CATAPULT
Cell and Gene Therapy

# Cell and gene therapy GMP manufacturing in the UK:

## Capability and capacity analysis
November 2021

# Contents

# 1. Executive summary

This report provides up-to-date metrics on the capability and capacity of the UK's Medical Health Regulatory Authority (MHRA) Manufacturing/ Importers Authorisation (MIA) and Manufacture/ Importation of Investigational Medicinal Products MIA (IMP) authorised Advanced Therapy Medicinal Product (ATMP) manufacturing facilities. Included are Contract Development and Manufacturing Organisations (CDMOs) and facilities for in-house product manufacture, and early-stage translational centres in the academic and public sectors. Previous years' reports can be viewed at https://ct.catapult.org.uk/resources/publications/manufacturing-surveys/all We remain grateful for the continued support of all participating centres.

The trend of year-on-year growth within cell and gene therapy manufacturing has continued throughout 2021, despite the global COVID-19 pandemic. The total amount of manufacturing space has increased by 25% since 2020, primarily in multi-functional facilities. Whilst there remains a significant cluster of manufacturing activity in the South East (including around Stevenage and London), the greatest growth during 2021 has been in Scotland and Northern England. Activities in central London have more of a focus on NHS and academic centres whereas more commercial organisations are based throughout Southern England, Northern England, and Scotland. Most of the QC testing footprint (74%) remains in Scotland.

Employment in the sector continues to rise, and this report includes for the first-time data on apprentices. Half the companies surveyed employ at least one apprentice, with the majority of apprentices employed by gene-therapy dedicated facilities.

With GOSH, RoslinCT and SNBTS having now gained their MIAs, 2021 sees 5 establishments with granted commercial MIAs, compared to 2 in 2020, marking a significant increase. This may indicate a movement towards more late-stage clinical or commercial manufacturing in years to come, but at present 85% of manufacturing is reported to be for pre-clinical or early clinical phase therapies.

There has been an increase in the available manufacturing capacity across all three categories of facility reported: cell-therapy dedicated, gene-therapy dedication and multi-functional. Manufacturing capacity is essential to support the growing number of clinical trials taking place. A site with a utility of 80% is generally considered to be full. Southern England has the most utilised space with an average booked capacity of 75%. Most immediately available capacity is in Midlands/ Northern England region with 55% available for use. Across therapy types, dedicated cell therapy facilities maintain a lower booked up capacity (57%) than gene therapy facilities (68%), which indicates an opportunity for accelerating cell clinical development going forward, especially as academic sites have a greater available capacity (41%) compared to commercial organisations (28%).

# 2. Introduction and Methodology

According to the Alliance for Regenerative Medicine, 2021 is on course to be a record-breaking year with major clinical milestones, strong commercial progress, and record-breaking investment in cell and gene therapies. Their data show that the number of clinical trials in this sector continues to increase with more than 2,600 ongoing worldwide and 243 of those in Phase 3. The industry is on track to have the highest annual number of regulatory approvals of new gene therapy and gene-modified cell therapy products worldwide.

The Cell and Gene Therapy Catapult's UK cell and gene therapy GMP manufacturing survey has been carried out every year since 2014 to identify the national capability (technology and expertise) and available capacity (GMP facilities and associated quality requirements) for manufacturing cell and gene therapies following the House of Lords Committee's recommendation of an annual stocktake into Regenerative Medicine manufacturing. A yearly review of the national capability and spare manufacturing capacity for these advanced therapies is essential for the prospective growth and investment within the sector.

During October and November 2021, the eighth annual survey was carried out among the 26 MHRA MIA (IMP) and MIA licensed facilities in the UK. The response rate was 77%; with 6 of the 26 facilities unable to provide a detailed update, so 2020 data has been included as they remain operational.

The report has been compiled to provide an overall picture of the capability and capacity of MHRA-licensed cell and gene therapy manufacturing sites in the UK. Amongst other elements, the report highlights:

- Total manufacturing cleanroom footprint (including MALs and PALs)
- Total in-house QC footprint
- CRO capabilities
- Total number of full-time employees (including production, QA, QC, warehouse, and engineering staff only)
- Track record of experience (types of cells and/or viral vector/plasmid DNA and manufacturing processes)
- The distribution of the capabilities, footprint, and staff based on the geographical location of the facilities (London, Southern England (non-London), Midlands and Northern England and Scotland) and the product type (cell therapy, gene therapy or multifunctional)
- Predictions of the available manufacturing capacity at the facilities in 2022 and 2023

| | Organisation / facility name |
|---|---|
| **Multifunctional cell and gene therapy manufacturing facilities** | |
| 1 | Cell and Gene Therapy Catapult Stevenage Manufacturing Innovation Centre (CGTC Stevenage MIC) |
| 2 | Great Ormond Street Hospital (GOSH), Great Ormond Institute of Child Health |
| 3 | King's College London, Rayne Cell Therapy Suite (RCTS) and the Cell Therapy Unit (CTU) with the NIHR Welcome Trust King's Clinical Research Facility* |
| 4 | Roslin CT |
| 5 | Royal Free Hospital London, Centre for Cell and Gene Tissue Therapeutics** |
| 6 | TC Biopharm* |
| **Dedicated gene therapy manufacturing facilities** | |
| 7 | Cobra Biologics (a Charles River company) |
| 8 | Meira GTx* |
| 9 | Merck |
| 10 | NHS Blood and Transplant (NHSBT) Filton*** |
| 11 | NHSBT Langford |
| 12 | Oxford BioMedica, Oxbox Manufacturing Facility |
| 13 | Oxford BioMedica, Harrow House Manufacturing Facility |
| 14 | Oxford Biomedica, Yarnton Manufacturing Facility |
| 15 | Pharmaron Gene Therapy (formerly Allergan Biologics) |
| 16 | University of Oxford, Clinical BioManufacturing Facility (CBF) |
| **Dedicated cell therapy manufacturing facilities** | |
| 17 | Instil Bio UK (formerly Immetacyte Ltd) * |
| 18 | John Goldman Centre for Cellular Therapy, Imperial College London |
| 19 | Moorfields Eye Hospital, Cells for Sight Stem Cell Therapy Research Unit* |
| 20 | National Institute for Health Research (NIHR) Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust and King's College London (GSTT BRC) * |
| 21 | Newcastle University, Newcastle Cellular Therapies Facility |
| 22 | NHSBT Barnsley**** |
| 23 | NHSBT Birmingham |
| 24 | NHSBT Speke |
| 25 | Scottish National Blood Transfusion Service (SNBTS) |
| 26 | University of Birmingham, Advanced Therapies Facility |

***Table 1:*** *MHRA-licensed facilities included in the 2021 UK cell and gene therapy GMP manufacturing capability and capacity survey report*

**The facilities' 2020 data has been used in this report*

*** Moved from dedicated cell therapy in 2020 to multi-functional cell and gene*

**** Moved from dedicated cell therapy in 2020 to dedicated gene therapy*

***** New facility*

*Note: Cancer Research UK (CRUK), Biotherapeutics Development Unit removed from list (closed)*

# 3. National picture of UK cell and gene therapy manufacture

## Geographic locations

The map below (**Figure 1**) highlights the diverse geographical spread of ATMP GMP manufacturing sites across the UK. There remains a high number of sites around the Greater London Area (n=7). These facilities are primarily academic and hospitals, 3 of these facilities are multi-functional and 6 of the 7 are authorised for clinical trial manufacturing only. In line with the clinical and academic nature of these cleanrooms, the total footprint of cleanroom space in the Greater London Area only represents 11% of the UK total.

The licensing of NHSBT Barnsley adds to a growing cluster (12 sites) around the Northern England and Scotland. This northern cluster contains a range of cell therapy, gene therapy and multi-functional facilities with a higher proportion of commercial sites (6 out of the 12 sites) compared to the academic/ hospital picture in London. Scotland now has 28% of the total UK manufacturing cleanroom footprint, an increase of 76% from last year, primarily due to the expansion of Roslin Cells. Scotland also has 74% of the total UK QC testing footprint.

There are two facilities in Scotland with an MIA for the manufacture of authorised products: SNBTS and RoslinCT.

