

UK Biomanufacturing perspective

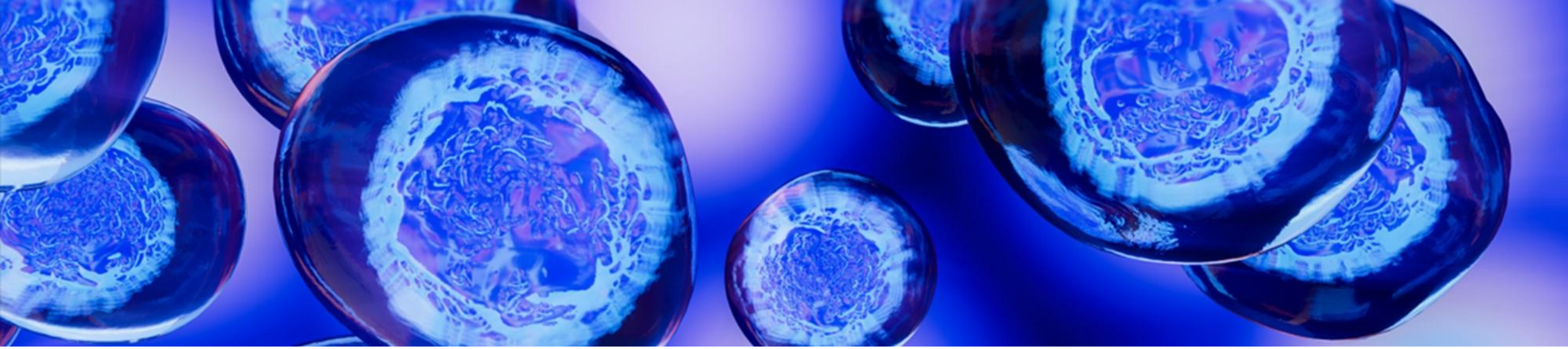


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#bioProcessUK



UK Biomanufacturing Perspective

bioProcess UK

November 2024

FUJIFILM Diosynth Biotechnologies

Dr Kit Erlebach



Overview

Announcements

Innovation

Industrial biotech

Manufacturing sites

- GMP licences
- Coming up

ATMP

News stories

Symbiosis expansion - <https://www.dailyrecord.co.uk/news/local-news/stirling-biotech-firm-create-50-33566904>



Vertex CRISPR therapy approved in UK & being manufactured at RoslinCT – <https://www.roslinct.com/insights/roslinct-to-manufacture-exagamglogene-autotemcel-exa-cel-for-vertex-pharmaceuticals-inc-following-an-extensive-development-collaboration>



Lilly pledges £279m to UK for biotech hub and obesity plan - <https://pharmaphorum.com/news/lilly-pledges-ps279m-uk-biotech-hub-and-obesity-plan>

Adaptimmune gets FDA accelerated approval <https://www.adaptimmune.com/investors-and-media/news-center/press-releases/detail/271/adaptimmune-receives-u-s-fda-accelerated-approval-of>



Imperial College Healthcare NHS Trust (ICHT) and Imperial College London (ICL) have announced that the first UK patients have received the experimental mRNA therapy in an ongoing phase 1/2 clinical trial to treat melanoma, lung cancer and other solid tumour cancers. <https://pharmatimes.com/news/first-uk-patients-receive-experimental-mrna-therapy-for-cancer-in-global-trial/>

Touchlight awarded tender to supply enzymatic dbDNA to CPI's RNA Centre of Excellence <https://www.touchlight.com/news/touchlight-awarded-tender-to-supply-enzymatic-dbdna-to-cpis-rna-centre-of-excellence>



