



**gaining your approval**

**REGULIS Consulting Ltd**  
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REGULIS is a small, independent, specialist consultancy company dedicated to providing you with flexible, tailored regulatory services and solutions. REGULIS offers you comprehensive pan-European regulatory affairs expertise covering:

- Regulatory Submissions and Support
- Strategic Consultancy
- Crisis Management
- Organisational Development
- Training

We also offer outstanding and unrivalled customer service to you through our commitment.

## **Regulatory Submissions and Support**

Our “hands on“ experience allows us to provide you with professional expertise across the full range of regulatory activities, covering pharmaceutical, biological, generic and OTC medicines, borderline products and devices including:

- Applications for new drugs and line extensions (centralised, mutual recognition, decentralised and national)
- CTD preparation of modules, overviews and summaries
- Dossier compilation
- Clinical trial applications
- Licence renewals and variations
- Summary of Product Characteristics, Patient Information Leaflet, labelling and prescribing information preparation and review
- Patient Information Leaflet User (Readability) Testing
- Free sales certificate applications
- Parallel import applications
- Legal status switches
- Drug Master File preparation
- Management of merger-driven licence changes
- Promotional material review and approval
- Pharmacovigilance and adverse event reporting

## **Strategic Consultancy**

We provide key strategic regulatory advice and thinking across a wide range of activities that ensure clients meet their business targets and objectives. These include:

- Advice on development plans
- Regulatory filing strategy
- Regulatory agency meetings
- Requests for scientific advice
- Negotiations with regulatory agencies
- Appeals and hearings
- Due diligence for in- and out-licensing
- Managing and improving your relationships with regulatory agencies

## **Crisis Management**

REGULIS are able to provide you with advice and experienced resource to manage the unpredictable events and urgent actions that you are often faced with in regulatory affairs. For example:

- Interim management
- Maternity cover
- An urgent demand from a regulatory agency
- A product withdrawal or recall
- An urgent safety change
- A Dear Doctor letter or national country equivalent
- Compulsory labelling changes
- Resolving product supply difficulties

## **Organisational Development**

REGULIS specialises in the provision of skilled consultants with first-hand knowledge and expertise on improving the efficiency and effectiveness of regulatory departments. We can help you establish a new European or national regulatory group, ensuring that it meets the needs of the business, as well as all legal obligations. In existing regulatory departments, processes and systems can be appraised, difficulties diagnosed and solutions generated to help you deliver improved performance. We cover:

- Key process design
- Problem diagnosis
- Process mapping and re-engineering
- Solutions generation
- Implementation assistance
- Regulatory database design
- Performance measurement
- Generation of Standard Operating Procedures, audit and staff training

## Training

As today's regulatory requirements become increasingly challenging and the skills required to meet them become more diverse, REGULIS has made it its business to provide you with tailored training on UK and European regulatory affairs. Courses and workshops are designed to offer a fresh approach to regulatory training. There is a high degree of interaction and problem solving, together with a commitment from us to make the courses enjoyable to attend and experience. Examples of the types of training courses currently offered are:

- An introduction to global Regulatory Affairs
- An Introduction to European Regulatory Affairs
- An Introduction to UK Regulatory Affairs
- An Introduction to Regulatory Affairs for secretaries and administrative staff
- Clinical Trial Applications
- A Guide to the MHRA
- How to prepare for a successful appeal
- Variations and notifications
- Negotiating for success
- The Common Technical Dossier

Courses are tailored to meet your individual requirements and can be conducted *in-house*. REGULIS will also develop specific training to meet your particular requirements.



## **Our Commitment to You**

Outstanding customer service is important to you and to us and REGULIS is committed to understanding and meeting your needs. Fine words you'll say, but what can I expect in terms of action.

As speed of response is important to you, we will normally tell you whether we can help you within the 48 hours of receiving your request.

Once you have identified a need for our services, we will speak further with you to understand exactly what you require, what your critical success factors are and to agree objectives for your project.

At regular intervals we will discuss with you how the project or contract is progressing to ensure that we are meeting all your needs. We will listen to your feedback and it will be acted upon swiftly and appropriately.

Soon after the project has been completed we will provide you with an opportunity to give us feedback and comments on how we did and to make suggestions on how our service could be improved for the next time.



## Why use Regulis?

### **Advantages**

- We specifically focus on regulatory affairs
- We enjoy excellent relationships with the relevant regulatory authorities
- We have a small number of consultants who have a wealth of “hands-on” experience, practical knowledge and a proven track record
- We have a network of local consultants located in most EU countries to manage local issues
- We have an Expert Advisory Panel of senior industry personnel covering medical, toxicological, commercial areas, business strategy and health economics
- We have experience of a wide range of therapeutic areas for prescription, generic and “over the counter” medicines
- Feedback from our clients demonstrates that we bring a commercial focus to our thinking and our work

### **Benefits**

- Our consultants work flexibly, either off-site or at your offices to integrate into your team or company
- Through our unique “commitment to you” we ensure that we provide exactly what you require, not what we think you require
- You choose from a comprehensive menu to tailor our services to meet your individual requirements
- We handle projects and contracts of any size and duration
- We provide you with cost-effective solutions, our fees being commensurate with the work undertaken and the experience of the consultant provided

## What our clients say

After securing clinical trial approvals in a number of European countries:

*“Thank you for your perseverance. This is greatly appreciated, as is your resilient good nature as we overcame the challenges. This is a first for us. Many thanks.”*

Following assistance and guidance on a CSM appeal that led to an unconditional approval in the UK for a previously rejected licence application:

*“Please accept my personal thanks for your support over the many months of this appeal and especially over this closing phase.”*

*“Many thanks for your significant help with a most important outcome.”*

Review of a potential centralised submission for a herbal product:

*“Thank you for all your hard and rapid work.”*

Following completion of a successful interim management contract:

*“The experience of the consultant was invaluable as a ‘sounding board’.”*

*“The flexibility and ‘contactability’ of the consultant was really appreciated and different to many other consultants.”*

Following the delivery of a specially designed training course on product lifecycle management:

*“The trainer was easy to listen to, not patronising, on a level with the trainees and relaxed, helping the trainees to be relaxed.”*