CONVERGE CONSULTING

where strategy and execution CONVERGE for life sciences

CMC Expertise: Speed to Clinic & Beyond

Development of advanced therapies requires innovative manufacturing and process engineering. CMC (Chemistry, Manufacturing, and Controls) activities expand, evolve, and refocus over time as companies move from toxicology studies through IND-enabling activities, and from preclinical and clinical testing through commercialization. Tasks and objectives change, but the need for speed, precision, and flexible thinking remain consistent.

CMC leaders must define and execute strategies for process, product, and analytical methods, along with formulation, characterization, and stability programs, while often working with lean teams and gated resources. Whether generating submission-enabling data, troubleshooting technical challenges, or grappling with GMP requirements, your effort will be more successful when driven by CMC strategies developed for your business and technology, and supported by extensive knowledge and best practice.

Accelerating Entry to the Clinic

Early in a program, important strategic choices must be made regarding critical parameters, buy or build, and external CMOs, CDMOs and testing lab partners. Many emerging companies struggle with generating and managing the increasing amount and complexity of process, product, and stability data. The work is compounded as the organization also moves to clinical material production while integrating internal and external partners.

A critical element is designing a stage-appropriate quality system (QS) that carries your product into the clinic with the ability to grow longer term. Achieving balance between characterization and appropriate controls at an early stage is essential and lays a foundation for scale-up and cGMP operations.

Converge practitioners can support your team to define critical CMC strategies, lead key IND-enabling initiatives, and execute activities to initiate clinical manufacturing.

Supporting the Commercial Transformation

As products move toward market approval and commercialization, the CMC focus shifts to scaling operations, BLA/NDA submission and PAI readiness.

Developing a commercial process, often via outsourcing, requires process and analytical development plus validation of commercial grade material while continuing to manufacture clinical material. Companies must also design and transition to a commercial QS to support these new operations.

Converge brings deep CMC expertise in driving the buildout of clinical and commercial supply and manufacturing operations. From development of a strategic roadmap through execution of the key activities, we work as part of your team to guide submission-enabling programs, technology transfers and scale-up, PPQ activities and validation at a commercial CDMO or your own commercial facility.

Our team of experts also manage and troubleshoot cGMP manufacturing during Phase 1 and Phase 2, and assist in structuring, managing, and authoring reports of required data, as well as drafting the CMC section for regulatory filings.

Ensuring Robust Execution

Even with commercial products and operations, many life science companies continue running lean CMC organizations with internal teams often only focused on the most urgent priorities.

Converge expertise can extend your in-house resources in support of new initiatives and lifecycle improvements. We also provide experienced practitioners for interim CMC leadership, strategic guidance and due diligence on investments and strategic transactions.

Our Services

We work independently or with client teams to deliver sound strategy, oversight, and execution that meets the challenges of CMC. Areas of expertise include:

- Product, Process & Formulation Development
- Analytical Method Development & Validation
- Characterization & Stability
- Manufacturing Strategy & Partner Selection
- Quality Systems & QbD
- CMC Regulatory Affairs & Compliance
- Clinical Supply Planning & Management
- Investment Due Diligence
- Integrated Manufacturing Execution
- CMC Organization Design, Budgeting & Roadmaps

Converge Consulting *serves the Life Sciences industry with strategy, operations, and execution expertise. We collaborate with biotech, pharmaceutical and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution.* [*www.convergeconsulting.com*](http://www.convergeconsulting.com)

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