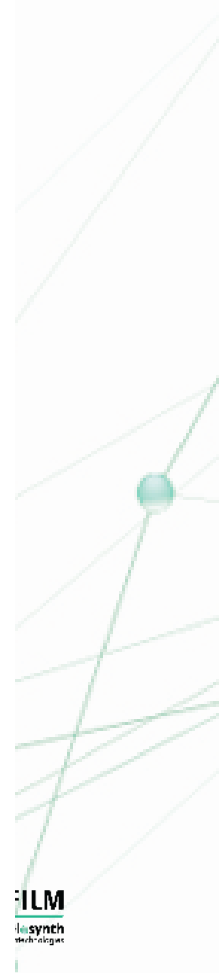
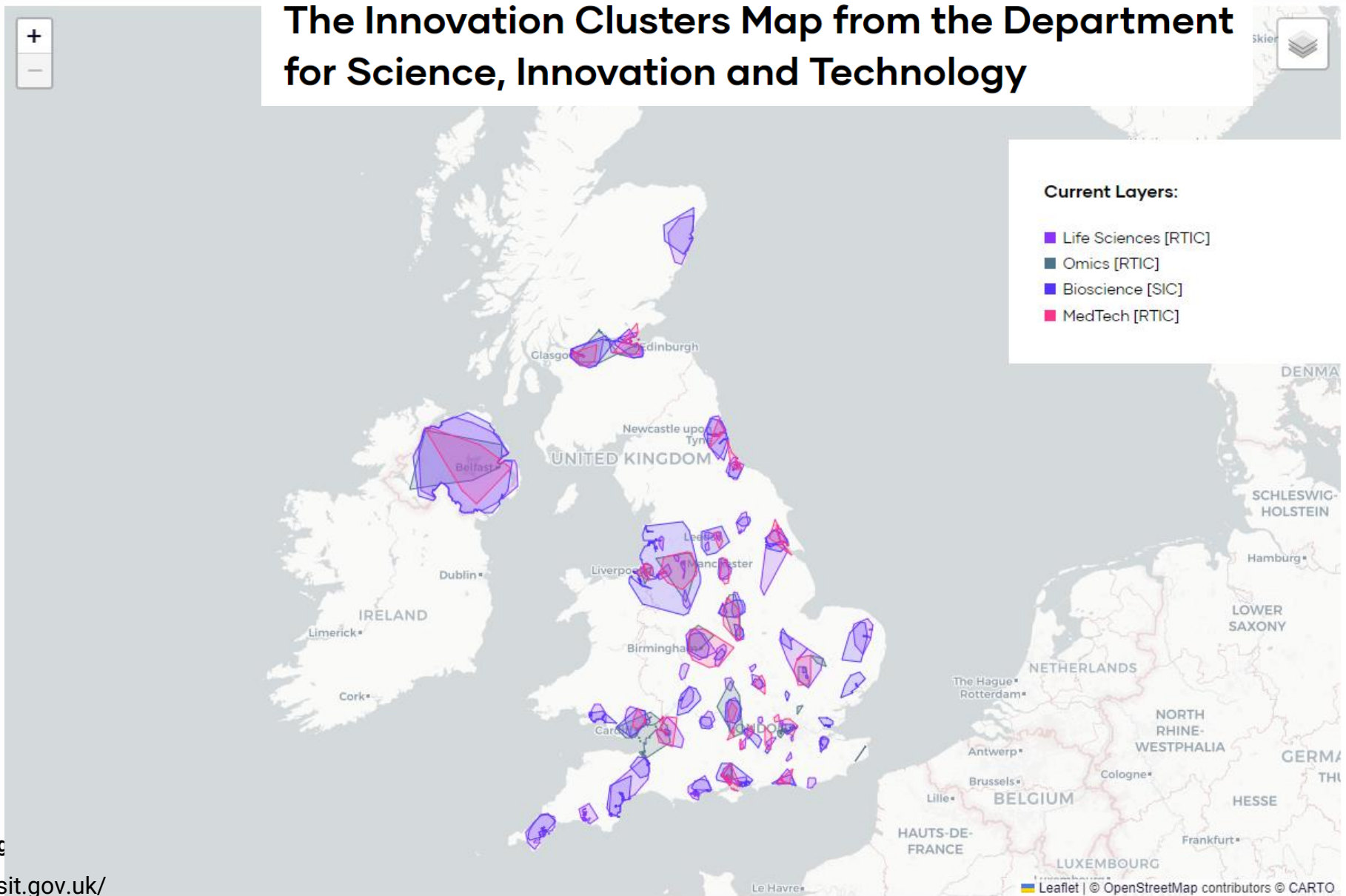
CGT Catapult, Pharmaron Biologics (UK) Ltd and Complement Therapeutics receive £1.4m grant to develop a perfusion process to improve production of gene therapies - <https://ct.catapult.org.uk/news/cgt-catapult-pharmaron-biologics-uk-ltd-and-complement-therapeutics-receive-1-4m-grant-to-develop-a-perfusion-process-to-improve-production-of-gene-therapies>

