MEDPACE

GLOBAL REGULATORY AFFAIRS SERVICES

ACCELERATE APPROVALS WITH A STRATEGIC PARTNER THROUGHOUT DEVELOPMENT

The Medpace Global Regulatory Affairs team has extensive experience covering pre-marketing and post-marketing regulatory strategies for a wide range of medical therapeutics, including drugs, biologics and medical devices worldwide.

REGULATORY AFFAIRS EXPERIENCE

- Non-Clinical
- CMC
- Clinical
- Pediatric
- Orphan Medicines
- Combination Products
- Advanced Therapy Medicinal Products (ATMPs)
- Genetically Modified Organisms (GMOs)

GLOBAL REGULATORY SERVICES

Medical Writing

- Investigational and marketing applications
- Summary document preparation
- Protocols
- Clinical Study Reports (CSRs)
- Investigational Medicinal Product
- Dossier (IMPDs)

Document Preparation & Submission

- Overview and summary document preparation
- e-CTD preparation, compilation and e-publishing
- Electronic Submission to Regulatory Authorities
- Submission maintenance and regulatory compliance

Strategic Development

- Gap Analysis and Target Product Profile development
- Clinical Synopsis development
- Evaluation of clinical trial design and endpoints
- Fast Track and PRIME
- Breakthrough, RMAT and QIDP
- Orphan Drug Applications
- Pediatric Plans
- Accelerated and conditional approvals
- Clincal Development Plans

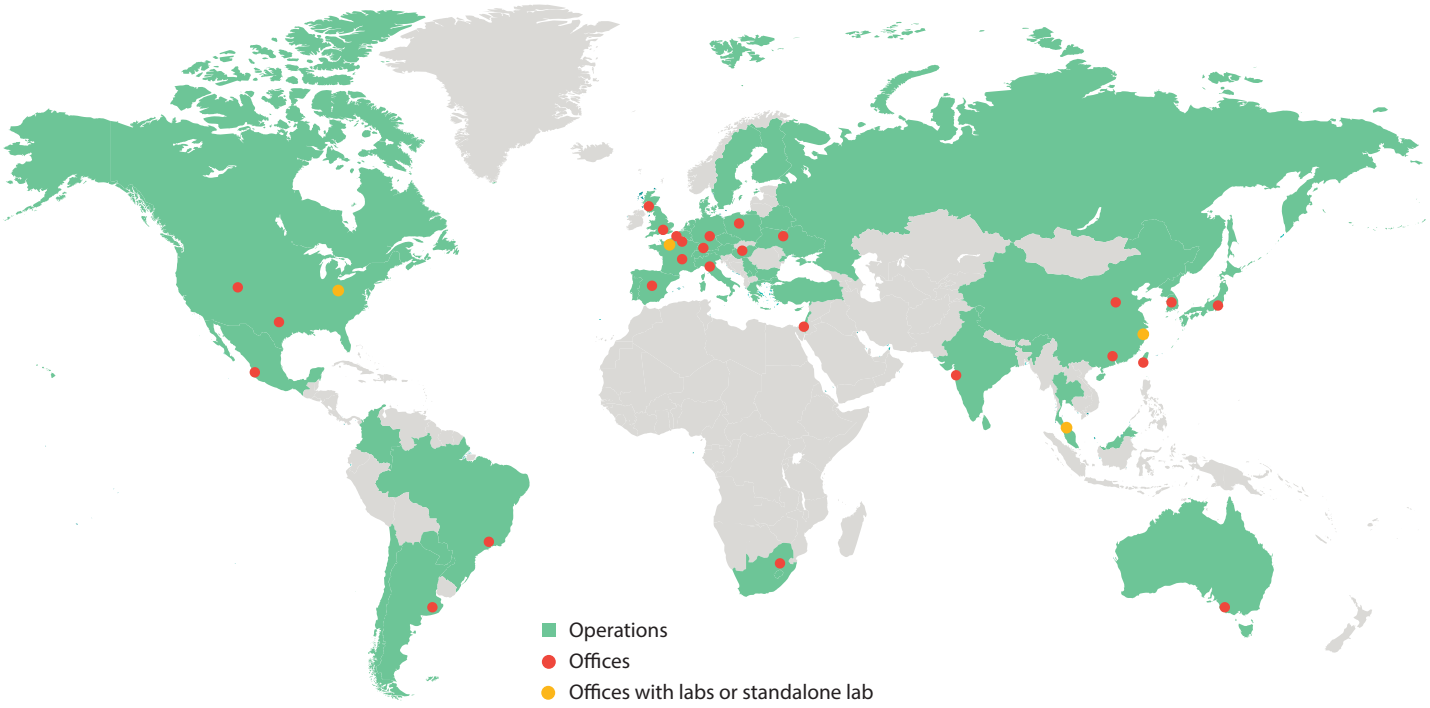
Regulatory Agency Interactions

- Strategy and planning
- Meeting requests and briefing documents
- Meeting rehearsals and facilitation
- Meeting minutes and follow-ups

MEDPACE

GLOBAL REACH IN STRATEGIC GEOGRAPHIES

MEDPACE IS OPERATIONAL WORLDWIDE, WITH 4,800 EMPLOYEES IN 41 COUNTRIES AND SUBMISSIONS IN OVER 60 COUNTRIES



NORTH AMERICA

- 3 offices/labs
- Headquarters in North America

LATIN AMERICA

- 3 offices
- Operations in 4 countries

EMEA

- 15 offices/labs
- Operations in 24 countries

ASIA/PACIFIC

- 9 offices/labs
- Operations in 11 countries

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

CRO-0024-R0922

MAKING THE COMPLEX SEAMLESS™