

FIRST PRINCIPLES CMC

Strategic CMC and Technical Operations Leadership

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Overview

First Principles CMC provides scientific and operational leadership to emerging biotechnology teams developing complex therapeutic modalities. Grounded in core scientific reasoning and disciplined execution, we design and deliver CMC strategies that are technically rigorous, scalable, and aligned for regulatory and clinical success.

Core Capabilities

- CMC Strategy & Program Leadership — Integrated planning across drug substance, drug product, and analytical/quality systems.
- Manufacturing & Tech Ops Build-Out — CDMO/CRO selection, onboarding, and oversight for early to late-stage programs.
- Control Strategy & QbD Implementation — Risk-based approaches ensuring process robustness and regulatory defensibility.
- IND / IMPD / CTA Preparation — Authoring and review of CMC sections supporting global submissions.
- First-in-Human Execution — Translating research-grade molecules into scalable, GMP-compliant processes.

Approach

Our name reflects our method: start from first principles. Every program is built on a foundation of sound molecular understanding, data-driven design, and long-view scalability. We combine technical depth with pragmatic execution to help teams advance efficiently and confidently toward the clinic.

Representative Experience

- Built and led cross-functional CMC organizations from inception through IND.
 - Delivered accelerated first-in-human programs across antibody-drug conjugate and protein therapeutic platforms.
 - Established integrated control strategies ensuring process robustness and global regulatory readiness.
 - Supported regulatory submissions across multiple geographies and modalities.
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