Autolus Therapeutics Announces FDA Approval of AUCATZYL® (obecabtagene autoleucel – obe-cel) for adults with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) <https://autolus.gcs-web.com/news-releases/news-release-details/autolus-therapeutics-announces-fda-approval-aucatzylr>



Innovation clusters

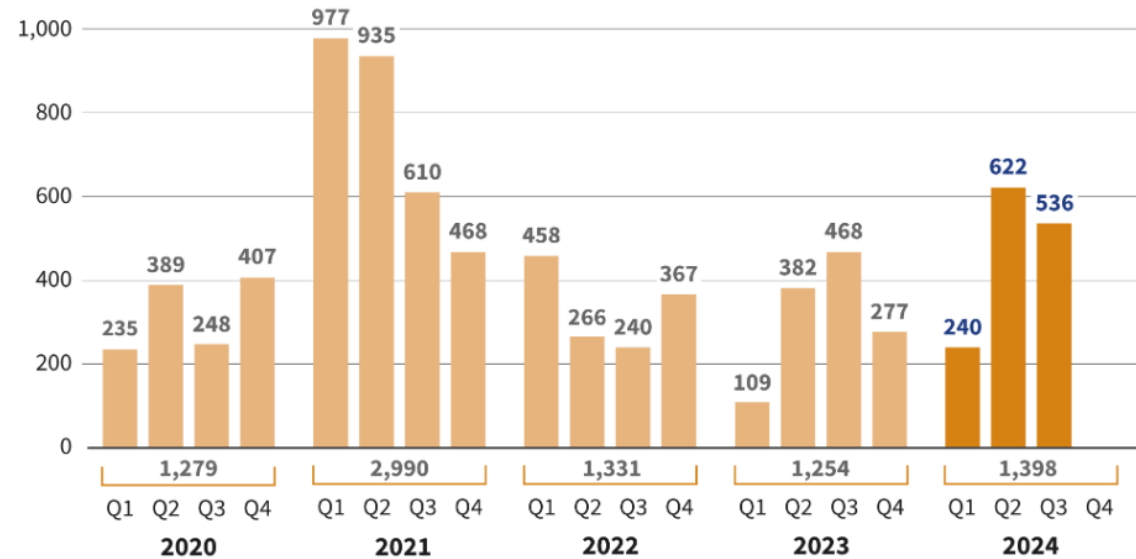
The Innovation Clusters Map from the Department for Science, Innovation and Technology



Venture capital IPO funding

Total venture capital raised by quarter, for the past five years

Total raised (£m)



<https://biotechfinance.org/>

Enara Bio £32 M - <https://enarabio.com/news/enara-bio-raises-32-5-million-series-b-financing-to-advance-first-in-class-pipeline-of-tcr-based-immunotherapies-targeting-novel-dark-antigens>

PureSpring Tx £80 M - <https://purespringtx.com/purespring-therapeutics-raises-80-105-million-in-a-series-b-financing-to-transform-the-treatment-of-kidney-diseases/>

Resolution Tx £63.5m Series B - <https://resolution-tx.com/series-b-new-chair/>

Virocell Biologics completes oversubscribed financing - <https://www.businesswire.com/news/home/20240814147754/en/ViroCell-Biologics-Completes-Oversubscribed-Financing>

Myricx raises £90m after pivot to ADCs for cancer - https://www.linkedin.com/posts/biomax_myricx-raises-90m-after-pivot-to-adcs-for-activity-7217136240872091648-tWt7?utm_source=share&utm_medium=member_desktop

Theolytics successfully closes latest financing raising total of £19M (\$24.5M) and welcomes Sound Bioventures as new investor - https://www.linkedin.com/posts/biomax_theolytics-successfully-closes-latest-financing-activity-7188606243530309632-JaaJ?utm_source=share&utm_medium=member_desktop

NanoSyrinx lands £10m investment to enhance intracellular delivery technology <https://www.thebusinessdesk.com/westmidlands/news/2090115-coventry-biotech-firm-closes-10m-funding-round>

