

Drug Substance CMC Regulatory Support

Rely on the expertise of our agile Regulatory Affairs team

Veranova's Regulatory Affairs team provides both strategic and operational support for global filings — including new drug application (NDA), marketing authorization application (MAA), and equivalent submissions — by providing comprehensive drug substance chemistry, manufacturing, and controls (CMC) support.

Global Experience and Region-Specific Expertise

The team combines broad experience across the United States, Europe, China, Japan, and other markets around the world, with region-specific expertise to help address local regulatory expectations.

Key Service Areas

- Drug substance CMC documentation and submission support
- Manufacturing process and control strategy summaries
- Process development, scale-up, and technology transfer documentation
- Critical Quality Attribute (CQA) and Critical Process Parameter (CPP) assessments
- Raw material, specification, and control strategy support
- Technical justifications and responses to support regulatory agency inquiries
- Global submission support for US, EU, and other international markets
- Lifecycle management and post-approval regulatory support

End-to-End Support

Our services include preparation, review, and compilation of regulatory-ready drug substance documentation, data summaries, and technical support related to drug substance manufacture, control, and lifecycle management.

Bringing Clarity to Complexity

We work closely with clients to present complex technical information in a clear and compliant manner while supporting regulatory interactions throughout the product lifecycle.

Regulatory Expertise Based on Development and Manufacturing Excellence

The work of our Regulatory Affairs team is grounded in Veranova's practical experience in drug development and manufacturing. As a leading drug substance CDMO, Veranova has over 50 years of experience in the development, manufacturing, and analytical testing of novel modalities and complex small molecules. We have supported 18% of the small-molecule drugs approved by the FDA since 2014.

Our dedicated team has more than 25 years of experience handling regulatory submissions in the US, UK, EU, China, Japan, and other global markets.

CMC Filings Backed by Analytical Expertise

Analytical method development is a core underpinning of CMC. Our analytical expertise supports the precise determination of critical quality attributes and provides robust data to set critical process parameters, ensuring product safety and efficacy. Our Regulatory Affairs professionals excel at translating this data into concise, compliant submissions for regulatory authorities.

Drug Substance CMC Regulatory Support

FDA, EMA, MHRA, NMPA, PMDA

Development
CQAs, CPP, QTPP

CMC Dossier
Data summaries

Submission
Filing support

Post-approval
Change filings

Grounded in cGMP manufacturing development
and analytical testing

Cross-Functional Operation

Regulatory Affairs, like Quality Systems, must operate across the organization. Our expert Regulatory Affairs team partners with multiple internal functions and with clients to ensure full alignment between operational performance and regulatory compliance.

Relationships Built on Competence

The highly skilled professionals in our Regulatory Affairs team maintain relationships with many regulatory agencies. These relationships are built on a foundation of competence and supported by professional communication, thorough documentation, and expeditious handling of inquiries.

Global Submission Support

Our team has experience with CMC filings with agencies around the world, including:

- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- Medicines and Healthcare products Regulatory Agency (MHRA) of the UK
- National Medical Products Administration (NMPA) of China
- Pharmaceuticals and Medical Devices Agency (PMDA) of Japan

Post-Approval Filings: Support for the Full Lifecycle of Your Product

Regulatory support does not stop with the submission of your NDA or MAA. Our team facilitates the lifecycle management of your drug by guiding filings for post-approval manufacturing changes.

Meeting the Strictest Standards

Our expertise in CMC regulatory affairs also reflects our strict adherence to current Good Manufacturing Practices (cGMP), which is seen in the quality and reliability of our products; how we manage our people, processes, and facilities; and our solid regulatory audit record. Health authorities worldwide, as well as customers, routinely audit our facilities. Rigorous quality system evaluations and our internal quality audit programs also provide consistent monitoring. Our daily focus on process controls and product quality shines through our CMC documentation and filings.

Veranova: Your partner in navigating drug substance CMC filings and regulatory complexities



Get in touch with our experts today to learn more about how we can accelerate your innovation with collaboration.

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