Cell and gene therapy GMP manufacturing in the UK:

Capability and capacity analysis

November 2020

CATAPULT
Cell and Gene Therapy

Contents

1 Executive summary

This report is the seventh in the Cell and Gene Therapy Catapult's series of annual survey reports on the status of the UK's MHRA MIA and MIA (IMP) licensed ATMP manufacturing facilities. The report provides up-to-date metrics on the capability and capacity of MHRA-licensed cell and gene therapy manufacturing facilities in the UK, covering the growth in both industrial centres, including CDMOs and facilities for in-house product manufacture as well as 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 and we remain grateful for the continued support of all participating centres.

The UK cell and gene therapy industry has continued to grow over the last 12 months despite the unprecedented COVID-19-related restrictions and challenges. Since November 2019, the manufacturing space in the industry has increased by 48% (from 7,970 m^2 in 2019 to 11,756 m^2 in 2020) through the addition of: Oxford BioMedica's third facility in Oxford – Oxbox for commercial manufacturing of viral vectors; the expansion at Cobra Biologic's pre-existing facility in Keele to enable the company to expand its clinical and commercial viral vector services as a CDMO; and the expansion at the Cell and Gene Therapy Catapult's facility in Stevenage, creating additional manufacturing capacity for companies looking to develop their own products in a collaborative environment. The number of skilled staff necessary to manufacture, test and release products has also increased this year – from 1,139 full-time staff in 2019 to 1,310 full-time staff in 2020. The total commercially-owned cleanroom space is significantly larger, over 3 times the size, along with higher staffing levels compared to the academic and public sector.

The total number of UK licenced facilities has remained at 26 despite the addition of Oxbox manufacturing centre. The University of Manchester Cleanroom Facility recently closed this year resulting in the loss of cleanroom space for the manufacture of pluripotent stem cells. Of the 26 facilities in the UK, 11 are commercially-owned – including 2 with commercial production (MIA) licences – Oxford BioMedica and the Cell and Gene Therapy Catapult Stevenage. 15 facilities are distributed between early-stage translational centres in the academic and public sectors. The cleanroom footprint of industrial facilities has grown significantly at over 164% the last 3 years. This is projected against a backdrop of the total growth across all centres of over 102%; demonstrating rapid industrial growth. This continued growth in industrial-scale facilities, however, is built on the foundational investments in translational and collaborative manufacturing spaces which continue to grow at far more modest pace compared to the industrial sector. There has also been an increase in product-pipeline manufacturing space, operated by 10 cell and gene therapy companies. At the Cell and Gene Therapy Catapult facility in Stevenage – Achilles, Adaptimmune, Autolus, Freeline, and TCR^2 are producing their own products whilst Allergan, Oxford BioMedica, Meira GTx, Instil Bio UK (formerly Immetacyte), and TC Biopharm operate their own stand-alone facilities for their pipelines.

The network of 26 facilities in the UK, operated by 21 organisations, comprises 11 dedicated cell therapy sites, 8 dedicated gene therapy sites, and 7 multifunctional sites. 57% of the total cleanroom operational space in 2020, (~6,694 m^2) is dedicated to gene therapy, whilst the dedicated cell therapy footprint is 13% (~1,517 m^2). Multi-functional facilities manufacturing both cell and gene therapies comprise 30% (3,545 m^2) of the total footprint.

96% of the gene therapy-dedicated capacity is commercially owned space, the remainder of which is distributed between UK academia and the NHS. There has been a 72% increase in the dedicated gene therapy manufacturing space (6,694 m^2 in 2020 from 3,889 m^2 in 2019) through the addition of Oxford BioMedica's new facility and expansion at Cobra Biologics. Two cell therapy dedicated facilities in 2019 (RoslinCT and GOSH) and one site dedicated to the manufacture of gene therapies in 2019 (Allergan) have become multifunctional this year while Instil Bio and SNBTS (multifunctional in 2019) have this year specialised in cell therapy. The total footprint for cell therapy-dedicated sites has increased by 8% (1,405 m^2 in 2019 to 1,517 m^2 in 2020) while the total multifunctional space, excluding Allergan's footprint, has increased by 33% (from 2,675 m^2 in 2019 to 3,545 m^2 in 2020).

The regional split of the total cleanroom footprint shows that the majority of the cell and gene therapy manufacturing activities are still located in Southern England (non-London) (51%), followed by Scotland (20%), Midlands and Northern England (16%) and London (13%). This breakdown reflects the dominance of early translational facilities in the London and the Midlands and Northern regions compared to larger commercial facilities located in Scotland and the Southern regions outside of London.

The national average booked capacity is currently at 86%, an increase of 14% compared to last year, with gene therapy again completely booked out at 95% utilisation. With 80% utility generally accepted as full, this trend shows that the demand in certain centres is outstripping supply for 2020 and into 2021, due to the rapidly increasing pipeline of cell and gene therapies. With increased production throughput comes an additional burden on analytical control services, particularly for autologous products where each individual therapy is a batch specific to a single patient. Hence, the QC footprint at the UK facilities has been tracked for the last two years to identify trends in QC delivery for both autologous and allogeneic product release. The total QC space available at the UK sites has increased from 8,354 m^2 in 2019 to 9,182 m^2 in 2020; with the majority of this space located in Scotland (78%), due to its strong CRO sector, followed by Southern England (11%), the Midlands and Northern England (8%), and London (3%).

The UK is developing further capacity in cell and gene therapies, with over 700 m^2 of additional total footprints, including non cleanroom manufacturing spaces expected to be licenced during the next 12 months. As major investments in facilities and manufacturing capacity continue, the sector anticipates a significant increase in the number of highly skilled jobs required to service the industry in the coming years. The Cell and Gene Therapy Catapult shall continue to report on this growth in future reports and continue to work with Industry and Government, to prevent skills provision from becoming a restriction to ATMP manufacturing growth.

2 Introduction and Methodology

During the course of the COVID-19 pandemic in 2020, the UK cell and gene therapy industry has demonstrated exceptional agility and resilience, adjusting well to the restrictions and challenges created by the pandemic while ensuring patients continue to benefit from advanced therapies on the market and in trials. According to the Alliance for Regenerative Medicine, the number of clinical trials ongoing worldwide has remained steady year-on-year, and global financing is poised to break records despite the pandemic. In response to the COVID-19 pandemic, several UK advanced therapy developers are investigating the application of viral vector based vaccines to treat COVID-19, showing the importance of flexible facilities and staff. The increasing number of advanced therapy candidates, along with their rapid progression through various phases of clinical development, creates an increasing demand for facilities that offer GMP manufacturing services for the therapies. It is expected that the Vaccines Manufacturing and Innovation Centre (VMIC), which is being fast-tracked for early completion in 2021, will provide further dedicated vaccine capacity at significant scale, for the UK.

