Daedalus online database provides regulatory intelligence for the medical device market

An online database called 'Daedalus', developed by German company RegIntA, is shining a light in the darkness of internationally varying legal regulations for medical devices and pharmaceuticals. Medical technology and pharmaceuticals are one of the most heavily regulated sectors in industry. Country-specific regulations and laws that cover the entire life cycle of a product, from its development to market approval, change notifications and re-registrations, as well as market surveillance, are increasingly complicating business for manufacturers who want to sell abroad. Daedalus provides a solution for this.

Katrin Rosen, founder and managing director of RegIntA, commented: "Country specific regulations are always a challenge for international expansion. Regulations and requirements are constantly changing, becoming more stringent and opaquer. For many companies, the need to check the requirements on an ongoing basis is becoming increasingly time-consuming and costly, as well as a real business risk. With our Daedalus database, we offer a 24/7 up-to-date country- specific insight that helps companies meet the legal requirements in their respective markets, all based on a simple booking and billing model."

Continually updated data

The online platform bundles the concentrated know-how of international legal regulations and relieves companies' regulatory affairs departments from having to do time-consuming and cost-intensive research of the their own. To this end, an international team of native speakers – from Chinese to Arabic – evaluates the latest legal requirements from a wide range of sources around the clock. All sources undergo a separate impact assessment in the specially designed document management system. As a result, the customer receives bundled and clearly arranged information on all aspects of the life cycle of the medical device, such as product registration or safety notifications.

Rosen added: "With our information, the customer gets everything they need to bring their product to market without delay and in compliance with the national regulations. Daedalus saves human resources and minimizes the risk of making mistakes during the critical registration phase."

She said this was also useful if, for example, changes are made to the product down the line and it again becomes necessary to comply with the requirements of the respective authority.

Regulatory information

RegIntA generated its Quality Management System and the related processes based on ISO 9001:2015. The most stringent quality checks are performed at every stage of development of the regulatory information, before the new version is uploaded for the customer.

The regulatory information is offered in different packages. Depending on the package, this includes among others the legal framework, definitions, documents to be submitted for registration, special requirements for tests or clinical studies, language requirements or submission types, change notifications, re-registrations and labelling. In addition, the manufacturer can download original documents such as registration forms or guidance documents.

The listed countries can be selected separately and, if not yet included in Daedalus, will also be prepared at the customer's request. Changes in regulatory information are marked for the customer within the online database and documented in the history section. In addition, the customer receives an e-mail notification of any changes. In this way, the customer remains continuously up to date.

Katrin Rosen, founder and managing director of RegIntA

Individual consulting

RegIntA also offers its expertise as part of individual consulting related to country-specific regulatory affairs questions for medical devices as well as for medicinal products.

Rosen explained: "In addition to Daedalus, we make our expertise available offline and take manufacturers by the hand with customized consulting services – regardless of whether this involves support with national approval processes, analysis of individual regulatory hurdles during market entry, support for pharmacovigilance and vigilance processes, and the Quality Management System."

The extended range of services can be used either on its own or as an additional service to Daedalus.

- For more information, visit *www.reginta.de*. MEH