Medicines Manufacturing Industry Partnership

Follow the green, high-tech road:

A path to UK growth, net zero and health resilience from innovation in medicines manufacturing

June 2023

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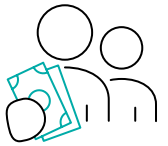
About the Medicines Manufacturing Industry Partnership

The Medicines Manufacturing Industry Partnership (MMIP) 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 an attractive, world-class, advanced centre for medicines manufacturing. MMIP represents the voice of medicines manufacturers in the UK, encompassing the full spectrum of companies from SMEs to large multinationals, and it is an expert sub-group of the government's Life Sciences Council.

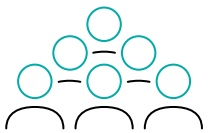
MMIP's remit includes both medicines and vaccines and throughout this report the term medicines manufacturing will be used to refer to the manufacture of both medicines and vaccines.

Almost **45%** of the **£36.9bn** value delivered by life sciences is from **medicines manufacturing**

Medicines manufacturing sites generated **£35.1bn UK turnover** in 2021 and exports of over **$25bn** in 2020



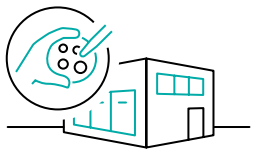
The **average medicines manufacturing job** contributes **£128,000** to the wider economy



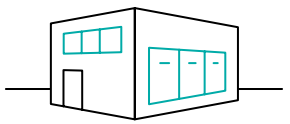
Life sciences manufacturing employs **115,200** people

Size of the prize

Opportunity for £15bn new medicines manufacturing investment over 10 years, supporting 116,600 jobs



There are over **2,000 medicines manufacturing sites** in the UK, **27%** of total **life sciences sites** in 2021



UK manufacturing space for advanced therapies now totals **17,000m²**

The **global vaccines market** is expected to grow at a rate of **10.2%** up to 2026

The **global needle-free injection market** is expected to grow from **$124m in 2021** to **$272m by 2026**

Executive summary

A vision for 2030 and beyond

Medicines manufacturing delivers the largest share of economic activity within the UK life sciences sector. Notwithstanding the strength of UK medicines research and development, it is manufacturing that generates the majority of the life sciences jobs and revenues that power the UK economy. The diverse geographic footprint of medicines manufacturing facilities across the UK also means the sector contributes high quality, well-paid jobs in traditionally less prosperous areas.

For the UK to achieve the status of a global life sciences superpower, it must maximise its participation in this vibrant global growth sector.[1] Every effort should be made to ensure not just that we discover and develop the medicines of the future, but that we make a significant share of them in the UK too.

The manufacture and supply of advanced medicines is rapidly changing, offering a huge opportunity for the UK. In this report, MMIP calls for focused action for medicines manufacturing in key areas that build on the work of recent years and accelerates progress in improving the UK's competitive position versus other potential investment locations.

MMIP believes the UK can be recognised as the best global location for innovative and environmentally sustainable medicines manufacturing, delivering health security and nationwide economic prosperity. This paper sets out a series of targeted policy recommendations which, if adopted, could reasonably be expected to attract a portfolio of new investments worth around £1.5bn each year over the next decade, creating 26,500 new jobs in the sector and supporting 90,100 jobs in the wider economy.

Medicines manufacturing has been a traditional strength for the UK, which in recent years has performed particularly strongly in the Advanced Therapy Medicinal Products (ATMPs) sector. However, other leading destinations for medicines manufacturing investment such as Ireland, Singapore, France and the US have performed strongly and are driving intense competition with ambitious, well-funded government support in place.

Manufacturing investments have long lead times and, once made, are "sticky", anchoring future activity due to the significant investment in physical infrastructure and specialist workforce requirements. The UK must plan now for 2030 and beyond, focusing on future healthcare and economic needs and ensure the right government support is consistently in place over several years to deliver a competitive global performance.

The innovative path to growth

The rapid pace of medical innovation is having profound consequences for medicines manufacturing. Serious medical conditions are increasingly being treated with highly innovative advanced therapies. Making these therapies requires new approaches and, as a result, manufacturing innovation is fundamental. Countries that create a strong manufacturing innovation ecosystem will attract the greatest investment from life sciences companies.

1 Pharmaceutical Manufacturing Market Size Report, 2021-2028 (grandviewresearch.com); (accessed 31/03/23)

The UK has already demonstrated how success can be achieved. In 2016, the Advanced Therapies Manufacturing Taskforce delivered a strategic plan that included: the establishment of dedicated innovation centres; joint funding to support increased industry manufacturing capacity; an end-to-end skills plan; and a network of treatment centres to enhance NHS readiness to adopt the innovation. This approach has been highly successful, with the UK now occupying a strong global position and year-on-year growth in advanced therapy manufacturing capacity and capability. Two of the 10 Advanced Therapy Medicinal Products (ATMPs) approved for use in the UK are in-part manufactured here, and UK-based companies attracting £5.5bn of investment.[2]

The flexibility and agility of this infrastructure and domestic capbility was also instrumental in enabling rapid manufacturing of the Oxford/AstraZeneca Covid-19 vaccine during the COVID-19 pandemic. This highlighted the benefits of a strong manufacturing base within established companies for health resilience and also helped attract companies such as Moderna, BioNTech, Catalent and Fujifilm to make major investments in the UK.

Building on this success, the UK now has the opportunity to create a vibrant innovation ecosystem that will attract the next wave of manufacturing investments. With leading research, infrastructure, skills and capabilities in digitalisation, automation, robotics and more, the UK can be a global leader in the manufacture of the next wave of growth technologies such as oligonucleotides, nucleic-acid based-medicines and vaccines, as well as continue to drive its leadership position in ATMPs.

The green path to growth

The healthcare sector contributes 4-5% of global carbon emissions, much of which comes from supply chains. The NHS and other national healthcare systems are demanding greener medicines. Countries that provide an environment conducive to the manufacture of green, low-carbon medicines will be well placed to facilitate exports to a global market and attract investment from global companies which increasingly have their own ambitious environmental sustainability targets.

The transition to green medicines manufacturing will also be underpinned by innovation. There is now a significant opportunity for the UK to gain global competitive advantage, and to capture investment from locations without the same net zero commitment, through a clear focus on innovating in environmentally sustainable medicines manufacturing. This will require a three-pronged strategy: defining international manufacturing standards for greenhouse gas emissions; establishing the infrastructure for sustainable medicines and vaccines technology; and creating a technology and innovation roadmap for environmentally sustainable medicines manufacturing.

2 Cell and Gene Therapy Catapult Annual Review, 2022 (digitaloceanspaces.com); (P.8 accessed 16/05/23)

An operating environment conducive to growth

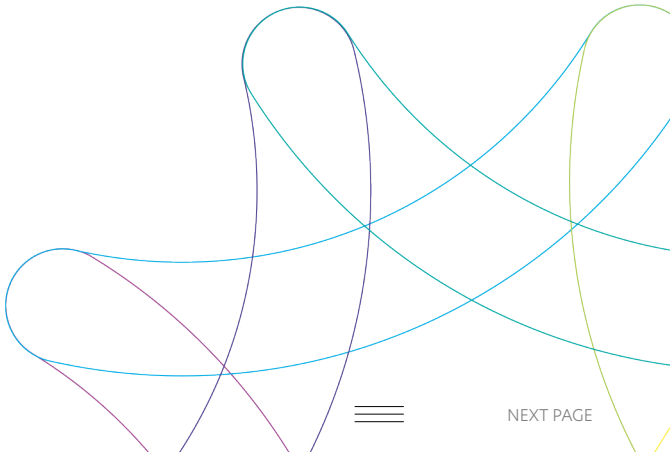
This report focuses primarily on the future of medicines manufacturing and the huge opportunities available to the UK to lead in environmentally sustainable and innovative manufacturing given our infrastructure and capabilities. However, the overall life sciences policy and regulatory environment is also critically important. Recent success in attracting investment in ATMP research, development and manufacturing highlighted the value of an overall favourable ecosystem in which, for example, the NHS played a key part by facilitating early adoption of cell therapies into NHS treatment via its Advanced Therapy Treatment Centres.

Key areas where policy has a large bearing on UK competitiveness for medicines manufacturing investment include: taxation; the attractiveness of the domestic commercial environment; access to a highly skilled workforce; the effectiveness with which government interacts with potential investors; and ease of trade with other countries.

MMIP welcomes recent government measures to improve the fiscal operating environment for innovative and capital-intensive businesses, such as the introduction of the Full Expensing Capital Allowances scheme, and highlights further fiscal and taxation reforms which would increase the UK's ability to compete for globally mobile life sciences investments.

Focused approach

MMIP strongly believes that focusing government support around these three key themes will deliver growth from medicines manufacturing, as well enhanced health resilience and accelerated progress to Net Zero and sustainability goals. A joined-up approach also is required across the medicines manufacturing ecosystem, from research phases through to industrial deployment, to ensure policy and investments are targeted in these key areas for maximum impact.



Summary of recommendations

MMIP is making nine key recommendations to government and looks forward to an ongoing partnership to build support for their adoption and implementation:

To drive growth from leadership in environmentally sustainable manufacturing:

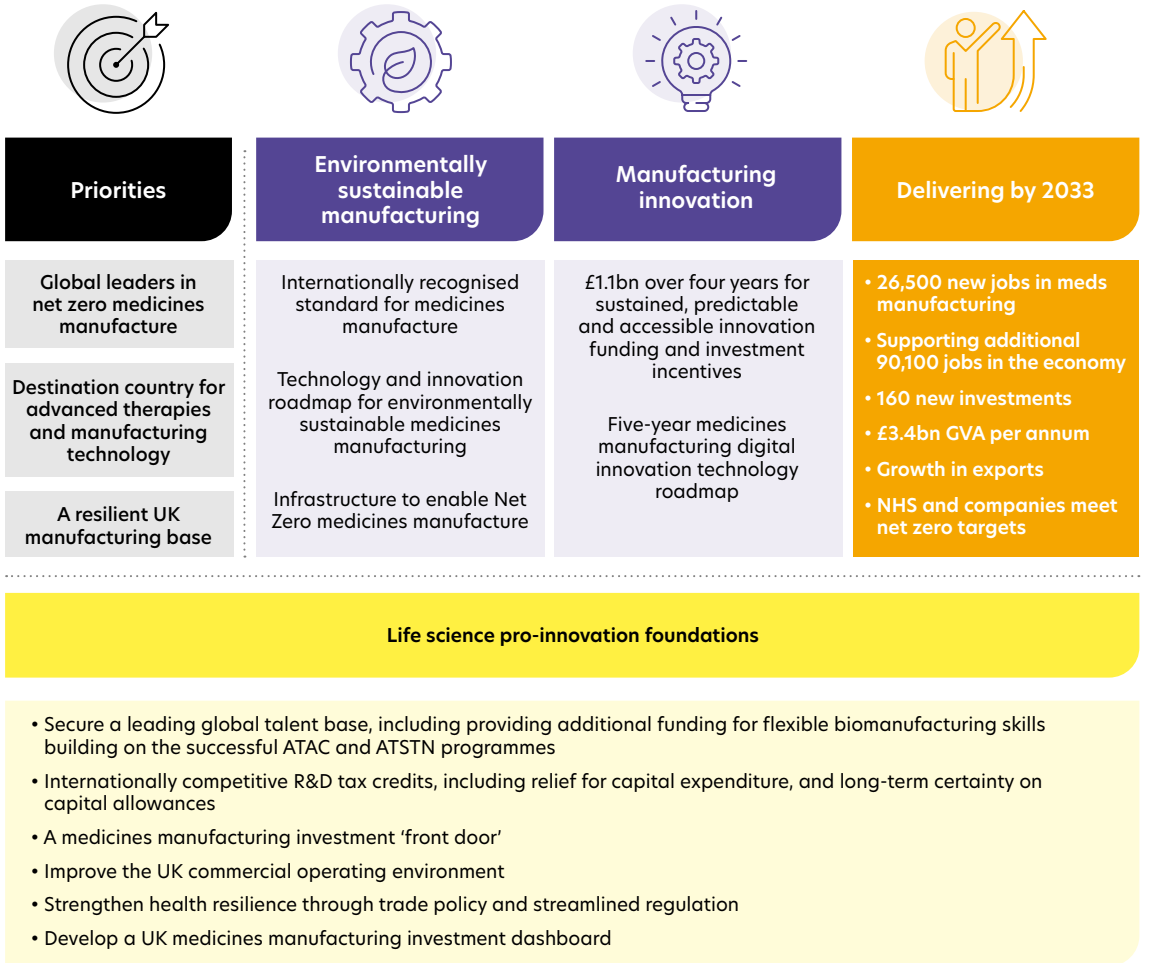
- Implement a three-point plan to deliver global leadership in environmentally sustainable medicines manufacturing:
  - Develop an internationally recognised standard for medicines manufacturing Greenhouse Gas emissions
  - Develop a technology and innovation roadmap for environmentally sustainable medicines manufacturing
  - Establish the infrastructure to enable net zero medicines manufacture

To drive growth from leadership in manufacturing innovation:

- £1.1bn over four years to provide sustained, predictable and accessible innovation funding and investment incentives:
  - £200m over four years for collaborative R&D grants
  - £900m over four years for medicines manufacturing capital grant funding to unlock £6bn of industry investment
- Create a five-year digital innovation in medicines manufacturing technology roadmap, including:
  - Establishing a world-class UK Medicines Manufacturing Data Institute
  - Fund next generation oligonucleotide manufacturing capacity

To drive growth by fostering a pro-innovation operating environment:

- Set internationally competitive R&D tax credits, including relief for capital expenditure, and long-term certainty on capital allowances
- Create a medicines manufacturing investment “front door”
- Secure a leading global talent base, including providing additional funding for flexible biomanufacturing skills building on the successful programmes such as the Advanced Therapy Apprenticeship Programme (ATAC) and Skills and Training Network (ATSTN)
- Improve the UK commercial operating environment
- Strengthen health resilience through trade policy and streamlined regulation
- Develop a UK medicines manufacturing investment dashboard



Introduction

In January 2023 MMIP published a white paper[3] setting out progress made in creating a vibrant ecosystem for medicines manufacturing as identified in the Government's 2021 Life Science Vision.[4] This follow-up paper sets out a longer-term vision for UK medicines manufacturing, identifying opportunities and areas of priority focus required for the UK to position itself as a location of choice for manufacturing investments. It puts forward ambitious and actionable recommendations that government can take forward to create a globally competitive investment environment for medicines manufacturing. In doing so, the UK can capture more of the downstream economic benefits from a world-leading research and innovation ecosystem and from the global green-led economic transformation that is underway.[5]

The report is timely given the recent creation of a Department for Science, Innovation and Technology (DSIT) to drive the innovation that will "create new and better-paid jobs and grow the economy". MMIP fully supports the vision set out by DSIT in its recently published Science and Technology Framework for the UK to become a science and technology superpower by 2030, and considers that the recommendations made here can help turn that vision into reality.

a. Manufacturing as the major life sciences contributor to the UK economy

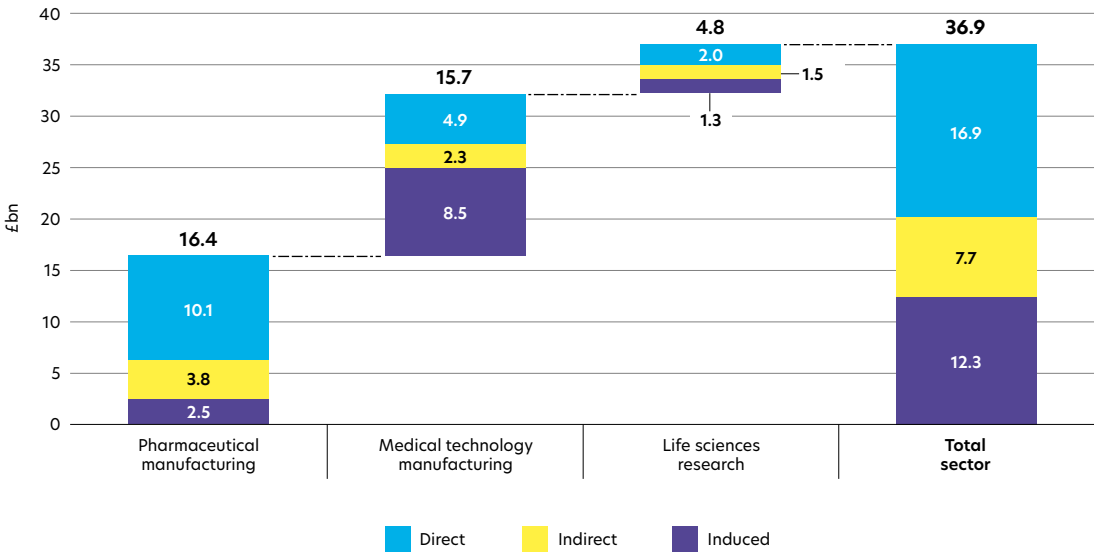
Within the UK life sciences sector, medicines manufacturing is the largest contributor to the economy. The UK has a globally leading position in scientific research and the early stages of medicines development across many emerging and established technology areas, such as immunotherapies, vaccines, cell and gene therapies, but it is manufacturing that delivers the largest share of jobs and economic activity. New paradigms of patient-centric healthcare that are now emerging will require a much closer interaction across the entire manufacturing and treatment cycle.

Learning from previous loss of value, it is critical that the UK not only discovers and develops new medicines but also manufactures them for domestic and export use, to capture the full economic benefits the sector has to offer and provide a resilient manufacturing base for future healthcare crises. For example, much of the critical early innovation and discovery work for monoclonal antibodies was performed in the UK but unfortunately very little of the long-term manufacturing is established here. It is critical that the UK not only discovers and develops new medicines but also manufactures them, for domestic use and export, in order to capture the full economic benefits the sector has to offer and provide a resilient manufacturing base for future healthcare crises.

Almost 45% of the £36.9bn of Gross Value Added delivered by the life sciences industry can be attributed to medicines manufacturing alone[6] (2019 data – see Figure 1). Manufacturing sites generated £35.1bn of turnover in the UK in 2021[7] and exports of over $25bn in 2020.[8]

3 Fulfilling the potential identified in the Government's Life Sciences Vision, 2023 (abpi.org.uk)
4 Life Sciences Vision, 2021 (assets.publishing.service.gov.uk)
5 Industrial Strategy, 2017 (assets.publishing.service.gov.uk)
6 Life Sciences Superpower, 2022 (abpi.org.uk)
7 Bioscience and health technology sector statistics, 2021 (gov.uk); (Section 8.1)
8 Life Sciences Competitiveness Indicators, 2022 (gov.uk)

Figure 1. Gross Value Added delivered by the life sciences industry



b. High quality jobs nationwide

There are over 2,000 medicines manufacturing sites in the UK, representing 27% of the total number of sites operating in the life sciences industry (2021 data)[9], ranging from flexible clinical trial sites to larger commercial operations. Life sciences manufacturing employs 115,200 people[10], with the UK in fourth place out of 12 high-income comparator countries.[11] These jobs are high quality and well-paid, generating an average GVA contribution to the economy of £128,000 per employee,[12] and encompass opportunities for STEM school leavers, apprentices, university graduates, and people changing careers later in life.

9 Bioscience and health technology sector statistics, 2021 (gov.uk)
10 ibid
11 Life Sciences Competitiveness Indicators, 2022 (gov.uk); (Figure 14)
12 Life Sciences Superpower, 2022 (abpi.org.uk)

Importantly, employment is already well dispersed across the country with regions such as Yorkshire and North-West England benefitting significantly from investments in the sector[13] (See Figure 2). Additional investment in medicines manufacturing can therefore be expected to benefit less economically advantaged regions of the country. **A recent example includes the £151m investment by Pharmaron, supported by a Life Sciences Innovative Manufacturing Fund (LSIMF) grant, in their gene therapy manufacturing facility in Speke, Liverpool.**[14]

Distributed impact is also seen through the supply networks required to support these operations, from construction and advanced engineering through to component manufacturers and training centres.