The Cell and Gene Therapy Catapult's UK-wide 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 2020, the seventh annual survey was carried out among the 26 MHRA MIA (IMP) and MIA licensed facilities in the UK. The response rate was ~96%; with 1 of the 26 facilities unable to respond to the survey this year. Where no updated data could be provided, information gathered for the 2019 review was used and this is noted in this report in table 1. In addition, the figures reported for 2017-2019 may vary from the published 2017, 2018 and 2019 reports since some data has been revised and utilised in this report to provide an accurate baseline as possible for comparison to this year's data.

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
- 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 on the basis of 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 2021 and 2022

	Organisation / facility name
Multifunctional Cell and Gene Therapy Manufacturing Facilities	
1	Allergan Biologics (part of the Abbvie Group)*
2	Cancer Research UK (CRUK), Biotherapeutics Development Unit**
3	Cell and Gene Therapy Catapult Stevenage (GCTC Stevenage)
4	Great Ormond Street Hospital (GOSH), Great Ormond Institute of Child Health
5	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
6	RoslinCT
7	TC Biopharm
Dedicated Gene Therapy Manufacturing Facilities	
8	Cobra Biologics
9	Meira GTx
10	Merck BioReliance Services
11	NHS Blood and Transplant (NHSBT) Langford
12	Oxford BioMedica, Oxbox Manufacturing Facility
13	Oxford BioMedica, Harrow House Manufacturing Facility
14	Oxford Biomedica, Yarnton Manufacturing Facility
15	University of Oxford, Clinical BioManufacturing Facility (CBF)
Dedicated Cell Therapy Manufacturing Facilities	
16	Instil Bio UK (formerly Immetacyte Ltd)
17	John Goldman Centre for Cellular Therapy, Imperial College London
18	Moorfields Eye Hospital, Cells for Sight Stem Cell Therapy Research Unit
19	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)
20	Newcastle University, Newcastle Cellular Therapies Facility
21	NHSBT Birmingham
22	NHSBT Filton
23	NHSBT Speke
24	Royal Free Hospital London, Centre for Cell and Gene Tissue Therapeutics
25	Scottish National Blood Transfusion Service (SNBTS)
26	University of Birmingham, Advanced Therapies Facility

Table 1: *MHRA-licensed facilities included in the 2020 UK GMP Manufacturing Capability and Capacity Report*

**Cleanroom footprint is not included in this report.*

*** Number of employees, number of cleanrooms, cleanroom footprint and available capacity based on 2019 data*

3 National picture of UK cell and gene therapy manufacture

Geographic locations

The map below (Figure 1) highlights the diverse geographical spread of sites across the UK, with a clear aggrergation around the Greater London area (seven facilities). MHRA-licensed facilities specialising in cell therapy manufacture are shown by blue markers, gene therapy manufacture by green markers, and multifunctional facilities by purple markers. It should be noted that King's College RCTS and King's College CTU are combined for analysis throughout this review.

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

The infographic on the following page (Figure 2) shows a snapshot of the overall capacity and capability for cell and gene therapy manufacture within the UK: a network of 26 facilities is in place, 7 of which have multifunctional cell and gene therapy production capabilities. The facilities supply approximately 11,756 m^2 of licensed total cleanroom space between them compared to 7,970 m^2 in 2019 (adjusted post 2019 publication) via the addition of Oxford BioMedica's third facility in Oxford and expansion of Cobra Biologic's facility in Keele and CGT Catapult's facility in Stevenage. The closure of the University of Manchester's cleanroom facility this year has resulted in the loss of 219 m^2 of manufacturing space for the sector. It should be note that Allergan's cleanroom footprint for viral vector and cell therapy manufacturing in Speke, Liverpool, is not included in this report for confidentiality reasons. The average booked capacity for 2020 is already at 86% with gene therapy-dedicated capacity completely booked. A total of 1,310 full-time staff – including production, QA, QC, warehouse, and engineering staff are employed across 159 cleanrooms, compared to 1,139 full-time staff captured in the 2019 survey.

26 Facilities

8 Dedicated gene therapy manufacturers

11 Dedicated cell therapy manufacturers (↓1 from 2019)

7 Multifunctional manufacturers (↑1 from 2019)

~11,756m²* Cleanroom footprint (↑ 48% from 2019)

~9,182m²** In-house QC footprint (↑ 10% from 2019)

86% Overall booked capacity (95% for gene therapy)