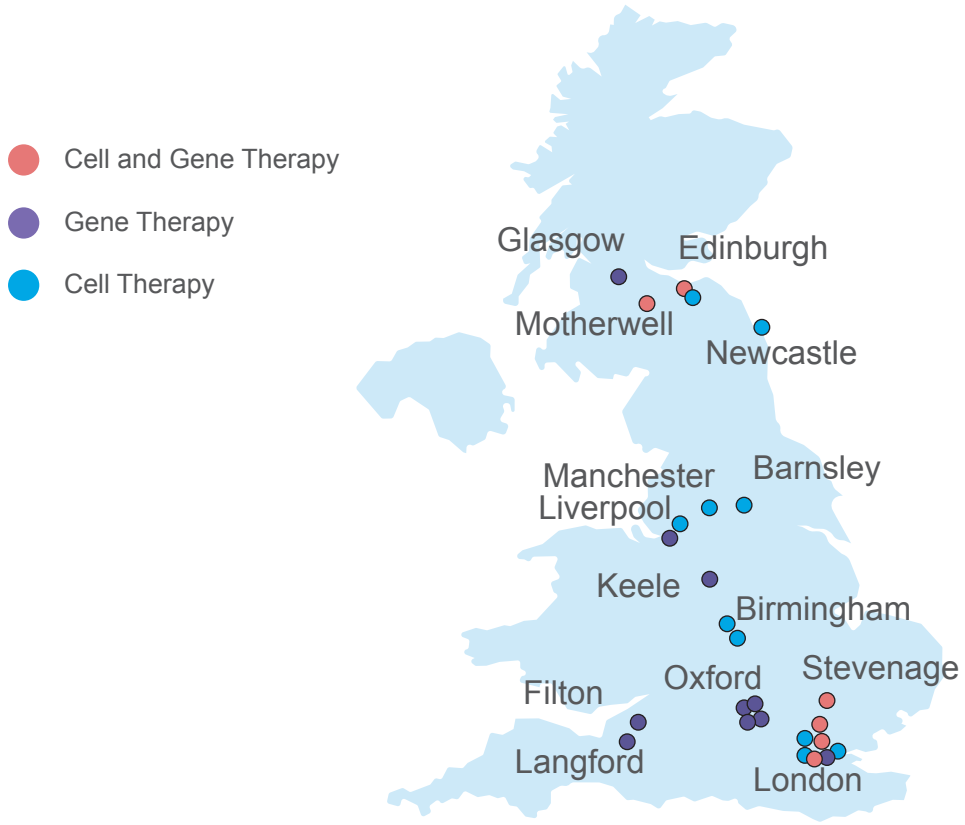


***Figure 1:*** *Location of MHRA-licensed cell and gene therapy manufacturing sites within the UK*

*Following a change in the licence model of the Cell and Gene Therapy Catapult Manufacturing Innovation Centre in Stevenage, there is an additional MIA(IMP) in place for Autolus (gene modified cell therapy manufacturing). The overall site manufacturing footprint and functionality remains unchanged.*


***Figure 2:*** *Snapshot of cell and gene therapy facilities in the UK*

***QC space at Merck (6,558m²) encompasses analytical control services for ATMPs as well as conventional biologics*

**Figure 2** shows a snapshot of 26 facilities that form the overall capacity and capability for cell and gene therapy manufacturing within the UK. There was no overall change in the number of facilities from 2020 as the opening of NHSBT Barnsley (under the overall NHSBT MIA(IMP)) was offset by the closure of CRUK.

The increase in 2 gene therapy manufacturers is caused by two facilities changing their classification. NHSBT Filton changed from cell to gene therapy and Pharmaron have changed from multi-functional to dedicated gene therapy facility.

Increases in cleanroom footprint have been fuelled by the expansion of RoslinCT (a tenfold increase in cleanroom footprint), opening of NHSBT Barnsley and an increase in the number of cleanrooms at NHSBT Filton. There was no increase in the number of Grade B cleanrooms, a 10% increase in the number of Grade C cleanrooms and a 26% increase in the number of Grade D cleanrooms, reflecting the continuing development and closing of manufacturing processes.

The overall booked up capacity has reduced from 86% to 63%. There is some regional variation with Southern England recording 75% booked up capacity (and a small decrease in available footprint compared to 2020) whereas the Midlands and Northern England reporting 45% booked up capacity, potentially reflecting the 63% increase in cleanroom footprint in this region, compared to 2020.

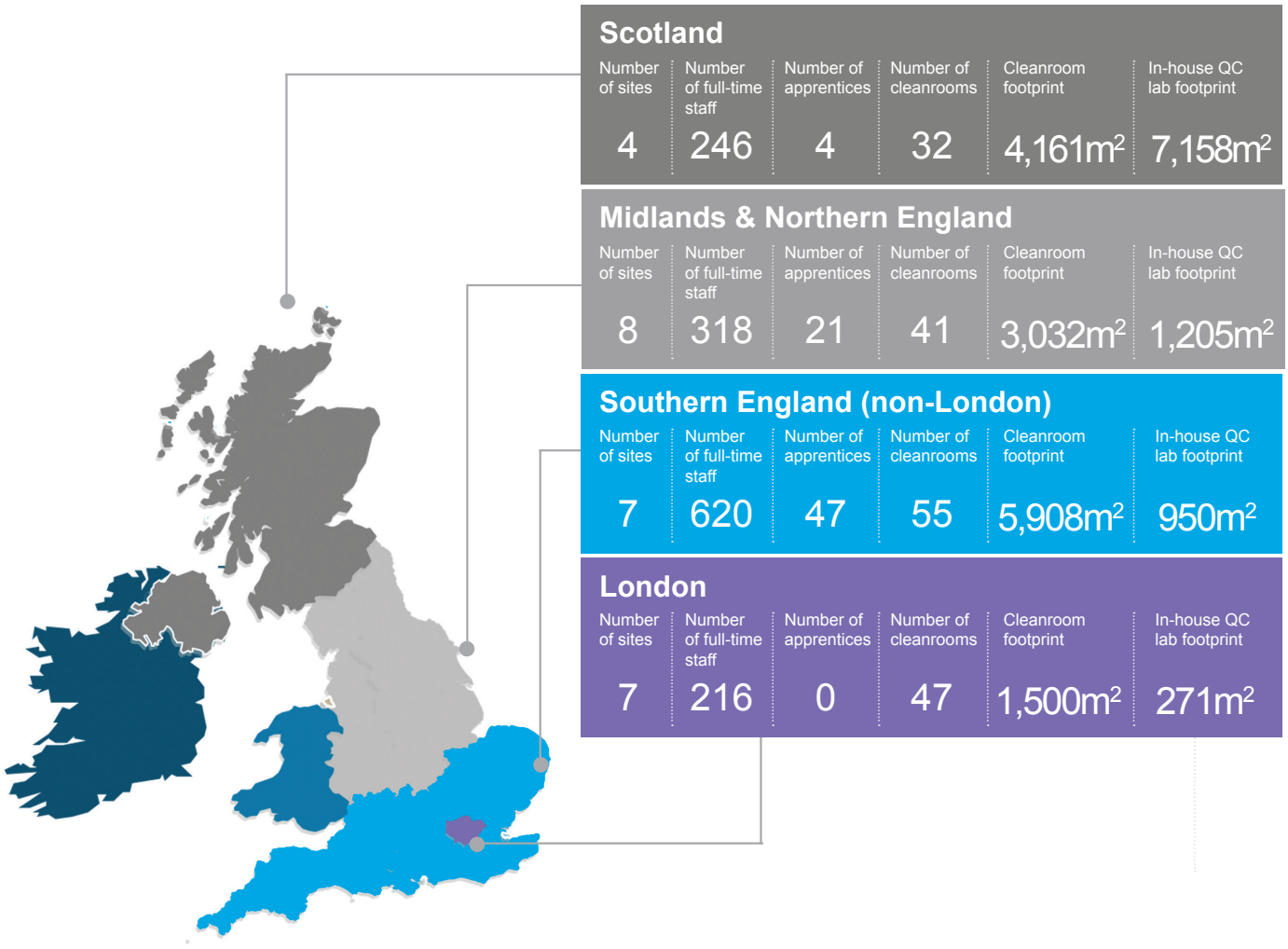


***Figure 3:*** *Distribution of cleanroom footprint, QC footprint, and staff across the facilities in London, Southern England (non-London), Midlands and Northern England and Scotland (these charts incorporate cell therapy, gene therapy, and multifunctional sites).*

**Figure 3** provides a regional breakdown of the total cleanroom footprint, in-house QC footprint, number of cleanrooms, full time employees and apprentices within the UK.

