
VIGILANCE
STAY SAFELY ON COURSE.
Master vigilance requirements efficiently and to deadlines
by outsourcing them to the orangeglobal group.
medical globalisation
orangeglobal
group


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STEER THROUGH ALL WATERS
QUICKLY AND SURELY

Would you like to outsource your vigilance processes? If you wish to outsource all or some of your regulatory activities, the orangeglobal group can take care of everything across the whole product life cycle.

The challenge

Tasks in pharmacovigilance for medicinal products and in risk management for medical devices are becoming ever more complex and are subject to constant change. Due to the increasing volume of work, many companies are starting to realise that the demands of authorities are beyond their capacity and are looking for suitable solutions.

In orangeglobal you have a strong, experienced partner at your side, whom you can trust to handle even the most urgent of processes efficiently – even in choppy waters.

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 vigilance and can assist you with our hands-on expertise or apply our specialist knowledge – including in a consultancy capacity. You can find out more about the range of services we offer on the following pages.

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.

WHEN IT COMES TO VIGILANCE AND RISK MANAGEMENT, PRECISION IS PARAMOUNT.

orangeglobal can assist you with any questions you have concerning the pharmacovigilance of your medicinal product:

orangeglobal is your specialist when it comes to monitoring the safety of globally authorised medicinal products and is skilled in offering you comprehensive support to ensure you comply with your regulatory obligations in pharmacovigilance.

orangeglobal is your competent contact for establishing pharmacovigilance systems and compiling risk management plans. If required, orangeglobal can take on your entire drug safety process.

1. Pharmacovigilance system management

Implementation and maintenance of a pharmacovigilance system, compilation and revision of SOPs, creation of PSMFs, QPPV services.

2. Safety monitoring and reporting

Literature searches, monitoring of authority websites, signal management, creation of PSURs, ICSR reporting, XEVMPD management, IDMP compliance.

3. Risk management and effectiveness measurement

Implementation and maintenance of a risk management system, post authorisation safety studies.

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:

