

# Professional regulatory services

RRG provides a range of professional regulatory services to the pharmaceutical industry, 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 needs.



end of phase meetings

regulatory agency

approve

development assessments

acquisitions

end of phase meetings  
development assessments

Regulatory

appeal

scientific advice

Submissions

Submissions

Regulatory agency contacts

contacts

adviso

Submissions

advisory panels

Submissions

acquisitions

# A range of services to suit your needs

RRG offers a range of services that 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.

## Regulatory Strategy

The success of a new development often depends on getting the right regulatory strategy in place at the outset. RRG takes a proactive approach to strategy development and project management, anticipating potential problems and keeping any associated risks under constant review.

## Product Development

A particular area of expertise offered by RRG is setting up and driving the construction and implementation of development programmes. RRG can advise on which trials to conduct and how to tailor the product development process to meet the needs of the regulatory agencies. This helps to maximise the return on investment and ensures that you provide the regulators with the right information.

## Regulatory Submissions

A thorough knowledge of regulatory dossier requirements and regulatory procedures is essential to ensure rapid submission and approval. RRG has wide-ranging experience in all therapeutic areas and types of dossier. The preparation of regulatory submissions is one of the largest areas of our work and we are proud of the successes we have achieved.

For many of our clients, RRG's involvement begins before Phase I and continues through the licensing process into the ongoing management of the dossier. This experience enables us to take on projects at any point in the product lifecycle and provide the right regulatory support.

Our experience with global regulatory agencies enables us to help our clients prepare submissions that will meet with the widest possible approval.

working alongside proac  
wide ranging skills  
dedicated team support  
partners  
strategy  
innovative solutions  
experienced specialist help  
project manag  
dedicated consultants  
professional long term rela  
tailored  
risk management  
str  
partne  
management commercially awa  
experienced specialist help  
integrated  
team support  
pro  
long term relationships

# Working in partnership

When you commission RRG to support your 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 projects forward in a spirit of partnership.

## Dedicated Consultants

Our clients expect consistency, hence a dedicated consultant will be assigned to oversee your projects 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 formulae can be applied to the regulatory process and RRG helps you to assess and manage the regulatory risks at each stage of your project.



verbal  
ucts

inical

levels of expertise

skills

professional  
development

audit

logistic  
advant

co

courses

objectives

working  
practice

e diligence

munication

iance & change

onal development

# Regulatory training

RRG has an excellent track record in providing both in-house and external courses that are tailored to meet our clients' needs. For many of our existing clients, we provide ongoing regulatory training to maintain levels of expertise and help to develop the proficiency of the in-house regulatory team. Efficiency can be enhanced through improved communication following our cross-functional training programmes where professionals from different disciplines gain a better understanding of each other's needs. For new clients, we recommend the Professional Development Audit as a valuable first step.

## Professional Development Audit

The RRG Professional Development Audit is designed to provide a unique roadmap for developing the skills and understanding of your regulatory team. As part of this process, we are able to highlight areas where the current skill set may not be sufficient to meet business objectives. We can introduce more efficient working practices and help to prepare the team for forthcoming legislative changes.

## Bespoke Training

Where a client has a very specific training requirement, we will develop customised modules to suit their needs. Most of our training is provided on the client's premises, which has obvious economic and logistical advantages.

## External Courses

RRG also runs a number of respected external courses, most notably the 'Quality Aspects of the CTD', formerly known as 'The Chemistry/Pharmacy Dossier' which has been run in collaboration with David Begg Associates, since 1991. This course has become an industry standard and is distinct because it brings people together from all the disciplines involved in pharmaceutical development and licensing of drug products.

## RRG Training Modules

- Regulatory Strategy*
- Regulatory Project Management*
- Regulatory Procedures*
- Regulatory Due Diligence*
- Regulatory Compliance & Change Management*
- Regulatory Negotiating*
- Clinical Trials Directive*
- Common Technical Document*
- Drug Substance Requirements*
- Drug Master Files and Certificates of Suitability*
- Drug Product Requirements*
- Non-clinical Requirements*
- Clinical Requirements*
- Herbal Products*
- Cosmetics*
- Devices*

This is just a sample of the courses we offer. New modules are being developed all the time, often in response to specific client requests.

# Why choose RRG?

RRG has continued to develop its services and expertise since it was established in 1990. It has remained a relatively small consultancy to ensure clients receive a high quality personal service. 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 all RRG's work is either repeat business or via recommendations. Our aim is to make sure that our clients never need to seek elsewhere for professional regulatory services.

## Director Profiles

**LYN FERGUSON** BPharm, MRPharmS, MBIRA  
*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.*

**JENNY LAMPORT** BPharm, MRPharmS, FBIRA  
*Jenny has worked in the pharmaceutical industry for more than 20 years in various regulatory roles in industry and consultancy. She co-founded RRG in 1990. Jenny is a pharmacist and has a particular interest in training.*

**TACYE CONNOLLY** BSc(Hons), MBIRA  
*Tacye has worked in the pharmaceutical industry for more than 20 years in various regulatory roles including auditing in industry and consultancy. She became a director of RRG in 1999. Tacye has a particular interest in clinical development and sits on project development boards for several companies.*



compliance  
strategy dev  
dossier  
project management  
regu  
p  
core  
regulatory

Regulatory Resources Group Ltd  
Innovation House  
Unit 6  
Albany Park  
Frimley, Camberley  
Surrey  
GU16 7PL

Tel: +44 (0)1276 671166  
Fax: +44 (0)1276 670960  
E-mail: [mail@rrgconsultants.co.uk](mailto:mail@rrgconsultants.co.uk)  
Web: [www.rrgconsultants.co.uk](http://www.rrgconsultants.co.uk)



management  
development  
**training**  
regu  
strategy  
issu  
miss



