REGULATORY RESOURCES GROUP

rrg

a different approach

a range of services to suit your needs

A Different Approach.....

About Regulatory Resources Group

Established in 1990, RRG provides a range of regulatory services to the pharmaceutical and healthcare industries, helping companies to manage every stage of the drug development process. This may include the design of the regulatory and clinical strategy through to the preparation and management of the dossier during the regulatory approval process. After the product has been marketed, RRG frequently plays a role in the subsequent management of the product life cycle. Training is a large and growing part of our service and we provide external courses and a range of in-house programmes that are tailored to meet the client's requirements.

We have built our reputation on getting our clients' pharmaceutical and healthcare products to market in the shortest possible time frame and keeping them there. Our clients range from large multinationals to smaller start-up companies and are located across the globe.

Our attention to quality has resulted in over 75% of our work being repeat business and over 90% coming via referral.

A Range of Services to Suit your Needs

RRG services are designed to meet the needs of every type of organisation, large or small. RRG can support the in-house Regulatory Affairs Department by undertaking specific projects and by providing ongoing staff training. Alternatively, we can take overall responsibility for a project and manage the entire regulatory process. RRG has over 20 years practical regulatory experience and has worked with most major therapy areas and product formulations. RRG also has experience with medical devices and drug-device combinations.

Our Services include:

- Product Development
- Regulatory Strategy
- Regulatory Submissions
- Training
- In-House Support
- User Testing

Product Development

"None of us is as smart as all of us"
Phil Condit

Our belief is that all product development has a regulatory purpose. RRG provides integrated strategic and project management services to support the efficient development of pharmaceutical and healthcare products from inception right through to marketing authorisation – helping you to execute your product development plans to achieve regulatory and commercial success.

A Different Approach to Virtual Product Development

Our approach focuses on the central importance of an effective team to steer the project and execute the project plans, to review progress and make key decisions to ensure a successful outcome. This is particularly critical in projects where there is significant out-sourcing in a virtual development approach. RRG are experts at taking on the role of project leader in setting up and managing a core team.

RRG can provide support for:

- Regulatory
- Clinical
- Non-clinical
- CMC
- Project Management

Regulatory Strategy

"A goal without a plan is just a wish"

Antoine de Saint-Exupery

Almost everything the company does during the development phase of a product's life is aimed at satisfying the regulators of its quality, safety and efficacy. RRG's approach recognises the importance of a living, comprehensive regulatory plan to support your product from conception through to the end goal – successful marketing.

This is facilitated by extensive experience and expert knowledge in:

- regulatory requirements across a wide range of therapy areas and product formulations
- the preparation of detailed strategy documents
- the ability to anticipate problems and develop plans to address them
- utilising our wide network of contacts
- Scientific Advice meetings at national and EMA level and with FDA
- the submission of successful dossiers for both clinical trials and MAAs

The integration of our regulatory strategy service with our product development and regulatory submissions offerings ensures that the strategy adopted is effectively implemented to reach your end goal.

Regulatory Submissions

"Success generally depends upon knowing how long it takes to succeed"

Montesquieu

At RRG, we have a proven track record of successful submissions for clinical trials and marketing authorisations across a wide range of therapy areas and types of dossier. With the help of our highly experienced administrative support team, we can prepare submissions of any size, but our service does not stop there.

We can manage the whole regulatory process including:

- authoring and /or reviewing submission documents
- preparing and participating in pre-submission agency meetings
- submission compilation – paper or electronic
- preparing and coordinating responses to questions
- preparing and participating in hearings and appeals
- post approval life cycle management including variations, amendments and renewals

"The class was terrific… comprehensive and well executed. The tutors were extremely well prepared and clearly explained the ideas/content. They were very receptive to questions. I really enjoyed the group work. Great overall experience! "
Jessica Norman, MPI

"Great Course!"
Scott McMillan, AMAG, US

"Great instructors, excellent materials and references"
Kate Silva, AMAG, US

"The notes/slides are the best handouts I've seen provided with a course….."
Brian Custard, Sanofi-Pasteur, US

"I really enjoyed the course and learnt a lot. Excellent presentations."
Chantal Lammineur, Baxter, Belgium

"Very intense but excellent course. Very skilfully and professionally managed and led."
Mira Tomanovic, Pfizer, Sandwich, UK

"The course was excellent. A fantastic overall view of the dossier requirements. I will definitely recommend this course to my colleagues. Lectures were terrific, great presenters with good sense of humour. I was engaged the entire time!"
Rowena Neunhoffer, Regulatory Affairs, Hospira, UK

Training

"What use is knowledge if there is no understanding?"

Joannes Stobaeus

RRG has been providing training to the pharmaceutical industry since 1990.

We tailor our training to meet your specific needs and believe that people learn best in a stimulating, interactive training environment.

RRG offers a variety of in-house and public training courses on topics relating to regulatory affairs and the interface between regulatory affairs and both clinical development and manufacturing.

