



## **Quality Assurance Training Courses**

Established in 1998, RSSL Pharma Training has an enviable reputation as a provider of high quality industry specific programmes. Industry experts bring current and future thinking to the knowledge content, whilst an emphasis on the latest problem based learning methods ensures that our delegates leave with a pragmatic understanding of the subject, and the confidence to put it into practice in the workplace. All the courses detailed below can be tailored and run for you on site, offering a cost effective way of relating topics to company specific situations.

## What delegates have said about recent courses:

"This was probably the best classroom based course I have ever been on"

"Lively, interesting presentations with useful anecdotes and examples; excellent take away materials"

## Control of Biotechnology Products

Providing an overview of the quality and regulatory issues surrounding the development and production of biopharmaceuticals for global use, this one day workshop is suitable for QA professionals and newly-appointed managers who are moving into biopharmaceuticals, and regulatory professionals who need to understand the quality issues associated with their manufacture. It covers the regulatory approaches used in Europe and the US, differences between small molecule drugs and biopharmaceuticals from a quality point of view, the different types of biopharmaceutical and associated quality issues, the importance of the manufacturing process - production systems, issues associated with scaling up, the importance of facilities design, the role of the genetic construct in reproducible manufacturing and the use of Master Cell Banks and Master Working Banks.



## Failure Investigation and CAPA

This course provides an introduction to the requirements of systematic failure investigation and corrective and preventive action practices as described in ICH Q9 and made a regulatory requirement in Europe by Annex 20 of the Guide to GMP and in the USA by the Federal Register/FDA Guidance for Industry. The course is focused on company responsibilities within a Quality Risk Management system and several investigational tools are explored to help build up knowledge of techniques that might be used to provide a structure for systematic investigation of failure. Opportunities to try out simple techniques are provided throughout. Examples of the use of, and outputs from, more complex techniques are presented.

## Clinical Trials

A detailed introduction into the clinical trials arena and explanation of the key purposes, practices and principles involved. It examines the legislation, standards and guidelines that impact on performing such trials. You will benefit from this course if you work in pharmaceutical R & D, have been newly appointed to clinical research or provide clinical supplies and other trial support services.

## Documentation

Documentation is the cornerstone of any company's Quality Management System and is an essential GMP requirement. It is critical that anyone dealing with GMP documents and documentation systems understand the regulatory requirements and adopts best practice. As such this course provides a step by step explanation of what to do when managing GMP Documentation and Documentation Systems and is appropriate to a wide ranging audience, from QA and QC, through to production and clinical trials professionals.

## Environmental Monitoring

The course addresses environmental monitoring for the manufacturing of both sterile and non-sterile products. It looks at the legislation and guidance available, techniques employed to monitor pharmaceutical environments, data trending and how to manage out of limit results. Additionally a review of risks associated with contamination sources, monitoring methods, trending and reporting of results is undertaken. This course is aimed at personnel in production and quality functions who wish to increase their understanding of regulatory requirements and expectations for the environmental monitoring of pharmaceutical operations.

## Hazard Management using HACCP

Hazard Analysis and Critical Control Point (HACCP) principles have been used as the key tool for the management of product safety in the food industry for over 30 years, but its application within the pharmaceutical industry has been limited. HACCP principles provide a framework for the identification of significant hazards specific to a production process and their subsequent management.

The importance of HACCP has been gaining momentum since the publication of ICH Q9 and the FDA GMPs for the 21st century which advocate risk management. The application of HACCP is considered to represent a very effective, logical and systematic approach to a requirement that can be daunting for those charged with completing the task. This highly

practical workshop is suitable for anyone who needs a better understanding of HACCP principles, what is involved in their application and how the technique can be applied effectively in a pharmaceutical environment.

## Introduction to Pharmaceutical Microbiology

The course is designed to give background knowledge on the wide-ranging impact of microbiology on many aspects of pharmaceutical control. The course looks at the nature of micro-organisms, contamination sources and control, sterilization and disinfection, and testing methodology (including modern counting and identification techniques). The course will be of value to all personnel whose roles would benefit from a clearer understanding of this specialist area.

