Pharmaceutical Training

Industry leading
Unique and flexible approach

rsst
science with service
About Us

Our outstanding reputation as one of the most trusted pharmaceutical training providers, gives you the confidence that we are training your biggest asset to the highest standards. Investment in training not only gives your staff the key knowledge and skills they need but also ensures that they feel valued contributors to your organisational goals.

Our tutors are all industry specialists, bringing current and future thinking to the knowledge content, whilst the emphasis on problem based learning methods will guarantee that attendees leave with a pragmatic understanding of the subject, and the confidence to put it into practice in the workplace.

Once registered for a training course with us, you will have the support of a dedicated Client Relationship Manager and the most relevant subject matter experts who will be able to answer your questions and challenge your thinking, during and after the course.

In-house Training at Your Site

All of the courses on our ‘open’ schedule can be run for you on site or at another location of your choice, which means that:

- A number of staff can be trained at the same time, saving on individual course fees and ensuring a consistent message
- There are no employee travel and accommodation costs
- By tailoring the course, you only pay for the level of content and degree of expertise required for your particular needs, and nothing else
- You have the opportunity to continuously relate issues to your own company situation

We offer three simple approaches:

‘Off the shelf’
If one of our standard ‘open’ courses is what you are looking for then give us a call and simply tell us which one you would like, when, where and for how many! We will ask a few simple questions just to make sure that the training will meet your objectives.

‘Bespoke’
We can develop a programme from scratch. If you are unsure of exactly how to achieve the results you need, one of our Training Consultants will work with you to design the right solution – and deliver the outcome you require.

‘Tailored’
If one of our courses looks interesting, why not take the opportunity to have it tailored to suit your specific requirements – taking account of internal systems, procedures and policies. We will discuss the learning outcomes you want to achieve, and then tailor the course to meet them, using your own examples in exercises.

RSSL in action

Having made major investments in state of the art facilities and manufacturing equipment, the senior management team at Mentholatum believed it was also essential to invest in staff training to ensure everyone had a full appreciation of their GMP responsibilities, taking the opportunity to introduce and share best practice across the whole organisation.

RSSL met with the senior leadership team, and designed a two year programme to drive a GMP ‘culture from the heart’, across all departments from the very bottom right up to the very top.

Leadership workshops, the introduction of a ‘GMP Ambassadors’ programme, standard GMP training days and specialist courses for specialist departments have all added up to a company wide ‘evangelism’ for compliance.

Whilst the activities and the methods were designed around a wide variety of day to day pragmatic issues, and tailored for different learning styles, the message was clear and consistent throughout.

The investment was appreciated by all as a sign of the company’s commitment to a ‘get it right first time’ approach, ensuring buy in at all levels. Significantly, this has been recognised and commended by the regulatory authorities.

GMP culture from the heart

“Tell me and I’ll forget; show me and I may remember; involve me and I’ll understand.”
Chinese Proverb
Qualified Person

Why become a Qualified Person (QP)? The role of the QP is essential to the safe control of medicines; you will have the personal responsibility to ensure that medicinal products are certified as complying with required authorisations, national legislation and good manufacturing practice (GMP). You will need to have comprehensive training and an in-depth understanding of all aspects of pharmaceutical manufacturing.

Becoming a QP will open up new career opportunities for you, however it involves a level of investment and commitment. You need to ensure that you get the best and most cost effective training available, and that it suits your needs – this is where we can help. Our outstanding reputation as one of the most trusted pharmaceutical training providers, gives you confidence that the training provided is of the highest standard and is relevant to the aspiring QP. Our outstanding first time success rate of >90% and the unique, flexible and innovative approach we take to training makes us the preferred training partner of choice for many companies and individuals alike.

How our training will benefit you

Our industry experts provide face to face, in-depth tuition with an emphasis on the latest case study and problem based learning methods.

- Our 11 modules are designed to meet the requirements in EC Directives 2001/82/EC and 2001/83/EC and the latest UK Qualified Person Study Guide
- All of our modules are presented twice in a single calendar year, which means you can schedule your study at a time and pace to suit you
- Our industry experienced tutors include current QP assessors
- Our modules are practical in nature, focusing on the key elements and competencies delegates need to make sensible judgements and rational decisions
- We limit delegate numbers to maximise delegate/tutor interaction

"Doing my QP training with RSSL has been a great experience. The atmosphere is relaxed and intimate, where no question is a stupid question! The exercises in smaller groups are an ideal way to really get to know the other future QPs and to share work experiences and knowledge. This networking has led to several site visits and contacts which have been invaluable for my viva preparation. It has been a fantastic opportunity to interact with other like-minded people all on a similar career path."
Our Pharmaceutical Training Portfolio

Auditing

Auditing – Active Pharmaceutical Ingredients (1-day)
This course provides the basic knowledge base and skills to enable effective auditing and reporting of audits on those suppliers of active pharmaceutical ingredients (APIs). The course is focused on the requirements of ICH Q7 and EU GMP Part II and the expectations of regulatory bodies both in the USA and Europe.