CASE STUDY: Merit

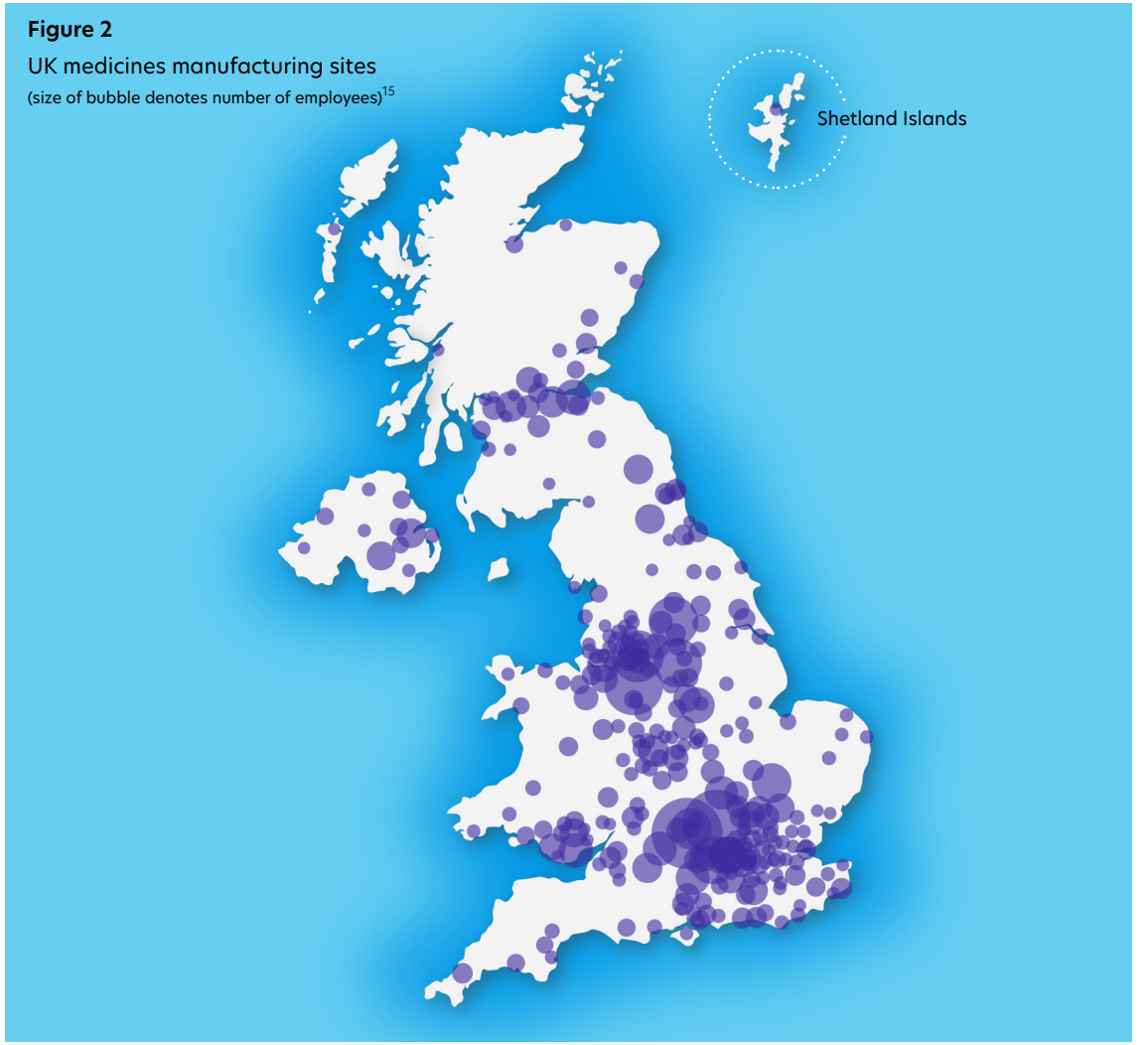
Based in the North East of England, and employing 329 staff, Merit completes 95% of its facility construction and validation off-site. Combining this off-site manufacturing with a standard design process, using standardised methodologies, its facilities can be validated in days, and are net-zero in their operations. Merit's approach was first proven when it worked with the Cell and Gene Therapy Catapult to deliver six new flexible manufacturing modules for the Stevenage Manufacturing Innovation Centre expansion.

Following this, it has also delivered Autolus Therapeutics' cell therapy facility in Stevenage, three years earlier than traditional construction methods, a mRNA vaccine manufacturing facility for CPI, Darlington, in 32 weeks compared to 18 months, and is set to build one of the two buildings that will make up the new Moderna Innovation and Technology Centre (MITC) at Harwell Campus. Merit's ability to deliver Moderna's laboratories in less than 12 months has enabled Moderna to accelerate its development work in the UK.

Figure 2

UK medicines manufacturing sites

(size of bubble denotes number of employees)[15]



13 Bioscience and health technology sector statistics, 2021 (gov.uk); (Section 8)

14 Pharmaron Invests £151M into UK Gene Therapy CDMO with Support from UK Government Grant, (pharmaron.com); (accessed 18/04/23)

15 BaHTSS (using pharmaceutical development and manufacturing SIC codes (CSV file)

c. Resilience in the face of future health emergencies

The close collaboration and partnership between UK-based medicines manufacturers and the government in response to the COVID-19 pandemic is well documented, including the importance of a strategy driven by leaders with real expertise in the field. For example, collaboration between staff at the UK manufacturing innovation centres, Oxford Biomedica and members of the University of Oxford/AstraZeneca consortium was critical to enable the sector to mobilise at speed to manufacture the AstraZeneca COVID-19 vaccine.

The COVID-19 pandemic also demonstrated that the capability to manufacture new medicines at scale during a health emergency is a critical factor in ensuring health resilience. Countries with substantial manufacturing capacity and skilled workforces were able to repurpose facilities to produce treatments and vaccines domestically that reduced their dependence on stretched international supply chains during a period of high global demand.

Increasing inward investment in medicines manufacturing in the UK will expand the UK's domestic manufacturing footprint and skilled workforce, increasing the breadth and capability of the sector to deploy countermeasures to a future unknown health emergency or respond to global supply challenges, resulting in corresponding increases in health resilience.

CASE STUDY: Oxford Biomedica: Rising to the COVID-19 vaccine challenge

Founded as a spin-out from the University of Oxford in 1995, Oxford Biomedica was the first commercial manufacturer of viral vector-based vaccines and therapeutics in the UK. Today, the company is split across several locations in Oxfordshire and employs more than 670 highly-skilled people. Throughout its growth, Oxford Biomedica has benefited from capital funding through the Medicines Manufacturing Challenge to expand its manufacturing facilities. This has attracted further investment through the public markets, enabling the building of Oxbox, a manufacturing site in Oxford that was opened in January 2020 and became integral to the UK's COVID-19 response. Through a collaboration with the Vaccines Manufacturing Innovation Centre (VMIC), the company was able to secure a deal with AstraZeneca to produce over 100 million doses of its vaccine. These vaccines were used to protect nearly a third of the UK population, helping to bring society back to normality.[16]

CASE STUDY: Moderna

A 10-year UK government partnership with Moderna will see the company make a significant investment in resesarch, development, and manufacturing in the UK. The Moderna Innovation and Technology Centre (MITC) at the Harwell Campus in Oxfordshire will manufacture mRNA vaccines for a wide range of respiratory diseases. The site will employ more than 150 people and manufacture between 150-250 million vaccines doses per year from 2025, increasing onshore supplies of COVID vaccines and bringing much-needed resilience to the UK's vaccine capability.

d. Intense global competition for investment

Despite the economic importance of the medicines manufacturing sector in the UK, the highly competitive global environment has seen manufacturing investment in the UK challenged in recent years. Though there has been significant growth in certain modality areas, such as cell and gene therapies and vaccines, overall the growth of manufacturing sites in the UK has fallen behind that of non-manufacturing sites.[17] The UK's exports, whilst still substantial, have steadily declined in the 5 years leading up to 2020,[18] whilst other comparator countries increased their export volumes.

16 Medicines Manufacturing Challenge Report, 2021 (ktn-uk.org); (P.13 accessed 19/04/23)
17 Bioscience and health technology sector statistics, 2021 (gov.uk); (Figure 17)
18 Life Sciences Competitiveness Indicators, 2022 (gov.uk); (Figure 17)

Exports 2015-2020[19]

Table 1: Medicine exports and trade balance for UK and comparator countries

Country	Exports ($m)		Trade Balance ($m)	
	2015	2020	2015	2020
Belgium	16,693	48,832	3,008	9,267
France	30,732	38,684	4,538	7,233
Ireland	33,423	66,222	27,053	56,670
Italy	21,112	37,757	-2,522	7,016
UK	36,749	25,916	2,132	-842

Recent challenges in attracting medicines manufacturing into the UK reflect the intense global competition for investment into this high value sector. Competitor countries are working extremely actively to offer incentives to attract globally mobile investments. The Biden administration in the US, for example, recently announced a biotechnology and biomanufacturing strategy supported by an initial $2bn in funding with an objective to improve and expand domestic biomanufacturing production capacity and processes.[20] Members of the European Union have proposed a Critical Medicines Act with a "toolbox of different instruments" to reduce EU dependency on third countries for the supply of medicines.[21]

This emphasises the need to act to secure future investment and growth in high-tech manufacturing capabilities. For the UK to compete effectively in the future it will require an offer that matches or exceeds that available in other advanced economies.

19 Life Sciences Competitiveness Indicators, 2022 (gov.uk); (accompanying data tables (Tables 19 and 21))
20 Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable Safe and Secure American Bioeconomy, 2022 (whitehouse.gov); (accessed 12/05/23)
21 Non-Paper Security of Medicines Supply, 2023 (politico.eu); (accessed 12/05/23)

CASE STUDY: France

France has set an ambition to shape the country into 'the leading European nation in innovation and sovereignty in healthcare'. The ambition is supported by a €7 billion funding target, which includes €800M for the development and production of biomedicines and €1 billion to support 123 projects that will rebuild healthcare manufacturing capabilities.[22] Just Recently, the French government announced plans to offer price increases for domestically produced medicines "for which it is necessary to secure supply, due to their innovative character or to the existence of a risk of stock shortages."[23] The fruits of this strategy may already be visible, with Pfizer recently announcing plans to make a €520 million investment in the country over the next five years, aiming to bring additional manufacturing and R&D to France of its antiviral COVID-19 treatment.[24]

CASE STUDY: Ireland

Ireland is one of the leading locations for manufacture of medicines in Europe.[25] The historically low corporation tax rate (12.5%), a highly regarded investment "front door" service, a strong talent pool and government support has secured over €10bn in inward investment in biopharmaceutical manufacturing.[26] Other initiatives intended to help promote the growth of Ireland's knowledge economy have equally supported this investment, with a national network of technical training institutes developed in the 1970s and a concerted effort since the early 2000's to offer skilled labour and support specifically for biopharmaceutical manufacturers.[27] Recent announcements by Pfizer and AstraZeneca to invest €300m and $360m respectively in new manufacturing sites[28,29] along with government funded expansion of the National Institute of Bioprocessing Research and Training (NIBRT)[30], have cemented this position.

22 Heathcare Innovation 2030 - Strategic Council for the Healthcare Industries (CSIS), 2021 (investinfrance.fr);
23 Neil Grubert France PLFSS Pharmaceutical Activity LinkedIn Post, 2023 (linkedin.com); (accessed 01/05/23)
24 Pfizer Announces 20 million Euro Investment in France to Fight Covid-19, 2022 (france24.com)
25 A Resurgence in Irish Pharma, 2016 (pharmaboardroom.com)
26 Life Sciences Superpower, 2022 (abpi.org.uk)
27 A Resurgence in Irish Pharma, 2016 (pharmaboardroom.com)
28 Astrazeneca Chooses Ireland for $360m Manufacturing Site, 2021 (pmlive.com)
29 Pfizer Announces 300m Euro Investment Irish Manufacturing Sites, 2020 (pharmafile.com)
30 NIBRT Announces Construction Start for a New Advanced Therapeutics Facility at its Dublin Site, 2022 (nibrt.ie)

A UK success story: Cell and gene therapy (ATMP) manufacturing

Cell and gene therapies (classified as Advanced Therapy Medicinal Products or ATMPs) are amongst the most complex and advanced therapies under development. They use genes, cells, or tissues to precisely target and treat the underlying cause of a disease,[31] often achieving exceptional health outcomes.

