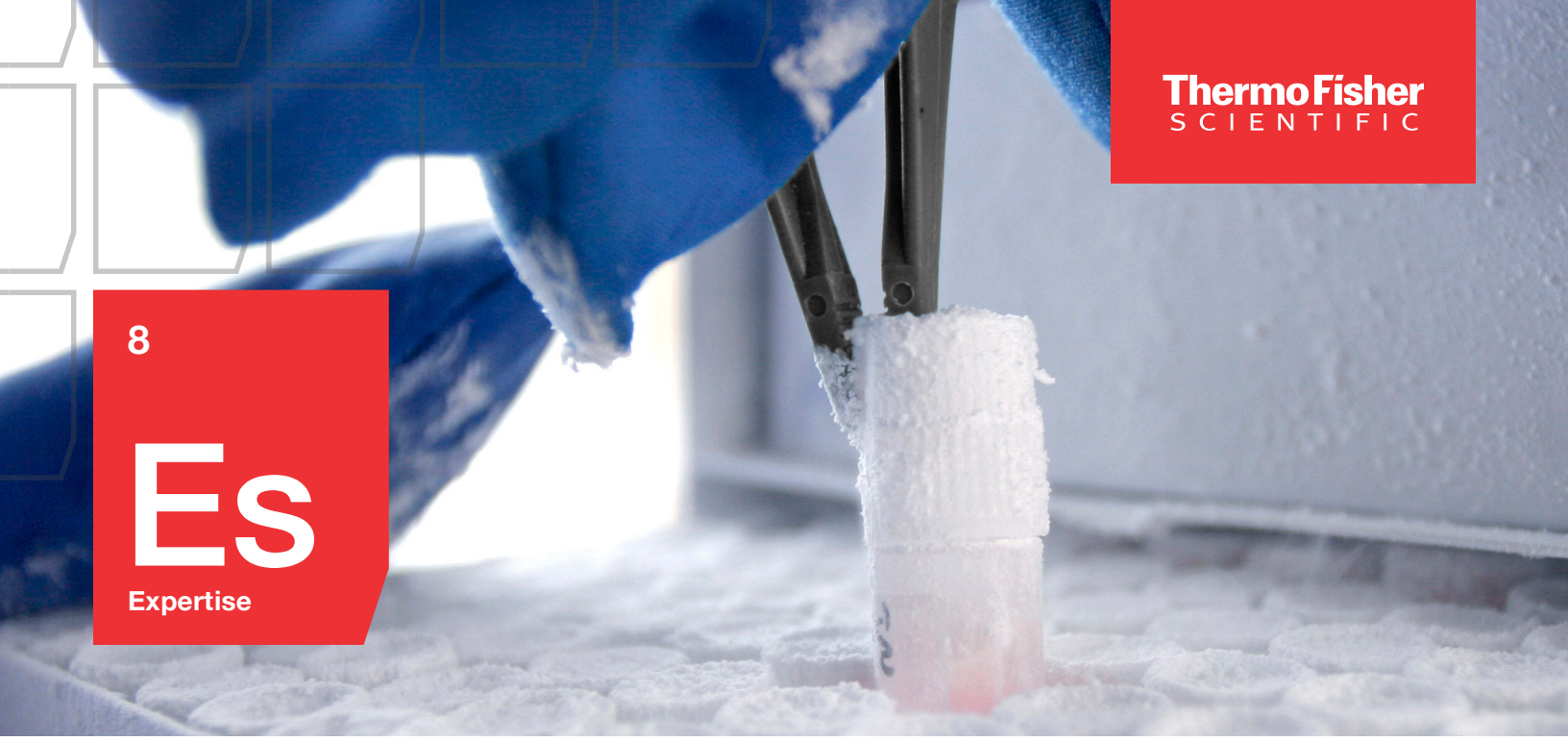


8

Es

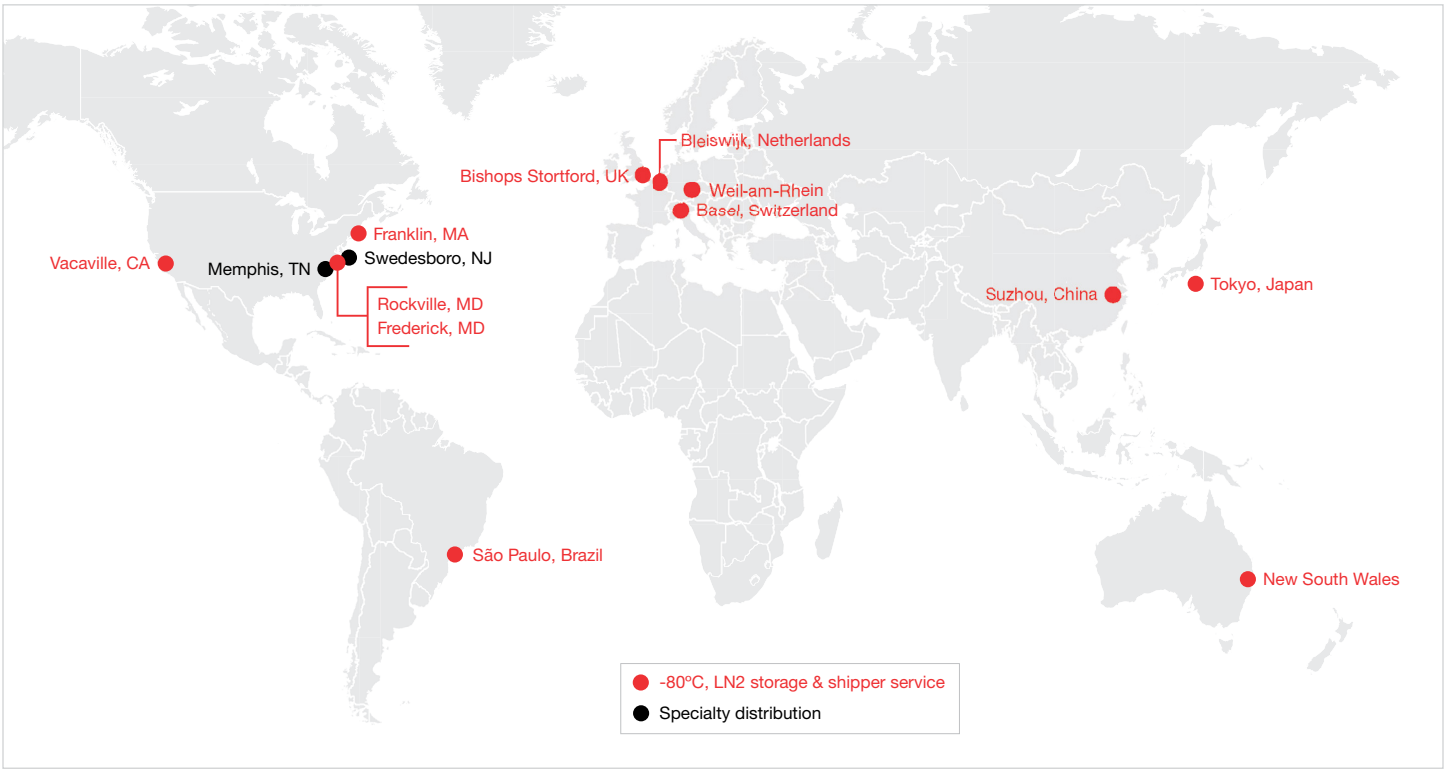
Expertise

Commercial services for cold and ultracold materials

Over 35 years of experience managing ultracold and cryogenic material from storage, the secondary packaging, labeling, and distribution.

The cell and gene therapy market is about to reach a commercialization inflection point, with the FDA anticipating 10-20 new approvals per year through 2025[1]. As innovators approach their commercial filing, it is vital to consider how the drug will be packaged, labeled, and distributed to hospital sites. Many questions regarding courier services or tertiary packaging and data loggers are addressed in clinical trials. However, the standards for commercial drug product are very specific, and your filing will need to demonstrate validated processes for every aspect of your logistics strategy, from labeling to shipping.

Patheon's global network of ultracold capabilites



Additional regulatory guidelines may impact your current packaging processes. For example, the Drug Supply Chain and Security Act (DSCSA) and Falsified Medicines Directive (FMD) require drug product to be serialized, requiring specialized equipment and software to enable global distribution. Leveraging 35+ years of experience in manufacturing and commercializing drug products and handling critical biological material at ultracold and cryogenic temperatures, Thermo Fisher Scientific has developed a commercial packaging, labeling, and distribution solutions to meet the needs of your life-saving cell or gene therapy. We have also established best practices for labeling and distribution at ultracold and cryogenic temperatures to seamlessly transition your product from clinical trial to commercial approval.

