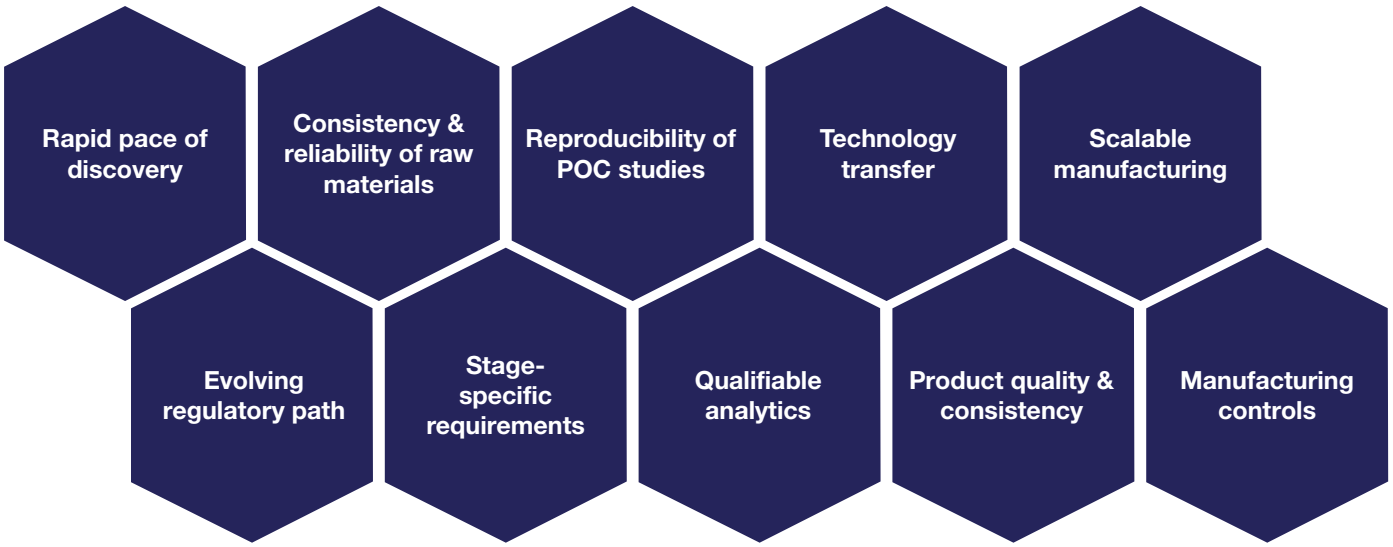
TRANSLATIONAL SERVICES FACT SHEET

Accelerate cell and gene therapies from discovery to clinical manufacturing

Patheon translational services

The path from designing cell and gene therapies for research studies to manufacturing them in a cGMP environment and making them available to patients is costly, time-sensitive and filled with numerous risks. By partnering with an experienced service provider that follows a begin-with-the-end-in-mind approach, such as Patheon Translational Services, you can reduce risk, speed up drug development, and seamlessly transition products to cGMP manufacturing resulting in faster patient access to life changing therapies.

Challenges leading to risks and delays in clinical manufacturing of cell and gene therapies



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Mitigating risks and enhancing efficiency in cell and gene therapy development

Proof of concept → **Pre-clinical** → **Clinical and commercial**

Patheon translational services support cGMP-destined customers by offering:

Viral vector

- Scaled-down processes based on cGMP platforms
- Suspension, serum-free LV and AAV production
- Scale-specific downstream processing and purification

Cell therapy

- Autologous/allogeneic process evaluation and establishment
- Research cell banking
- Viral and non-viral gene delivery
- Assay establishment
- Raw material evaluation

Molecular biology

- Cloning (GOI; rep/cap)
- Deletion of undesired sequence(s)
- Antibiotic resistance swapping
- Small scale plasmid expansion

Analytics

- Same platforms used in GMP QC
- Qualifiable assays
- Controls & Standards
- Predictive analytics

Extensive capabilities and direct access to integrated services

Interdisciplinary team with >30 years of cGMP manufacturing, quality and regulatory experience

Facilitate easier technology transfer of processes to cGMP manufacturing

Enhanced facility features and practices driven by a Quality Management System

Customers seeking proof-of-concept material or candidate selection that is representative of the final product

Use of raw materials that have cGMP-compatible option to avoid rework

Scaled-down processes and qualifiable assays on the same platforms used in cGMP

De-risk and expedite cGMP transition for cell and gene therapies through the early establishment of standardized processes and qualifiable analytical assays.

Contact us: **patheontranslationalservices@thermofisher.com**

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