1,310 (1,139 in 2019) Full time employees

159 Cleanrooms

7 Cleanrooms per facility (median)

10 Commercial Pipeline developers (↑ 1 from 2019)

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

**Cleanroom footprint does not include Allergan's footprint*

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

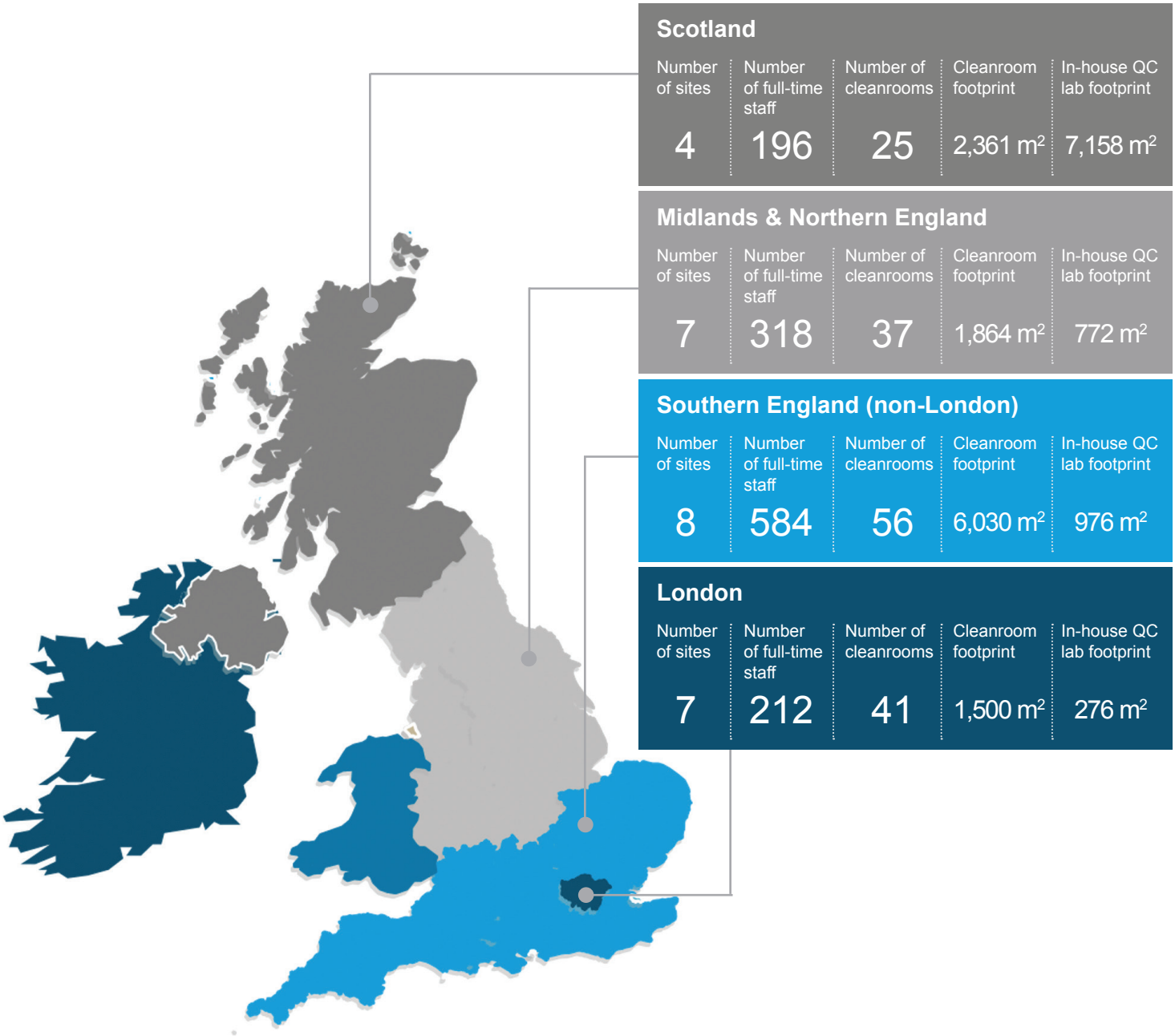

Figure 3: *Distribution of cleanroom footprint, QC footprint, and staff across the facilities in London, South England (non-London), Midlands and North England and Scotland (these charts incorporate cell therapy, gene therapy, and multifunctional sites).*

Figure 3 provides a regional breakdown of the total cleanroom footprint, in-house QC footprint, the number of cleanrooms and full-time employees within the UK with respect to London, Southern England (non-London), Midlands & Northern England, and Scotland. Commercially focussed facilities in Scotland and Southern England are generally larger in footprint and have a several-fold increase in staff numbers, compared to earlier translational centres that dominate in London and the Midlands & Northern England. Southern England (non-London) hosts 51% of the total UK footprint (6,030 m^2), which has increased by 113% compared to 2019. Scotland's 2,361 m^2 remains proportionally the second largest in the UK. The cleanroom footprint for the Midlands & Northern England region (excluding Allergan's), 1,864 m^2 has increased by 45% compared to 2019 while London's remains at 1,500 m^2. It should be noted that cleanroom footprint is defined to include essential personnel airlock (PAL) and material airlock (MAL) areas for all analyses in this report.

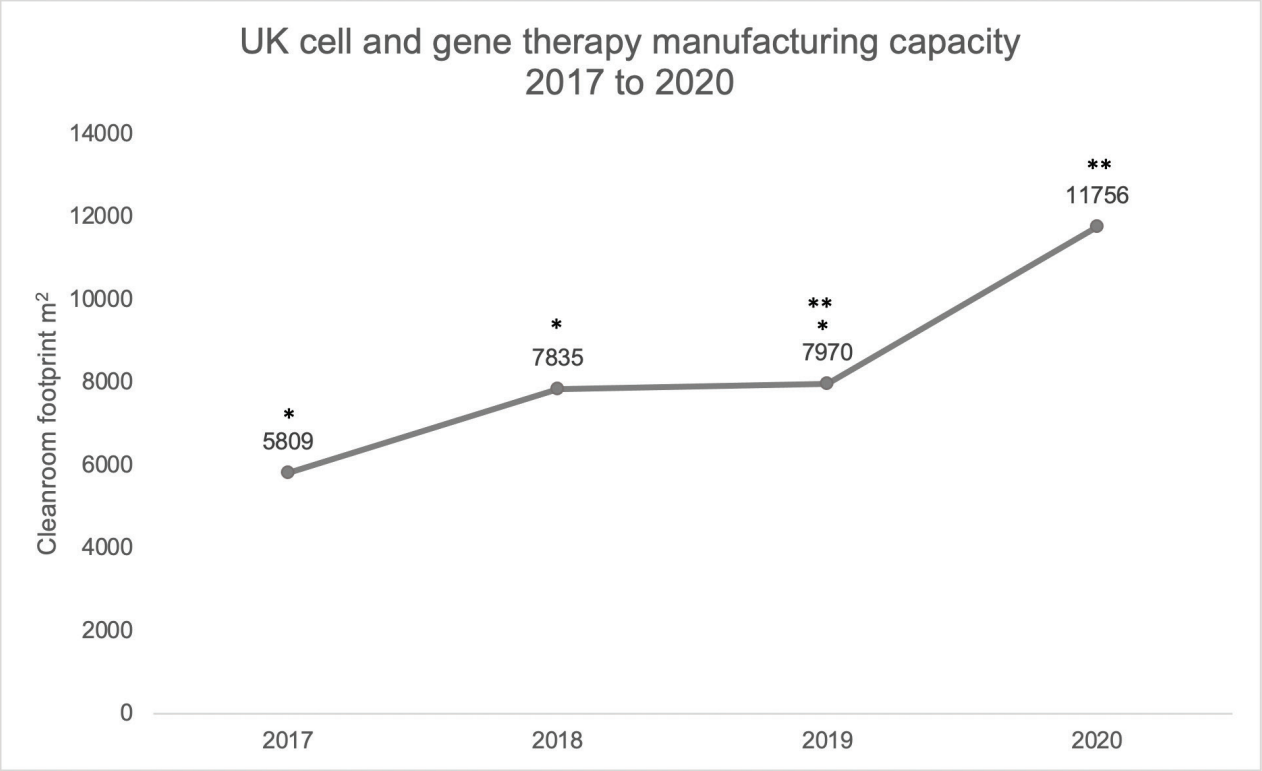

Figure 4: *UK cleanroom footprint for manufacturing cell and gene therapies, 2017 to 2020*

** Figures for 2017-2019 have been updated since this report was last published to include data that was not available at the time of the publications*

*** Cleanroom footprints for 2019 and 2020 do not include data for Allergan*

An overview of the national cell and gene therapy GMP manufacturing footprint for the years 2017-2020 is captured in Figure 4. In this period, the overall GMP footprint has increased from 5,809m^2 to 11,756m^2,demonstrating over 102% growth in three years. Overall the sector has an extremely positive outlook with numerous planned expansion projects on the horizon. Particularly encouraging is the future capacity that will be brought online for commercial manufacture by RoslinCT, demonstrating the commercial realisation of the UK industry. Further details are presented in section 4 of this report.