MIP Discovery Rebrands as Tozaro as it Completes Transition to Supporting Cell and Gene Therapy Viral Vector Analytics and Purification following £7m series A funding round <https://www.businesswire.com/news/home/20240806025819/en/MIP-Discovery-Rebrands-as-Tozaro-as-it-Completes-Transition-to-Supporting-Cell-and-Gene-Therapy-Viral-Vector-Analytics-and-Purification>

OGL Bio secures £650k in follow-up funding to expand market presence - <https://www.scottish-enterprise-mediacentre.com/news/ogi-bio-secures-gbp-650k-in-follow-up-funding-to-expand-market-presence>

Industrial Biotechnology

UK industrial biotechnology landscape – selected clusters

Glasgow

Industrial Biotechnology Innovation Centre (IBioIC)

Edinburgh

Biofoundry, Roslin Institute, Centre for Mammalian Synthetic Biology

Manchester

Future Biomanufacturing Research Hub, strong SynBio R&D, Henry Royce Institute

Teesside

ICI spin-outs, Centre for Process Innovation's (CPI) flagship National Biologics Manufacturing Centre, Teesside University's National Horizons Centre

Cambridge

Strong biotech R&D, strong biotech start-up cluster, MRC Laboratory of Molecular Biology.

Norwich and Earlham

Quadram Institute, Norwich Research Park, John Innes Centre, Biofoundry, Earlham Institute

Central and Greater London

Significant biocluster, SynbiCITE, Biofoundries, Centre of Excellence for Engineering Biology, Metrology and Standards, start-ups, strong VC presence, Pirbright Institute, Stevenage Bioscience Catalyst

Liverpool

Microbiology cluster, CPI, UniLever's Materials Innovation Factory, Biofoundry,

Oxford

UK Catalysis Hub, biocluster, strong start-up ecosystem

Bristol

BrisSynBio, strong biotech start-up ecosystem

Wilton

Centre for Process Innovation

The Engineering Biology Leadership Council has suggested considering a blend of local clustering and national networking options, building around the key hubs and centres of expertise established to date (EBLC, 2021).

Note that some companies rely upon facilities outside the UK for R&D work (EBLC, 2021).

Government funding announcements

VPAG Funding - [£78m for Life Sciences](#) Clinical trials, NICE and sustainability

£520m Capital grants – announced in autumn 2024 budget <https://www.find-government-grants.service.gov.uk/grants/life-sciences-innovative-manufacturing-fund-lsimf-1>