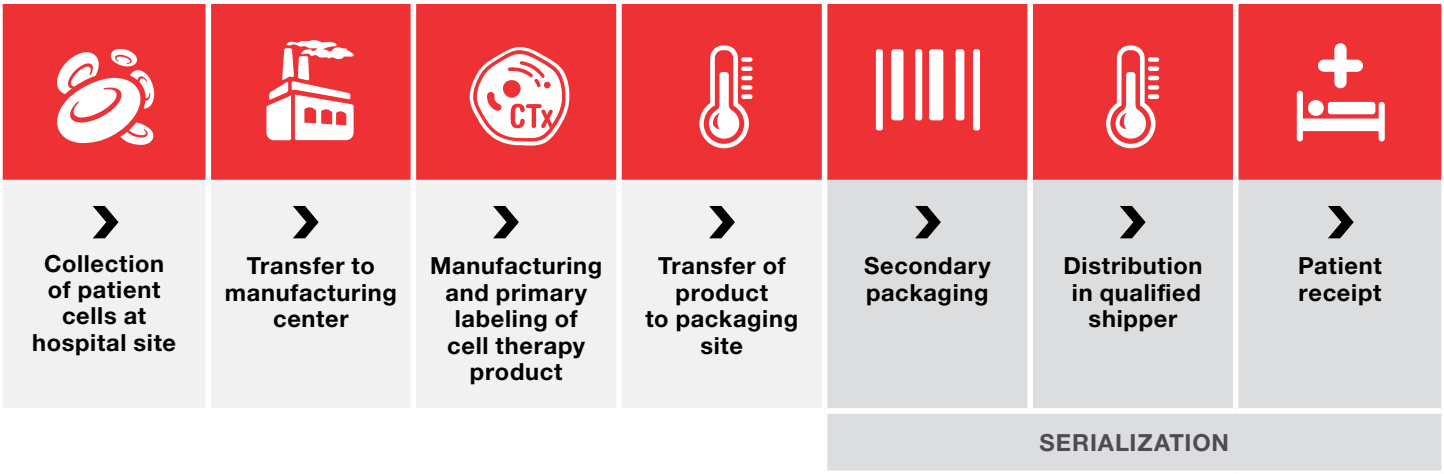
GMP quality at all stages of development and commercialization

Our global network of GMP facilities are equipped with state-of-the-art technology, enabling the commercial storage, packaging, labeling, serialization, and distribution of materials at ultracold and cryogenic temperatures, without any time out of environment (TOE). Starting your clinical journey with a commercial-ready partner can pave the way for a successful commercial launch.

	Site	Cold and ultracold commercial capabilites								
		Product storage				Secondary packaging/ kitting	Commercial packaging	Commercial labeling	Just in time labeling	Serialization
		Cold (2°C to 8°C)	Frozen (≤ -20°)	Ultra frozen (-80° C)	Cryo (-150°C)					
Americas	Franklin, MA USA	•	•	•	•	•				
	Frederick, MD USA									
	Memphis, TN USA	•	•	•						
	Rockville, MD USA	•	•	•	•	•			•	
	Swedesboro, NJ USA	•	•	•						
	Vacaville, CA USA	•	•	•	•	•			•	
	Sao Paulo, Brazil	•	•	•	•	•			•	
Europe	Basel, Switzerland	•	•	•		•				
	Bishops Stortford, UK	•	•	•	•	•			•	
	Bleiswijk, Netherlands	•	•	•	•	•	•	•		•
	Weil am Rhein, Germany	•	•	•	•	•	•	•	•	•
Asia Pacific	Toyko, Japan	•	•	•	•	•			•	
	Suzhou, China	•	•	•	•	•			•	

Serialization services compliant with the Drug Supply Chain and Security Act and Falsified Medicines Directive (FMD):

What is serialization and how does it apply to your product? Serialization creates a unique product identity that can be tracked from the packaging site through distribution to the hospital or point-of-care. Serialization is a central tenet of the US Drug Supply Chain and Security Act and the EU Falsified Medicines Directive[2], developed to ensure that product identity is maintained throughout the supply chain. While autologous products on the market today may receive an exemption from serialization, allogeneic products will need to comply with these regulations. Our sites have invested in the equipment and software to facilitate your product serialization, and we have the expertise to develop your packaging, labeling and distribution strategy within the US and EU.



Transportation services – seamless and secure end-to-end logistics support for your critical materials

Patheon's 4PL transportation services specialize in white-glove courier solutions for high-value shipments, offering complete supply chain oversight. From initial lane validation for regulatory support to comprehensive commercial launch strategies, our team selects top-performing, cost-effective carriers from a qualified network. We also provide customs and regulatory guidance, integrated real-time shipment tracking, and have qualified shippers on-site for just-in-time distribution. As your product expands to new markets, our scalable transportation solutions guarantee exceptional service in each geography.

Seamlessly transition with confidence from clinical to commercial with a trusted partner. For more details on our capabilities and end-to-end solutions, contact your Thermo Fisher Scientific representative.

1. Alliance for Regenerative Medicine. (March 5, 2020). The Alliance for Regenerative Medicine Releases 2019 Annual Report and Sector Year in Review. https://alliancerm.org/press-release/the-alliance-for-regenerativemedicine-releases-2019-annual-report-and-sector-year-in-review/

2. FDA. (January 15, 2019). Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies https://www.fda.gov/news-events/press-announcements/statement-fdacommissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

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