propharma

CMC Management and Execution

Science-driven CMC solutions to de-risk filings, accelerate approvals, and maintain compliance across pharmaceutical, biologic, and combination product development.

Integrated CMC Expertise

CMC underpins every stage of drug development, ensuring product quality, safety, and consistency.
Companies often face challenges such as evolving global regulations (FDA, EMA, PMDA), data gaps leading to Complete Response Letters, tech transfer and scale-up risks, complex drug-device integration, supplier variability, limited in-house expertise, and virtual biotech operational constraints. Our integrated approach delivers strategy, execution, and coordination to support timely and compliant global submissions.

Our Approach

We bring together Regulatory, Quality, Project Management, Supply Chain, and Digital Transformation expertise to deliver tailored, practical solutions that guide your product from development through successful global submission, including:

- End-to-end CMC planning, project management, tracking and documentation
- Risk-based strategies that address process, formulation, and regulatory challenges
- Seamless coordination of module completion from development to submission
- Streamlined, risk based lifecycle and post-approval management

Key Capabilities

- CDMO and CLO selection and management
- Process, analytical, supply chain and formulation development
- Regulatory CMC strategy, event sequencing, submissions, and health authority interactions
- Quality and compliance (validation, inspection readiness, CSV)
- Tech transfer, scale-up, and 3rd party vendor management
- Emerging areas: AI integration, automation, nitrosamine and impurity risk assessments

Why Partner with Us

- 40+ global CMC experts, averaging 20+ years' experience
- 350+ tech transfers and 150+ unique products supported in last 2 years
- Tailored, right-sized solutions aligned with your product, timelines, and modality
- Parallel MAA/NDA preparation to accelerate approvals
- Deep scientific and regulatory insight driving compliant, confident outcomes

From discovery to commercialization, we provide a science-driven CMC foundation that ensures regulatory confidence, operational efficiency, and successful global product development.

CMC Expertise Throughout the Complete Product Lifecycle

Quality Target Product Profile → **Managing Processes**

Set Regulatory Strategy & Gather Intelligence → Implement Strategy as Defined in Product Development Plan → Prepare Dossier for Submission → Product Approval & Launch → Lifecycle Management

- QTTP Guidance
- Process Development & Validation
- Analytical Method Development & Validation
- Formulation Development
- Leachables & Extractables Study
- Stability
- API Selection & Upstream Process Optimization
- Scientific Advice/Guidance
- Risk Assessments for Potential Impurities
- CMO Selection & Contract Negotiation
- Tech Transfer (incl. Scale Up)
- Line Extensions
- Post-Approval Variations

Regulatory/Health Authority Interactions and Submissions Support

Cross-Functional Capabilities: Financials Mgmt, Project Management, Process Improvement, Data Analysis/Reporting, Digital Transformation, AI

Your Mission is Our Mission: Improving patient health and safety

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

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