REGULATORY AFFAIRS

SET SAIL SUCCESSFULLY AND STAY ON COURSE GLOBALLY.

Master regulatory affairs requirements efficiently and to deadlines by outsourcing them to the orangeglobal group.

medical globalisation
orangeglobal group


210
240
270
180

WITH A STEADY HAND AT THE HELM
YOU CAN SUCCESSFULLY STEER CLEAR OF EVEN THE MOST PERILOUS ROCKS.

Would you like to outsource all or part of your regulatory processes?
The orangeglobal group will be delighted to take care of everything across the whole product life cycle.

The challenge

Regulatory submission and approval management is a complex field and is particularly inhomogeneous outside the EU. Regulatory requirements are also subject to constant change and are becoming increasingly extensive throughout the world. Few companies manage to keep their bearings in the choppy waters of laws, regulations and directives without assistance. At the same time, developing an optimal regulatory strategy is also becoming increasingly important. The reason for this is globalisation and the imperative it brings with it to position new products on the global market as quickly as possible.

The solution

Secure a quantifiable competitive advantage for yourself now!
With a wealth of experience and experts on all continents, the orangeglobal group is your ideal partner for all your outsourcing needs.
We will be delighted to take care of all your duties in the field of regulatory affairs and can assist you with our hands-on expertise or offer our specialist knowledge – including in a consultancy capacity. Whichever service you choose, you are provided with all the information you require at a glance, saving you a great deal of tedious research and often laborious communication with authorities. You will discover exactly what needs to be done and save money at the same time.

Launching a product and keeping it on the market involves a whole range of complex regulatory duties as well as intensive project management. The orangeglobal group handles the entire process efficiently and thoroughly to guarantee maximum conformity and to allow you to free up your internal capacities effectively.

WE SEE TO IT THAT YOU ALWAYS KEEP A STEADY COURSE DURING YOUR SUBMISSION AND APPROVAL PROCESSES.

orangeglobal is your specialist for international marketing authorisation of medicinal products.

We enable you to effectively outsource all of the regulatory processes involved in marketing authorisations – either completely or partially. This includes consultancy services and strategy planning for all types of regulatory submissions and approvals, the compilation of all the necessary documentation right up to complete application dossiers, the processing of authorities' requirements during and following the regulatory submission procedure and the maintenance of marketing authorisations. Professional communication with authorities in their national language goes without saying.

The orangeglobal group helps you before, during and after the marketing authorisation of your medicinal products.

1. Management of marketing authorisation applications
Consultancy services and strategy planning for all types of regulatory submission and approval procedures as well as applications all over the world. Scientific advice, regulatory intelligence, regulatory information management, regulatory due diligence, in-licensing and transfer of the marketing authorisation, reimbursement, ISO IDMP, etc.

2. Regulatory documentation management
Compilation and revision of all necessary documentation (modules 1 to 5, especially SmPCs, PLs, ERAs, PIPs, summaries/overviews, EDMFs, study reports), review of documents (4-eyes checks), readability compliance, technical translations, etc.

3. Regulatory submission management
Execution of national, MR/DC and centralised procedures for medicinal products, support in the preparation of applications for marketing authorisation, conformity checks with regulation, compilation of complete medicinal product dossiers (CTD/eCTD), preparation and submission of the dossiers to the responsible authorities, communication with authorities, responding to questions from authorities, etc.

4. Regulatory maintenance
Revision and maintenance of dossiers and updates of regulatory documentation, variation management, line extensions, renewals, sunset clause strategies, deregistration, etc.

WE HELP YOU MEET YOUR CHALLENGES.

ALL OF THEM. ON OUR OWN. END OF CHALLENGE.

The orangeglobal group is a certified partner for all internationalisation processes. Our expertise covers the **entire value chain** and nearly **every country** – including their linguistic, cultural and regulatory peculiarities:

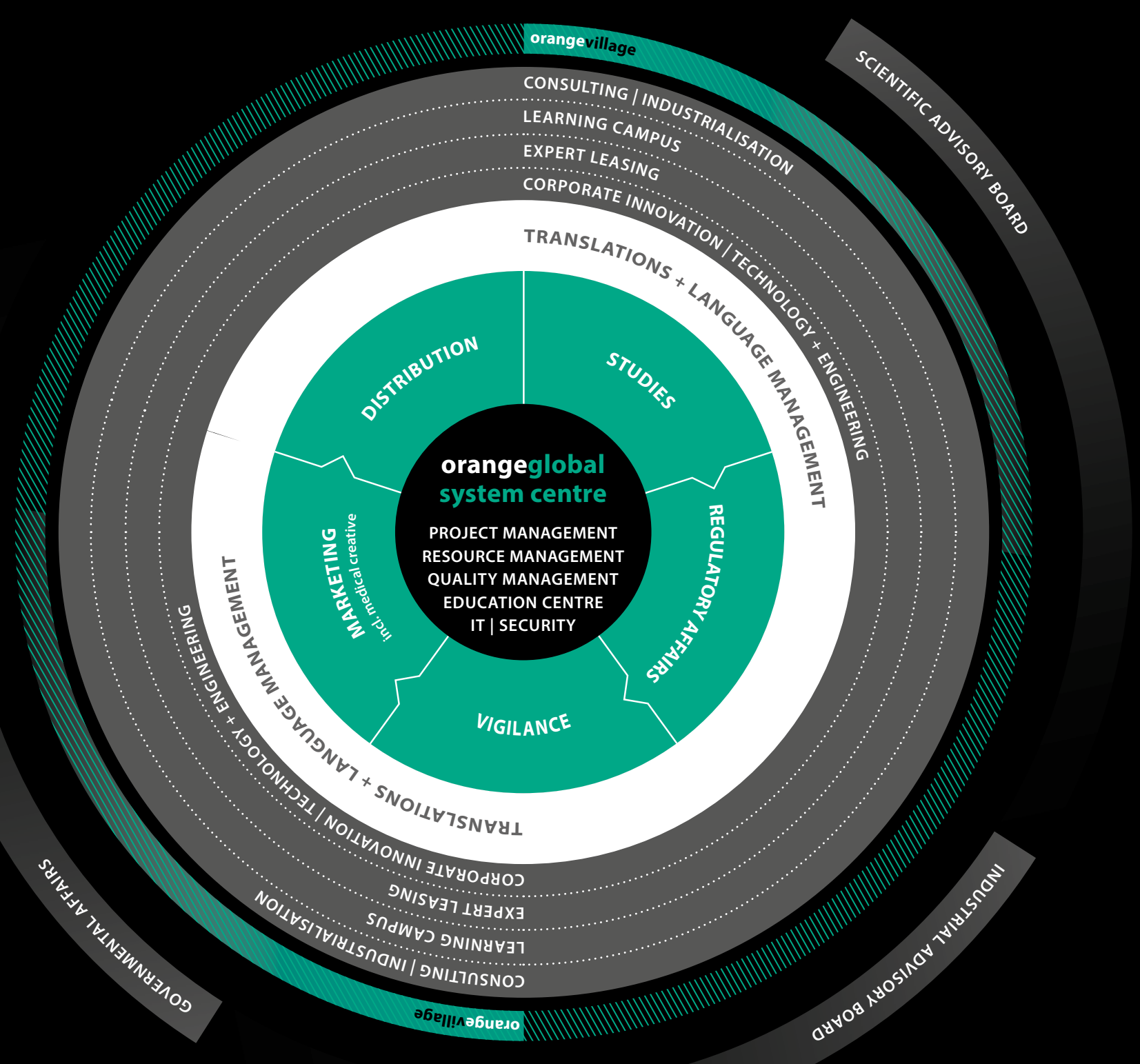
- **Studies:** planning, coordination, implementation, QA, evaluation – at a global level and in compliance with ICH-GCP
- **Regulatory Affairs:** consultation, documentation, submission and maintenance – worldwide competency
- **Vigilance**: drug safety and risk management – reliably and in conformity with the law
- **Marketing**: market research, design, creation, brand management – 360° on- and off-line communication
- **Distribution**: identification of suitable sales and distribution partners – specifically for each target market
- **Translation and Language Management**: professional translation processes specifically tailored to industry requirements delivered on time and of outstanding quality.

What makes us so sure that we can help you?
The fact that we have built up a pool of **more than 3,000 highly-qualified healthcare experts** over the past 40 years. Worldwide. And because we know inside out the special requirements and processes that dominate the healthcare industry.

YOUR ADVANTAGES

- Shorter time-to-market
- Cost minimisation
- Quality enhancement
- Greater security

Try us: +49 (0) 731 954 95 - 0



More than 800 active customers across the globe greatly value our **five centres of competence** and our comprehensive service portfolio.

orangeglobal is your specialist for international medical device and IVD registration.

In addition to the support it provides for the pharmaceutical industry, orangeglobal also offers the corresponding services for medical devices and IVDs. We can assist you with your questions you have concerning the classification of your medical device, we can compile all the necessary documentation and accompany you throughout the entire conformity evaluation procedure including CE certification and the worldwide registration of your devices. It goes without saying that support with the lifecycle management of your medical device and IVD is also included in our range of services.

orangeglobal helps you before, during and after the registration of your medical devices and IVDs.

1. Management of registration and approval
Regulatory development support and consulting, classification of your medical device and support with demarcation queries concerning combination products, defining requirements in terms of registrations and approvals for new markets, development of customised regulatory strategies around the world, etc.

2. Regulatory documentation
Compilation and revision of all regulatory documentation, risk management dossiers in accordance with ISO 14971, clinical assessments in accordance with MEDDEV 2.7.1., usability dossiers in accordance with EN 62366 (including usability testing). Instructions for use, either as printed or electronic media in accordance with Commission Regulation (EU) No. 207/2012, labelling, G-BA applications and list of approved assistive technology products approved by the German health insurance companies, process documentation (SOPs), regulatory and expert reports, technical translations, etc.

3. Registration and approval procedure
Compilation of technical documentation or summary technical documentation, verification of compliance with the “essential requirements” and regulatory requirements around the world, support, assistance and monitoring of conformity evaluation and registration and approval procedures, communication with authorities and “notified bodies”, premarket notification 510(k).

4. Regulatory maintenance
Revision and maintenance of your technical documentation, review of international regulatory requirements.

We see ourselves as your partner for the rapid and flexible execution of demanding tasks, which we accomplish with the help of our international network of experts.

You will benefit from considerable time and cost savings by optimising the fundamental processes in the field of submissions and approvals.

ARE YOU READY TO SET SAIL WITH US?

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