ThermoFisher SCIENTIFIC

CELL AND GENE THERAPY SOLUTIONS

DELIVERED WITH

INNOVATION AND INTEGRITY

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Viral Vector Services Regulatory Offering Menu

The regulatory environment for Cell and Gene Therapies is evolving at a rapid pace. Many companies, especially new and emerging ones, often lack the internal resources, or expertise to support regulatory filings. Companies need a partner who continuously monitors the changing regulations and has the capabilities to support them with their regulatory needs. Patheon Viral Vector Services provides a comprehensive range of regulatory consulting services for the cell and gene therapy innovators.

Regulatory Services Advantages

- Range of regulatory services
- Services based on 15 years of interactions by Pharma Services Group with authorized agencies
- Deliverables provided to latest regulatory standards
- Expertise focused on ICH Common Technical Document (CTD) Quality/Module 3
- Regulatory liaison can reduce number of intermediaries and lead times

Document Review

Activities	Description
Gap analysis	• According to applicable regulations in agreement with the Client • Draft summary form with CTD granularity
ICH region (EU and US)	**Author** outline and **review** summary on CTD Quality Drug Substance (DS) or Drug Product (DP) modules or subsections (3.2.S, 3.2.P, and/or 3.2A.1)
CTD quality / CMC file review and preparation	Customer registration file **review** for overall consistency versus PSG site current practices and regulatory standards

Document Preparation[1]

Activities	Description
Complete CMC dossier	**Preparation of a complete, ready-to-submit quality module or subsections, comprising: regulatory requirements ("agreement"), data collection, file writing, review rounds (internal and customer), and comments integration**
New Application[2]	
ICH region (EU and US)	• EU Marketing Authorization Application (MAA) • US Biologics License Application (BLA)
Partial CMC dossier	**CMC post-approval changes, including but not limited to Annual Reports (AR), Prior Approval Supplement (PAS), Changes Being Effective (CBE).**
Regulatory feedback (EU and US)	**Answers to Regulatory Authority questions**

[1]In English with possibility of technical translation. Excludes eCTD publishing-related activities per ICH M2.
[2]Offers assistance with the application process

Technical Support

Activities	Description
Master referentials	**The following items are provided without legalization in the context of a client's regulatory submission**
Manufacturer license / GMP certificate	Copy of current document (according to Eudra GMDP format) as applicable to the region
Site master documents	• Site master file (according to PIC/S format) • US DMF Type V

CMC Regulatory Expertise

Activities	Description
Project regulatory liaison	• Preparation and participation in client's project team sessions and milestone meetings • Regulatory interaction and meeting support
Regulatory consulting	Assessment of client regulatory request and provision of guidance
Regulatory training / workshop	Preparation and delivery of client-specific training on US and EU regulatory framework, procedures, GMP news, and trends

Find out more at **patheon.com**

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