Example

Lonza - <https://www.lonza.com/media-advisories/2024-08-15-10-00>

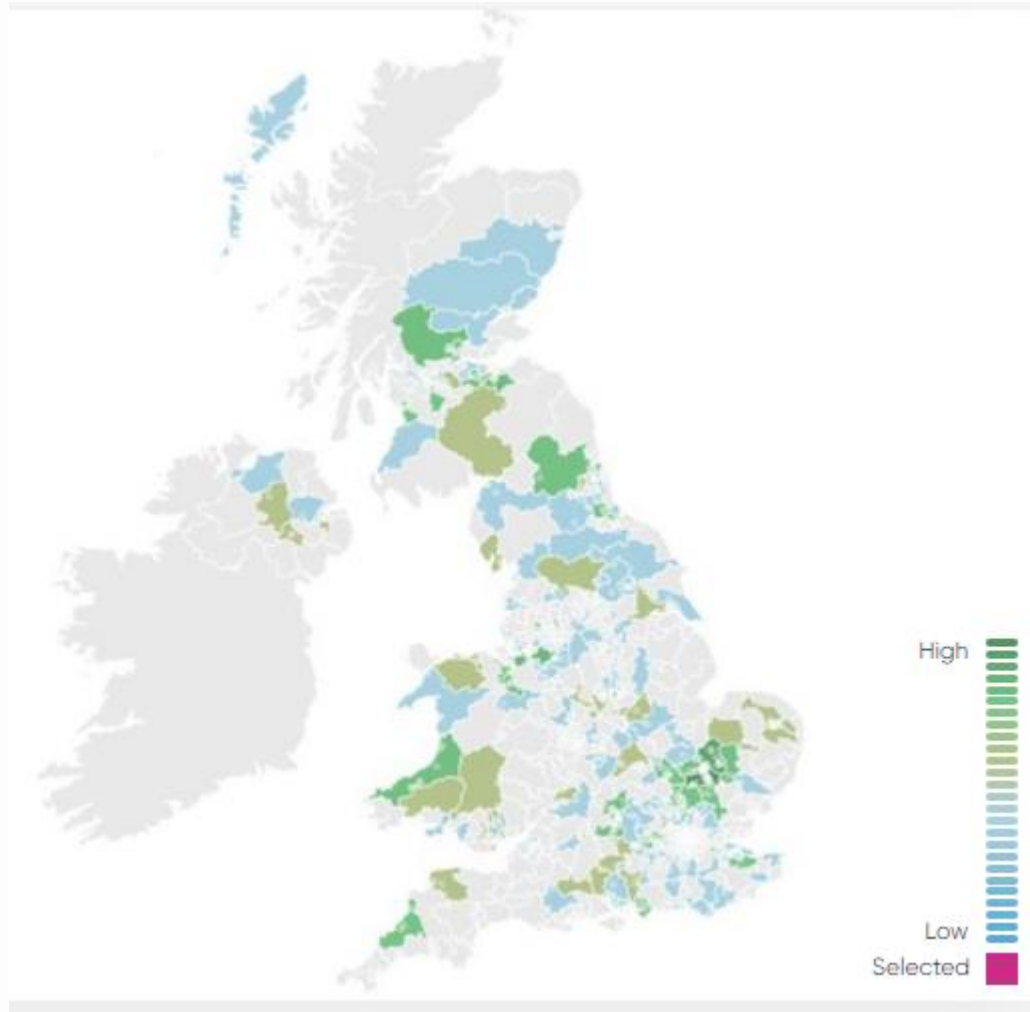
New Centre

CPI Scotland announces [OMICE](#)

Training

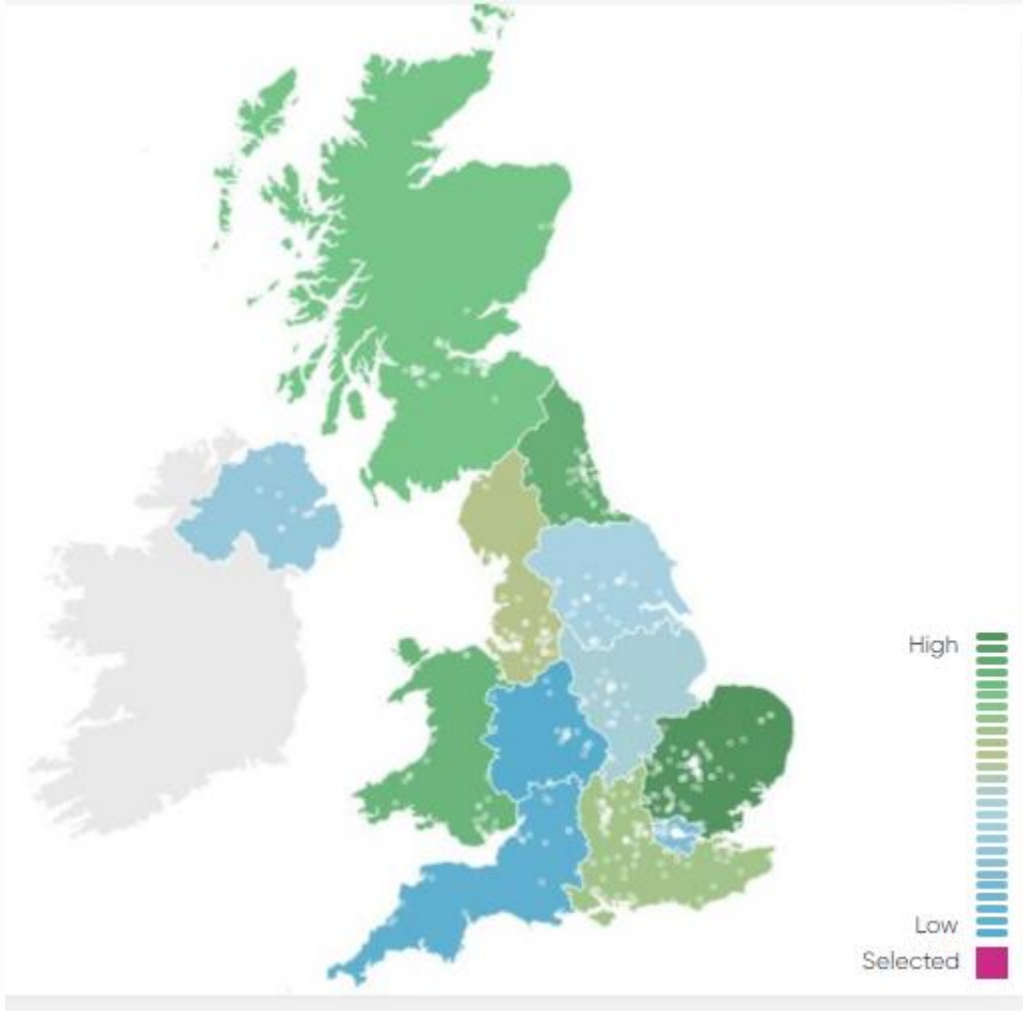
[RESILIENCE](#) and [Industry Skills Accelerator \(CGTC/CPI/Cogent\)](#)

