CERTARA

FACT SHEET

Certara Chemistry, Manufacturing, and Controls (CMC) Services and Nonclinical Drug Development Support

Expert Support from Discovery through Post-Market

In today's rapidly evolving pharmaceutical landscape, drug developers encounter several significant challenges in Chemistry, Manufacturing, and Controls (CMC):

- **Accelerated Development Timelines:** The push for faster drug development often places CMC activities on the critical path, necessitating rapid yet thorough process development and regulatory compliance.
- **Regulatory Compliance:** Ensuring adherence to stringent and evolving global regulatory standards is essential to avoid delays or rejections in the approval process.
- **Complex Modalities:** The rise of complex therapeutics, such as cell and gene therapies, introduces intricate CMC challenges, including limited data and understanding of mechanisms of action.
- **Data Integration:** Traditional document-centric approaches can lead to data silos, hindering efficient decision-making and process optimization.

Having a specialized team of CMC experts with knowledge in nonclinical drug safety services is essential.

Comprehensive CMC Services to Support Every Stage of the Drug Development Journey

Certara provides CMC support spanning from early preclinical development through Phase 3, Product Registration, and post-launch activities for both small and large molecules, and diverse routes of administration. The CMC strategy covers quality standards, regulatory meeting preparation and documentation (pre-IND, EOP2, pre-NDA/BLA, Type B/Type C), CDMO recommendation and evaluation, gap assessment, and due diligence of potential opportunities to name a few.

Discovery

- Pre-IND CMC Support
- Salt & Polymorph Selection
- BCS/ Bioenhancement
- Formulation Selection
- In silico/ Model-informed CMC Support
- Phase 1 Specs & Methods
- Early Stability
- Early Clinical Trial Supplies
- Bioanalytical Assay Development

Pre-clinical

- ID key starting materials for API, raw material suppliers
- Tech transfer
- Scale up
- Continue supplies for longer term tox/clinical
- Radiolabel material
- Analytical test method qualification and validation

Clinical

- First commercial image drug product design
- Pivotal trial supplies readiness
- Commercial supply chain
- Process qualification/ validation batches campaign strategy
- Registration stability
- NDA/BLA package prep

Post-market

- Addressing agency questions (Information Request, CRL)
- Bridging/ Biowaiver Strategies
- Support post-approval CMC changes
- Formulation support for product line extension (PLE)

Our tailored CMC services address these challenges:

- **End-to-End Support**: From concept to commercialization, our team provides guidance across the entire drug development lifecycle, ensuring alignment with regulatory standards and best practices.
- **Integrated Expertise:** Our multidisciplinary team collaborates closely with nonclinical and clinical experts to ensure cohesive development strategies and thorough safety evaluations.
- **Regulatory Documentation:** We author and review CMC documentation for regulatory submissions, perform gap analyses, and advise on regulatory strategies to facilitate successful interactions with agencies.
- **Process Optimization:** Our experts develop robust manufacturing processes, implement appropriate control strategies, and ensure batch-to-batch consistency to maintain product quality.

Connect with Our CMC Experts

Partnering with Certara's specialized CMC team can streamline your drug development process, mitigate risks, and accelerate time to market.

Deven Shah, BPharm, PhD
Sr. Director, Integrated Drug Development

Deven Shah is Certara's Chemistry, Manufacturing & Controls (CMC) lead helping clients with their drug development CMC needs. Deven also supports the Certara Global Health practice area spending a significant amount of time attending to the Bill & Melinda Gates Foundation work.

Hien-Anh (HA) Bruno, PhD
Associate Director

Hien-Anh (HA) focuses on technical operations for novel therapeutics discovery and development, with an emphasis on clinical bioanalytical assays and CMC manufacturing processes across all therapeutic modalities (complex biologics, cell and gene therapies as well as small molecules).

Learn more: certara.com/cmc

CERTARA