Notwithstanding the efforts of governments in competitor countries, in the ATMP sector the UK has shown that it can be successful and achieve a strong position in medicines manufacturing by adopting a strategic and proactive approach involving close collaboration between industry and government.

a. Focused and sustained government support

Focused and sustained support from the UK government consolidated the UK's early lead in ATMP research, development and manufacturing. The joint UK Government and MMIP 2016 Advanced Therapies Manufacturing Action Plan set out six key asks to anchor commercial scale manufacturing of ATMPs in the UK. Following this, the Industrial Strategy Challenge Fund invested in a holistic, UK ATMP ecosystem by: delivering increased viral vector manufacturing capability and capacity with the expansion of Oxford Biomedica, Cobra Biologics[32] and the Cell and Gene Therapy Catapult; initiating an end-to-end UK wide talent plan of relevant skills via the Advanced Therapy Apprenticeship Programme (ATAC) and Skills and Training Network (ATSTN); establishing a world-first network enabling best practice and NHS readiness for ATMPs via the Advanced Therapy Treatment Centres (ATTCs); and through joined-up, innovative and responsive regulation via the Medicines and Healthcare products Regulatory Agency (MHRA).

b. Strong global position

The result of these, and other targeted investments and initiatives, is that the UK remains in a strong, global position to capture the economic value of ATMPs. Whilst there has been a 13% decline in ATMP clinical trials worldwide,[33] the number in the UK has increased year on year.[34] Commercially sponsored trials accounted for around 80% of all UK ATMP clinical trials, demonstrating the attractiveness of the UK to commercial sponsors.[35]

31 Advanced Therapy Medicinal Products Overview, (ema.europa.eu)
32 Improved Healthcare for All Pioneering Projects Get Funding, 2018 (gov.uk); (accessed 29/03/23)
33 Clinical Trials Database Report, 2022 (digitaloceanspaces.com); (accessed 29/03/23)
34 ibid
35 ibid

UK ATMP manufacturing space has grown year-on-year, and now totals 17,000m^2.[36] Of the ten ATMP therapies that are approved in the UK, and reaching patients,[37] two have manufacturing operations in the UK.[38] More future growth is expected, bolstered by the UK government's Life Sciences Innovative Manufacturing Fund.

c. Global competition

This early success story has been driven by a supportive policy environment, allowing the UK to capitalise on its excellent research base and get ahead of global competitors.

However, as the ATMP field advances, so does global activity. The US Biden-Harris Administration recently announced their goals and priorities to advance American biotechnology and biomanufacturing, including cell-based therapies and gene-editing.[39] According to the Alliance for Regenerative Medicine, Asia-Pacific countries have had the greatest increase in therapy developer numbers, with China the fastest growing country.[40]

d. Stay competitive

Due to their complexity, ATMPs are some of the most difficult medicines to make, test and characterise. For these reasons, once established in a facility with a highly skilled team, they are hard to relocate. ATMP manufacturing also provides the UK with health resilience as the skills and biological manufacturing capacities can be adapted for other modalities, such as vaccines, as demonstrated during the Covid-19 pandemic.

It is therefore imperative that the UK continues to develop ATMP manufacturing activities, including both early and late-stage production, to secure future, larger manufacturing operations and maintain these "sticky", high value-added jobs. Whilst space and facilities are important, ATMP manufacturing should be co-located with research centres of excellence, process and analytical development and adjacent industries in high productivity clusters distributed around the UK. A pipeline of highly skilled manufacturing personnel, supported through the skills programmes delivered by the Cell and Gene Therapy Catapult and widely adopted by organisations across the sector, will best position the UK to continue to take advantage of this revolution in healthcare.

36 Cell and Gene Therapy GMP Manufacturing in the UK Capability and Capacity Analysis, 2022 (digitaloceanspaces.com); (accessed 29/03/23)
37 Cell and Gene Therapy Catapult Annual Review, 2022 (digitaloceanspaces.com); accessed 29/03/23
38 Internal CGTC data, extracted from Global Data
39 Biden-Harris Administration Announces New Bold Goals and Priorities to Advance American Biotechnology and Biomanufacturing, 2023 (white-house.gov) and Bold Goals for U.S Biotechnology and Biomanufacturing, 2023 (whitehouse.gov)
40 Alliance for Regenerative Medicine, 2022 (alliancerm.org); (accessed 29/03/23)

CASE STUDY: Autolus: From spin out to a potential billion-dollar business

Autolus makes personalised cancer treatments known as CAR-T cell therapies. These are created by harvesting a patient's own immune cells, modifying them, before returning them to the patient where they locate and destroy tumours. Since its founding in 2014 as a spin-out from UCL, Autolus has received £7.4m in funding from Innovate UK's Medicines Manufacturing Challenge Fund, to help develop innovative manufacturing approaches, and has received additional investment of approximately $995m to date.

Autolus originally established its clinical trial manufacturing capability in collaboration with the Cell and Gene Therapy Catapult Manufacturing Innovation Centre in Stevenage. It is currently building a 70,000sq ft flagship manufacturing facility in Stevenage, which will provide capacity for approximately 2,000 batches per year with room for expansion.

A 10-year vision for renewed leadership

Medicines innovation is evolving rapidly and is providing highly effective means of treating patients with new technologies and scientific modalities. Technologies such as cell and gene therapies and oligonucleotides utilise very different approaches to those of traditional medicines. For example, cell therapies used in the treatment of blood cancers involve genetically engineering the patient's own blood cells to target and fight cancer cells. This requires highly complex manufacturing approaches and new skills that are distinct from those involved in manufacturing traditional "small chemical molecule" medicines. New technology such as artificial intelligence and robotics are providing far-reaching opportunities to transform manufacturing processes and significantly enhance productivity.

At the same time, the global drive for a reduction in carbon emissions to address climate change requires imagination and innovation by medicines manufacturers. Governments can play a role by providing an environment conducive to the manufacture of low-carbon, sustainable medicines. Those that do will be well-placed to facilitate exports to a global market and attract investment from global companies who, in turn, have their own, in many cases very ambitious, emissions and sustainability targets.

Vision statement

Vision statement MMIP believes the UK has the potential to be the best global location for innovative and environmentally sustainable medicines manufacturing, delivering health security and nationwide economic prosperity.

Investment ambition

Implementing the strategy and specific interventions set out in this paper, along with sustained partnership across the manufacturing ecosystem can realistically be expected to secure a portfolio of new manufacturing investments for the UK worth an estimated £1.5bn annually for the next ten years. With the focused approach to policy development and government support advocated here, this investment will not only deliver economic benefits, including an estimated 26,500 new jobs in the sector, but also make a major contribution to environmental sustainability and health resilience.

Expected annual new investment portfolio

New manufacturing investments (per annum)	Value (per investment)	Estimated direct employment
1 large	£250m - £500m	400 est. range 300-500
5 medium	£100m - £250m	1000 est. range 200 per investment
10 ecosystem supplier investments	<£50m	1250 est. range 125 per investment
10-YEAR TOTAL:	**£15bn**	• 26,500 direct employment • Supporting an additional 90,100 jobs in the economy[41] • £3.4bn additional GVA per annum into the Life Sciences sector[42]

Methodology

MMIP produced estimates for the number of new targeted investments that could be expected to be secured for the UK if a range of new policy measures and incentives were introduced. The estimates were based on interviews with a number of industry experts. Interviewees were also asked to provide estimates for the number of jobs associated with each investment. These estimates were then validated against the total value of applications into the Life Sciences Innovative Manufacturing Fund (LSIMF) (£2bn). The total number of new investments annually (15) represents approximately 1.5% year on year growth of UK medicines manufacturing sites with 50 or more employees.

41 Multiplier of 4.4 used from: The Economic Contribution of the UK Life Sciences Industry; PWC; 2017 (abpi.org.uk); (P.11,35 accessed 03/05/23)

42 £128k Life Sciences Manufacturing GVA per Employee Used from PWC/ABPI Life Sciences Superpower, 2022 (abpi.org.uk); (P.28 accessed 03/05/23)

Growth opportunities

Significant opportunities exist for the UK to leverage existing infrastructure and capabilities to attract manufacturing investment for emerging new technologies. In addition to ATMPs, MMIP is highlighting two additional technologies, oligonucleotides and vaccines where the UK is well positioned to capitalise with the right intervention and support:

Oligonucleotides

Oligonucleotides are a novel class of therapeutic molecule for the treatment of a wide variety of diseases. They are short pieces of modified DNA, typically around 20 nucleotides in length, and their ability to interact with cell protein expression mechanisms provides a unique flexible platform capable of targeting genes associated with specific diseases. Historically, they have been used to treat rare diseases, however there is now an exponential growth in their application to large-population, chronic diseases, often untreatable by traditional small molecule therapeutics.

The recent acceleration in regulatory approvals (currently 15 approved oligonucleotide therapeutics), combined with the advances in cellular delivery and organ targeting mechanisms, have significantly increased confidence in the oligonucleotide therapeutic market. In 2019, the global market size was US$2.7bn, and it is expected to reach US$8bn by the end of 2026, with a "compound annual growth rate (CAGR) of 16.7%.

Global companies have signalled the intention to make large investments into current manufacturing capacity and have unanimously confirmed the critical need for manufacturing innovation, as well as skills and investment support, to secure oligonucleotide commercial viability.

The UK has a significant opportunity to attract major inward investment by capitalising on its current investments in the Nucleic Acid Therapy Accelerator (NATA), the joint Innovate UK and industry-funded Grand Challenge programme at CPI's Medicines Manufacturing Innovation Centre (MMIC), and through collaborative innovation such as the Innovate UK Transforming Medicines Manufacturing programmes.

Vaccines

The demonstrated success of technologies such as mRNA and viral vector vaccines during the COVID-19 pandemic brought vaccination into the public eye in an unprecedented way. The pandemic also highlighted the need for continued innovation, for example, to increase the speed of vaccine deployment and administration and thereby prevent disease mortality and damage to economies.

Traditional modes of delivery, such as cold chain-dependent storage, needles and vials (requiring medically trained staff), add to the cost and complexity of the global roll-out of vaccines. It is therefore clear that there is a need for alternative routes of vaccine administration both in the UK and globally.

Vaccines are also being developed to prevent or treat non-infectious diseases such as cancer through immunotherapy. This presents additional challenges, such as the need for personalisation and rapid development of vaccines for single, or small patient cohorts. This means flexible platforms (including mRNA) are key, alongside innovation in manufacture and supply chain to reduce the cost of development and manufacture.

The global vaccines market is expected to grow at a CAGR of 10.2% up to 2026. Specifically, the global needle-free injection market was valued at USD 124 million in 2021 and is projected grow at a CAGR of 17% to reach USD 272 million in 2026. This demonstrates the huge potential growth and impact of this market in the protection against a breadth of diseases.

The UK is well positioned in this market to build on existing investments such as:

- the Cell and Gene Therapy Catapult Manufacturing Innovation Centre which gained significant funding to develop the additional capability to produce pandemic vaccines at scale in 2021;
- the announcement in June 2022 that Moderna will open a UK vaccine research and manufacturing centre, enabling NHS patients to have access to the next generation of mRNA vaccines and treatments helping to future-proof the UK against emerging health threats;
- the CPI-coordinated Intracellular Drug Delivery Centre (IDDC), a collaboration between UK Catapult centres and academic partners, funded by Innovate UK, to provide access to state-of-the-art equipment and support for the design, formulation, characterisation, and manufacture of nano-delivery systems for nucleic acid-based vaccines and therapeutics.

