INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

# SUPPORT REGULATORY AFFAIRS INTERNATIONAL

**All markets still have their specific requirements for the registration of a medical device. Our experience in Europe, North and South America, Asia as well as the Middle East enables us to give you full support in an efficient achievement of the targeted market approval.**

## Your Advantage

**R&D, Project Leaders**
Within your development project you will be assisted in the compilation of all necessary registration documents for the markets in focus. That allows you to fully concentrate on your core tasks. The early integration of regulatory affairs reduces your overall efforts for a submission on schedule.

**Quality Management**
We take over the registration in the markets aimed by the customer. The planning reliability will be increased in markets so far unknown to you as we are familiar with the market specific procedures and delays. The transfer of knowledge is part of our service: All summaries and dossiers compiled by us will be at your disposal, which will allow you to base your next project on our documentation.

**Management, Marketing & Sales**
You are fully involved in the in-depth clarification of the assignment including the clarification of the responsibility. That will give you precise contacts and maximum planning reliability of your registration strategy.

## Our Services

**General**
You decide on the volume of our services. The possibilities range from single consulting through to the takeover of the responsibility for the first filing and the preservation of the acquired licence of your products in the developed markets.

**Outsourcing of RA**
We handle all regulatories for several companies from different areas of expertise. This also gives access to a professional and efficient handling of regulatory affairs to small and medium-sized companies.

**USA**
Preparation and submission of dossiers, essential listings, negotiation with the local agent, after submission prompt reply to inquiries from the FDA.

**Asia**
Support in developing a submission strategy, compilation of the dossiers (STED and CSDT format if possible or requested, required additional documents), assistance with the negotiations and communication with your local partner. We have a native Chinese speaker in our team.

**Latin America**
The CE marking itself does not give market access. We will assist you in providing the additionally required documents.

**Your contact**

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