We have developed a modular approach to training – modules can be combined to tailor-make a course which will meet your precise needs.

Content Management and Tutor Expertise

- Regularly updated course modules
- High quality course notes with internet links to key guidelines
- Enthusiastic trainers sharing their extensive experience of regulatory affairs at a global level
- Trainers currently working as regulatory consultants to pharmaceutical and other healthcare companies.

Interactive Approach

- Interactive structure with workshops and team work sessions
- Detailed discussion of the clients' own real-life projects
- Use of in-house documents to develop tailored workshops
- Cross-functional training, to develop and improve interdepartmental performance.

Flexibility

- Develop your own course from our modular approach
- Do not waste time re-learning what you already know
- Choose a time, location and course length to suit your needs
- Adapt the level of detail and focus to your requirements.

In-House Support

RRG understands that there are times when companies go through peaks and troughs in their workload. Resource is at hand for those companies that need to manage maternity cover, sick leave or just an increasing work load. All our consultants will be interviewed by a director at RRG in advance to ensure that they will be a good fit with your requirements. Our consultants work on a contract basis for whatever duration you need.

A Different Approach to In-House Support

RRG has been successfully providing regulatory services and training to the pharmaceutical industry for more than 20 years. However what you may not know is that we also have a team of experienced consultants who we can place in-house. Our team can handle all sorts of assignments but are particularly suited to deal with complex projects and interim management positions.

User Testing

"If you can't explain something simply you don't understand it well"

Albert Einstein

Our Patient Information Leaflet (PIL) User Testing Service combines regulatory, medical information and clinical expertise. All our interviews are conducted by qualified nurses who are trained in managing patients' understanding of the clinical situation. We offer whatever level of service necessary to meet the needs of our clients, from the strategic management of an EU PIL harmonisation process to the testing of a single leaflet.

Working in Partnership

When you commission RRG to support your regulatory and development activities we work alongside you, providing experienced specialist help to your in-house teams. This integrated team approach has proved to be highly effective because changes in one area of a regulatory project can have a knock-on effect on many others. RRG takes a proactive, focused, professional approach, helping to drive your project forward in a spirit of partnership.

Dedicated Consultants

Our clients expect consistency, hence a dedicated consultant will be assigned to oversee your project through to a successful conclusion. Additional specialist help, which includes non-clinical, clinical and GMP experts, will be provided from within the RRG team when necessary. Because all our consultants have at least 10 years' experience, we approach each project with a confidence and sureness of touch that enables us to deliver a high quality of service that is both flexible and responsive.

Commercial Awareness

Regulatory teams are always under intense pressure from the rest of the business because the submission milestone is often set ahead of identifying the full extent of a project. At RRG, we understand these pressures and can help you to find sensible and innovative solutions that meet everyone's needs.

A Risk Management Approach

Because each product is different, no standard formula can be applied to the regulatory process and RRG helps you to assess and manage the regulatory risks at each stage of your project.

Why Choose RRG?

RRG has continued to develop its services and expertise since it was established in 1990. The relationship between a client and its regulatory affairs consultancy is based on trust, mutual understanding and shared professional standards. Once that relationship has been established and a client knows that its critical regulatory procedures can be safely outsourced, an enduring and stable partnership is formed.

That's why over 75% of our work is repeat business and over 90% of our new business comes from referrals. Our aim is simple – to make sure that our clients never need to seek elsewhere for professional regulatory services.

RRG Directors

Lyn Ferguson BPharm, MRPharmS, MTOPRA

Lyn is a pharmacist with more than 30 years' experience in both the UK regulatory agency and the pharmaceutical industry. She co-founded RRG in 1990.

Tacye Connolly BSc(Hons), MTOPRA

Tacye has worked in the pharmaceutical industry for more than 20 years in various regulatory roles, in industry and consultancy. She became a director of RRG in 1999. Tacye has a particular interest in product development for SMEs and training.

Shaun Stapleton BSc(Hons), MTOPRA

Shaun has over 20 years' experience in pharmaceutical Regulatory Affairs, working in industry and more recently as a consultant. Shaun has been with RRG since 2006 and became a Director in 2008.

The Wider RRG Team

Regulatory Consultants

RRG has a team of highly experienced regulatory consultants who have worked in a wide variety of industry roles often at senior levels. In addition to their experience in regulatory submissions and strategy in a range of therapeutic areas, our consultants also have specific expertise in areas such as biotechnology, devices, cosmetics and radiologicals.

In addition to our regulatory team, RRG has also built up a large network of consultants who we work with on a regular basis to provide integrated development solutions to meet our clients' needs.

This team includes:

- Medical experts
- Clinical trial monitors
- Non clinical experts
- Analytical experts
- Clinical project managers
- Licensing/partnering specialists
- GMP specialists
- GCP auditors
- Statistics and data management specialists
- Pharmacovigilance experts

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