Global leadership in environmentally sustainable medicines manufacturing

Environmentally sustainable medicines manufacturing is critically important to preserve natural resources, reduce harmful waste and reduce carbon emissions and help the country, the NHS and companies meet net zero targets. MMIP believes there is a major opportunity to establish the UK as a global leader in net zero medicines manufacturing.

Greenhouse gas emissions are still rising globally. The healthcare sector represents 4-5% of global greenhouse gas emissions,[43] and the connection between the climate crisis and the health of patients is clear. To meet the 1.5°C commitment from the Paris Agreement,[44] healthcare needs to decarbonise rapidly and extensively. This means there is a strong value proposition associated with transitioning to net zero medicines manufacture in the UK.

A Net Zero approach will provide medicines manufactured in the UK with the low carbon footprint required to meet the Scope 3[45] commitments of the NHS.[46] In addition, it will provide an opportunity for the UK to be a world leader and therefore an exporter of low carbon footprint medicines, lowering the Scope 3 emissions of health system purchasers worldwide, enabling them to meet their decarbonisation goals and contribute to the decarbonisation of healthcare globally.

Creating a strong ecosystem in the UK for sustainable medicines manufacturing, will be additionally attractive to global healthcare companies that have set their own challenging net zero goals[47, 48] (See Figure 3).

43 Health Care's Climate Footprint - Health Care Without Harm and Arup, 2019 (noharm-global.org)
44 Adoption of the Paris Agreement - English Text, 2015 (unfccc.int)
45 For an explanation of Scope 1-3 emissions see: What are Scope 1,2 and 3 Emissions?, (deloitte.com)
46 Delivering a Net Zero National Health Service, 2020 (england.nhs.uk)
47 Ambition Zero Carbon, 2023 (astrazeneca.com)
48 GSK Sets New Environmental Goals of Net Zero Impact on Climate and Net Positive Impact on Nature by 2030, 2020 (gsk.com)

Figure 3. The UK Government, NHS and companies all have similar, ambitious carbon emissions reduction targets

Pfizer[49]	**2040** - 90% reduction in value chain emissions (scope 3) **2040** - 95% reduction in company emissions (scope 1&2)
GSK[50]	**2045** - Net Zero emissions (all scopes)
AstraZeneca[51]	**2026** - 98% reduction in GHG emissions (scope 1&2) **2045** - 90% reduction in GHG emissions (scope 3)
NHS England[52]	**2040** – Net Zero (Scope 1, 2 and some 3) **2045** – Net Zero (All scope 3)
HM Government[53]	**2050** - Net Zero emissions

Key recommendation 1: MMIP proposes implementing a three-point plan to enable the UK to become a leader in environmentally sustainable medicines manufacture:

a. Define the standard for measuring greenhouse gas emissions in medicines manufacture

The Lifecycle Assessment (LCA) methodology enables the environmental footprint of medicines to be assessed, including greenhouse gas emissions.[54,55] The LCA is a proven method of quantifying greenhouse gas emissions and is increasingly utilised in medicines manufacture. However, there is no single, agreed global standard approach to quantify the greenhouse gas emissions at a unit or patient level. Many pharmaceutical companies are working on developing internal standards to drive improvement and many healthcare providers, such as the NHS, are developing standards to assess the medicines they purchase.

49 Pfizer Announces Commitment to Accelerate Climate Action and Achieve Net-Zero Standard by 2040, 2022 (pfizer.com); (accessed 24/04/23)
50 Climate GSK, 2023 (gsk.com); (accessed 24/04/23)
51 Ambition Zero Carbon, 2023 (astrazeneca.com); (accessed 24/04/23)
52 Delivering a Net Zero NHS, 2022 (england.nhs.uk)
53 Net Zero Strategy: Build Back Greener, 2021 (publishing.service.gov.uk)
54 A Newcomer's Guide to LCA - Baselines and Boundaries F Paper 3, 2015 (publishing.service.gov.uk)
55 Life Cycle Assessment - GSA Sustainable Facilities Tool, (sftool.gov)

For the UK to take a leadership approach, MMIP recommends that an internationally recognised standard for measuring greenhouse gas emissions in medicines manufacture is developed in the UK via the British Standards Institute (BSI) in collaboration with medicines manufacturers, the Office for Life Sciences and the NHS. Such a standard would demonstrate net zero leadership from the UK with a view towards becoming an international standard through the International Standards Organization.

Increased collaboration across the pharmaceutical industry has recently been shown to be successful, with the publication of joint minimum climate and sustainability targets, to address emissions across the value chain and reduce the complexity of multiple asks of suppliers.[56] This collaboration can be furthered by consensus on LCA methodology for measuring medicines environmental and carbon footprint.

b. Establish the infrastructure to enable net zero medicines manufacture

In parallel to the important step of developing a standard for the measurement of greenhouse gas emissions, it is necessary to ensure that the appropriate infrastructure is in place to enable net zero medicines manufacture. One of the key areas of infrastructure is access to renewable energy – both electricity and gas. Heat and power in healthcare supply chains contributes approximately 25% of the total emissions within the healthcare sector.

In order to reduce emissions, access to renewable energy is key. Leading manufacturers currently report challenges in accessing reliable sources of renewable energy in the UK and accelerating provision of this, particularly renewable gas (biomethane), could provide an attractive incentive for companies to manufacture medicines in the UK. This opportunity could be extended further to include a leadership position in 'green logistics', thereby creating the opportunity to manufacture and supply net zero medicines from the UK.

c. A technology and innovation roadmap for environmentally sustainable medicines manufacturing

It is critical to innovate to develop new, more efficient methods of medicines manufacture, given that approximately 50% to 80% of greenhouse gas emissions occur during the early stages of the supply chain during raw material sourcing and processing.[57] Developing new methods which significantly reduce these activities would enable a significant reduction in greenhouse gas emissions, for example by increasing manufacturing efficiency and yields through continuous processing or transitioning away from using solvents in the synthesis of the Active Pharmaceutical Ingredient.

Away from the early stages of the supply chain, where the greatest greenhouse gas emissions occur, there are other key opportunities to increase innovation, for example in 'green' packaging and 'green' transport.

There is a unique opportunity for the UK Government to take a key role in providing leadership and coordination in this area, which is currently fragmented with many companies and other stakeholders working independently towards their own net zero goals.

56 HSTF Supplier Targets, (storyblok.com)
57 SMI HSTF Supply Chains Whitepaper, 2023 (storyblok.com)

MMIP recommends the establishment of a Sustainable Medicines Manufacturing Technology and Innovation Roadmap, supported by government partners, to inspire and coordinate the funding of innovation in net zero medicines manufacturing techniques. The Roadmap would identify the highest value innovation needs (for example solvent recycling or access to renewable energy sources) and set out a plan to deliver innovation funding over time via the various UK government funding bodies.

Examples of existing "green" innovation projects being delivered by CPI's Medicines Manufacturing Innovation Centre:

Carbon accounting project

Aims at detailed carbon footprint data collection from a site and a process, linking to a visualisation dashboard. This will enable overall monitoring to reduce the carbon footprint from operations.

Intelligent HVAC controls

Reduce the HVAC (Heating, Ventilation and Air Conditioning) use in periods of lower activity e.g. reduction of air exchange rates, adjust temperature levels (within allowed limits, backed-up by online monitoring)

Grand Challenge 3

Develops an alternative for production of synthetic oligonucleotides which reduces the demand for acetonitrile.

SUMMARY: Delivering global leadership in sustainable medicines manufacturing

- **Implement a 3-point plan to deliver global leadership in environmentally sustainable medicines manufacturing:**
  - **Develop an internationally recognised standard for medicines manufacturing greenhouse gas emissions**
  - **Develop a technology and innovation roadmap for environmentally sustainable medicines manufacturing**
  - **Establish the infrastructure to enable net zero medicines manufacture.**

Global leadership in manufacturing innovation

The advent of ever-more complex medicines and therapies requires the UK to continue to adopt new and innovative approaches to manufacturing to capture a disproportionate share of growing markets. The advancement of digital sciences to drive innovation and increase automation will increase our ability to deliver quality medicines to patients and improve the efficiency of small molecule manufacturing from drug substance through to final product and packaging. Other examples of innovations helping to drive efficiency include continuous drug substance manufacturing and continuous direct compression used in tablet manufacture.

Support for and adoption of technologies in the services surrounding manufacture, such as storage, transport, supply chain and new construction and engineering approaches, will also be critical to improve the resilience and responsiveness of manufacturing and supply.

A UK manufacturing ecosystem built around innovation will offer companies opportunities for much greater efficiency and enhanced productivity, increasing its attractiveness as an investment location.

Key recommendation 2: £1.1bn over four years to provide sustained, predictable and accessible innovation funding and investment incentives

With the support of MMIP, the UKRI Medicines Manufacturing Challenge Fund made significant progress in establishing UK medicines manufacturing innovation as a foundation for economic growth and health resilience, with significant impact during the COVID-19 pandemic as described previously. As a result, the UK has established a unique innovation ecosystem to support the de-risking and deployment of sustainable manufacturing technologies across the sector.

The Medicines Manufacturing Challenge Fund exemplifies the impact that innovation funding has in supporting sector growth, with the challenge fund investments having generated **over 700 jobs, 300 apprenticeships, nine new spin-out companies, and £720m of additional investment** into funded companies at the time of writing.

In order to maximise the benefits that the prior investments in UK medicines manufacturing innovation ecosystem offer, MMIP believes that continued innovation funding support is necessary. Such support will facilitate collaborations between the sector, the innovation ecosystem and the strong UK base in innovative technology providers that together can deliver the sustainable medicines manufacturing technologies of the future.

i. Aligning early research

UKRI provides significant support for relevant academic research through the Engineering and Physical Sciences Research Council, the Biotechnology and Biological Sciences Research Council and the Medical Research Council. Evidence suggests early-stage, basic research into manufacturing provides substantial economic returns.[58] With industry co-investment, this funding has established Doctoral Training Centres and Future Manufacturing Hubs such as the Centre for Continuous Manufacturing and Crystallisation (CMAC), the Future Vaccine Manufacturing Research Hubs (VaxHubs), the Future Targeted Healthcare Manufacturing Hub and the Nucleic Acid Therapies Accelerator (NATA). MMIP proposes to establish closer strategic relationships with the research councils to align the academic research more closely with the technology and innovation roadmap, providing a pipeline for direct translation into UK medicines manufacturing.

ii. Collaborative research and innovation funding

The success of the UKRI Medicines Manufacturing Challenge Fund demonstrates the interest and appetite the sector has for collaborative R&D funding. This funding supports delivery of key aspects of the MMIP technology and innovation strategy, as outlined in the MMIP's technology and innovation roadmap of 2020.[59] However, there is often less funding available through the funding bodies than the value of the high impact projects that could be supported. MMIP also believes there are further opportunities to increase the competitiveness of the UK collaborative R&D offering as compared to other countries to make them more attractive to SMEs, large pharma companies and contract development and manufacturing organisations (CDMOs).