Scotland has 74% of the total UK QC testing footprint and has seen the biggest increases in both the numbers of full-time staff (26%) and number of overall cleanrooms as a consequence of the expansion of RoslinCT. There has also been a significant increase in the number of cleanrooms in Midlands and Northern England with the opening of NHSBT Barnsley and expansion of NHSBT Filton. This region has seen a 63% increase in cleanroom footprint and 56% increase in QC footprint.

In Southern England, the number of cleanrooms and overall cleanroom footprint has fallen slightly by 2% with the closure of CRUK, but the sector is creating more jobs with a 6% increase in the total number of employed staff to 620 in 2021 compared to 584 in 2020. Overall Southern England still represents 40% of the UK cleanroom total footprint.

Although London has the highest number of facilities in a small area, there has been very little change

compared to 2020. As the cleanrooms in London are primarily NHS and academic, the relative size of the cleanroom footprint in London (11% of UK total) is low compared to Southern England and Scotland where there are more commercial manufacturing activities.

The total number of employees in the UK in ATMP GMP manufacturing facilities has risen by 7%, from 1,310 in 2020 to 1,400 in 2021. For the first time this year we have included the number of apprentices in this report. There has been a rise in the number of apprentices in the sector following the setup of the Advanced Therapies Apprenticeship Community (ATTC) which now counts 213 apprentices, of which 72 are employed in the surveyed facilities. 70% of the 72 apprentices reported here are employed in gene-therapy dedicated facilities, although this figure is heavily weighted by the large number of apprentices at Oxford Biomedica. Geographically, there is a similar spread of apprentices across the UK; as a proportion of apprenticeships per full time staff 15% are in the Midlands and Northern England with 13% in Southern England.

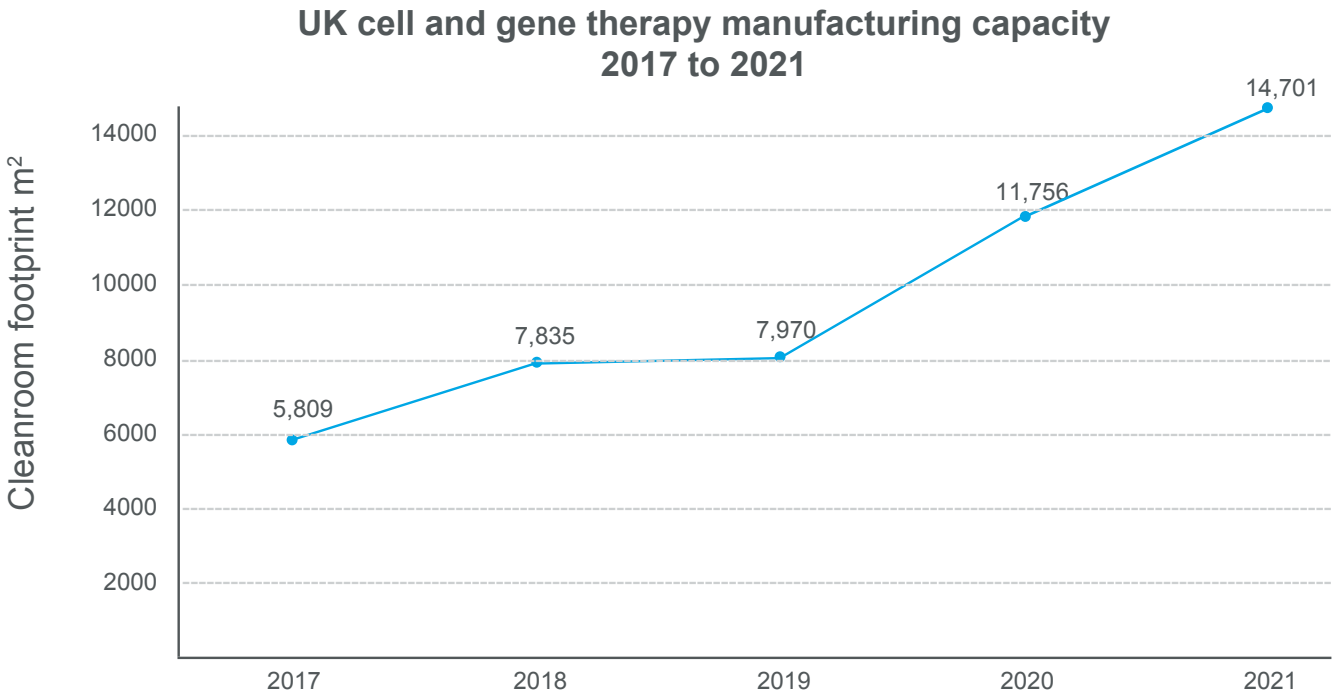


***Figure 4:*** UK cleanroom footprint for manufacturing cell and gene therapies, 2017 to 2021

Changes in the national cell and gene therapy GMP manufacturing footprint for years 2017 to 2021 are displayed in **figure 4.** The GMP manufacturing footprint continues to expand year on year. Over the last five years (2017-2021) the overall GMP footprint has increased by 153% and there has been a 25% increase in the cleanroom footprint in the last year. With a number of planned expansion projects on the horizon, the outlook for future growth remains extremely positive. Further details are presented in section 4 of this report.

### 3.1 Cell therapy manufacturing

A snapshot of dedicated cell therapy GMP manufacturing is given in **figure 5.** This sector contains the largest number of NHS and academic translational facilities and hence the lower reported proportional footprint and staff number per centre.

The total number of facilities has reduced from 11 in 2020 to 10 in 2021 with the addition of NHSBT Barnsley offset by a change in classification of NHSBT Filton and the Royal Free from cell therapy to gene therapy manufacturing. Consequently, the total cleanroom footprint in this category has reduced by 13% compared to 2020 but the median number of cleanrooms per facility is unchanged at 4.

The average booked up capacity has reduced from 86% to 57%. The majority of organisations in the cell therapy manufacturing category are NHS and academic translational centres and it is likely that the ongoing COVID-19 pandemic has impacted planned manufacturing activities and supply chains in this sector. Significant facility expansions are planned for cell-therapy dedicated manufacturing facilities, refer to Section 4 for further details.