3.1 Cell therapy manufacturing

A snapshot of the nation's GMP resource dedicated to cell therapy manufacture in 2020 is captured in Figure 5 with a network of 11 facilities in place. The facilities supply approximately 1,517m^2 of licensed total cleanroom space between them for the manufacture of cell therapies. This sector contains the largest number of academic translational sectors and hence the lower proportional footprint and staff number per centre. Two companies within this category, RoslinCT and GOSH, have become multifunctional since their appearance in the 2019 review, adding gene therapy to their manufacturing capability. In addition, manufacturing space in this sector has been reduced this year due to the closure of the University of Manchester Cleanroom Facility.

Overall, the cleanroom footprint in this category has increased from 1,405 m^2 in 2019 (adjusted post 2019 publication) to 1,517 m^2 in 2020 through the addition of SNBTS and Instil Bio UK, which were multifunctional last year, but are currently dedicated to the manufacture of cell therapies.

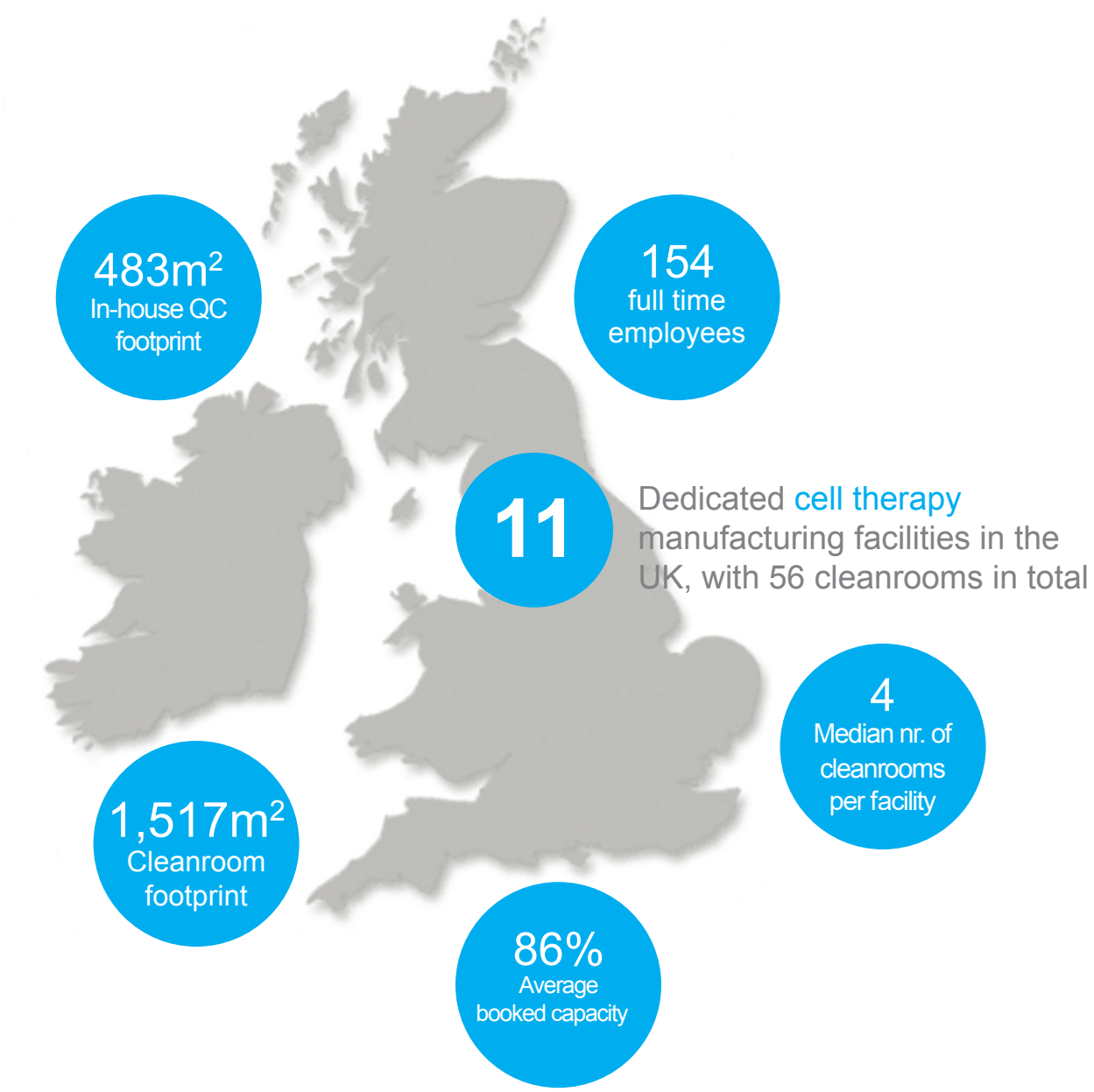

Figure 5: *Snapshot of dedicated cell therapy facilities in the UK*

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 (11) and multifunctional cell and gene therapy facilities (7) are included in the total number of sites in this figure.

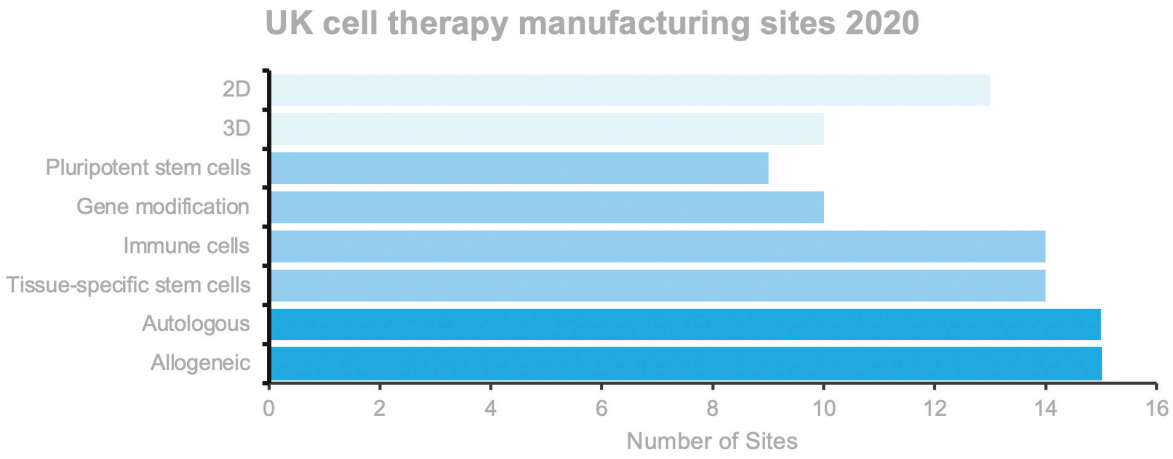

Figure 6: *Summary of cell therapy process capabilities at dedicated cell therapy and multifunctional facilities across the UK*