MMIP recommends a £200m collaborative R&D fund confirmed over a 4-year period, to drive both industry-led collaborative innovation projects and leverage the innovation infrastructure to de-risk commercialisation and adoption of novel manufacturing technologies. This would enable the funding bodies and potential beneficiaries to plan and deliver impactful innovation programmes over a typical pharma industry investment cycle. The competitiveness of this offering could be significantly improved by having:

- A well-publicised regular cycle of funding calls to bid into
- A more streamlined assessment and due diligence process
- A variety of grant funding "products" alongside the classic collaborative R&D funding models.

58 Impact Assessment EPSRCs Manufacturing The Future Programme2005-2020, 2022 (ukri.org); (accessed 03/05/23)
59 Technology and Innovation Roadmap, 2021 (abpi.org.uk); (accessed 03/05/23)

CASE STUDY: SageTech Medical: Recycling anaesthetics to reduce carbon emissions

SageTech was founded in 2015 with the goal of reducing the cost and environmental impact of inhaled anaesthetics. Inhaled anaesthetics are essential in modern surgery, but patients in the operating theatre take up less than 5% of the anaesthetic they breathe in. The rest goes into the atmosphere, adding up to an estimated 3 million tonnes of CO^2 equivalents every year, globally - the equivalent of powering half a million homes for a year. SageTech has developed patented technology that captures, extracts and purifies inhaled anaesthetics so they can be recycled and reused. The ultimate goal is to extract the captured volatile waste and purify it to meet MHRA standards, so producing a drug that can be clinically reused to anaesthetise patients. These gases are also used in the veterinary sector, so there is additional significant benefit from the technology. The gases are used around the world in both human and veterinary medicine, making this a relevant global solution.

In 2018, SageTech, in collaboration with the University of Exeter Medical School, received funding through Innovate UK to help commercialise its technology, developing a waste anaesthetic collection programme across NHS hospitals and creating a commercial-scale purification plant. Its work has attracted nearly £5m to date in private investment that will help further scale-up, commercialisation and geographic expansion.

CASE STUDY: Fujifilm[60]

December 2021 FUJIFILM Diosynth Biotechnologies confirmed a £400m planned investment package at its UK facility in Billingham, Teesside. The package more than doubled the site's existing development and manufacturing footprint and is expected to create up to 350 highly-skilled jobs. The new facilities are expected to be operational by late 2023. The new multi-modal campus will include two new state-of-the-art facilities: a viral gene therapy GMP2 facility and a GMP mammalian cell culture facility, reflecting strong growing demand for microbial, cell culture and viral gene therapy services.

iii. Life Sciences Innovative Manufacturing Fund

In recent years, the UK has made positive steps to address the lack of a capital grants facility for life sciences manufacturing, with the introduction of the £20m Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF), the £60m Life Sciences Innovative Manufacturing Fund (LSIMF) and, most recently, the announcement of a £38m Biomanufacturing fund (BMF).

Both funds have been significantly oversubscribed, and as such, many high-quality applications have missed out on funding. The first tranche of LSIMF funding allocated by the Government has leveraged £260m in private sector manufacturing investment from just £17m of government funding.[61] Total applications to the scheme demonstrated up to £2bn in potential manufacturing investments where companies saw government support as crucial to ensuring the investment could go ahead in the UK. The MMIP estimates that a total government contribution of between £200m-£300m would be required to secure the entire £2bn worth of investment appetite – offering a huge potential boost to growth, jobs and health resilience supporting pandemic preparedness and security of supply for essential medicines.

It is clear therefore that the scale of the fund is a limiting factor in the UK's ability to attract and secure investment. Building on the strengths of the scheme, there are a number of other changes that could significantly increase the competitiveness of the UK's offer by improving the predictability of the scheme and reducing the burden on applicants.

As such, MMIP recommends that a new scheme should seek to embody the following characteristics:

- **Scale:** To achieve the goals set out in this paper we recommend the establishment of an expanded capital grants facility of £900m available over a 4-year period (or £225m per year for the duration of a spending review period) to unlock £6bn industry investment (£1.5bn annually at a 15% grant to investment ratio, in order to be internationally competitive, and offer certainty to prospective investors).
- **Speed:** A mandated application processing period of no more than 3 months from application deadline to final decision with multiple application windows
- **Simplicity:** Streamlining of scheme criteria and requirements
- **Longevity:** A long term commitment to a rolling life sciences capital grant facility is needed. MMIP recommends a 4-year minimum funding cycle for a future scheme.

iv. Leading in advanced digital manufacturing

Digitisation, automation of medicines manufacturing hold the potential to increase the pace of drug development, address more complex product development, improve cost efficiencies, reduce batch failures and deliver more sustainable products and processes.

While a huge amount of attention has been focused on the application of machine learning and AI approaches to accelerate discovery of new molecular entities to target specific diseases, similar approaches have not yet holistically impacted the development area of the lifecycle where the design and development of manufacturing processes occur.

MMIP has long recognised this issue and in 2017, the Industrial Digitalisation Review 'Made Smarter' report

60 Fujifilm Breaks Ground at Microbial Plant in UK, 2022 (bioindustry.org)

61 Life Sciences Companies Supercharged with 277 million in Government and Private Investment, 2023 (gov.uk); (accessed 03/05/23)

similarly considered the opportunities that digital technologies might offer in the pharmaceutical sector and the levels of investment required to deliver. To date, MMIP has supported a number of initiatives in this space to exemplify how adoption of digital technologies might support a step-change in productivity.

One such example was ADDoPT (Accelerated Digital Design of PharmaTherapeutics), funded in the U.K through the Advanced Manufacturing Supply Chains Initiative (AMSCI). ADDoPT successfully explored the potential for digital and predictive tools to provide more sophisticated and efficient definition, design and control of pharmaceutical manufacturing processes using data analysis and first-principle models.

Similar successes have been and are being replicated across a number of collaborative projects. The concept that digital tools and predictive approaches can significantly impact productivity of medicines design is clear and, on a case-by-case basis, individual companies across the sector are reporting time and cost efficiencies.

There are still several common challenges across the industry, including complexity, cost, risk, long timelines, and lack of appropriate skilled resources. To address these common barriers, there is a major opportunity to leverage the capabilities of the existing translational centres in addition to funding core research and development activities.

Building on investments in academic research by the UKRI research councils, Innovate UK has provided support to digitalisation and automation activities through the "Made Smarter Innovation Challenge" (at facility and supply chain level) and the Transforming Medicines Manufacturing programme (at the process development and manufacturing level).

MMIP recommends the following initiatives to accelerate the momentum to leadership in advanced digital manufacturing:

KEY RECOMMENDATION 3: Develop a five-year digital, automation and robotics medicines manufacturing technology roadmap

MMIP recommends the formation of a task and finish group to develop an ambitious 5-year, funded programme with the aim of delivering a sustainable pipeline of digitised workflows from Technology Readiness Level (TRL) 4 right up to TRL 8, a skilled pool of resources for further development and deployment and a framework which allows the UK to be a world leader in delivering digital, automation and robotics solutions for medicines manufacturing. This will help align existing activities and ensure that future funding is coordinated to drive current and new activities in academia, collaborative research and development, and to leverage existing infrastructure to act as demonstrator centres to accelerate and support industry adoption.

i. Establish a world-class Medicines Manufacturing Data Institute

An opportunity for the UK now lies in unlocking mechanisms for the sector to share data describing molecules comprising medicines that will simultaneously afford commercial IP protection and opportunity provision for advancing digital and predictive tool innovation by the academic research community.

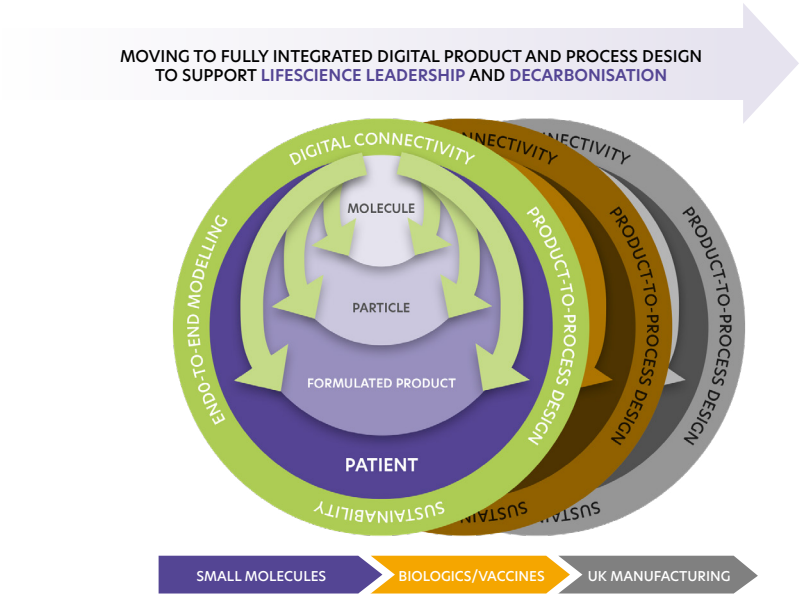
MMIP proposes the establishment of an enduring, transformative, world-class **Medicines Manufacturing Data Institute** in the UK to serve as a collaborative hub for industry, academia, and government agencies to use cutting edge data driven approaches to accelerate sustainable design and manufacture of medicines.

The mission of the Institute will be to enable and exploit the capture, curation, storage, retrieval and analyses of relevant data associated with; synthesis, purification, drug product formulation, control of quality and bioperformance of the next generations of medicines for patients worldwide.

The intent of the institute will be one that is open to collaboration, and one which will endure through replication of its blueprint which would be established in the first instance with small molecule medicines. It should then subsequently move into biologics and vaccines, to support sector growth in these areas, and further expand potential for the UK to assert its leadership in the life sciences. The institute should explicitly incorporate data driven decarbonisation principles to support the pharma sector in establishing sustainable design processes for new medicines, in line with UK net zero ambitions.

Establishing such an institute would be a global first and as such, give the UK an international competitive advantage, including development of highly skilled employees and collaborators to support the sector's digital ambitions. Through MMIP, a variety of diverse organisations in the UK ecosystem have been consulted to gather evidence to gauge appetite and readiness to engage in such an institute and feedback has been resoundingly positive both from in-principle engagement and delivery perspectives.