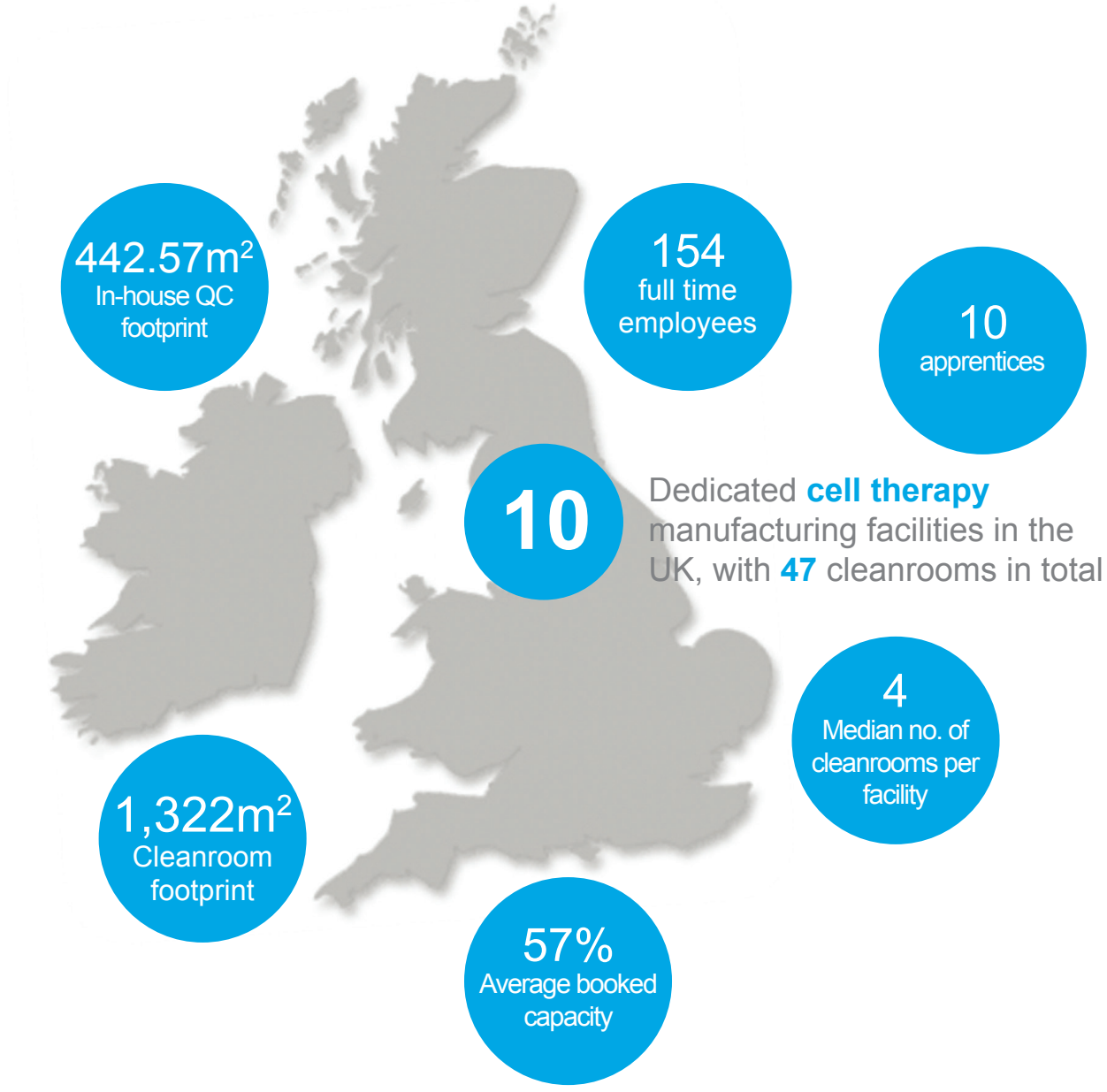


***Figure 5:*** *Snapshot of dedicated cell therapy facilities in the UK*

**Figure 6** shows a breakdown of the types of processes and cell types that the various organisations are currently working with. Both dedicated cell therapy manufacturers (10) and multifunctional cell and gene therapy facilities (6) are included in the total number of sites in this figure.

There has been a reduction in the number of sites offering allogeneic cell therapy manufacturing capability caused by NHSBT Filton changing from cell therapy to gene therapy manufacturing, the closure of CRUK and RoslinCT no longer offering allogeneic cell therapy manufacturing capacity.

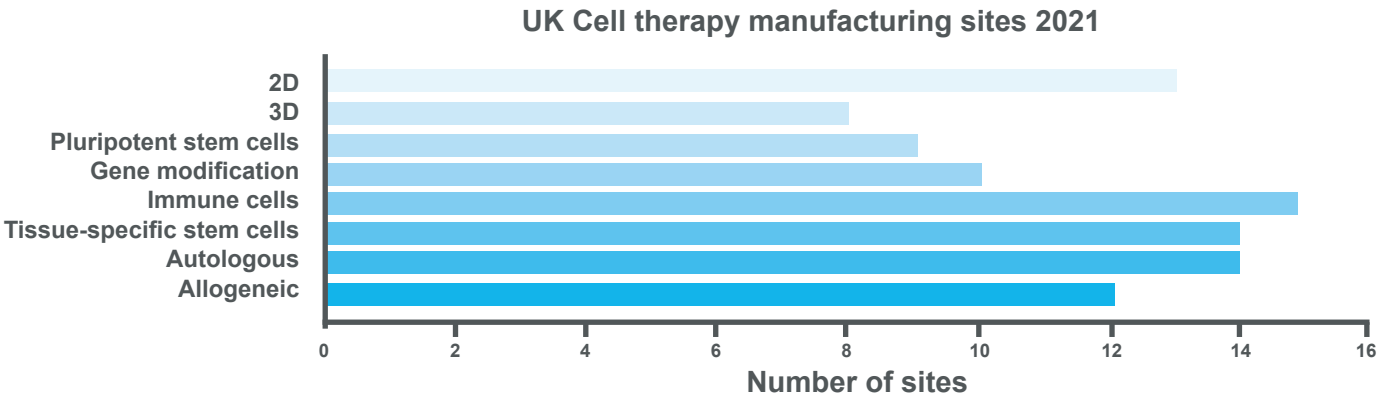


***Figure 6:*** *Summary of cell therapy process capabilities at dedicated cell therapy and multifunctional facilities across the UK*

***Key:*** *Gene modification – ex vivo modification of cells to be used as a medicinal product; pluripotent stem cells – culture of induced pluripotent stem cells from donor tissue or culture of human embryonic stem cells from donor tissue; 3D – culture of cells in a 3D environment; 2D – culture of cells in a 2D environment.*

**Table 2** provides a comprehensive breakdown at facility-level for capability as well as the projected available capacity for cell therapy manufacture for 2020-2022 throughout the UK.

The spread of capabilities highlights the strong and diverse manufacturing base in the UK for clinical development through to commercial supply. Spare capacity is predicted in 2022, 2023 and 2024 at all centres reflecting the overall increase in available capacity seen nationwide.

It should be noted that despite having cell therapy manufacturing capabilities, the types of processes and cell types with which Pharmaron, Merck and TC Biopharm are working with is for their own product pipelines and are not disclosed in this report.

| Organisation | Parallel products (open/ closed) | Capability | | | | | | | | Spare Capacity | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Autologous | Allogeneic | Immune cells | Pluripotent stem cells | Tissue-specific stem cells | Gene modification | 3D | 2D | 2021 | 2022 | 2023 |
| CGTC Stevenage MIC* | DoP | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | 25 | 25 | 25 |
| GOSH* | 7 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | 100 | 100 | 100 |
| GSTT BRC | 4 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | × | × | 30 | 40 | 40 |
| Instil Bio | 4 | ✓ | × | ✓ | × | × | × | × | × | - | - | - |
| John Goldman Centre | 3 open (or 4 with temporal segregation) | ✓ | ✓ | ✓ | × | ✓ | ✓ | × | ✓ | 10 | - | - |
| Kings (RCTS & CTU) * | 6 or 8 | ✓ | ✓ | ✓ | × | ✓ | ✓ | ✓ | ✓ | 20 | 20 | 20 |
| Moorfields | (4/0) | ✓ | ✓ | ✓ | ✓ | ✓ | × | ✓ | ✓ | 50 | 50 | 50 |
| NHSBT Barnsley | 3 | × | × | ✓ | × | ✓ | ✓ | ✓ | ✓ | 60 | 80 | - |
| NHSBT Birmingham | 3 | ✓ | ✓ | ✓ | × | ✓ | × | ✓ | ✓ | 50 | 50 | - |
| NHSBT Speke | 3 | ✓ | ✓ | ✓ | × | ✓ | × | ✓ | ✓ | 60 | 60 | - |
| Roslin* | 5 | ✓ | × | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | 15 | 15 | 15 |
| Royal Free* | 2 (6/2) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | × | ✓ | 10 | 20 | 20 |
| SNBTS | 10 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | × | ✓ | 10 | 20 | 30 |
| Uni of Birmingham | Up to 7 (up to 2 open or closed processes simultaneously) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | × | ✓ | 50 | 40 | 40 |
| Uni of Newcastle | 2 (9 with temporal segregation) | ✓ | ✓ | ✓ | ✓ | ✓ | × | × | ✓ | 70 | 70 | 70 |

***Table 2:*** *Summary of GMP Cell therapy capability and availability of UK organisations*
***Key:*** *DoP – Dependent on Process; *Multifunctional organisations with both cell and gene therapy manufacturing capabilities*

### 3.2 Gene therapy manufacturing

**Figure 7** gives a snapshot of the dedicated gene therapy manufacturing facilities in the UK, which contains higher numbers of commercial facilities and higher overall staffing levels, compared to dedicated cell therapy facilities.

The total dedicated gene therapy manufacturing space is 8,034m$^2$, an increase of 20% from 2020 with expansions of NHSBT Filton and Pharmaron.

This sector has increased overall compared to 2020 with increased in-house QC footprint, full time employees and overall numbers of facilities. As a consequence, booked up capacity has significantly reduced from 95% in 2020 to a more positive 68% this year. There are the same median number of cleanrooms per facility as in 2020.

