ThermoFisher SCIENTIFIC

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COMPLIANCE & CARE

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Global regulatory services backed by industry experts

Navigating a complex regulatory environment is vital to the success of your product's lifecycle. Thermo Fisher Scientific provides a range of flexible regulatory solutions that can help easily address your molecule's unique needs and challenges, while being backed by a global network and seasoned regulatory experts.

Integrated regulatory services for fewer intermediaries and shortened timelines

- Accessing a range of CMC regulatory services for all product types manufactured across our sites
- Delivering ICH Common Technical Document (CTD) Quality/Module 3 for clinical and commercial applications and life cycle maintenance
- Supporting multi-jurisdictions such as US, EU as well as international/Rest-Of-World (ROW) registrations
- Providing deliverables that are in alignment with the latest regulatory standards
- Liaising closely with our Subject Matter Experts (SMEs) for direct project assistance resulting in faster dossier preparation

Document preparation[1]

Activities	Description
Complete CMC dossier sections [Module 3.2.S, 3.2.P, 3.2.A 3.2.R]	• Preparation of complete or partial, publishing-ready, Drug Substance (DS), Drug Product (DP) and/or Appendices modules, including authoring, review rounds (internal and customer) and comments integration • Authoring and review of responses to agency questions
ICH regions[2]	**Clinical trial applications (CTA Phase 1, 2 and 3):** • US Investigational New Drug Application (IND) • EU Investigational Medicinal Product Dossier (IMPD) • Related Amendments **Marketing applications:** • US New Drug Application (NDA) • US Biological License Application (BLA) • US Abbreviated New Drug Application (ANDA) • EU Marketing Authorization Application (MAA) **Post approval changes:** • US Prior Approval Supplement (PAS) • US Change Being Effective (CBE)/(CBE30) • US Annual Report (AR) • EU Type II variation • EU Type IB variation • EU Type IA variation
Non-ICH regions	Authoring and editing of dossiers case-by-case

[1] In English, with the possibility of technical report translation

[2] Includes countries that accept the ICH CTD

Document review

Activities	Description
CMC dossier review	• Assessment of customer's submission drafts for consistency with current Thermo Fisher Scientific site practices and regulatory standards • Gap analysis summary report of current dossiers, in support of technology transfers and product inspection preparedness, per CTD granularity

Technical support

Activities	Description
Site-related	
Reference documents	All following items are provided to the customer or an Agency (as applicable) **without legalization** in support of a regulatory submission: • Manufacturer license • GMP certificate/GMP compliance package • Site Master Files/US DMF Type V • Foreign accreditation
Product-related	
Pharmaceutical declarations	Preparation of compliance statements such as GMP, BSE/TSE, allergens, melamine, residual solvents, elemental impurities, nitrosamines
Document legalization	Legalization of relevant documents by the appropriate official body

Regulatory expertise

Activities	Description
Project regulatory liaison	Participation in customer's project team sessions and/or milestone meetings
Regulatory consulting & strategy	• Provision of ad hoc regulatory consulting and strategies across product life-cycle per customer request • Assistance in regulatory agencies meetings (e.g. requests, briefing books, minutes)
Regulatory training & workshop	Preparation and delivery of customer-specific training or workshop on applicable regulatory topics, frameworks, procedures, GMP and trends

General terms and conditions

- All deliverables provided in English
- Any item not listed may be considered upon customer request
- New or substantial changes in scope are subject to specific services agreement revision
- Quotations for services will be provided in relevant currency based on scope of services (including product type), required resources and timelines
- Invoicing provided for services based on terms within business agreement

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