Auditing to Pharmaceutical Standards (1-day)
It is a regulatory requirement for organisations within the Pharmaceutical and Allied Industries to audit active pharmaceutical ingredient (API) manufacturers, suppliers of key excipients and packaging materials, and contracted-out laboratory services. This course is aimed at reviewing the key relevant standards that one might expect to audit against, providing a strong foundation for the application of auditing skills. Specifically this course covers the EU GMP Parts I, II and III; PS 9000; ISO 17025; ISO 15378 and ISO 13485. Several elements of ISO 9001 (Quality Management Systems) are explored in detail.

QMS Auditor/Lead Auditor (IRCA Ref A18215) (5-day)
This modified course focuses on auditing to the ISO 9001 standard and the PQG’s Application Standards for suppliers to the pharmaceutical industry.

Successful completion of this course provides the delegate with a qualification in auditing that is recognised by the International Register of Certified Auditors (IRCA) and the Pharmaceutical Quality Group (PQG).

Frequent opportunities are provided to check knowledge acquired before the staged formal assessments, and delegates are supported by regular constructive feedback. This 5-day residential course is focused on providing you with the knowledge and skills required to perform first, second and third-party audits of quality management systems, against ISO 9001 and the specific GMP standards that have been developed for the supply of packaging, excipient and Active Pharmaceutical Ingredient (API) materials to the pharmaceutical industry. ISO 9001 is covered in detail and this will enable pharmaceutical auditors to converse in the language that is universally used by its suppliers.

On successful completion of this course, delegates may apply for professional recognition as an IRCA certified QMS Lead Auditor. IRCA (Ref A18215) and PQG Accredited Course.

Pharmaceutical Practical Auditing Skills (2-day)
This course provides an introduction to the requirements of internal auditing described in the international standard ISO 19011. Frequent opportunities to practice key steps are provided through role play in a no risk environment, with supportive feedback provided throughout. The course is focused on pharmaceutical GMP and several subjects are explored in detail which helps build up knowledge and confidence in GMP.

The range of other standards appropriate to external auditing (e.g. GDP, ISO 9001) are described briefly but not explored in depth.

Good Manufacturing Practice

Good Manufacturing Practice (1-day)
This interactive course examines why we have Good Manufacturing Practice (GMP), its legal status and the key GMP issues surrounding pharmaceutical manufacture such as documentation, training and facilities. This informative course introduces the EU Guide to GMP and considers its implementation in the modern pharmaceutical regulatory environment.

Good Manufacturing Practice and Packaging (1-day)
The packing process is a complex series of operations, often performed at high speeds and against tight deadlines. Despite the increased use of many on line detection/rejection systems, the majority of pharmaceutical quality complaints and recalls are packaging related.

This course gives a detailed background into the complicated issues associated with pharmaceutical packaging. It examines all of the key stages from artwork design, component suppliers through the packing process to final product release. It also examines the important role people play in packing operations. It identifies major areas of risk and discusses how these can be removed or managed.

Good Manufacturing Practice for Medical Devices (1-day)
The course covers the requirements of the Medical Device Regulatory Standard ISO 13485 and the regulatory framework and documentation required to market a medical device.

Those attending will get an understanding of the requirements and documentation required to market and maintain compliance for medical devices in the market place. There are tutorials on the Directives, the regulatory system, the marketing of a device and the ISO 13485 Medical Device Standard. Added to this there is an introduction to risk management and the vigilance system.

The course is interactive with many practical exercises and discussions.
Good Manufacturing Practice in the Laboratory (1-day)

This course is an adaptation of our standard 1-day GMP course, designed specifically for laboratory staff who have unique, additional requirements laid out in GMP both in the European and USA regulations and guidance documents.

