

# Why Ireland for Cell and Gene Therapy Development and Manufacturing

Q3, 2020



Track









Facility Design, Consultancy

Transport & . Cold Chain Logistics

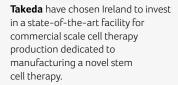
Global Services

# Well Established Biopharma Track Record

## Growing Cell and Gene Therapy Investment

- 85+ Biopharmaceutical sites in Ireland.
- 9 of the top 10 global pharmaceutical companies have substantial operations in Ireland.







In 2019 Allergan announced a gene therapy research collaboration with NIBRT that will address key challenges in the manufacture and characterisation of Adeno-Associated Virus (AAV)-based gene therapies.



Avectas is a cell engineering business focused on improving the cost, manufacturing and patient outcomes for the next generation of cellular therapies. Avectas is developing a unique delivery technology platform, Solupore®, to enable the ex-vivo manufacture of gene modified cell therapy products, with partners.







## **Excellence in Advanced Manufacturing**

#### Manufacturing in Ireland accounts for

**32%** of GDP

(c €140.6bn in exports)

Source: CSO, 2019

**261,400** direct employees (11.2% of workforce)

35% gross value added (EU average 16%)

Recognised leaders in



**Design for** Manufacturing



Operational and **Innovation Excellence** 



Global **Launch Sites** 



**New Product** Introductions

- Strength in implementation of next generation manufacturing technologies (robotics, automation, systems integration).
- Ireland has the most Shingo prizes globally per capita.
- DePuy Synthes recognised global Digital Lighthouse (World Economic Forum).



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# **R&D** and Training

Over €12m of research funding awarded in Ireland in areas of gene therapy and cell therapy in the last ten years by Science Foundation Ireland (SFI).

4 collaborative cell and gene therapy projects awarded €25.5m under first two Calls of Disruptive Technologies Innovation Fund (DTIF).

IDA Supports: 25% R&D tax credit IDA Ireland offers a variety of grants available for qualifying R&D & Training.



#### **National Institute for Bioprocessing** Research and Training (NIBRT)

- + Trains over 4,500 people annually
- + NIBRT offer practical based training for industry in cell and gene therapy development and manufacture
- 2 new courses 2020:
  - Fundamentals of Stem Cell Therapy Manufacture (in collaboration with CCMI)
  - Advanced Cell Therapy Technology Course (in partnership with GE Healthcare)
- + Industry Partners: Allergan, Pfizer, GE Healthcare



## Regenerative Medicine Institute

- + Multidisciplinary research in fundamental and applied cellular biotechnology
- + Clinical collaborations in corneal stem cell transplant and pancreatic islet transplant for treatment of type 1 diabetes.
- + Industrial & Ecosystem partners: Harvard Medical School, Royal College of Surgeons in Ireland, St. Vincent's University Hospital

## Clinical Trials in Ireland

Ireland has an evolving clinical trial ecosystem. 291 trial sites now open across the Irish network.

Multiple cell & gene clinical trials ongoing in collaboration with Galway University Hospital and St. James's Hospital.





There are seven clinical research facilities and centres across Ireland within an integrated clinical research network known as HRB Clinical Research Coordination Ireland (HRB-CRCI).

Source: HRB 2018

## Regulatory & Compliance

Ireland has Exemplary compliance record with regulatory agencies, the Irish Health Products Regulatory Authority (HPRA), European Medicines Agency (EMA) and the Food and Drug Administration (FDA).

Regulatory Science Ireland - a multidisciplinary stakeholder network informing industry and regulators on emergent regulatory requirements.



## Ireland's CMO/CRO Support Sector

- APC Ltd: CMO in cell and gene process development.
- Centre for Cell Manufacturing Ireland (CCMI): dedicated GMP cell therapy manufacturing facility with capacity in adenoviral vectors and adult mesenchymal stem cells.
- PPD® Laboratories: Contract analytical capabilities to support development and manufacturing.
- Almac Group: Partnering to advance human health.
- Eurofins BPT Ireland: part of the World's largest network of trusted contract GMP analytical labs supporting life changing therapeutics.











## Facility Design, Build & Consultancy

Ireland is home to a number of excellent providers delivering bespoke building solutions in cell and gene development and manufacturing locally/globally.

Significant expertise in guiding companies on optimal build configurations (green field, brown field conversion, modular).

# **Transport & Cold Chain Logistics**

Multiple global and speciality providers in cell and gene therapy logistics operating in Ireland include:











- 10 Freight Forwarders & Courier Servicers
- 2 Freight Forwarders
- 2 Courier Servicers
- 1 Fullfilment Company



### Global Business Services

Ireland is a global location for centralised data management and advanced analytics

- + The world's top 5 Software companies along with 7 of the world's top 10 Technology companies have operations in Ireland.
- + Ireland's technology sectors spans hardware, software, cloud, analytics, health IT.
- + Vibrant digital health cluster.

## Cyber Security

- + The world's top 5 cyber security companies have operations in Ireland.
- + Ireland has developed a leading cluster Cyber Ireland.
- + Capability in threat research, security operations, platform development, risk.

#### Al & Data

- + Open, vibrant cross sectoral capability in Al Trial and test bed facilities.
- + World class researchers, highest per capita number of EurAl Fellows.

#### Internet of Things

- + Perfect collaboration environment hardware, software, connectivity, microelectronics & sensors, Data and analytics.
- Open, engaged partnerships to Collect data, Connect devices/systems and Transform data in actionable insights.

#### **Data Management**

- + Manufacturing Data
- + Clinical Trial Data
- + Patient Data + Logistics Data
- Regulatory Data + Supply Chain Data
- OPTUM\*
  - **€** Cerner IBM

























**IDA** Ireland