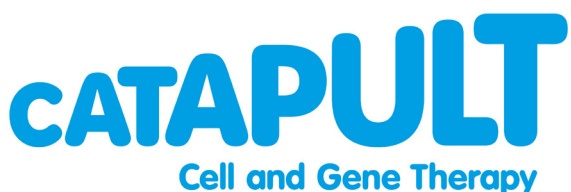


London Laboratory and GMP Manufacturing Roundtable White Paper

Hosted by MedCity and the Cell and Gene Therapy Catapult



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Access to affordable small-scale manufacturing space, close to centres of R&D intensity, is a significant challenge for many SMEs in the cell and gene therapy sector. As the cluster organisation representing life sciences in London, MedCity's purpose is to catalyse growth, and we want to ensure this by working with our partners to support supply of appropriate real estate in order to optimise the expansion of healthcare and industry.

– Neelam Patel, CEO, MedCity

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Developing London's unique position within the wider UK ATMP ecosystem, particularly in terms of its access to world class skills and research, will further establish the capital as an increasingly powerful component of ATMP growth strategy.

The pursuit of robust connectedness for those early-based companies looking to secure access to GMP manufacturing, and to the wider infrastructure and supply of facilities within the UK clusters, will move them closer to delivering life-changing advanced therapies to the world.

– Matthew Durdy, CEO, Cell and Gene Therapy Catapult

INTRODUCTION AND BACKGROUND

A “desperate lack of provision for start-ups and small companies in London for wet-laboratory space” was the conclusion of MedCity’s [London Life Sciences Real Estate Demand Report](#) published in December 2021, in association with Creative Places. It also found that fast-growing companies have their expansion rate limited by the lack of readily available, fit for purpose and cost-effective property, in the right locations.

The 2021 Demand Report also found businesses needed:

- Affordable workspace for start-ups
- Better provision of wet laboratory and GMP clean room space in London, available at higher specification but not necessarily at great scale
- Universities and hospitals making their equipment and facilities more usefully available, with agreed protocols around use
- Ever more endeavour to grow skills and talent

In follow up to the 2021 Demand Report a roundtable was convened by MedCity, in conjunction with Cell and Gene Therapy Catapult, that brought together cross-sector representation from research, start-ups and commercial organisations. The objective was to review the findings of the 2021 Demand Report and develop outline solutions to the challenges identified. This paper summarises the outcomes from the roundtable.

ROUNDTABLE SUMMARY

London occupies a unique position in the UK Advanced Therapy Medicinal Product (ATMP) industry ecosystem combining globally recognised academic research, process development and small-scale GMP manufacturing facilities with clinical trial sites and a rich talent pool of scientific expertise.

Workshop participants broadly agreed that, as ATMP processes are not yet fully matured, strong connections must be maintained between Research & Development and manufacturing. This would ensure that future manufacturing processes are fit for purpose and able to serve expanding clinical needs.

London has significant process development expertise within its universities, and it is important that this expertise is not lost when products rapidly progress through clinical trial phases and out of the immediate small-scale GMP manufacturing sphere.

Some of the roundtable’s participants indicated that they would prefer to remain in London as they scaleup due to the availability of talent pools, resulting in an increasing demand for both wet-lab and scalable GMP manufacturing space in London. However, larger-scale GMP manufacturing demands significant engineering, storage, distribution and logistics capacity and the roundtable participants agreed that the capacity of London to support full-scale, commercial manufacturing remains limited.

Throughout the UK, the GMP footprint for ATMPs is expanding (reference the annual Cell and Gene Therapy Catapult GMP Manufacturing Report 2021). Outside London, the UK has strong existing and developing ATMP clusters that include translation, GMP manufacturing and analysis, and the associated supply chain and logistics. It is important that the London ecosystem is strongly connected to these clusters to ensure a direct pathway from research and development, through to clinical and eventual commercial manufacturing.

The roundtable participants believe connectedness between UK regions will strengthen the UK's attractiveness to both small and large organisations wishing to develop and scale their research and development pipeline and manufacturing capabilities.

Facility scale and availability is not the only restrictor to business growth; a workforce that is skilled and experienced in GMP manufacturing is essential, covering the spectrum from early phase GMP manufacturing through to full-scale commercial manufacturing.

Finally, manufacturing facilities require a Pharmaceutical Quality System (PQS), together with a suite of facility, operational and safety processes to ensure that products produced are appropriately controlled for human use. Together these were termed as the "operationalisation" of a facility.

KEY THEMES

Discussions in the workshop centred around four key themes:

Ecosystem / cluster requirements

The UK has a rich and diverse ATMP ecosystem, including many areas of development and GMP manufacturing excellence outside London. However, participants felt that visibility of UK-wide capabilities and capacity was limited. A more comprehensive roadmap outlining the requirements of each stage in the company journey from start up to full-scale manufacture, alongside available mechanisms to help meet those requirements would be beneficial, especially for companies planning GMP manufacturing.

