

Training and seminars



Our consultancy services will provide you with comprehensive training programmes designed to improve your business functionality.

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The importance of effective regulatory affairs training cannot be overemphasised for various personnel within the pharmaceutical industry.

Regulatory affairs executives need to be familiar with legislation and procedural matters as well as having the skill to recognise potential pitfalls in the scientific data. The scientists generating the laboratory data need to be able to conduct and report the work to standards that will satisfy the authorities. The secretarial and administrative team can provide more effective support if they too understand the basics of regulatory affairs.

Our experienced consultants design training programmes to meet clients' specific requirements. From one-to-one training to complete seminars, we can help improve the effectiveness of your regulatory affairs operations.

This service is offered, based on extensive experience working on regulatory projects for client companies worldwide, much of it in a problem-solving capacity. Regulatory affairs is not only a science but also an art and we are pleased to share our knowledge.

Individual Training

There is nothing more effective than one-to-one training particularly when a new or inexperienced member of staff joins the team. Small and very busy departments are particularly vulnerable where there is no person or time available to carry out the necessary training.

Regulatory affairs training is essential for those involved in day-to-day registration projects. It is also highly valuable for those who work closely with this team. With a basic understanding of regulatory affairs the scientists responsible for generating reports are better able to create texts which meet the authorities' criteria and secretaries and administrators can provide a much higher level of support.

Training programmes can be tailored to your specific requirements and to meet your budget. You can choose a concentrated period of instruction or spread the training over an extended timescale on a 'little and often' basis. Intensive training courses can be arranged



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off-site to maximise benefit and minimise interruptions.

Alternatively, we can work side by side with your member of staff in-house, using real projects as the training material. In this way the trainee spends less time away from productive work. Our expert(s) can also be available on an ad-hoc basis at the end of a telephone to answer queries as and when they arise or provide relevant advice.

Let us know your training requirements and we will be pleased to propose a suitable package.

Here is an example of some of the courses we have designed:

- Analytical chemistry for non analysts
- Analytical Validation
- Appeals, Hearings and Representations
- Centralised, Decentralised & Mutual Recognition Procedures
- Chemistry of the Drug Substance
- Clinical Trial Authorisations
- Dossier Content, Style & Presentation
- European Mutual Recognition and Decentralised Procedures
- EU Pharmaceutical Regulation of Clinical Trials
- EU Paediatric Regulation
- EU Pharmacovigilance Legislation
- EU Product Information
- Expedited Reporting of Safety Reports in the European Union
- Introduction to Pharmacovigilance – For Administrators
- Introduction to Pharmacovigilance – For Sales Representatives
- Introduction to the Common Technical Document (CTD)
- Marketing Authorisation Applications in the EU
- Orphan Medicinal Products in the EU
- Overviews and Summaries
- Pharmacovigilance System Components & Responsibilities
- Pharmacovigilance
- Pharmacovigilance Inspections
- Periodic Safety Update Reports
- Project Planning
- Reasons for Rejecting a Marketing Authorisation Application
- Regulatory Report Writing
- Regulatory Authority Pharmacovigilance Inspections
- Roles and Responsibilities of an EU Qualified Person for Pharmacovigilance
- Scientific Advice in the EU
- The science behind variations

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

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