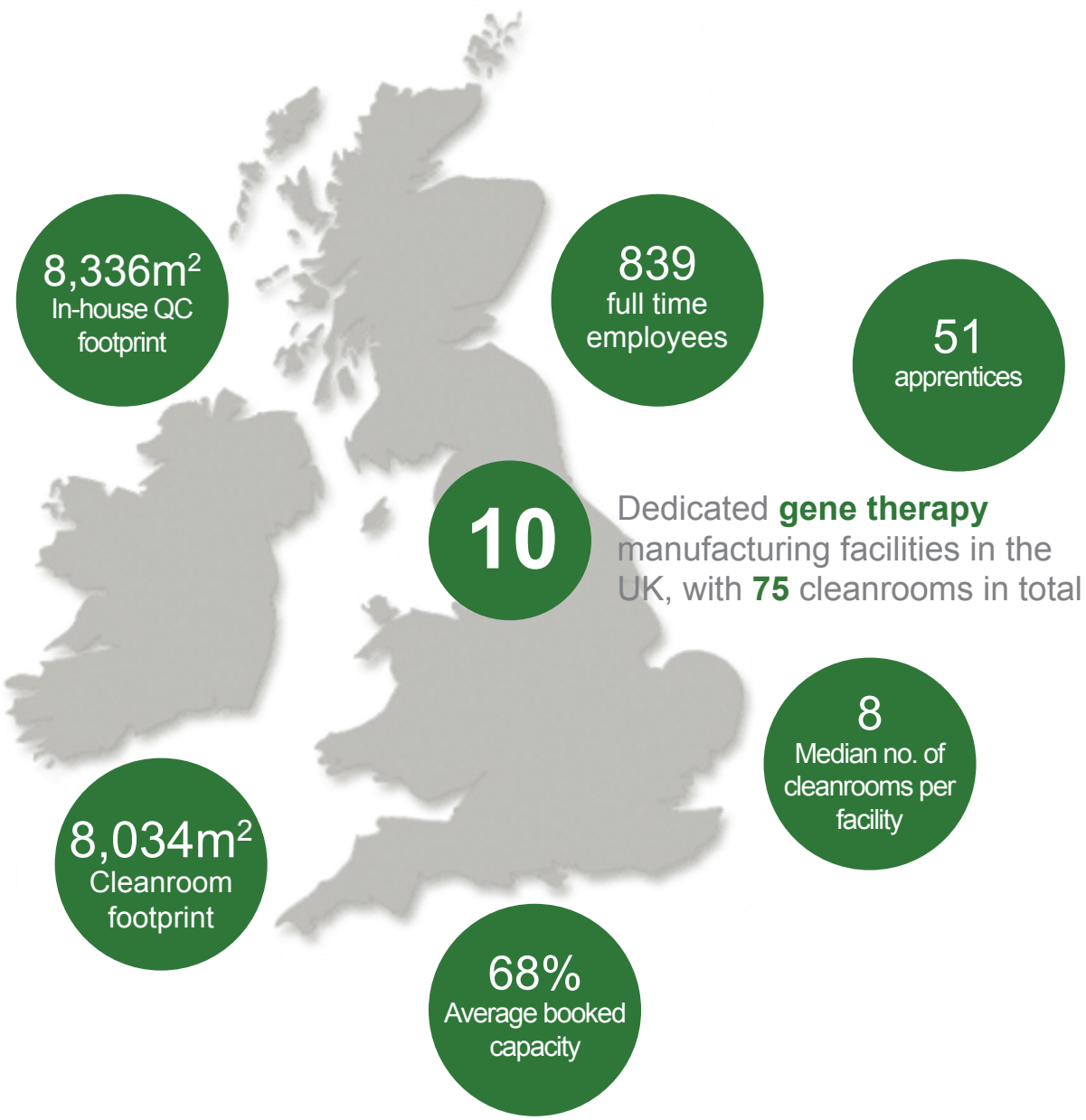


***Figure 7:*** *Snapshot of dedicated cell therapy facilities in the UK*

**Figure 8** shows a breakdown of the types of plasmid, vector, and cell producer systems handled in the facilities with gene therapy capabilities. This data includes dedicated manufacturers (8) and multifunctional gene therapy facilities (7). There remains the same broad coverage of capabilities seen in 2020, with some internal changes in the different capabilities offered by different facilities. Capabilities range from plasmid DNA production through to GMP-grade manufacture of lentivirus and gamma-retrovirus, which are two of the main viral vectors used in ex vivo gene modification processes and manufacturing of Adeno-associated virus (AAV) – a common tool for delivery of in vivo gene therapies.

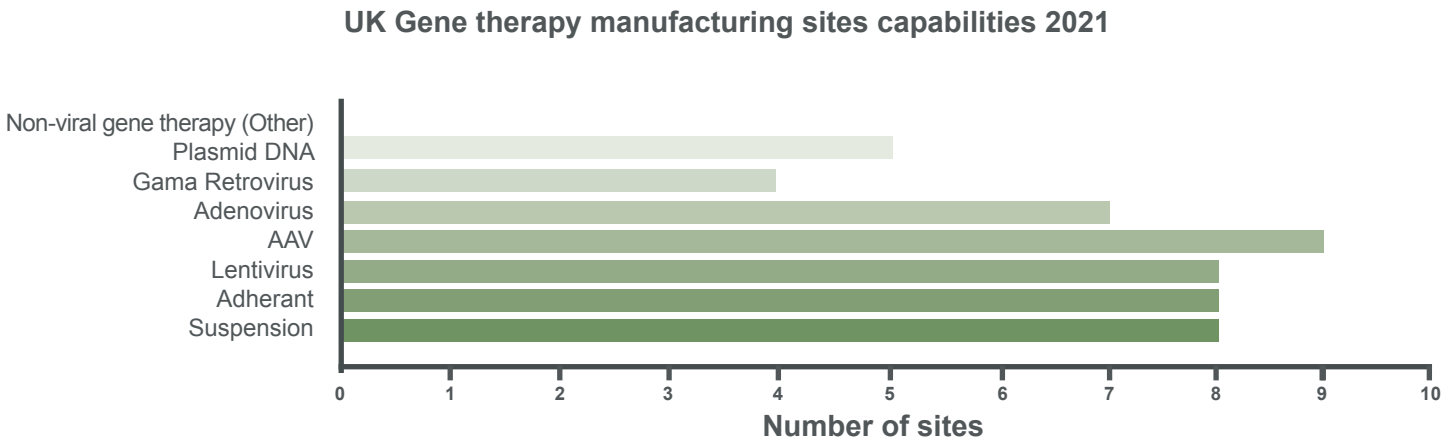


***Figure 8:*** *Summary of gene therapy capabilities across dedicated gene therapy and multifunctional facilities in the UK*

***Key:*** *Plasmid DNA – material used directly as IMPs and/or starting material used for transient infection to enable manufacture of viral vectors; Adenovirus/Gamma Retrovirus/Lentivirus/Adeno-associated virus (AAV) – key types of viral vectors used directly as IMPs and/or starting material used for transduction of cells ex vivo; Adherent – culture of anchorage-dependent cells; Suspension – culture of anchorage-independent cells.*

***Note:*** *For this table, Oxford Biomedica's three sites have been incorporated together*

**Table 3** shows a summary of the capability and availability at each of the gene therapy production centres, apart from TC Biopharm and the Royal Free's capabilities which are undisclosed.

Spare capacity at the manufacturing centres is essential for prospective growth within the UK gene therapy sector particularly since the number of clinical trials that utilise viral vectors continues to increase year on year. The booked capacity in 2020 was reported at 95%, a figure which could not support ongoing clinical trials. With facility expansions coming online in 2021 (and more planned for the future, refer to Section 4 for details), the booked capacity has fallen to 75% which offers more support to the growing clinical trial programmes.

