as France (33%), Germany (30%-33%), US (35%-40%), Japan (30%), Ireland (12.5% trading income/25% non-trading income), Switzerland (10%-25%).
- **Patent box** – Tax on profits attributable to qualifying patented technologies is reduced to 10%. Enterprises undertaking all development and manufacture in the UK, might therefore expect a log term effective tax rate in the region of 11%-13%.
- **R&D relief** – Available to all companies undertaking qualifying R&D activities inc manufacturing for clinical development
  - For SMEs (less than 500 employees and either Annual turnover <€100m or Balance sheet <€86m) the relief ranges between 25p-33p/£ on qualifying expenditure and either reduces the tax liability or is repaid as a credit. Qualifying expenditure includes work contracted out to 3rd parties.
  - Where a group exceeds the SME criteria, it can claim a taxable credit (RDEC) of 11p/£ of qualifying expenditure. For Large Enterprises (non SMEs), qualifying expenditure does not include work contracted to 3rd parties or overseas connected companies.
- **Clinical manufacture** – With planning, a significant element of clinical manufacturing expenditure should attract the R&D incentive either at 33p/£ or 11p/£. This would include labour cost, materials and attributable utility costs. If this activity was undertaken in-house but outside the UK not only would these incentives no longer be available for large enterprises, it could impact the amount of patent box relief that is subsequently available.
- **Tax losses** – These can be carried forward indefinitely and offset against future profits and therefore shelter taxable income arising after product launch. Group relief also allows effective loss relief between connected parties.



Benefits of the UK for EMEA medicines manufacture

- **The UK as a Holding Company**
  - There is no withholding on dividends paid by UK companies
  - There is typically no corporation tax charged on dividends received from overseas subsidiaries
  - There is a capital gains tax exemption for gains arising on the sale of substantial shareholdings (where the holding company owns more than 10% of the ordinary share capital).
- **Double Tax Treaties** – The UK enjoys a comprehensive treaty network worldwide, resulting in the reduction or possible elimination of withholding taxes.
- **Tax Losses** – These can be carried forward indefinitely and offset against future profits and therefore shelter taxable income arising after product launch. Group relief also allows effective loss relief between connected parties.
- **CFC regime** – That only targets profits artificially diverted from the UK.
- **Tax Relief on Intangible Assets** – Intellectual Property Rights transferred to UK companies will attract tax relief in the UK as the assets are amortised or at 4% p.a.

MMIP

Medicines Manufacturing Skills

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