Franklin Biolabs

CHEMISTRY, MANUFACTURING & CONTROLS (CMC) CONSULTING

Franklin Biolabs provides end-to-end CMC solutions purpose-built for genetic medicines and biologics projects, giving preclinical teams the manufacturing and analytical foundation they need to reach IND with confidence. We align CMC, analytics, and preclinical development into a single, integrated path that reduces risk, eliminates guesswork, and accelerates timelines. Leveraging deep scientific expertise and insights drawn from thousands of programs, we equip innovators with phase-appropriate processes, robust analytical strategies, and clear development roadmaps, bridging the gap between discovery and IND readiness so complex modalities can advance faster and more predictably.

Our CMC Consulting Services Include:

IND/IMPD Strategy

Build a clear, de risked path to first in human studies with an integrated CMC strategy that aligns development, analytics, and comparability plans, accelerating regulatory acceptance and reducing costly rework.

Manufacturing Process Development

Create scalable, efficient, and compliant manufacturing processes that minimize variability, streamline tech transfer, and ensure your product is ready for every phase of development and commercialization.

CDMO Selection & Oversight

Secure the right partners and maintain strong execution with expert guidance across vendor selection, tech transfer, and day to day oversight, so your program stays on track without operational bottlenecks.

Quality & Supply Chain Strategy

Strengthen compliance and ensure uninterrupted supply with phase appropriate GMP systems, smart outsourcing strategies, and resilient supply chain design, including audits and batch record support.

Analytical & Formulation Development

Achieve consistent product quality and regulatory confidence through robust analytical methods, stability strategies, reference standards, and formulation approaches tailored to your molecule's needs.

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INFO@FRANKLINBIO.COM

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Our CMC Consulting Services Include:

CMC Regulatory Support

Submit with confidence. We craft and review high quality CMC content for IND, CTA, IMPD, NDA, and BLA filings, prepare briefing packages, and guide you through health authority interactions to avoid delays.

IND Readiness Assessments

Identify and close critical gaps early with comprehensive evaluations of manufacturing, analytics, and quality systems, ensuring you're fully prepared for first in human submissions.

Integrated CMC & Nonclinical Roadmaps

Align CMC, toxicology, PK, and efficacy plans into a unified development roadmap that reduces risk, prevents misalignment, and keeps your program moving efficiently toward key milestones.

On Demand Regulatory Writing

Access expert, fast turnaround support for Module 3 and quality documentation, including clear, defensible responses to regulatory questions that keep your submission timelines intact.

Flexible CMC Leadership & Program Support

Add seasoned CMC leadership without increasing headcount. We embed directly into your team to manage CDMOs, drive execution, and provide strategic direction, ideal for organizations without dedicated internal resources to lead the program.

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