UK Pharma manufacturing by constituency

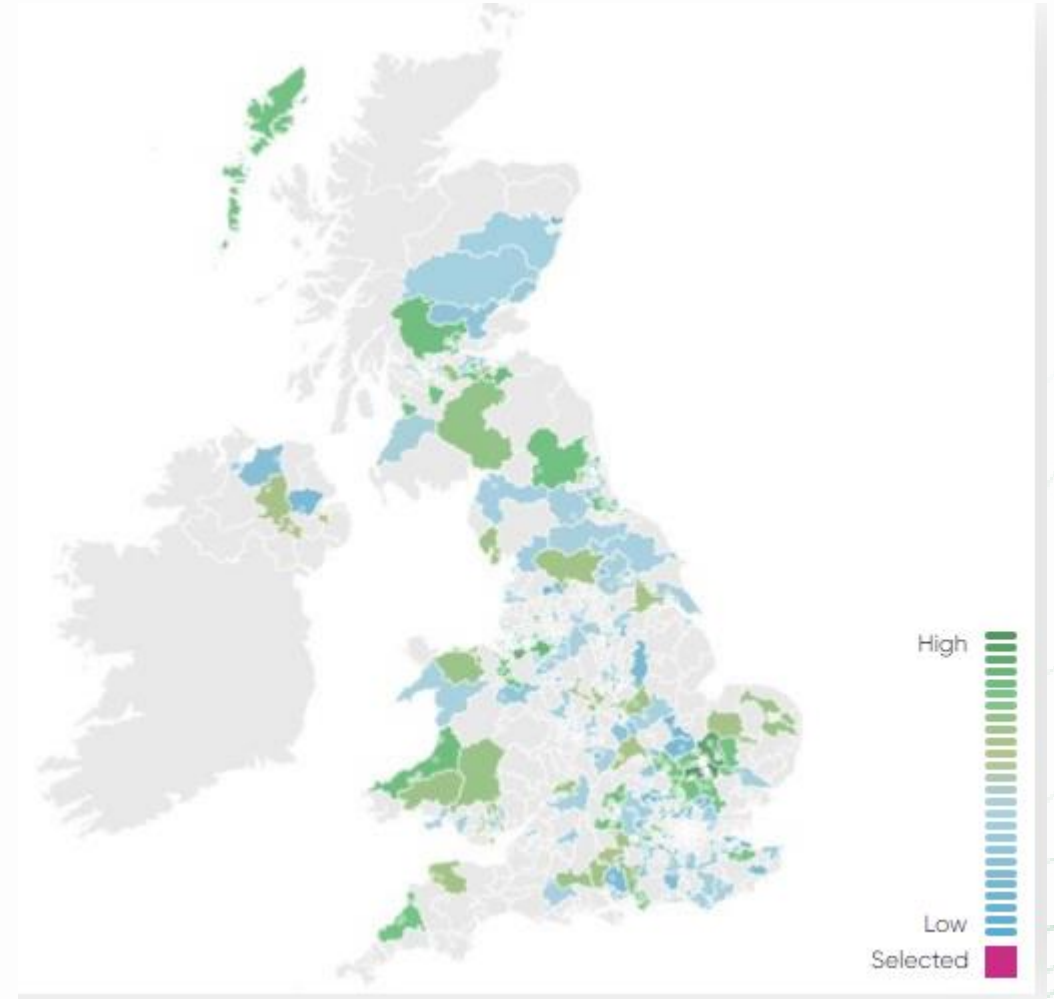


UK Pharma jobs /100K

by region



by constituency



New GMP licences

eXmoor – Sept 24 expands with Quell Tx in their facility

<https://www.exmoorpharma.com/press-release-quell-exmoor-gmp-partnership/>



CGTC Braintree Mar 24 - <https://www.stevenagecatalyst.com/braintree-manufacturing-innovation-centre-receives-mhra-licence-manufacture-advanced-therapies/>



CPI RNA Facility Feb 24 - <https://www.uk-cpi.com/news/cpis-rna-centre-of-excellence-passes-major-milestone-with-gmp-certification>



Rentschler approved Sept 23 <https://www.rentschler-biopharma.com/en-us/news-events/press-releases/rentschler-biopharma-s-atmp-facility-in-stevenage-uk-receives-mhra-approval/>



Launching 2025

FUJIFILM Diosynth Biotechnologies Billingham

<https://fujifilmdiosynth.com/about/news/fujifilm-diosynth-biotechnologies-confirms-400-million-investment-plans-to-create-the-largest-multi-modal-biopharmaceutical-manufacturing-site-in-the-united-kingdom/>



Moderna UK – completes 2025

<https://assets.modernatx.com/m/2ea3e7bdbb4e4045/original/CONSTRUCTION-COMMENCES-AT-MODERNA-INNOVATION-AND-TECHNOLOGY-CENTRE-IN-THE-UK.pdf>



Others

UK Biomanufacturing Perspective

**Capability and capacity analysis of ATMP GMP Manufacturing
provided by the Cell and Gene Therapy Catapult**

bioProcessUK - November 20, 2024

Launching today at bioProcessUK 2024:



ATMP GMP Manufacturing Report 2024



ct.catapult.org.uk/manufacturing-surveys

Questions? **Stephen Ward** Stephen.ward@ct.catapult.org

UK ATMP manufacturing continues to grow against a challenging funding landscape

- ✓ **Overall picture of ATMP manufacturing remains positive** – Total cleanroom footprint has grown again this year, with 53% growth since 2020
