



### Regulatory Affairs in Europe

In Europe, a team of senior professionals with international experience and reputation, based in Zürich and focused on regulatory, medical, and statistical expertise, offers the following regulatory services.

### Assistance through development

Top therapeutic and regulatory experts deliver innovative and customized solutions:

- Provide regulatory advice and support at all stages of the drug development and authorisation process
- Prepare product labelling and advise on packaging
- Prepare and manage European Paediatric Investigational Plans (PIP)
- Liaise with the regulatory authorities and prepare for and conduct meetings
- Test readability of patient information leaflets
- Represent companies with no legal presence
- Assist with due-diligence

### Marketing applications (MAA, NDA)

More than 22 applications completed:

- Advise on regulatory strategies for FDA, EMEA, and other agencies
- Liaise with regulatory authorities / expert committees
- Manage pre-submission meetings / related activities
- Write and prepare (e)CTDs
- Prepare, submit, and manage marketing authorisation applications - through to approval
- Support life-cycle strategies

### Clinical trial initiation

A dedicated global team of over 55 professionals with local expertise:

- Prepare and collect documentation (IND, IMPD, IB)
- Manage submission to Competent Authority (CA) and IRB/EC, including questions, amendments, notifications, and closeouts
- Procure import/export licenses and country and global insurance
- Design investigational product labelling
- Translate trial materials
- Negotiate clinical trial agreements with sites

### Contact

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### The Medpace difference

Medpace is a global, research-based drug development company led by top therapeutic and regulatory experts who are driven to further the advancement of pharmaceutical agents for use in multiple therapeutic areas including cardiology, metabolism, and oncology. Medpace has assembled the industry's most experienced and therapeutically-focused team to execute at all levels of our operations, providing complete and seamless drug development services.

Through specialized regulatory expertise and therapeutically-focused clinical operations, Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development – from program planning and execution to product approval. With clinical trial experience in over 40 countries, Medpace has the global reach and capability to successfully conduct studies and navigate regulatory requirements worldwide.

### Medpace family of businesses

**Medpace**

**Imagepace**

**Medpace Bioanalytical Laboratories**

**Medpace Clinical Pharmacology**

**Medpace Reference Laboratories**