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 2020, 2021, and 2022 at various centres and this is potentially indicative of project cycles ending, contracts yet to be finalised, and facility expansions. It should be noted that despite having cell therapy manufacturing capabilities, the types of processes and cell types with which Allergan and TC Biopharm are working is for their own product pipelines and are not disclosed in this report. In addition, Instil Bio UK's spare capacity is only available for internal projects and is 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	2020	2021	2022
CRUK*	2	×	✓	×	✓	×	✓	×	×	0	0	100
CGTC Stevenage*	DoP	✓	✓	✓	✓	✓	✓	✓	✓	42	25	25
GOSH*	5	✓	✓	✓	×	✓	✓	✓	✓	40	40	60
Kings (RCTS & CTU)*	6 or 8	✓	✓	✓	×	✓	✓	✓	✓	20	20	20
RoslinCT*	4	✓	✓	×	✓	✓	✓	✓	✓	25	40	50
GSTT BRC	4	✓	✓	✓	✓	✓	✓	×	×	0	30	40
Instil Bio	4	✓	×	✓	×	×	×	×	×			
John Goldman Centre	(4/6)	✓	✓	✓	×	✓	✓	×	✓	10	10	10
Moorfields	(4/0)	✓	✓	✓	✓	✓	×	✓	✓	0	50	50
NHSBT Birmingham	3	✓	✓	✓	×	✓	×	✓	✓	0	40	50
NHSBT Filton	3	✓	✓	✓	×	✓	×	✓	✓	0	60	70
NHSBT Speke	3	✓	✓	✓	×	✓	×	✓	✓	0	50	60
Royal Free	7 (4/3)	✓	✓	✓	✓	✓	✓	✓	✓	0	10	10
SNBTS	10	✓	✓	✓	✓	✓	✓	×	✓	0	10	20
Uni of Birmingham	4 (2/2)	✓	✓	✓	✓	✓	✓	✓	✓	60	50	40
Uni of Newcastle	2 (or 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 encompasses the largest number of commercial facilities and highest staffing levels compared to dedicated cell therapy and multifunctional facilities. Despite the addition of Oxford Biomedica's Oxbox manufacturing facility, the total number of facilities in this sector has remained at 8 compared to 2019 as Allergan's facility, which was previously gene therapy specific has become multifunctional.

The cleanroom footprint at the dedicated gene therapy facilities has increased substantially by 72% from 3,889m^2 in 2019 to 6,694m^2 in 2020, as UK industry continues to build out new capacity to cater for increasing demand for viral vector and plasmid DNA.

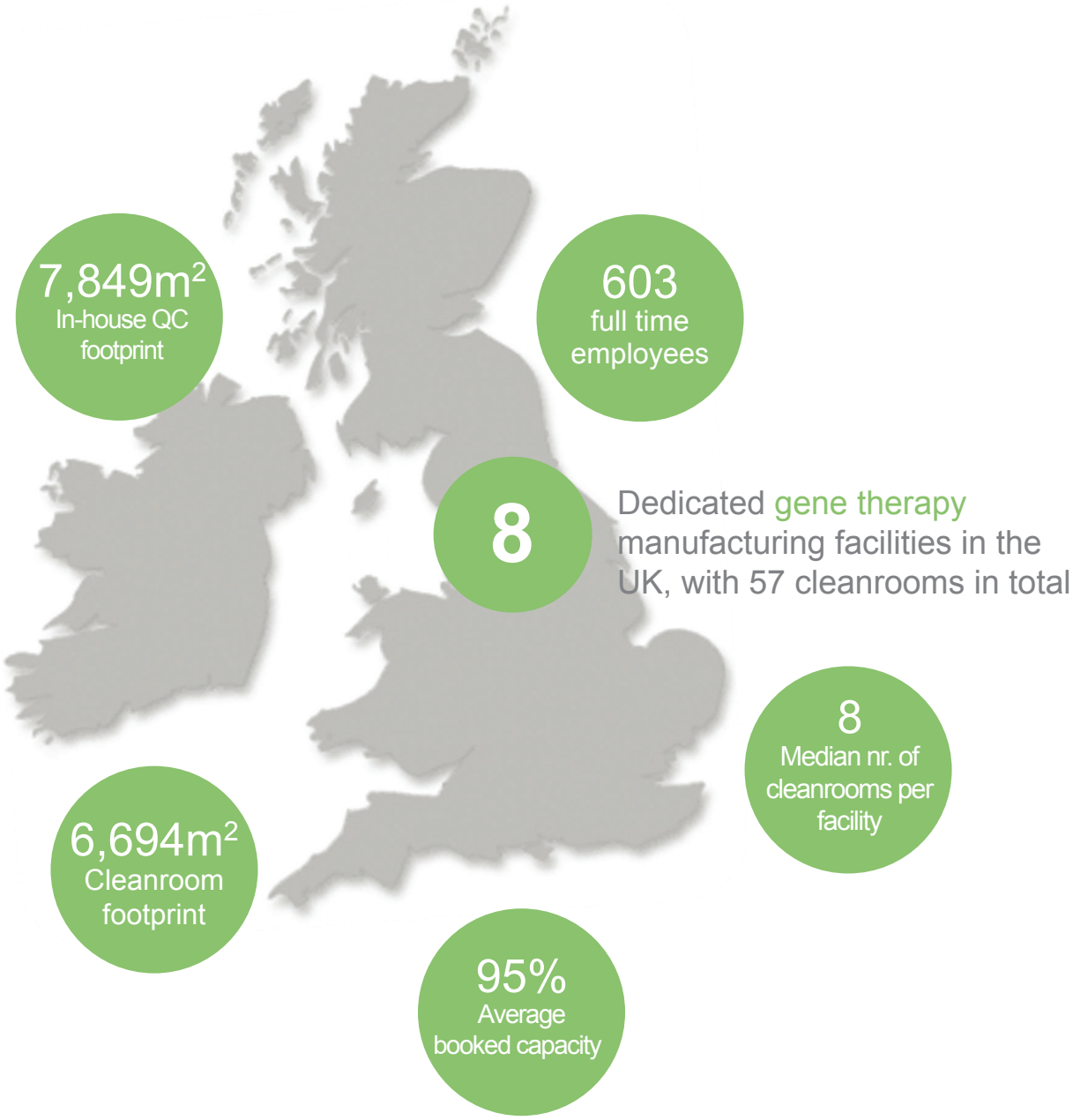

Figure 7: *Snapshot of dedicated-gene therapy facilities in the UK*

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 is broad coverage of capabilities 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 AAV – a common tool for delivery of in vivo gene therapies.