The pharmaceutical quality control laboratory serves one of the most important functions in the manufacturing environment. Many of the GMP regulations and guidances apply to control laboratories but in particular Chapter 6 (QC and Good Control Laboratory Practice) of the EU Guide to GMP. The course also covers the role of documentation, pharmacopoeias, laboratory reference standards, calibration, calculations and results. The final session of the course brings all this together by a session on preparing for regulatory inspection.

Managing Good Manufacturing Practice Compliance (1-day)

The revision of Chapter 1 (Quality Management) and Chapter 2 (Personnel) of Part I of the EU guide to GMP to incorporate ICH Q10 brings into sharp focus the management responsibilities for implementation and assessment of quality systems within an organisation. Most notably the changes specify Senior Management responsibilities for quality.

This stimulating workshop is designed to make delegates think about where such responsibilities lie within their own organisation and the potential reputation and cost consequences of non-compliance.

Starting with a brief consideration of the key elements of the proposed revisions to the GMPs, the course moves through a series of case study scenarios and the consequent implications. Potential approaches to discharge management responsibilities are explored.

Good Distribution Practice (1-day)

This intensive 1-day course is intended to evaluate Good Distribution Practice (GDP) as required by Directive 2001/83/EC, Directive 2004/27/EC, EU Guidelines on Good Distribution of Medicinal Products for Human Use 2013/C 343/01 and the new requirements included in the MHRA Orange/Green Guides. It offers a practical explanation of the guidelines for those who are active in the field of setting up and implementing GDP, as well as those involved in the management of quality systems for pharmaceutical products.

It reviews GMP/GDP supply chain integrity and examines the risk of counterfeit pharmaceutical products, a growing concern today. The course also reviews sample deficiencies found by regulators and how to improve compliance in these critical areas.

Responsible Person Refresher (1-day)

The refresher course is aimed at RP’s and Deputy RP’s who have already undertaken initial RP training but who need to keep updated with current regulations and expectations of the competent authorities for Continuing Professional Development (CPD). Note, it is not a suitable alternative for those who have yet to undergo initial RP training.

This ‘update’ course would also benefit quality managers, and personnel in regulatory, compliance, distribution, warehousing, supply chain management and customer service who need to appreciate the implications of the changes. It is designed for all those who need to understand the revised key GDP quality components necessary to operate as a holder of an MHRA or EU.

Responsible Person (2-day)

This intensive 2-day course evaluates the key roles and responsibilities of the Responsible Person (RP) and Deputy RP in relation to Directive 2001/83/EC, Directive 2004/27/EC, EU Guidelines on Good Distribution of Medicinal Products for Human Use 2013, and the new requirements included in the MHRA Orange/Green Guides. This course is designed to cover the key elements of the new Responsible Person Gold Standard.

Fully reviewing Good Distribution Practice (GDP) as required by Licence Holders, it provides an understanding of the key GDP Quality Systems required to operate and fully meet regulatory requirements.
Cleaning Validation (1-day)
This practical 1-day course covers basic issues in cleaning processes in pharmaceutical manufacturing, and the validation of those processes. After an introduction to the overall objectives, the course then covers process design, pitfalls and associated validation issues including sampling and testing. The course is designed so that the most important and fundamental issues associated with cleaning validation or verification are broken down and explained. Numerous practical exercises are run throughout, providing clear demonstrations of techniques to employ - and pitfalls to avoid!

Cosmetic Regulations (1-day)
The in-depth, interactive course which gives delegate a full overview and understanding of the EU Cosmetics Regulation 1223/2009, and what you need to know to market a product. This regulation was fully implemented in July 2013 and makes many changes to the previous Cosmetics Directive 76/76/EEC. These changes include aspects of the Product Information File, notification, labelling, claim substantiation and also include a greater emphasis on Good Manufacturing Practice and compliance with a harmonised standard such as ISO22716. There are a number of aspects of the Regulation that are under review and the course tutors will endeavour to give the latest industry opinion where appropriate.

Data Integrity (1-day)
This course is designed to provide guidance on how data should be controlled and managed from initial generation and recording, through processing, use, retention, archiving and retrieval. Data integrity is assuming greater importance in cGMP, with both the FDA and European Regulatory Agencies placing a high degree of focus on the subject. This course will help to interpret expectations, and guide you in defining and implementing an appropriate data governance process in relation to manual (paper) and electronic data.

Documentation (1-day)
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.

Effective Report Writing (1-day)
This course is designed to provide a clear process for writing any report, with or without a template or required outline. The result is the ability to produce a better report and to make far better use of the time available. The emphasis is on planning, reader analysis, structuring the message and writing clearly. This is not a grammar and punctuation course, although examples of work submitted in advance will be reviewed by the tutor and comments on use of English will be made as appropriate.