- ✓ **New Cell and Gene Therapy manufacturers** across 32 facilities spread across the UK including commercial supply facilities
- ✓ **Global export of products** with 6 commercial products (+4) exported
- ✓ **The size of the workforce is stable** – +7% increase in the number of full time employees, with some sites downsizing but others upscaling, well spread across the UK with hot spots in Scotland, East and South East England. Apprentices remain a strong cohort, despite a loss of 6 posts.
- ✓ **Continued support is essential given the number of clinical trials in the UK** - with at least 199 therapies being produced for Phase I – III clinical trials in 2024
- ✓ **Strong pipeline of future growth across the UK** – against the backdrop of intense global competition, this pipeline indicates continued confidence in the UK as a supportive environment to set up and expand advanced therapy manufacturing

Breakdown of increase in manufacturers



The manufacture of cell and gene therapies is spread across the UK

- London remains to have the highest number of individual manufacturing facilities
- The number of sites in the East has doubled – with the addition of *Autolus*, *The Nucleus* and *CGT Catapult*, *Braintree MIC*
- Increased manufacturing infrastructure in the South West – with the licensure of *eXmoor Pharma*’s site

Cell and Gene Therapy	Locations
	Braintree x1
	Bristol x2
	London x3
	Stevenage x2
	Stirling x1

Cell Therapy	Locations
	Barnsley x1
	Birmingham x2
	Edinburgh x2
	Liverpool x1
	London x4
	Motherwell x1
	Newcastle x1
	Oswestry x1
	Sawston x1
	Stevenage x2

Gene Therapy	Locations
	Abingdon x1
	Darlington x1
	Glasgow x1
	Keele x1
	Liverpool x1
	London x1
	Oxford x2
	Stevenage x1



UK manufactured therapies exported globally



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