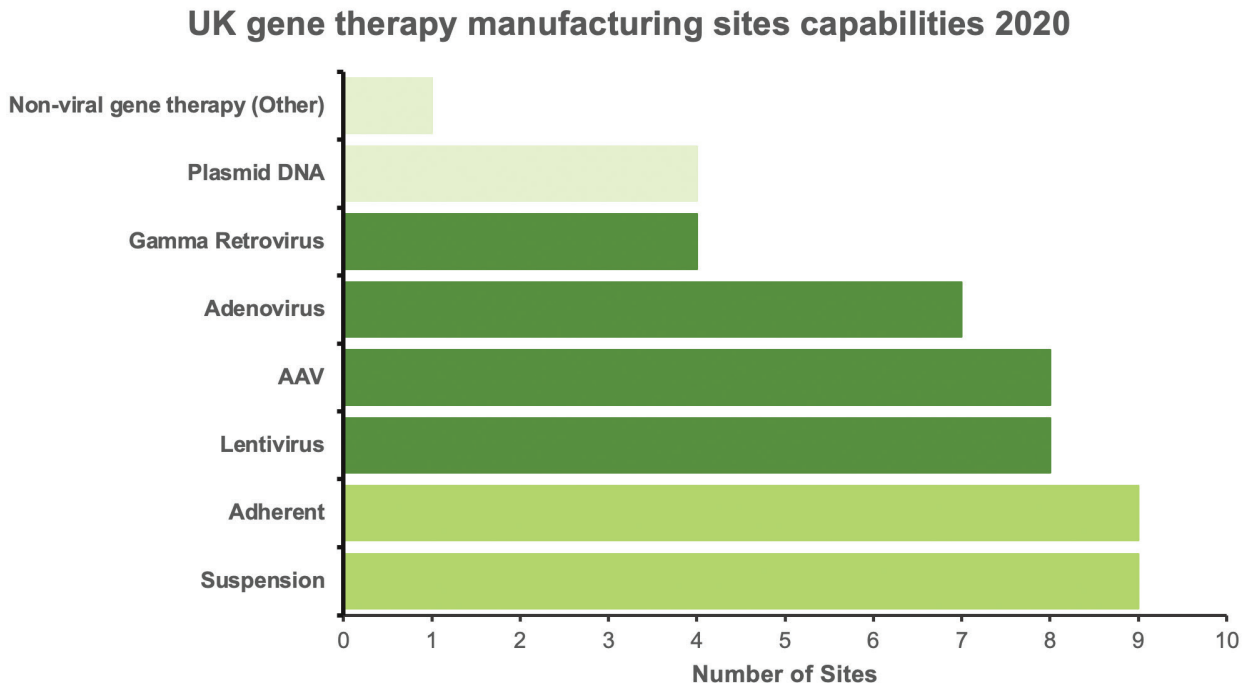

Figure 8: *Summary of gene therapy capabilities across dedicated gene therapy and multifunctional facilities in the UK*

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 the purpose of 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, with the exception of TC Biopharm'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. In 2020, pipelines are once again full, with averaged booked capacity at 95% for dedicated gene therapy facilities (80% booked capacity being generally considered to be full). The situation should improve with expansions expected to come online next year, including facilities at multifunctional sites: King's College, RoslinCT, and a new NHSBT dedicated gene therapy facility in Filton, Bristol. However, it is highly likely that not all space at the multifunctional facility expansions will be utilised for gene therapy products, in contrast to the dedicated-gene therapy space.

Organisation	Parallel products (open/ closed)	Capability								Available Capacity (%)		
		Suspension	Adherent	AAV	Lentivirus	Gamma Retrovirus	Plasmid DNA	Adenovirus	Non-viral gene therapy	2020	2021	2022
Allergan*	Undisclosed	✓	✓	✓	✓	×	✓	✓	×			
CGTC Stevenage *	DoP	✓	✓	✓	✓	✓	×	✓	×	42	25	25
CRUK*	2	×	×	✓	✓	×	✓	×	×	0	0	100
GOSH*	5	✓	✓	✓	✓	✓	×	✓	×	40	40	60
Kings (RCTS & CTU)*	6 or 8	✓	✓	✓	✓	✓	×	×	×	20	20	20
RoslinCT*	4	✓	✓	×	×	×	×	×	✓	25	40	50
Cobra	4	✓	✓	✓	✓	×	✓	✓	×	0	50	100
Meira GTx	3	×	×	✓	×	×	×	×	×	25	25	
Merck Bioreliance	8	✓	✓	✓	✓	✓	×	✓	×	0	50	80
NHSBT Langford	2	×	×	×	✓	×	✓	×	×	5	100	50
Oxford BioMedica	7	✓	✓	×	✓	×	×	✓	×	0	25	50
Uni of Oxford	0 (1/0)	✓	✓	×	×	×	×	✓	×	0	0	

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 the purpose of this table, Oxford Biomedica's three sites have been incorporated together*

3.3 Multifunctional facilities

Seven facilities are multifunctional with cell and gene therapy production capabilities. The number of organisations in this category has increased again this year through the addition of Allergan (gene therapy specific in 2019) and GOSH and RoslinCT, which were dedicated to the manufacture of cell therapies in 2019. However, two organisations in this category in 2019 (SNBTS and Instil Bio) have specialised in the manufacture of cell therapies this year.

Overall, the cleanroom footprint in this category has increased by 32% compared to 2019 through the expansion at the CGT Catapult Stevenage, and the addition of GOSH's and RoslinCT's footprints. Summary data from the 7 facilities; Allergan, Cancer Research UK, King's College London (Rayne and CTU), GOSH, RoslinCT, TC Biopharm, and the CGT Catapult Stevenage are shown in Figure 9. See section 3.1 and 3.2 of this report for more information on these multifunctional facilities.