## Introduction to Validation

The course is based on the theory behind validation as specified and required by European and USA guidelines. It explains what is required in order to ensure that processes are operating to a safe and consistent standard. It covers the validation approach, documentation, protocols, reports, change control and revalidation and is suitable for anybody working in this field.

## Manufacturing Sterile Products

A comprehensive introduction to the regulatory requirements governing pharmaceutical cleanroom operation, with details of the aseptic filling and terminal sterilization methods for producing sterile products. Delegates will gain an appreciation of the significance of sterile products to the patient, and understand why there is intensive regulatory interest in the control of sterile product manufacture. The course content will provide a good foundation of knowledge for all personnel working in companies that manufacture sterile products.



## Cleaning Validation

Efficient and effective plant cleaning is a vitally important aspect of pharmaceutical manufacture. This entertaining and lively course is designed to highlight and explain the most important and fundamental issues associated with cleaning validation and verification. It focuses on maximum allowable carryover calculations, documentation, cleaning validation master plans, good and bad practices, visual inspection, sampling, testing and analytical method validation.

## Pharmaceutical Raw Materials

This course covers the key issues surrounding the production of APIs and excipients. It explains how bulk chemical raw materials are manufactured and tested. Typical guidelines and standards that should be used when auditing such production facilities will be introduced. This practical course is invaluable for purchasing, raw material QC, QA, production and auditing personnel as well as the Qualified Person.

## Practical Analytical Method Validation

Analytical chemists are by their nature innovators and seekers of improvement. The desire for continuous improvement spills over into the interpretation of methods for quality control. The purpose of this one day course is to provide a sound basis for ensuring methods selected are based upon sound scientific principles, which can be shown to be robust and reliable for the sample type under test. This course also provides the basis for ensuring the instrumentation used has been qualified and calibrated.

## Stability Testing

The course aims to provide a comprehensive coverage of the current industry and regulatory requirements for stability testing. It focuses on storage conditions, tests and protocols, stress testing, stability facilities, existing products and line extensions, guidelines (e.g. ICH Q1 series), photo-stability and matrixing of stability studies. The course is appropriate to anyone conducting or managing stability testing.

## Technical Report Writing

Report writing requires many skills including planning, managing large quantities of information and the ability to get a message across to a non-technical audience. This course is for everyone who writes reports and would like to do it more efficiently, more confidently and with better results. A practical approach is taken and individuals receive feedback on their writing style.

## Support throughout your Training

Our Pharmaceutical Training Manager and Client Relationship Manager are here to ensure that your experience with us is excellent from your first enquiry to our warmest welcome and attentive follow-up. We can provide advice and feedback on your individual circumstances and offer advice on the best training approach for you.

Once registered for a course with us, you will have access to the most relevant subject matter experts who will be able to answer your questions and challenge your thinking, during and after the courses.

For further information or to book a place please contact us by telephone, email or via our website as follows:

**RSSL Pharma Training**

The Science and Technology Centre  
Earley Gate  
Whiteknights Road  
Reading  
Berkshire, RG6 6BZ

Tel: +44 (0) 118 918 4168

Fax: +44 (0) 118 935 7345

**E-mail:** [pharma.training@rssl.com](mailto:pharma.training@rssl.com)

**Web:** [www.rssl.com](http://www.rssl.com)

**Terms & Conditions**

There will be no charges providing cancellation is more than 20 working days before the course start date. Cancellation made within 20 working days of the course start date will be charged at the full rate. Delegate substitution is acceptable – but please inform us in advance whenever possible. In the event of unforeseen circumstances, RSSL reserve the right to alter the programme, speaker(s), course date or venue. If a course is cancelled by RSSL, a full refund will be offered, if rescheduling of the course is either not possible or not acceptable to the delegate. However, RSSL Training will not be liable for any other costs incurred by the delegates, associated with the course.