SCIENTIFIC & STRATEGIC DEVELOPMENT

CMC REGULATORY & STRATEGY

NONCLINICAL REGULATORY & STRATEGY

CLINICAL REGULATORY & STRATEGY

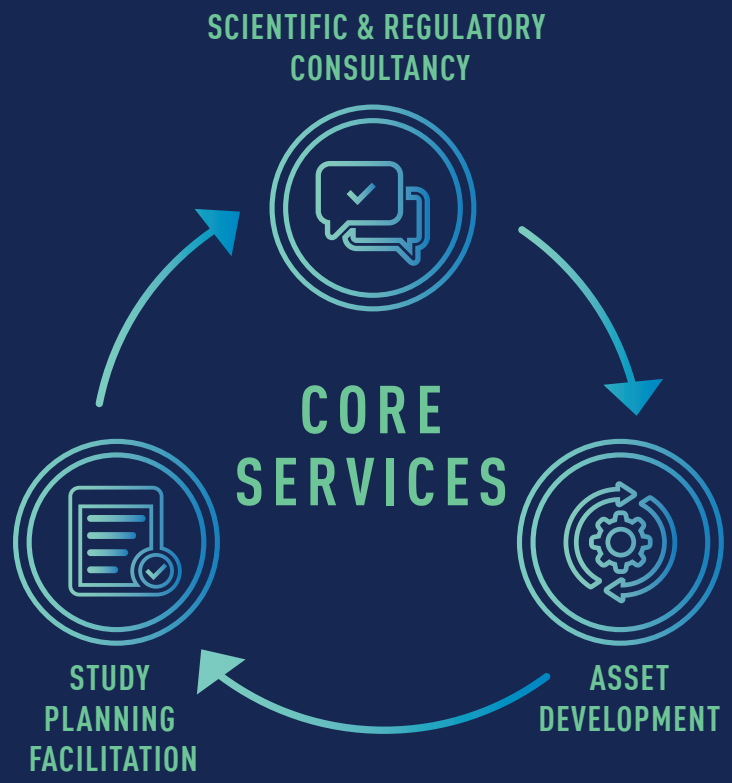
CLINICAL PHARMACOLOGY

MEDICAL DEVICES & DIAGNOSTICS

COMBINATION PRODUCTS

REGULATORY & COMPETITIVE INTELLIGENCE

NONCLINICAL REGULATORY & STRATEGY



EXPERTISE AND AGILITY TO ACCELERATE DEVELOPMENT

- Scientific guidance, data interpretation, and strategic support for regulatory documents and queries
- Nonclinical program planning to support efficient clinical development from early safety evaluations to regulatory filings
- Identification of target organs and support for clinical safety monitoring strategies
- Determination of maximum recommended clinical starting doses using multiple approaches (NOAEL, MABEL, HNSTD)
- Strategic utilization of nonclinical data to justify product impurities and CMC changes
- Immunogenicity planning, anti-drug antibody (ADA) sampling, and mitigation strategies
- Nonclinical study facilitation — nonclinical CRO interactions; review and input on proposals, protocols, and study designs; data interpretation; impact assessment
- Due diligence support for in-licensing opportunities
- Considerable experience in all therapeutic areas with all therapeutic modalities (small molecules, biologics, ATMPs) at all phases of development

INTERESTED? EMAIL US AT INFO@MEDPACE.COM

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