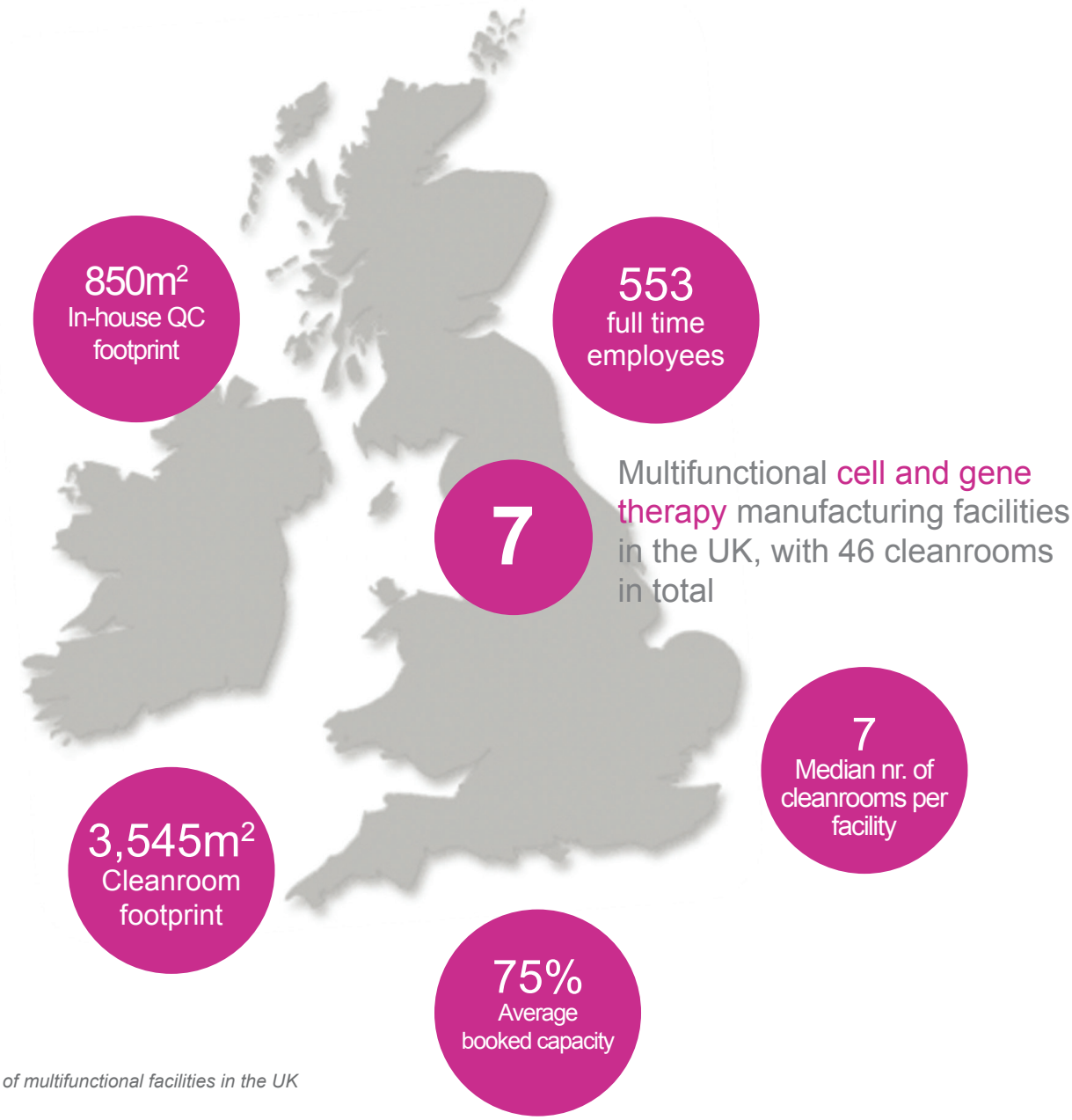

Figure 9: *Snapshot of multifunctional facilities in the UK*

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:

- The Great Ormond Street Hospital has recently completed the construction of seven new cleanrooms, which occupy the top floor of the Zayed Centre for Research. This expansion has created an additional 175m^2 of cleanroom space for the organisation to allow multiproduct procecessing. Two of the rooms will be used for core NHS service and 5 other rooms will support manufacturing for clients. The organisation expects to ramp up the usage of these rooms over the next 5 years. The facility is due to be open and licensed by March 2021.

- NHSBT is in the process of expanding its gene therapy capacity through the construction of a new facility in Bristol expected to come online in mid 2021. The facility will double the capacity for plasmid manufacture, up to approximately 48 batches per year. In additon, the new facility will include AAV, lentiviral vector, and recombinant protein manufactuirng capability. The facility will also have R&D / process development laboratories. In addition, the organisation has constructed a new dedicated cell therapy facility in Barnsley with 2 Grade B and 2 Grade C cleanrooms (155m^2), which is expected to come online end 2020.

- RoslinCT is currently expanding its manufacturing capacity to include a further 3 Grade B and 2 Grade C clean room suites to enable commercial manufacturing. The facility is expected to be licenced July 2021. Additional capacity of 1,600m^2 (450 m^2 ex MALS and PALs) is currently under construction.

- The Rayne Cell Therapy Facility at King's College London has recently completed building a new suite of cleanrooms. The additional ~80m^2 of cleanroom space will be available in Q1 2021 following operational qualification. In addition, a further 80 m^2 of new cleanrooms are due to be built in 2021 with operational qualification in 2022. These additions will boost King's vector production capacity by 50%.

- 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 with a planned facility start up in early 2021. The remaining space within the Oxbox will be available for future "Phase II" expansion.

- CPI is in the process of preparing for MHRA inspection of a 150m^2 viral vector manufacturing facility in Darlington. The facility consists of 2 Grade D and 1 Grade C cleanroom suites and is expected to be licenced in 2021.

- Advent Bioservices is currently managing the development of a state-of-the-art facility for multiproduct GMP production outside Sawston in Cambridgeshire, which will allow scale up of commercial production and initiate the provision of contract manufacturing services. The facility consists of GMP lab space and process development and additional areas for future expansion. Initial construction work has focused on the building of 2 separate GMP suites with grade B/C classified areas, in house QC testing and office space as well as a multipurpose cryogenic storage unit. The facility will operate the facility under a comprehensive IT infrastructure including eQMS and an eBMR, with a LIMS with secure storage for client documents and paperless systems.