| Organisation | Parallel products (open/ closed) | Capability | | | | | | | | Spare Capacity | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Suspen-sion | Adherent | AAV | Lentivirus | Gamma Retrovi-rus | Plasmid DNA | Adenovirus | Non-viral gene delivery | 2021 | 2022 | 2023 |
| CGTC Stevenage MIC* | DoP | ✓ | ✓ | ✓ | ✓ | ✓ | × | ✓ | × | 25 | 25 | 25 |
| Cobra Biologics (a Charles River company) | 4 | ✓ | ✓ | ✓ | ✓ | × | ✓ | ✓ | × | 50 | 100 | 100 |
| GOSH* | 7 | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | × | 100 | 100 | 100 |
| Kings (RCTS & CTU) * | 6 or 8 | ✓ | ✓ | ✓ | ✓ | ✓ | × | × | × | 20 | 20 | 20 |
| Meira GTx | 3 | × | × | ✓ | × | × | × | × | × | 25 | - | - |
| Merck* | 8 | ✓ | ✓ | ✓ | ✓ | ✓ | × | ✓ | × | 80 | 80 | - |
| NHSBT Filton | 4 plasmid and 2 viral vector | × | × | ✓ | ✓ | × | ✓ | × | × | 50 | 50 | - |
| NHSBT Langford | 2 | × | × | × | × | × | ✓ | × | × | 50 | - | - |
| Oxford Biomedica | 7 | ✓ | ✓ | ✓ | ✓ | × | × | ✓ | × | 25 | 50 | 50 |
| Pharmaron Gene Therapy (formerly Allergan) | undisclosed | ✓ | ✓ | ✓ | ✓ | × | ✓ | ✓ | × | 0 | 80 | 100 |
| Roslin* | 4 | ✓ | ✓ | × | × | × | × | × | ✓ | 40 | 50 | 50 |
| Uni of Oxford | 0 (1/10) | ✓ | ✓ | × | × | × | × | ✓ | × | 0 | 25 | 50 |

***Table 3:*** *Gene therapy capability and available capacity at UK facilities*

***Key:*** *DoP – Dependent on Process; *Multifunctional organisations with both cell and gene therapy manufacturing capabilities*

***Note:*** *For this table, Oxford Biomedica's three sites have been incorporated together*

### 3.3 Multifunctional facilities

Six facilities are multifunctional across the UK, with cell and gene therapy production capabilities.

The net number of organisations in this category has decreased by one. The CRUK site in Potter's Bar suspended manufacturing activities and Pharmaron (formally Allergan) have reverted to being gene therapy specific (multi-functional in 2020, gene therapy dedicated in 2019). However, the Royal Free hospital has moved from being dedicated to cell therapies to being multi-functional.

Overall, the total number of full-time employees has decreased in this category. However, the total cleanroom footprint increased by 51% from 3,545m$^2$ in 2020 to 5,345m$^2$ to date and the in-house QC footprint increased by 8% from 850 to 921m$^2$. This is mirrored by an increase in the median number of cleanrooms per facility from 7 in 2020 to 10 in 2021.

Reflecting the trend seen in cell and gene therapy dedicated facilities, the average booked capacity has decreased from 75% to 66% in 2021.

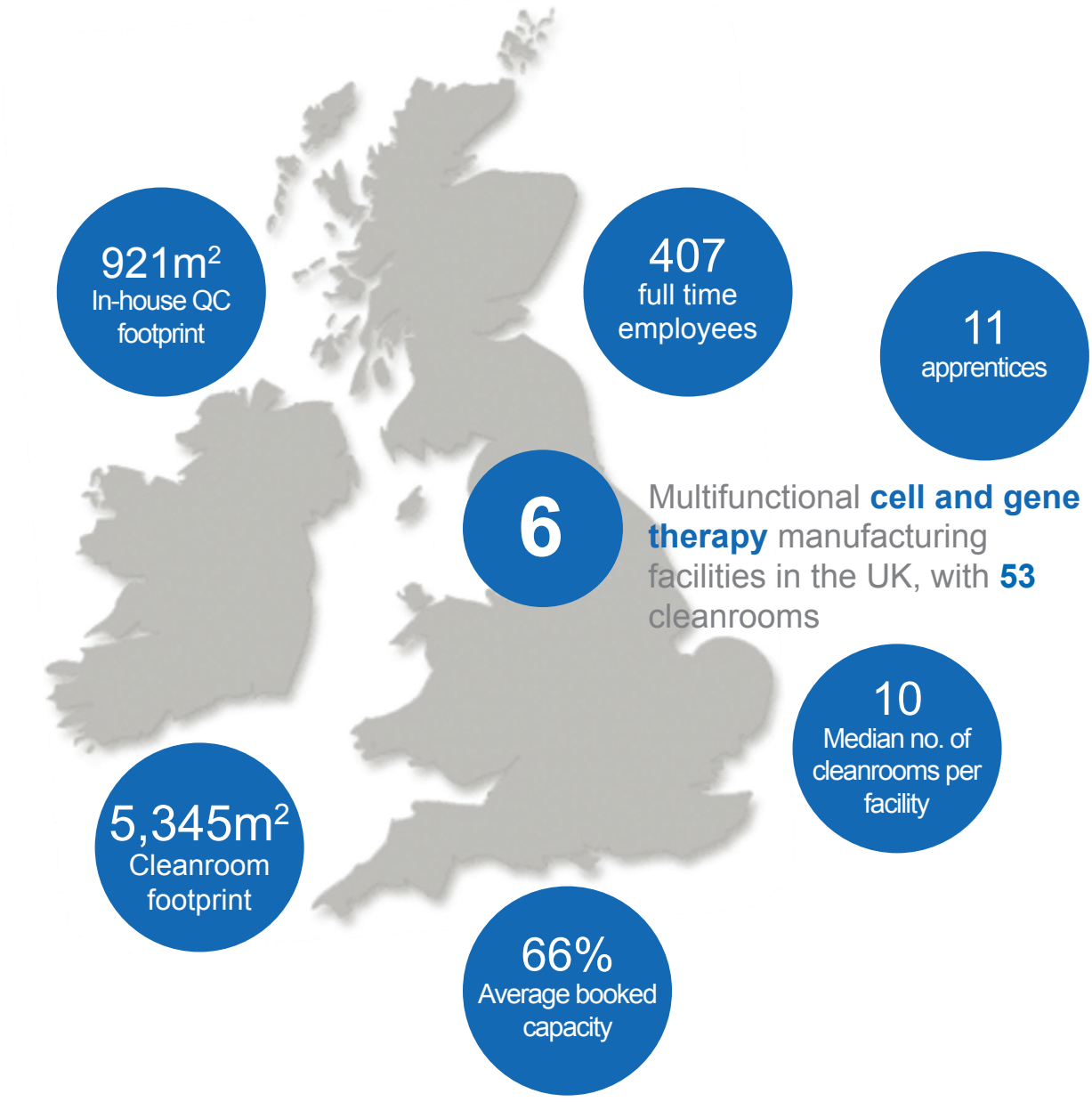


***Figure 9:*** *Snapshot of multifunctional facilities in the UK*

## 3.4 Therapies produced for pre-clinical, early clinical, late clinical, and commercial use

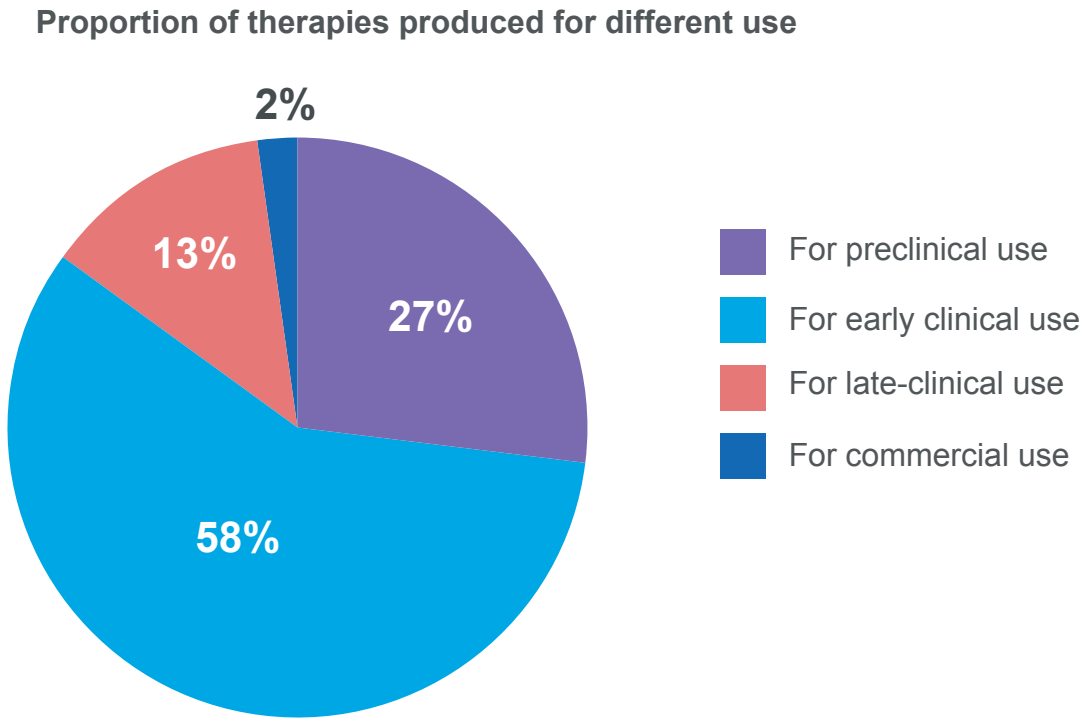


***Figure 10:*** *Therapies being manufactured for preclinical, early clinical, late clinical, and commercial use (n = 10)*

**Figure 10** shows the spread of clinical trials that therapies in the UK are being manufactured for. Over half the therapies are being manufactured for early clinical use with only 2% of manufactured therapies having a marketing authorisation. With the increase in MIAs for commercial manufacturing granted during 2021, this will be monitored over the coming years to see if this figure rises.

