

SCIENTIFIC & STRATEGIC DEVELOPMENT SERVICES

CMC REGULATORY & STRATEGY

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- Global CMC regulatory development support
- CMC program assessment and gap analysis
- Preparation and review of CMC documentation – IND Module 3, QOS, IMPDs, Briefing Packages, IBs, DDCMs
- Experience with therapeutic modalities, dosage forms, and routes

NONCLINICAL REGULATORY & STRATEGY

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- Scientific guidance and consultancy for nonclinical regulatory strategies, documents, and queries from early development to market
- Nonclinical study planning and facilitation to support clinical development
- Strategic application of nonclinical data for dose support, clinical monitoring strategies, and regulatory waivers

CLINICAL REGULATORY & STRATEGY

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- Guidance on global or country-specific regulatory strategies and clinical development plans
- Evaluation of clinical trial designs and selected endpoints for regulatory acceptance and approval
- Mechanisms of acceleration for regulatory pathways & benefit/risk assessments

CLINICAL PHARMACOLOGY

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- Evaluation of clinical trial designs, including early phase, drug-drug interactions, and special population studies
- Strategic assessment and gap analysis of ADME programs
- Guidance and support for accelerating clinical development with modeling and simulation

MEDICAL DEVICES & DIAGNOSTICS

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- Guidance and support with regulatory strategies and pathways to help bring medical devices and diagnostics to market safely, effectively, and efficiently
- Regulatory support for the design and conduct of clinical investigations for medical devices and clinical performance studies for in-vitro diagnostic products to ensure compliance with existing and new regulations and standards

COMBINATION PRODUCTS

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- Global regulatory and development strategy to facilitate path to market of combination products with drugs, biologics, devices, and in-vitro diagnostics including Companion Diagnostics
- Scientific and strategic support for regulatory document development and interactions with Regulatory Authorities

REGULATORY AND COMPETITIVE INTELLIGENCE

Our expertise is rooted in our strong regulatory and competitive intelligence capabilities to strategically leverage contemporary information to address your most complex regulatory and development challenges by delivering robust, state-of-the-art solutions as the foundational pillars of our business operations.

INTERESTED? EMAIL US AT INFO@MEDPACE.COM

MEDPACE

SCIENTIFIC & STRATEGIC DEVELOPMENT

ACCELERATING THERAPEUTIC DEVELOPMENT FROM EARLY
DISCOVERY TO CLINICAL PROOF OF CONCEPT