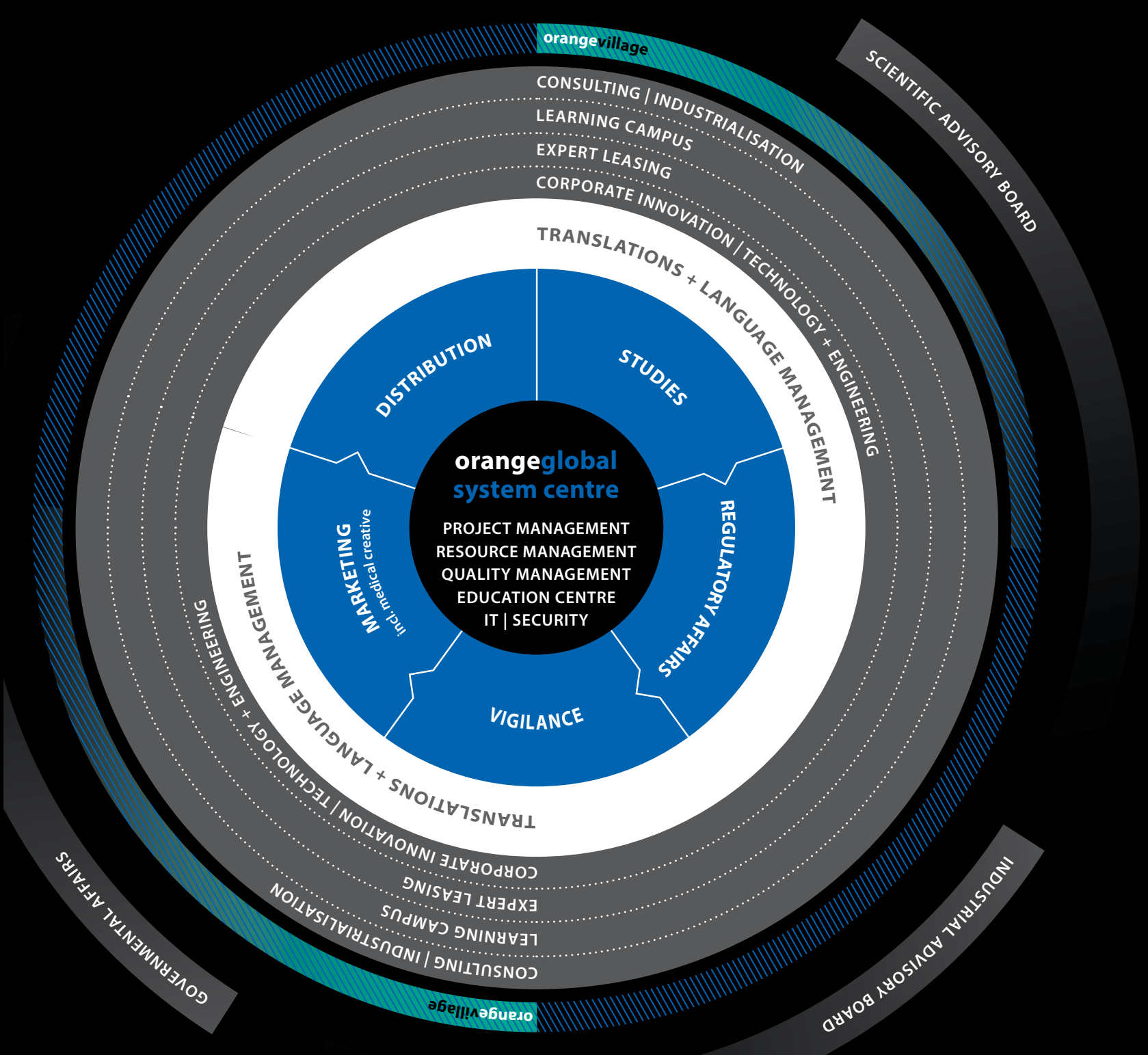
- **Studies:** planning, coordination, implementation, QA, evaluation – at a global level and in compliance with ICH-GCP
- **Regulatory Affairs:** consultation, documentation, submission and maintenance – worldwide competency
- **Vigilance**: drug safety and risk management – reliably and in conformity with the law
- **Marketing**: market research, design, creation, brand management – 360° on- and off-line communication
- **Distribution**: identification of suitable sales and distribution partners – with precision and specifically for each target market
- **Translation and Language Management**: professional translation processes specifically tailored to industry requirements and 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 can assist you with any questions you have concerning the vigilance of your medical devices and IVDs:

To meet the constantly evolving requirements for market surveillance of medical devices and IVDs, we also offer comprehensive services for ensuring vigilance compliance in this field. We assist you with your risk management throughout the lifecycles of your medical devices and IVDs in accordance with ISO 14971 up to and including adoption of the safety officer's responsibility.

1. Vigilance management

Implementation and maintenance of a vigilance system for medical devices and IVDs, provision of safety officer in accordance with the Medical Device Directive (MDD), coordination and ensuring that incidents are reported to the responsible authorities within the required timelines.

2. Post marketing surveillance

Active market monitoring following product launches, complaint handling, reports to authorities, regular systematic literature reviews, post market clinical follow-up, support in the continuous monitoring and evaluation of the benefit/risk ratio.

3. Risk management

Development of a risk management system, medical technical support with risk evaluation, presentation of the risk analysis and risk evaluation, implementation of corrective or preventive measures, monitoring of the implementation and efficiency of safety measures, risk research database, compliance with legal risk evaluation requirements, internal audit service for monitoring efficacy (risk management).

With our strong pool of experts in the pharmaceutical and medical device industries, we are outstandingly equipped and happy to help you with these diverse challenges all over the world.

orangeglobal provides you with comprehensive and competent support when monitoring safety and when implementing and maintaining your risk management systems to ensure that your medicinal products and medical devices also comply with legal requirements.

ARE YOU READY TO SET SAIL WITH US?

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