# Chemistry, Manufacturing, and Controls (CMC)

## *Comprehensive CMC Regulatory Support*

CMC is a complex and fundamental requirement of all pharmaceutical applications to regulatory authorities. CMC involves the manufacturing processes, controls, characterisation, and testing through each product development phase. These components are crucial in ensuring that quality, safety, consistency and regulatory compliance are maintained, ensuring the product is ready for human use as a marketed product.

## *Why Choose DLRC?*

Our highly qualified CMC consultancy team includes regulatory professionals with a combined expertise of more than 150 years, including pharmacists, chemists, and former agency assessors.

Our team specialise in advising and supporting clients with CMC aspects of product development and lifecycle management, ensuring this strategy integrates with your broader product development strategy and critical path to market.

DLRC provides a highly flexible virtual regulatory department. We ensure every CMC project is supported by extensive skills and experience to efficiently meet all technical needs and problem-solving requirements, however complex.

- A Trusted Regulatory Partner
- Exceptional standards
- Global Regulatory Expertise
- Customised Regulatory Project Management
- Flexible Regulatory Staffing Solutions

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## Comprehensive Support

- CMC Product Development Planning
- Global Regulatory Strategy
- Risk and Technical Assessments
- Technical Authoring
- Gap Analysis and Submission-readiness
- Post-approval change management

## Extensive Product Experience

- All conventional delivery systems
- Small molecules, biologics and ATMPs
- Sterile Products
- Inhalers
- ENDS (Electronic Nicotine Delivery Systems)
- Radiopharmaceuticals
- Antibody drug conjugates (ADC)
- Repurposed products

## Development

- Strategic consulting for product development including starting material definition, nitrosamine risk assessment, process development and validation, specification setting and stability program requirements
- CMC Development Plans
- Global Regulatory Strategy
- Due Diligence, Risk Analysis and Gap Analysis
- Technical Authoring & Review

## Filing & Agency Interaction

- MAA - Module 2 QOS (inc. Quality Expert sign-off)
- MAA - Module 3 Quality
- ASMF/CEP/DMF authoring
- BLA/NDA/ANDA - Module 2 & Module 3 Quality
- Response to Agency questions including complex RTQ authoring

## Post-approval

- Post Approval Variations - Type IA, Type IB, Type II
- Post-approval change management protocols
- Site transfer, analytical and supply chain variations
- Line extensions

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