SCIENTIFIC & STRATEGIC DEVELOPMENT

CMC REGULATORY & STRATEGY | NONCLINICAL REGULATORY & STRATEGY | CLINICAL REGULATORY & STRATEGY | CLINICAL PHARMACOLOGY | MEDICAL DEVICES & DIAGNOSTICS | COMBINATION PRODUCTS

REGULATORY & COMPETITIVE INTELLIGENCE

CHEMISTRY, MANUFACTURING AND CONTROLS (CMC) REGULATORY & STRATEGY

EXPERTISE AND AGILITY TO ACCELERATE DEVELOPMENT

- Regulatory assessment and gap analysis of CMC programs
- CMC regulatory strategic development
- Global support of CMC submissions from early phase development to commercialization
- Preparation and review of:
  - Briefing Documents
  - Investigational New Drug applications (IND – Module 3/2.3)
  - Investigational Medicinal Product Dossiers (IMPD)
  - New Drug Applications (NDA) and Biologics License Applications (BLA)
  - Marketing Authorization Applications (MAA)
- Experience with multiple products (chemicals, biologicals, ATMPs, conjugated products)
- Experience with all dosage forms and routes of administration
- Support for Regulatory Agency meetings

INTERESTED? EMAIL US AT INFO@MEDPACE.COM

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