## 3.5 Contract research organisation bioanalytical testing services and capabilities

For the first time this year, respondents were asked if they used a contract organisation for their analytical and/or Quality Control needs. Of those that responded (n = 10) 60% did use a contract organisation, and of those, 83% were using a UK based contract organisation.

Details of UK and Ireland based contract analytical capability is given in section 6 of this report. There is a broad spectrum of starting material (including raw materials, human donor material and pluripotent cell banks, plasmids, master and working cell banks) and release testing (including bulk, drug substance and drug product) available encompassing both characterisation and biosafety testing for cell and gene therapies.

We will continue to monitor and expand this analysis in future surveys.

# 4. Future capacity and expansion

Annual reviews of the UK manufacturing landscape are important to identify facility expansions, increase in personnel numbers, and track records of the opening of new facilities. As a forward-looking statement, a description of upcoming expansions of existing facilities or newly licensed sites has been outlined below:

- Construction is underway for Autolus's multi-functional, 70 000 $ft^2$ manufacturing headquarters, anticipated to come online in 2023
- The University of Birmingham currently plans to increase capacity by 400 $m^2$ of cleanroom space. This will form part of the Birmingham Health Innovation Campus and will be delivered in 2024
- CPI has 150$m^2$ of GMP qualified clean rooms in the National Biologics Manufacturing Centre in Darlington. The facility consists of 2 Grade D and 1 Grade C cleanroom suites. The facility is fully utilised until mid-2025 at the earliest. CPI has also established the UKs RNA Centre of Excellence at Darlington which will be licensed in Q1 2022. This consists of 160$m^2$ of grade C clean rooms and 75$m^2$ grade D suites. This facility is designed primarily for RNA manufacture and encapsulation and is fully utilised throughout 2023
- eXmoor pharma concepts ltd are planning a new 50,000 $ft^2$ process development and clinical manufacturing facility in Bristol
- FujiFilm Diosynth Biotechnologies are expanding their UK operations and gene therapy offerings with the addition of viral vector process development and GMP manufacturing services at an expanded BioCampus in Billingham. The expansion lays the groundwork for further growth of manufacturing services for gene therapies.
- GSTT BRC aims to double its current manufacturing and QC capacity. This will become operational in 2021 (note, no update from 2020 data)
- Oxford Biomedica has recently brought online its Oxbox facility with its 4 vector drug substance suites being MHRA licensed in 2020. The company is currently in the final stages of adding fill and finish capability to its portfolio. Concept designs for the remaining space are well development for a future "Phase II" expansion, provisionally expected H2 2023
- The University of Oxford CBF plans to add 2 Grade C cleanrooms in adjacent building to complete construction in 2023
- Pharmaron plans a major expansion of development laboratories in the next 1-3 years and commercial manufacturing is anticipated in 2-5 years
- Following their recent expansion, Roslin CT plans to add an additional 15 cleanrooms in a second phase
- SNBTS plans to expand QC capability and translational / tech transfer space in the coming years
- Expansion plans are also on the horizon for the Cobra Biologics (a Charles River company), MeiraGtx, the CRUK facility and Instil Bio (formerly Immetacyte)

To our knowledge no other new MHRA-licensed cell or gene therapy manufacturing sites are due to come online in 2021 / 2022 which offer collaborative potential. However, please contact lee.dunham@ct.catapult.org.uk if you have any information regarding new facilities of which we are not aware.

# 5. MHRA MIA (IMP) and MIA licensed facilities in the UK

| Organisation Name | Method of Working | LICENCE | | | | | Licenced Cleanrooms & Footprint | Future Capacity | Location | Contact |
|---|---|---|---|---|---|---|---|---|---|---|
| | | MIA (IMP) | MIA | MS | HTA | GMO | | | | |
| **CELL AND GENE THERAPY MANUFACTURING ORGANISATIONS** | | | | | | | | | | |
| CATAPULT Cell and Gene Therapy | Other | ✓ * | ✓ * | * | * | * | 12 Grade C 2,000m² | | Stevenage, SG1 2FX | Lee Dunham lee.dunham@ct.catapult.org.uk |
| Great Ormond Street Hospital | Hospital (NHS) | ✓ | ✓ | ✓ | ✓ | ✓ | 7 140m² | | London, WC1N 3JH | Barry Flutter barry.flutter@gosh.nhs.uk |
| King's College London NIHR National Institute for Health Research | Academic; Hospital (NHS) | ✓ | | ✓ | ✓ | | 2 Grade D at RCTS, 3 Grade B and 5 Grade D at CTU 455m² | | London, SE5 9NU and London, SE5 9RS | **RCTS** Faith Green faith.green@kcl.ac.uk Sabine Domning sabine.domning@kcl.ac.uk Rebecca Prue E: rebecca.prue@kcl.ac.uk **CTU** Cristina Trento-Quality Director cristina.trento@nhs.net T:020 3299 1854 |
| Roslin CT your advanced therapy solution | CDMO | ✓ | ✓ | | ✓ | | 5 Grade B 5 Grade C 2,000m² | 1b 3 additional cleanroom suites<br><br>Phase two, 15 cleanroom suites | Edinburgh Scotland, EH16 4UX | Janet Downie janet.downie@roslinct.com Tel: 0131 658 5182 Kevin Bruce kevin.bruce@roslinct.com Tel: 0131 658 5359 |
| NHS Royal Free London NHS Foundation Trust | Hospital (NHS) | ✓ | | ✓ | ✓ | | 5 x Grade B 1 x Grade C 4 x Grade D<br><br>200m² | | London, NW3 2QG | Dr Owen Bain owen.bain@nhs.net 0207 7940500 ext.33484 |
| TC BIOPHARM | Commercial | ✓ | | ✓ | ✓ | | 4 Grade B 450m² | Expansion includes 3 Grade B and 2 Grade C suites (additional 1600m² to be built). | Holytown, Motherwell, ML1 4WR | N/A |