Environmental Monitoring (1-day)
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.

Failure Investigation and CAPA (2-day)
This course provides an introduction to the requirements of systematic failure investigation (FI) and corrective and preventive action (CAPA) 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 by a company to provide a structure for systematic investigation of failure. Numerous exercises are run throughout the course to provide realistic examples of events requiring investigation, providing an opportunity to practice investigation and writing up of corrective actions within teams. Examples of the use of, and outputs from, more complex techniques are presented.

“A less formal, more personal approach to training.”
Excellent! Course content is comprehensive and detailed and feedback encourages relevance.

Quality Risk Management (1-day)
Successful completion of this 1-day course provides the delegate with understanding of the principles of Quality Risk Management (QRM) and its practical application.

The course is focused on ICH Q9 (QRM) and its support to ICH Q8 (Pharmaceutical Development), Q10 (Quality Systems) and Q11 (Drug Substance Development) along with its practical application in development, manufacturing, engineering and validation.

The course will be aligned to the latest science and risk based principles and regulatory guidances in the EU and US.

Inspection Preparation Management and Execution (1-day)
This course is designed to provide guidance on how to prepare for external inspections by customers and regulators, manage an external inspection and respond to inspection observations including addressing any deficiencies raised.

Introduction to Pharmaceutical Microbiology (1-day)
This course is designed specifically as an introduction to the important topic of pharmaceutical microbiology, it will review the impact of microbiology on many aspects of pharmaceutical manufacture and control.

This course looks at the nature of micro-organisms, contamination sources and control, sterilisation and disinfection, and testing methodology (including modern counting and identification techniques). It will also cover some group aspects related to the microbiology laboratory.

Introduction to Validation (1-day)
The course provides an overview of the concept of qualification and validation as described in Annex 15 to Eudralex Volume 4. It covers responsibilities and terminology (qualification, validation and verification), and looks at the requirements of equipment qualification (IQ, OQ and PQ), process and cleaning validation, analytical method validation. The need for effective change management and lifecycle management will be discussed. The course also examines the documentation and project management aspects of validation studies.

Manufacturing Sterile Products (1-day)
This course provides an extensive introduction to the regulatory requirements governing pharmaceutical clean room operation, and details the aseptic filling and terminal sterilisation methods for producing sterile products. The delegates will gain an appreciation of the significance of sterile products to the patient, and understand why there is intensive regulatory interest worldwide in the control of sterile product manufacture.

“Excellent! Course content is comprehensive and detailed and feedback encourages relevance.”
**Special Offers**

Help Your Training Budget Go Further!

**Group Booking Offer**

This offer is for companies wishing to send 3 or more employees on one of our standard training courses, and is only applicable to bookings made for the same course. To benefit from this please check the website for the current code to quote at time of booking.

- First booking charged at full published rate*
- Second booking charged at full published rate minus 20%*
- Third booking charged at full published rate minus 50%*

* Discounts applied to published rate before VAT. Not to be used in conjunction with any other offers or discounts.

**Early Bird Offer**

All training course places booked and paid for 8 weeks or more in advance* of the scheduled course date will benefit from a 10% discount which is applied automatically with no need to quote a code.

*This discount will be invalidated if payment is not received by the course date. Discount is applied to the published rate before VAT. Not to be used in conjunction with any other offers or discounts.

For more information or to make a booking please Contact Customer Services:

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- **Email:** enquiries@rssl.com
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**Reducing Human Error (1-day)**

This course is designed to provide an understanding of why we create errors, how the human brain operates and learns and tools, techniques and approaches to solve human performance problems.

**Senior Management Responsibility for the PQS (1-day)**

Recent changes to the EU Guide to GMP emphasise the importance of Senior Management involvement and commitment in the design, implementation, maintenance and monitoring of the Pharmaceutical Quality System (PQS). This is the first time that European guidance explicitly articulates the wide-ranging role of Senior Management beyond the Heads of QA and Production and the Qualified Person. It is therefore likely to be a key area of focus during regulatory inspection.

So how does a Senior Manager actually demonstrate their commitment and support for the Pharmaceutical Quality System?

This interactive one day course, which combines tutorials and exercises, enables Senior Managers to discover what their responsibilities are, how they can discharge them effectively, and develop an action plan to facilitate delivery in their organisations.

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* “Informative, exercises were great for getting you to apply what you have learnt.”*
Courses run at:

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