



patheon

## The leader in critical biological material management

**Your work holds the potential to deliver life-changing treatments.  
Our mission is to help you succeed.**

Ensure the integrity of your valuable material – from collection and storage through delivery to patient – with customized, end-to-end supply chain management solutions.



### Public health research

- Standardized processes to minimize pre-analytical variability
- Validated data systems to ensure biosample information management
- High throughput processing with flexible configurations



### GMP biologics management

- Regulatory compliance through our Quality Management System (QMS) based on US and EU cGMP requirements and international industry best practices
- Customized storage & packaging configurations for optimal material management
- Supply chain management to ensure material integrity and viability throughout transportation
- Collection and storage of biological samples for large scale cohort studies



### Advanced therapy

- Commercial packaging and serialization capabilities
- Comprehensive collection to delivery management of local and global supply chains
- Distribution and storage expertise, utilizing unified quality systems and global network of CryoHubs<sup>SM</sup>
- Experienced project managers to mitigate supply chain risk, timeout-of temperature and ensure delivery to patients globally



# Global Services

We provide customized end-to-end chain of custody solutions for our customers, ensuring the integrity of their valued material from collection, through manufacture, to the patient bedside.

## Cold chain logistics

- Supply chain management for material integrity and viability throughout transportation
- Point-to-point temperature monitoring devices
- All shipments prepared according to SOP
- Dedicated CryoCentre™ for cell and gene therapy
- In-house Qualified Person (QP) release (EU)
- HAZMAT and IATA-trained personnel
- Excursion sensors
- Controlled-temperature pack outs

## Secondary packaging and labeling

- Clinical packaging and labeling
- Commercial packaging and serialization
- Patient-specific identification labels and collection containers
- Chain of custody documentation
- Just-in-time labeling

## Biobanking and biorepository

- Ambient to cryogenic storage options
- Expert material management throughout sample lifecycle
- Risk mitigating operational redundancies
- 24/7 on-call staff

## GMP Kit production

- Collection of biological samples
- Patient administration
- Just-in-time production
- Storage & distribution

## Pharmacy services

- Direct-to-patient pharmacy services in support of free goods programs and clinical trials
- Nationwide prescription fulfillment
- Scalable and flexible operation constructed to accommodate high or low volume projects
- Fully validated Inventory Management System

## Laboratory processing

- Fully customized lab services
- High-throughput robotic sample processing
- Scalable and flexible NGS solutions
- DNA/RNA extractions
- Tissue/Blood/Buffy Coat/PBMC processing
- Sample QC

## Qualification/validation services

- Temperature mapping
- Equipment qualification
- Shipping lane validation
- Real-time transit studies

### Commitment to quality

ATMP QP service available in Germany and UK facilities

Our Quality System follows cGMP guidelines and complies with international governing bodies qualification data

- US cGMP - FDA
- 21 CFR 210, 211, 820, 1271
- 21 CFR part 11 and part 58 (where applicable) EU cGMP at US, CH, and UK facilities
- In-house QP release at CH and UK facilities ISO 9001:2015 certified (UK site)
- US facilities that are FDA registered