| Organisation Name | Method of Working | LICENCE | | | | | Licenced Cleanrooms & Footprint | Future Capacity | Location | Contact |
|---|---|---|---|---|---|---|---|---|---|---|
| | | MIA (IMP) | MIA | MS | HTA | GMO | | | | |
| **DEDICATED GENE THERAPY MANUFACTURING ORGANISATIONS** | | | | | | | | | | |
| COBRA BIOLOGICS | Partnerships | ✓ | | | | | 9<br>1,400m² | | Keele, ST5 5SP | Philip Ridley-Smith<br>philip.ridley-smith@cobrabio.com<br>Tel: 0208 246 5895 |
| MEIRAGTx | Commercial | ✓ | | ✓ | | | 3 Grade C, 4 Grade D<br>109m² | | London, N1 7NQ | Francois Toubhantz<br>francois.toubhantz@meiragtx.com |
| MERCK | CMO | ✓ | | | | | 8 Grade B<br>1,211m² | | Glasgow, G20 0XA | Lauren MacDonald<br>Tel: 0141 579 3249<br>lauren.macdonald@merckgroup.com<br>Karen McLennan<br>Tel: 0141 579 3290 |
| NHS Blood and Transplant | NHS clinical services (national) | ✓ | | | ✓ | ✓ | 3 Grade C - 2 mammalian and one fill and finish.<br>7 grade Ds -<br>4 up stream, 2 downstream and 1 buffer prep. 354m² | | Filton, Bristol, BS34 7QH | Jonathan Caddick<br>Jonathan.caddick@nhsbt.nhs.uk<br>Tel: 07471 147804<br>Laura Murray laura.murray@nhsbt.nhs.uk<br>Tel: 07384 879380 |
| NHS Blood and Transplant | NHS clinical services (national) | ✓ | | | ✓ | ✓ | 3 Grade C<br>4 Grade D<br>140m² | | Lower Langford, near Bristol, BS40 5DUX | Jonathan Caddick<br>Jonathan.caddick@nhsbt.nhs.uk<br>Laura Murray laura.murray@nhsbt.nhs.uk |
| OxfordBioMedica | Commercial | ✓ | ✓ | | | | 7 Grade C suites (20 cleanrooms) vector substance and<br>1 cleanroom suite being prepared for fill and finish (grade C)<br>3,205m² | OXB are currently in the final stages of adding fill and finish to their portfolio. Concept designs for the remaining space within the Oxbox are well developed for expansion in Phase II. Provisional timelines for this expansion are H2 2023 | Harrow: Oxford, OX4 6LX<br>Yarnton: Oxford, OX5 1QU<br>Oxbox: Oxford, OX4 2JZ | Jason Slingsby<br>enquiries@oxb.com<br>Tel: 01865 785300 |
| 康龙化成 PHARMARON | CDMO | ✓ | | | | | 8x Grade B/C<br>1,012m² | "Major expansion of development laboratories anticipated within the next 1-3 years and commercial manufacturing expected in the next 2-5 years." | Liverpool, L24 8RB | Christopher Sadler<br>Christopher.Sadler@Pharmaron-uk.com<br>Tel: +44 (0)151 728 1750 |
| UNIVERSITY OF OXFORD Clinical BioManufacturing Facility | Academic | ✓ | | | | | Grade B = 0<br>Grade C = 4 (+ 1 change area)<br>Grade D = 1 (+ 1 change and 1 ancillary area)<br><br>109m² | New adjacent building to complete construction in Q3 2023. Will include 2 Grade C cleanrooms. Footprint TBD. | Oxford, OX3 7JT | Catherine Green<br>cbfhead@ndm.ox.ac.uk<br>Tel: 01865 744845<br>Emma Bolam emma.bolam@ndm.ox.ac.uk<br>Tel: 01865 611356 |

| Organisation Name | Method of Working | LICENCE | | | | | Licenced Cleanrooms & Footprint | Future Capacity | Location | Contact |
|---|---|---|---|---|---|---|---|---|---|---|
| | | MIA (IMP) | MIA | MS | HTA | GMO | | | | |
| **DEDICATED CELL THERAPY MANUFACTURING ORGANISATIONS** | | | | | | | | | | |
| NIHR \| National Institute for Health Research | Academic; Hospital (NHS) | ✓ | | ✓ | ✓ | | 4 -Grade D 95m$^2$ | | Guy's Hospital, London, SE1 9RT | Arindam Mitra arindam.mitra@gstt.nhs.uk Tel: 0207 188 7188 ext 54880 Sakina Gooljar sakina.gooljar@gstt.nhs.uk Tel: 0207 188 7188 ext 56097 |
| InstilBio | Commercial | ✓ | | ✓ | ✓ | ✓ | 1 Grade D 70m$^2$ | | Manchester, M13 9XX | Nikki Price info@instilbio.com |
| Imperial College London | Hospital (NHS) | ✓ | | ✓ | ✓ | | We have 2 fully independent cellular therapy suites (1 with Cat II biocontainment) each with 1 Grade C prep 2 Grade A/B manufacturing 51m$^2$ | | The John Goldman Centre for Cellular Therapy, London, W12 0HS | Sandra Loaiza, sandra.loaiza@nhs.net Tel: 0203 3138408 |
| Moorfields Eye Hospital NHS NHS Foundation Trust | Academic | ✓ | | ✓ | ✓ | | Two Grade B suites 56m$^2$ | | London, EC1V 9EL | Julie Daniels j.daniels@ucl.ac.uk Tel: 0207 608 6996 |
| NHS Blood and Transplant | NHS clinical services (national) | | | | ✓ | ✓ | 2 Grade B 2 Grade C 155m$^2$ | | Barnsley, S75 3FG | Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Tel: 07471 147804 Laura Murray laura.murray@nhsbt.nhs.uk Tel: 07384 879380 |
| NHS Blood and Transplant | NHS clinical services (national) | | | | ✓ | ✓ | 2 Grade B 53m$^2$ | | Edgbaston, Birmingham, B15 2SG | Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Tel: 07471 147804 Laura Murray laura.murray@nhsbt.nhs.uk Tel: 07384 879380 |
| NHS Blood and Transplant | NHS clinical services (national) | | | ✓ | ✓ | ✓ | 2 Grade B 44m$^2$ | | Speke, Liverpool, L24 8RB | Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Tel: 07471 147804 Laura Murray laura.murray@nhsbt.nhs.uk Tel: 07384 879380 |
| Scottish National Blood Transfusion Service | Hospital (NHS) | ✓ | ✓ | ✓ | ✓ | | 4 Grade B 4 Grade C, extensive Grade B space 500m$^2$ | Expansion of QC capability and translational/ tech transfer space in coming years. | Edinburgh, EH14 4BE | Dr Neil McGowan Neil.McGowan2@nhs.scot Tel: +44 (0)131 314 5659 |
| University of Birmingham | Charity; Research institute; Hospital (NHS); Therapy developer; | ✓ | | ✓ | ✓ | | 4 – 2 Grade B, 2 Grade C 88m$^2$ | Proposal to add cleanroom space to Birmingham Health Innovation Campus. Increase on footprint by 400 m$^2$ with completion by 2024. | Edgbaston, Birmingham, B15 2TT | Dr Stuart Curbishley s.m.curbishley@bham.ac.uk Tel: 0121 4147668 |
| NHS The Newcastle Hospitals NHS Foundation Trust | Academic; Hospital (NHS) | ✓ | | ✓ | ✓ | | 5 Grade B 5 Grade C 1 Grade D 210m$^2$ | | Newcastle University, NE1 4EP | Kay Carruthers kay.carruthers@newcastle.ac.uk Tel: 0191 9177259 |

*MIA – MHRA manufacturing authorisation licence for commercial supply of licensed medicinal products*
*MIA (IMP) – MHRA manufacturing authorisation licence for Investigational Medicinal Products for use in clinical trials*
*MS – MHRA licence for manufacturing of unlicensed medicines 'specials'*
*HTA – Licence that authorises the processing of the tissues and cells*
*GMO – Licence that applies to the use of genetically modified organisms*
**Collaborating companies at the CGT Catapult Stevenage Manufacturing Innovation Centre are responsible for obtaining their own MS, HTA, and GMO licences. The collaborators also need to obtain their own MIA (IMP) and MIA licences and name CGTC-MC as a GMP manufacturing location in these licenses to be allowed to manufacture medicinal products for human use (clinical and/or commercial). CGT Catapult has its own MIA and MIA(IMP) licences that authorise the provision of such services*

# 6. UK / Ireland contract testing capabilities

| Organisation Name | Cell therapy | | | | Gene therapy | | | |
|---|---|---|---|---|---|---|---|---|
| | Starting material | | GMP release testing | | Starting materials | | GMP release testing | |
| | Characterisation | Biosafety | Characterisation | Biosafety | Characterisation | Biosafety | Characterisation | Biosafety |
| Covance | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Merck | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Intertek | ✓ | | ✓ | | ✓ | | ✓ | |
| Charles River IRL | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sartorius | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| RSSL | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |
| Wickham Labs | | ✓ | | ✓ | | ✓ | | ✓ |
| Moredun | | ✓ | | ✓ | | ✓ | | ✓ |
| SGS Vitrology | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

# 7. Appendix

## 7.1 Glossary of Terms

AAV – Adeno-associated virus

ATMP – Advanced Therapy Medicinal Product

CDMO – Contract Development and Manufacturing Organisation

CRO – Contract Research Organisation

DoP – Dependent on Process

GMO – Genetically Modified Organism

GMP – Good Manufacturing Practice

HTA – Human Tissue Authority licence that authorises the processing of the tissues and cells

IMP – Investigational Medicinal Product

MAL – Material Airlock

MHRA – Medicines and Healthcare Products Regulatory Agency

MIA – Manufacturing/ Importers Authorisation

MIA (IMP) - Manufacture/Importation of Investigational Medicinal Products

MS – Manufacturing Specials

PAL – Personnel Airlock

QA – Quality Assurance

QC – Quality Control

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Cell and Gene Therapy

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