Global Integrated Solutions

Clinical and Commercial Supply Chain Solutions

Protect your materials. Protect your investment. Protect your patients. Integrity from collection to delivery, safeguarded around the world.

fisher clinical services
by Thermo Fisher Scientific


ThermoFisher
SCIENTIFIC

There is a patient waiting.

Fisher Clinical Services, a part of Thermo Fisher Scientific, develops processes to ensure the integrity of your materials and keep you apprised of their status. From initiation of your clinical trial through commercialization, let our experience work for you to design, execute, and manage solutions for your materials and your patients. Consistent quality. Global network. Dedicated to you.

- Storage and Monitoring
- Cold-Chain Logistics
- Qualification/ Validation Services
- Secondary Packaging/ Labeling
- Kit Production

Formula For Success

The execution of a cell therapy clinical trial rests on the ability to deliver a viable, potent product.

Our formula for success encompasses the critical components to ensure your material's integrity remains intact throughout the chain of custody: temperature, identity, and security.

Our Project Managers work to ensure that each project runs smoothly. They collaborate with customers by addressing challenges and identifying solutions so projects are delivered on-time and on-budget.

Temperature

Due to their complex nature, cell and gene therapies, are highly sensitive to environmental changes. Reliable temperature maintenance is critical in minimizing time-out-of-environment (TOE) and ensuring the stability of your valuable material.

- CryoCarts for best practice in-facility handling
- Fleet of qualified LN_2 dry shippers
- Secondary packaging and labeling performed under controlled, cryogenic conditions

Identity

Your technology holds the potential to deliver life-changing treatments. We ensure that your cell and gene therapy products are delivered to the right patient at the right time, location, and temperature.

- Patient-specific identification labels, collection containers, and administration kits
- 21 CFR Part 11 compliant chain of custody documentation

Security

We are committed to protecting your cell and gene therapy products. Our controlled risk systems monitor and track material to ensure that the correct temperature is maintained throughout the entire supply chain. A record of this information is captured using our data management systems and provided to you upon request.

- Adherence to PDA guidelines for cold chain transport
- Storage and transit temperature alert and monitoring system
- Tamper-evident sealed dry shippers

Quality Systems

Quality is at the center of everything that we do, our regulatory compliance

Quality Management System

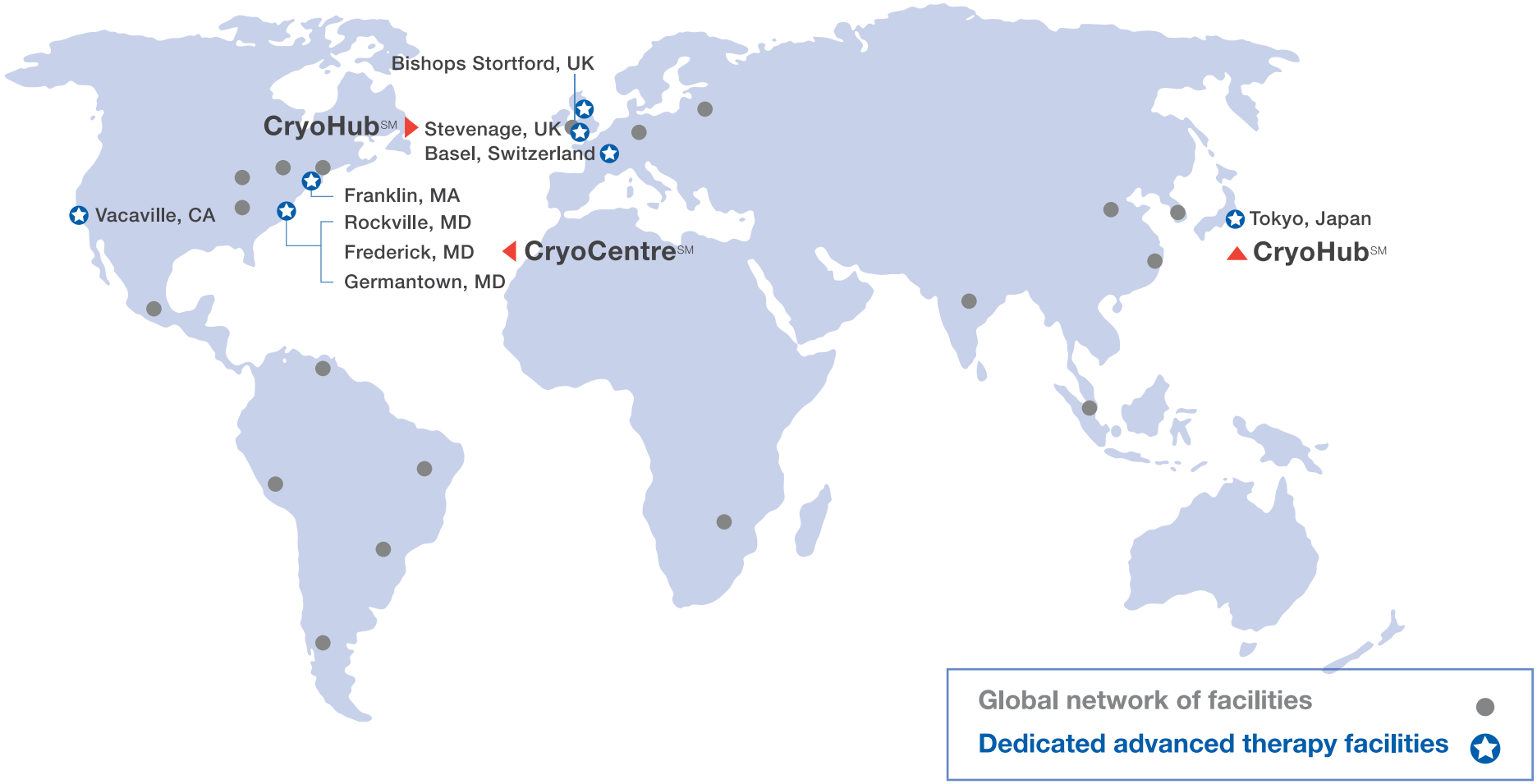
Fisher Clinical Services maintains a global, comprehensive, and integrated Quality Management System based on regulatory cGMP requirements and industry best practices. Our quality policies and standard operating procedures (SOPs) are implemented across our facilities, ensuring uniformity and adherence to customer and regulatory requirements.