Vision for a UK Medicines Manufacturing Data Institute



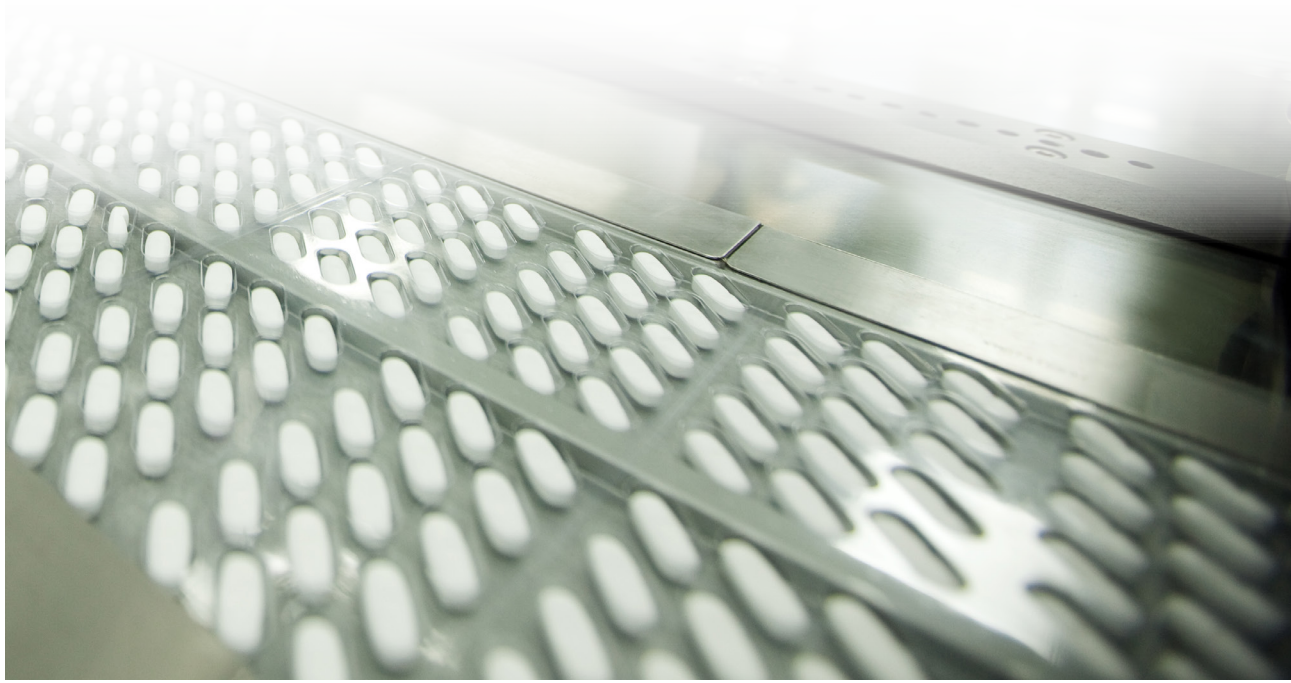
ii. Fund next generation oligonucleotide manufacturing capacity

MMIP supports the application for a £10m co-investment by the UK government with Scottish Enterprise in the £20m Oligonucleotides Manufacturing Innovation Centre (OMICE) and £5m support for the Oligonucleotides Training Academy. Scottish Enterprise previously invested in a demand study, scheme design and economic assessment resulting in joint SE/HVMC grant of £500k for a facility detailed design.

OMICE will generate a range of outcomes and impacts across the economy, society and environment by driving the acceleration of new innovative manufacturing technologies (supporting the up to 5 technologies per year), contributing to an enhanced skilled workforce (capacity to train circa 200 people a year) and increasing the attractiveness of the UK for private sector investment through supporting the acceleration of 15-20 clinical assets per year. In addition to the monetised benefits the project is expected to generate significant wider economic impacts, such as improved health resilience by increasing the UK's ability to pivot infrastructure, resources, and knowledge in response to a future health emergency.

SUMMARY: Delivering global leadership in manufacturing innovation

- £1.1bn over four years to provide sustained, predictable and accessible innovation funding and investment incentives:
  - Aligning early research
  - £200m over four years for the Transforming Medicines Manufacturing collaborative R&D grants programme
  - £900m over four years for the Life Sciences Innovative Manufacturing Fund to unlock £6bn of industry investment (15% grant to investment ratio)
- Create a five-year digital innovation in medicines manufacturing technology roadmap, including:
  - Establishing a world-class UK Medicines Manufacturing Data Institute
  - Fund next generation oligonucleotide manufacturing capacity.



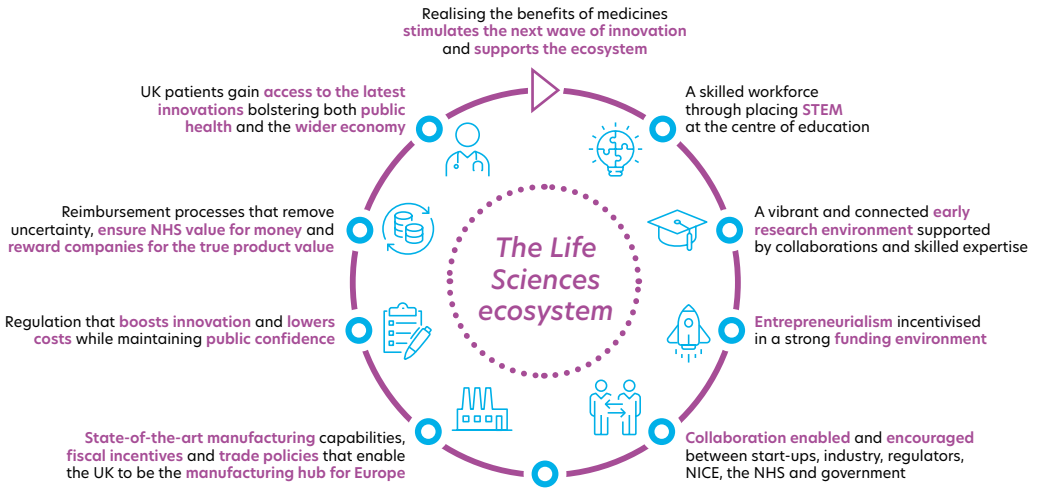
A pro-innovation life sciences investment environment

This report focuses primarily on the future of medicines manufacturing and the huge opportunities available to the UK to lead in environmentally sustainable and innovative manufacturing given our infrastructure and capabilities. The overall Life Sciences policy and regulatory environment is, however, also critically important. A recent PWC/ABPI report "Life Sciences Superpower: Growing the leading global hub in the UK" describes the importance of having a favourable ecosystem from skills all the way through to patient access to medicines (see illustration below).

The UK's success in attracting investment in Advanced Therapy Medicinal Product research, development and manufacturing is a clear example of this ecosystem in action, in which, for example, the NHS played a key part by facilitating early adoption of cell therapies in NHS treatment via its Advanced Therapy Treatment Centres.

In this section MMIP highlights key areas where policy has a large bearing on UK competitiveness for medicines manufacturing investment and where MMIP supports policy recommendations made by the industry more widely.

Key components in the Life Sciences ecosystem



From Life Sciences Superpower; June 2022; ABPI & PwC

KEY RECOMMENDATION 4: Globally competitive tax credits and allowances

The fiscal operating environment is a decisive factor in influencing internationally mobile investment decisions. Countries such as Ireland and Singapore have proven exceptionally effective at attracting and expanding medicines manufacturing capabilities in recent years through competitive taxation and incentive models.

Positive steps have been made in the UK in recent years which improve the UK's international offer including:

1. The introduction of the Full Expensing Capital Allowances scheme with a duration of 3 years. This follows the Super-Deduction policy which was introduced during the pandemic.
2. The establishment of the Life Sciences Innovative Manufacturing Fund (LSIMF) and its predecessor the Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF).

Whilst these policies are a step in the right direction, further action is needed if the UK is to become a financially attractive location for advanced medicines manufacturing. Alongside a compelling fiscal operating environment, fiscal stability is a prerequisite for success with investment decisions often requiring a 4-5year decision timeline. As such, proposals outlined below would benefit from concerted, long-term political support.

MMIP has identified the following areas as opportunities for the UK to attract inward manufacturing investment through fiscal and incentive policy reform:

i. Globally competitive R&D tax credits including relief for capital expenditure

If the UK aims to stimulate investment in advanced manufacturing, support the transition to net zero, and promote the scaleup of innovative early-stage manufacturing, then R&D tax credits are an essential lever. It is vital the UK benchmarks itself against international competitors to ensure there is a globally competitive headline rate of relief for both large companies and SMEs. Alongside the rate of relief, it is also vital that the UK continues to adapt the parameters for what expenditure qualifies for relief, and keeps pace with, or preferably stays ahead of developments in competitor nations. For example, the UK has recently made positive steps by allowing relief on data, cloud computing and pure mathematics costs.

Currently capital expenditure associated with R&D does not qualify under either the SME regime or Research and Development Expenditure Credit (RDEC), which represents a missed opportunity to incentivise this economically valuable investment, especially within loss-making companies unable to benefit from R&D Allowances or Capital Allowances (which do not provide cash payments).

Capital investments are essential in supporting manufacturing innovation, enabling and supporting process and efficiency improvements as well as the transition to net-zero and other environmental improvements such as waste reduction. Capital expenditure carries the added benefit of being a "sticky" investment, given it is associated with a physical good or piece of equipment. As such, it is harder to move or relocate than other

R&D activities and can anchor additional downstream investment. Incentivising investment via R&D tax relief in early-stage manufacturing facilities for the production of experimental medicines for clinical trials is therefore considerably more likely to lead to larger investments in commercial-scale manufacturing facilities down the line.

A selected example of countries that allow capital expenditure to be claimed within their R&D tax credit system or inclusion of related depreciation includes France, Ireland, Japan, the Netherlands, Australia, Belgium and Austria. These countries all have strong life sciences sectors and are direct competitors for attracting inward investment.

For these reasons, MMIP recommends the inclusion of capital expenditure within all future R&D tax relief regimes to address the current discrimination against loss-making companies, which see minimal or no additional tax expenditure benefit through capital allowances.

ii. Longer-term certainty on capital allowances

The announcements made at budget 2023 to adopt the full expensing model of capital allowances is a positive step. The UK has historically offered the least attractive incentives for capital expenditure out of all of the G7 countries and, partly as a result, suffers among the lowest levels of business investment in the G7. The Full Expensing model goes a significant way towards addressing this. However longer-term certainty on the capital allowances framework in the UK is needed given the major lead in times for investment decisions. Currently, the full expensing model has been confirmed for only 3 years. This follows on from the Super Deduction which lasted only 2 years. With stability of the fiscal environment being key, policymakers should provide longer term certainty to prospective investors by making the scheme permanent.

KEY RECOMMENDATION 5: Establish a medicines manufacturing investment "front door"

In the 2021 Life Sciences Vision, the government committed to providing a smoother, clearer, more efficient, and effective system to better support new inward investors to invest in the UK via an enhanced "investment front door".[62] Other countries, notably Ireland and Singapore, have more effective "front door" services, working strategically with companies to broker offerings, deliver against national plans and ultimately capture investments. MMIP recommends that the UK's investment "front door" is designed both to capture inward investment and retain and grow companies already located in the UK. A successful "front door" should supply information, enabling companies to understand the UK's complex infrastructure, and strong account management, with a single point of contact to support companies as they navigate through the process, convening technical experts or government representatives as required. The "front door" should serve both international and existing UK companies and provide benefit from showcasing what is already in place, as well as identifying areas of strategic improvement.