Connecting London-based companies to the infrastructure and talent elsewhere in the UK would benefit all areas. Those based in London would have transparency over opportunities for scale-up and areas outside London would be better connected to London's research and - most importantly - process translation/development expertise.

Infrastructure requirements

Panel respondents indicated that in the next 12 months they would require more wet laboratory space, GMP manufacturing space, or CDMO GMP manufacturing capacity. This echoed the findings of the MedCity Demand Report that 460,090 sq ft of wet lab with extract to air and manufacturing space would be required in London in the next 5 years. (This reflected the needs only of the sample surveyed).

Space flexibility was a key consideration for both laboratory and GMP manufacturing space. Respondents agreed that multi-user, “drop in” facilities granting access to common equipment would be beneficial to early-stage development companies. Industry support was seen as key in this area – providing access to (and training in) state-of-the-art, scalable development platforms. Ideally companies would then go on to adopt these platforms as they progressed through to later-stage GMP manufacturing. Better equipment training and access during process development would lead to more robust processes at scale.

Talent and skills

Participants agreed that a skilled workforce was as much of a barrier to growth as space, and that this workforce pool should expand beyond the graduate or post-doctoral market. Alongside access to specialist equipment, access to skilled people to operate this equipment is required to realise the potential of flexible equipment parks.

There was concern that processes were moving too quickly through the clinical trial process, limiting the time available for robust process development. Process development expertise is required as early as possible in the process and, crucially, for as long as possible in the process. London’s academic centres hold process development experience which should be utilised during the GMP manufacturing journey. Finally, a workforce with GMP manufacturing experience is required to support the transition to clinical trial and commercial supply.

Participants noted the apparent challenge in finding areas where both space for GMP expansion and the supporting skilled workforce were available

Business strategy

A clear pathway from research, through to process development, early-stage GMP manufacturing leading to late-stage/commercial GMP manufacturing is required, to showcase the route to commercial supply to companies currently at pre-clinical operations. This pathway needs to be supported by a large pool of talent at all stages of development.

Industry support was a recurring theme in the workshop, providing start-up companies with the flexible access to equipment and trained people required to support early process development.

Whilst access to space was a barrier, participants felt that setting up the processes and obtaining GMP authorisation to manufacture was also a significant challenge. Those manufacturing in the UK (or EU) face this challenge before clinical trial manufacturing whereas those in the US can defer the challenge until the product is authorised. A workforce experienced in GMP manufacturing is required to operationalise a facility successfully and swiftly.

RECOMMENDATIONS

1. Companies not yet conducting GMP manufacturing but planning to in the future would benefit from a clear pathway that describes both the requirements for each stage from research, process development and full scale GMP manufacturing, and the available UK resources to help meet those requirements. These requirements include not only physical space, but also the skills and operationalisation resources necessary for success. This will require greater connectedness between ATMP expertise in London and the rest of the UK.
2. Wider adjacent industry support is key to the success of early-stage companies in London and will have long-term benefits for the overall UK industry. For example, providing ready access to (and training in) state-of-the-art, scalable development platforms to start-ups. Better equipment training and access during process development would lead to more robust processes at scale.
3. Ensuring the on-going supply of facilities in a timely manner that meet industry needs is vital for the UK to remain world leading against strong international competition.

ABOUT MEDCITY

[MedCity](#) is the life sciences cluster organisation for London. Founded in partnership with London's three Academic Health Science Centres and the greater London Authority. MedCity fosters international collaborations between biotech, medtech and pharma companies and the capital's world-leading life sciences ecosystem to supercharge innovation, drive inward investment and build skills and talent across the sector in the UK.

Our work is wide-ranging across the ecosystem. We convene stakeholders in a neutral setting to facilitate issue resolution and raise awareness regionally and nationally of policy areas affecting life science sector growth. We connect private industry with partners in academic institutions, the NHS and the research charity sector to catalyse opportunities that advance R&D in areas such as AI, diagnostics and advanced therapies.

To ensure that the London cluster optimises areas of high growth potential, we inform development of the city's innovation districts by providing visibility of supply and demand, working closely with real estate developers, investors, London boroughs, academic institutions, and NHS Trusts. Through our international outreach we demonstrate the strengths of London and the rest of the UK to attract inward investment and stimulate economic growth. **CONTACT:** office@medcityhq.com

ABOUT THE CELL AND GENE THERAPY CATAPULT

The [Cell and Gene Therapy Catapult](#) is an independent innovation and technology organisation committed to the advancement of cell and gene therapies.

We are a team of experts covering all aspects of advanced therapies. Applying our unique capabilities and assets, we collaborate with academia, industry and health care providers to develop new technology and innovation.

Our outputs leverage research, transform barriers into industrial advantage and attract investment for our collaborators. We help people acquire new skills, organisation establish new capabilities and policy makers develop new perspectives.