Regulatory Compliance

Our Quality Management System follows current Good Manufacturing Practices (cGMP) guidelines and complies with governing bodies.

- US cGMP - Food and Drug Administration (FDA)
  - 21 CFR 210, 211, 820, 1271
  - 21 CFR part 11 and part 58 (where applicable)
- EU cGMP at our US, CH and UK facilities
- FDA registered and audited HCT/P establishment
- Employees are regularly trained to ensure compliance, especially for clinical trial support

Global Infrastructure



Our global infrastructure enables customers to seamlessly clinical trials acrtrials across multiple geographies while providing patients around the worldound the world with access to life changing therapies.

Through our global network of facilities we have access to the industry's largest network of fully owned cGMP facilities, strategically located around the world to support our customers. These state-of-the-art, redundant facilities ensure that we can supply the highest quality services to our customers globally and uninterrupted.

CryoCentre℠

The CryoCentre will help support the advancement of cell and gene therapies. It will provide operational scalability to meet the need of both clinical tirals and commercial distribution.

- 76,000 sq. ft. facility in Frederick, MD
- Cryogenic storage, packaging, and supply chain management
- Client specific SOPs and staff
- Fully licensed 3PL in 50 states
- FDA Registered and cGMP compliant

CryoHub℠

Our UK and Japan CyroHubs offer scalable, cryogenic storage and supply chain solutions that enable seamless support to global clinical trials. They include customizable modules that can be configured to meet your needs based on the volume and/or location of your trial.

- Receiving
- Freezers
- □m□ient□re□ri□erated□□ro□en□ultra□lo□□and LN_2 Storage
- LN_2 Charging Station
- Collection and Administration Kit Prep
- Outbound Shipping and Documentation

Scalable workflows

from collection, through manufacture, to final clinical site delivery

A reliable cell and gene therapy supply chain strategy is imperative to ensuring your cell and gene therapy products remain viable from the point of collection, through manufacture, to the final clinical site delivery.

Our highly configurable cell and gene therapy workflows have the flexibility to address the unique requirements of your specific product, whether autolgous or allogeneic. These workflows can be validated and standardized by our team of experts to ensure there is consistency in the entire supply chain, from cell collection through drug distribution. Through our tailored workflows and process validation, we develop customized solutions to meet your needs and deliver your cell and gene therapy products safely and efficiently.

Storage and Monitoring

We provide expert assistance in storing cell and gene therapy products at ultra-cold and cryogenic temperatures

- 24 hour temperature and humidity monitoring
- Facilities equipped with both uninterrupted power supply (UPS) systems and one or more back-up generators
- On-call staff, day or night, should the temperature of any unit deviate from its acceptable range
- 21 CFR Part 11 compliant inventory management system with near-real time online visibility through client online access portal

Cold Chain Logistics

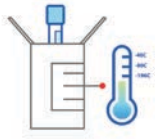
From collection, through manufacture, to final clinical site delivery, we have the knowledge, systems, and equipment required for transport of cell and gene therapy at ultra-cold temperatures anywhere in the world.

- Fleet of validated dry shippers
- Certified and trained in current Good Manufacturing Practices (cGMP)
- Point-to-point temperature monitoring devices
- All shipments are prepared according to SOP
- In-house Qualified Person (QP) release
- HAZMAT and International Air Transport Association (IATA)-trained personnel

Qualification/Validation Services

By validating processes and qualifying equipment, we ensure that risk is minimized, material integrity remains intact and regulatory requirements are met throughout the chain of custody.

- Pack out configurations based on maximum transit times, shipping routes, payloads and temperature requirements
- Test dry shippers using mock material loads in different thermal environments
- Real-time transit studies using mock payloads
- Provide comprehensive report of the qualification data in a timely manner



Secondary Packaging & Labeling

We offer client specific secondary packaging and labeling for clinical distribution.

- Patient-specific identification labels and collection containers
- Chain of custody documentation

Kit Production

We design complex, customized clinical collection and administration kits at any temperature, including cryogenic.

- Collection/Apheresis Kit
- Patient administration
- Post-administration sample collection

Contact Us

At Fisher Clinical Services, we understand that your technology holds the potential to deliver life-changing treatments. Connect with us today to learn how we can support you on your path to commercialization. After all, there is a patient waiting.

Find out more at **fisherbioservices.com/market-solutions/cell-therapy**

Talk with an expert:

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