Work is already planned to simplify UK life sciences information into a single-entry portal. We recommend that a Medicines Manufacturing Front Door is implemented by the Department for Science, Innovation and Technology, in close collaboration with industry. Industry should provide a key directory of technical experts to promote the UK and participate in inward investment discussions to land new manufacturing investments.

KEY RECOMMENDATION 6: Securing a leading global talent base for UK medicines manufacturing, including providing additional funding for flexible biomanufacturing skills building on the successful programmes of Advanced Therapies Apprenticeship Community and Advanced Therapies Skills Training Network

Ensuring that the UK has a globally leading talent base is foundational to any effort to attract new investment and grow the medicines manufacturing sector. Future attraction of talent into the sector requires positive reinforcement of the UK's leading position on the global stage and the attractiveness of the sector to work in.

Key talent recommendations to secure the UKs position as globally innovative and environmentally sustainable medicines manufacturing sector are to:

- Attract innovative UK talent to work within this skilled, productive, and rewarding sector
- Positively reinforce policy on the UKs position to attract global talent to the sector
- Fund scaling of talent development for innovative biomanufacturing skills within the UK.
- Map 'Green Skills' for an environmentally sustainable UK medicines manufacturing sector.
- Fund digital and automation skills development for innovative medicines manufacturing.

Attract innovative UK talent to work within a skilled, productive, and rewarding sector:
From schools and colleges, through apprenticeships and universities, UK medicines manufacturing is a sector which accepts and promotes a wide range of skills sets that offer long, varied and fulfilling career pathways yet is not well understood outside of the sector. MMIP supports collaboration across industry, training providers and policy makers to promote meaningful careers within UK medicines manufacturing and increase the flow of innovative UK talent interested in working and remaining within the sector.

62 Life Sciences Vision, 2021 (publishing.service.gov.uk)

Supportive immigration policy:
Attracting global talent brings skills and expertise to the UK which enriches our innovation and manufacturing workforce. It also promotes international collaborations, attracts inward investment, and creates informal ambassadors, strengthening the UK's trade, manufacturing, and diplomatic links. It is important that the UKs immigration system supports the industry in relocation, recruitment and retention of overseas talent that may lead, undertake, and support medicines manufacturing in the UK. MMIP urges that UK immigration policy should support international talent at different career stages to enter and remain within the UK, provide clear, welcoming, and consistent messaging, be cost effective, easy to navigate and allow easy transition between visa types and employers.

Fund scaling of talent development for innovative biomanufacturing skills within the UK:
The UK led the way in addressing a growing need for skills in advanced medicines manufacturing. The Cell and Gene Therapy Catapult's Advanced Therapies Apprenticeship Community (ATAC) and Advanced Therapies Skills Training Network (ATSTN) are highly effective initiatives. Both received government seed funding which released significant industry investment. Initially established for the ATMP sector these have now expanded to support diverse talent across wider biomanufacturing skills and training. However, there remains much more work to build long term workforce capability and capacity at all levels. MMIP recommends additional funding and collaboration, including Catapults and science/manufacturing hubs, across programmes in all areas of the UK.

MMIP recommends additional funding for national, innovative biomanufacturing skills development using the Advanced Therapies Apprenticeship Community (ATAC) and the Advanced Therapies Skills Training Network (ATSTN) as established levers and training models.

Now is the time to build and expand on the current ATAC & ATSTN model to deliver a highly skilled and flexible workforce covering the Life Sciences sector, as well as create and grow new programmes to fill skills gaps across the whole medicines manufacturing industry from school leavers through to returners to the industry. Investment is taking place where companies are maturing but a large SME community and a challenging climate means the training ecosystem requires ongoing Government funding support and partnership to embed and sustain the progress made.

ATAC has delivered almost 300 apprenticeships across advanced medicine manufacturing since 2018, utilising over £7.5m of previously unspent apprenticeship levy. Investment of specialist resources has reversed a national trend as the latest Life Science data show a general decline in apprenticeship starts and represents a skills risk to development of future manufacturing talent.[63] An additional £11m for the period from 2023-26 would deliver 450 new ATAC apprentices; 300 new Internships, industrial placement, and graduates programmes; 5,000 new ATSTN on-line training platform (OTP) licenses and 2,500 new National Training Centre learners. This funding will also deliver a new Technical, Vocational, Education and Training (TVET) strategy for the Life Sciences Sector and help achieve financial sustainability, opening the way for strategic international partnerships and alliances.

63 https://cogentskills.com/news/act-now-to-reverse-decline-in-science-sector-apprenticeship-starts/

Map 'Green Skills' for an environmentally sustainable UK medicines manufacturing sector:
As set out earlier in this paper, there is a major opportunity to establish the UK as a global leader in net zero medicines manufacturing. High quality, sector specific, skills and training will be required for a net zero approach to medicines manufacturing which is suitable for both new talents entering the sector and upskilling those already within the industry. IfATE have produced a Green Skills Strategy working with employers so that professional and technical education can help the country achieve sustainable growth while meeting net zero targets. For the UK to take a leading role in the skills required for sustainable medicines manufacturing, MMIP proposes that a map of current, sector relevant programmes should be developed with educators and policy makers to ensure the medicines manufacturing sector has access to relevant education and can address gaps through development of future skills frameworks.

Fund digital and automation skills development for innovative medicines manufacturing:
Digitisation and automation of medicines manufacturing holds the potential to increase the pace of drug development, address more complex product development, improve cost efficiencies, reduce batch failures, and deliver more sustainable products and processes. Collaborative partnerships will be key to accelerating skills growth of specialist and non-specialist roles, which are particularly important in a sector that requires traditional scientific skills as well as contemporary skills linked to innovation, digital technology, continuous manufacturing, and the associated data sciences. MMIP supports a focus on developing digital skills in line with medicines manufacturing digital strategies and technology roadmaps upskilling the existing workforce and training the next generation.

KEY RECOMMENDATION 7: Improve the UK commercial environment

Pharmaceutical companies have significant concerns which are well documented elsewhere about the commercial environment they currently face in the UK. In particular, action is needed in two key areas. Firstly, the ability of the NHS to rapidly adopt new innovative medicines, an area in which it is poor by international comparison. Secondly, reform is required of the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) which currently imposes unsustainable levels of rebate. The UK should strive to build a positive global reputation for a pro-innovation commercial environment through an improved VPAS and more streamlined mechanisms for adoption of new medicines into the NHS.

KEY RECOMMENDATION 8: Strengthen health resilience through trade policy and streamlined regulation

The COVID-19 pandemic shone a light on the importance of medicines manufacturing capacity, as well as the integrated and global nature of supply chains. Indeed, the ability of countries and companies to rally and respond collectively with medicines manufacturing and supply capacity was key to ending the pandemic. Many countries are now gathering the learnings from the pandemic and assessing the potential threats to future pandemic supplies and other potential health emergency threats.

Aside from risks associated with a pandemic, there have been recent ongoing issues with the supply of several essential medicines including antibiotics, hormone replacements therapies and insulin. And rising tensions with China could threaten 40% of all pharmaceutical ingredients that are globally sourced from a handful of Chinese manufacturing sites. In a recent survey of EU pharmacists, 76% of countries reported that shortages had worsened compared to the previous year.[64]

An EU report on the security of medicines supply highlighted the complexity, integrated nature and global reach of medicines supply chains, combined with insufficient demand data.[65] This has made medicine supply particularly vulnerable as the diminished capacity struggles to anticipate, cope with, resist and recover from external shocks to the supply chain.

MMIP recommends the following additional actions to enhance UK health resilience:

1. Focus the Life Sciences Innovative Manufacturing Fund to help address known gaps in the UK medicines manufacturing footprint.
2. Pursue a trade agenda which seeks to eliminate tariffs and supports the export of cutting-edge medicines by ensuring that UK IP standards are recognised and adhered to by preferred trading partners.
3. Seek to negotiate medicines supply agreements with easy and fast free movement of medicines and their components in all global trading discussions. Consider supporting Belgium, with other non-EU countries, with their recently proposed supply solidarity concept.[66]
4. Streamline regulatory processes for medicines manufacturers by negotiating mutual recognition agreements with key export markets to reduce duplicative regulatory processes.

64 Medicine Shortages PGEU Survey, 2022 (pgeu.eu); (accessed 16/05/23)
65 Vulnerabilities of the Global Supply Chains of Medicines, 2022 (health.ec.europa.eu); (accessed 16/05/23)
66 ibid

Measuring progress and success

KEY RECOMMENDATION 9: Develop a medicines manufacturing investment dashboard

For the UK to fully realise the potential opportunities for growth and success within the medicines manufacturing sector, robust methods for measuring progress are needed which are recognised by Government and allow analysis of this sector, including enabling international comparisons. The data captured needs to provide a clear summary for the sector as well as allowing trends to be visualised.

Detailed reporting will:

1. Enable the identification of areas within the sector where interventions would deliver growth or investment opportunities for the medicines manufacturing sector.
2. Highlight gaps and potential weaknesses within the sector - whether that be in skills or infrastructure - allowing a proactive rather than reactive response to address these.
3. Highlight how focused interventions could address these gaps.
4. Capture data in an understandable and easy to analyse way, would help build a picture for successive governments to understand the sector and build upon these successes.

MMIP will engage with experts from across the industry and from within the Office for Life Sciences to generate a plan covering what data exists and what else is needed. A set of key performance indicators will be generated, focussing on the sector's economic performance, resilience, innovation, sustainability, and skills within the sector. Then a framework will be developed to present this information in a clear and concise manner for the sector and government to use. This dashboard will then help set the direction for the UK medicines manufacturing sector to thrive.

SUMMARY: Delivering a pro-innovation life sciences investment environment

- **Set internationally competitive R&D tax credits, including relief for capital expenditure, and provide long-term certainty on capital allowances**
- **Establish a medicines manufacturing investment "front door"**
- **Secure a leading global talent base, including providing additional funding for flexible biomanufacturing skills building on the successful programmes of ATAC and ATSTN**
- **Improve the UK commercial operating environment**
- **Strengthen health resilience through trade policy and streamlined regulation**
- **Develop a UK medicines manufacturing investment dashboard.**

Conclusion

Now is the time to grasp the opportunities of medical innovation and environmental transformation to position the UK as a leading location for manufacturing investment. Government investments in the sector have been shown to work, helping to establish the UK as a leader in ATMP manufacturing and attracting new investments in cutting-edge manufacturing plants in locations across the country. With global competition at an all-time high, and likely to increase further, it is critical that the UK doubles down on the efforts and investments made to date to attract the next wave of industry investments, create prosperity and lead medicines manufacturing into a more innovative and greener future.

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Medicines Manufacturing Industry Partnership