- The University of Oxford CBF plans to add 2 new Grade B/C manufacturing suites with Grade D support and storage rooms in new building to commence construction in 2021. The final footprint has not yet confirmed and is expected to be operational Q2-Q3 2022.
- GSTT BRC aims to double its current manufacturing and QC capacity. This will become operational in 2021.
- Building works to update the CRUK's Facility is being planned by the organisation. This will likely alter the configuration of the cleanrooms with the possibility of increasing cleanroom footprint. It is anticipated that a new MHRA IMP licence will be applied for to accommodate these cleanrooms in 2021.
- The University of Birmingham currently plans to increase capacity by 400m^2 of cleanroom space. This will form part of the Birmingham Health Innovation Campus and will be delivered in 2023.
- SNBTS is in the process of adding 500m^2 of cleanroom space (Grade B-D) for multi-product manufacturing and cryopreservation across 2 sites in Edinburgh. Expansion of the supporting QC space and capability planned for 2020 will include a range of molecular testing.
- In October 2020, FUJIFILM Diosynth Biotechnologies announced plans to establish GMP manufacturing capability for viral vector, which will be located in the North of England. This site will complement FUJIFILM's current biologics facility in Teeside. The offering will also provide processes development services and is anticpared to support clinical supply of viral vector from Autumn 2021.
- Cell and Gene Therapy Catapult Stevenage is also expecting to increase its GMP QC collaboration footprint in 2021.
- Expansion plans are also on the horizon for the Cobra Biologics, MeiraGtx 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 2020/2021 which offer collaborative potential. However, please contact sharon.brownlow@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										
Allergan	Commercial	✓					8 Grade B/C		Speke, Liverpool, L24 8RB	Paul Young paul.young@allergan.com Tel: +44 (0)151 728 1750
CANCER RESEARCH UK	Charity	✓					3 Grade B 4 Grade C 300m²		Potters Bar, EN6 3LD	Dr Leonard K Pattenden Len.Pattenden@cancer.org.uk
CATAPULT Cell and Gene Therapy	Collaborative model	✓ *	✓ *	*	*	*	12 Grade C 2,100m²	.	Stevenage, SG1 2FX	Sharon Brownlow sharon.brownlow@ct.catapult.org.uk
Great Ormond Street Hospital	Academic; Hospital (NHS)	✓		✓	✓		2 Grade C 40m²	7 new cleanrooms at Zayed Centre due to be licenced by March 2021.	London, WC1N 3JH	Chris Longster chris.longster@gosh.nhs.uk
KING'S College LONDON NIHR National Institute for Health Research	Academic; Hospital (NHS)	✓		✓	✓		RCTS: 2 Grade D CTU: 3 Grade B and 5 Grade D 455m²	New cleanrooms, 80m² being qualified. Further new cleanrooms, 80m² to be built.	London, SE5 9NU and London, SE5 9RS	Rebecca Prue rebecca.prue@kcl.ac.uk Cristina Trento cristina.trento@nhs.net Tel: 020 3299 1854
Roslin CT your advanced therapy solution	CMO	✓			✓		2 Grade B 1 Grade C 200m²	Expansion includes 3 Grade B and 2 Grade C suites (additional 1,600m2 to be built).	Edinburgh Scotland, EH1 6 4UX	Janet Downie janet.downie@roslinct.com Tel: 0131 658 5182 Kevin Bruce kevin.bruce@roslinct.com Tel: 0131 658 5359
TC BIOPHARM	Commercial	✓		✓	✓		4 Grade B 450m²		Holytown, Motherwell, ML1 4WR	

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	CMO; Partnerships	✓					6 Grade C 3 Grade D 1,400m²		Keele, ST5 5SP	Philip Ridley-Smith philip.ridley-smith@cobrabio.com Tel: 0208 246 5895
MEIRAGTx	Commercial	✓		✓			3 Grade C 4 Grade D 603m²		London, N1 7NQ	Francois Toubhantz francois.toubhantz@meiragtx.com
MERCK	CMO	✓					8 Grade B 1,211m²		Glasgow, G20 0XA	Lauren MacDonald Tel: 0141 579 3249 lauren.macdonald@merckgroup.com Karen McLennan Tel: 0141 579 3290
NHS Blood and Transplant	NHS clinical services (national)	✓					3 Grade C 4 Grade D 140m²	New facility in Bristol: 354m² – online mid 2021	Lower Langford, near Bristol, BS40 5DU	Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Laura Murray laura.murray@nhsbt.nhs.uk
OxfordBioMedica	Commercial; Partnerships	✓	✓				7 Grade C suites (20 cleanrooms) 3205m²	Phase II" expansion to add fill finish capability	Harrow: Oxford, OX4 6LX Yarnton: Oxford, OX5 1QU Oxbox: Oxford, OX4 2JZ	Jason Slingsby enquiries@oxb.com Tel: 01865 785300
UNIVERSITY OF OXFORD Clinical BioManufacturing Facility	Academic	✓					5 Grade C 1 Grade D 135m²	Construction to begin for new facility - 2 Grade B/C suites and Grade D rooms	Oxford, OX3 7JT	Emma Bolam emma.bolam@ndm.ox.ac.uk Tel: 01865 744845 / 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										
NHS Imperial College Healthcare NHS Trust	Hospital (NHS)	✓		✓	✓		4 Grade B 2 Grade C 1 Grade D 51m²		London, W12 0HS	Sandra Loaiza, sandra.loaiza@nhs.net
InstilBio	Commercial	✓		✓	✓	✓	1 Grade D 70m²		Manchester, M13 9XX	Nikki Price info@instilbio.com
Moorfields Eye Hospital NHS Foundation Trust NHS	Academic	✓		✓	✓		2 Grade B 56m²		London, EC1V 9EL	Julie Daniels j.daniels@ucl.ac.uk Tel: 0207 608 6996
NIHR | National Institute for Health Research	Academic; Hospital (NHS)	✓		✓	✓		4 Grade D 95m²	Facility undergoing expansion by 100% of current capacity	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
NHS The Newcastle Hospitals NHS Foundation Trust	Academic; Hospital (NHS); Partnerships	✓		✓	✓		5 Grade B 5 Grade C 1 Grade D 210m²		Newcastle University, NE1 4EP	Dean Bradley, dean.bradley@nhs.net 0191 282 4062
NHS Blood and Transplant	NHS clinical services (national)	✓			✓	✓	2 Grade B 53m²	New facility in Barnsley: 2 Grade B and 2 Grade C cleanrooms (155m2) – online end 2020.	Edgbaston, Birmingham, B15 2SG	Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Laura Murray laura.murray@nhsbt.nhs.uk
NHS Blood and Transplant	NHS clinical services (national)	✓			✓	✓	2 Grade B 2 Grade C 150m²		Filton, Bristol, BS34 7QH	Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Laura Murray laura.murray@nhsbt.nhs.uk
NHS Blood and Transplant	NHS clinical services (national)	✓		✓	✓	✓	2 Grade B 44m²		Speke, Liverpool, L24 8RB	Jonathan Caddick Jonathan.caddick@nhsbt.nhs.uk Laura Murray laura.murray@nhsbt.nhs.uk
NHS Royal Free London NHS Foundation Trust	Hospital (NHS)	✓		✓	✓	✓	5 Grade B 1 Grade C 3 Grade D 200m²		London, NW3 2QG	Dr Owen Bain owen.bain@nhs.net 0207 7940500 ext.33484
Scottish National Blood Transfusion Service	Hospital (NHS)	✓		✓	✓		4 Grade B 4 Grade C Extensive Grade D space 500m²		Edinburgh, EH14 4BE	Dr Neil McGowan Neil.McGowan2@nhs.scot Tel: +44 (0)131 314 5659
University of Birmingham	Academic	✓		✓	✓		2 Grade B 2 Grade C 88m²	400m² as part of Health Innovation Campus	Edgbaston, Birmingham, B15 2TT	Dr Stuart Curbishley s.m.curbishley@bham.ac.uk Tel: 0121 4147668

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 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 Stevenage 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 Appendix

6.1 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

MHRA MIA – MHRA manufacturing authorisation licence for commercial supply

MHRA MIA (IMP) – MHRA manufacturing authorisation licence for Investigational Medicinal Products for use in clinical trials

MHRA MS – MHRA licence for manufacturing of unlicensed medicines ‘specials’

MS – Manufacturing Specials

PAL – Personnel Airlock

QA – Quality Assurance

QC – Quality Control

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