RSSL PHARMA

science with service

Auditing, Supply Chain, Inspection and Regulatory 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:

"Experienced tutors with a gift for teaching, providing comprehensive sensibly paced training that really can make a difference, not just in the classroom but in the audit room."

"I can't believe how much information the tutors managed to fit in and still make the course interesting and fun."

Good Distribution Practices (GDP) for the Pharmaceutical and Allied Sectors

This intensive one-day course is intended to evaluate Good Distribution Practices (GDP) as required by Directive 2001/83/EC, Directive 2004/27/EC, EU Guidelines on Good Distribution of Medicinal Products for Human Use 94/C 63/03 and the new requirements included in the 2007 Orange Guide. 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 the management of quality systems for pharmaceutical products.

The course is aimed at any company that has obtained, or is considering obtaining an MHRA Wholesale Dealer's Licence/EU Licence, Wholesalers/ Distributors, Manufacturers, Pharmaceutical Suppliers and Service/Transport providers. 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.

Internal Auditing

A highly interactive and practical training course aimed at people working in the pharmaceutical industry who are about to start auditing or those who already audit but have no formal training. It provides an introduction to the guideline for Quality Management Systems auditing specified in the international standard 19011:2002. Delegates will learn and then practice how to plan, execute, report and close-out internal audits as well as write non-conformity reports linked to a GMP clause.

The course focuses on EU GMP as an audit standard but the auditing techniques described are applicable to other standards applied including CFR21 210 and 211; a range of other standards appropriate to the pharmaceutical industry (PS 9000, GDP, ISO 9001) are described briefly but not explored. The course will be assessed and certified by RSSL in line with the requirements of its Lead Auditor course, which is certified by IRCA.

External Auditing

It is a regulatory requirement for organisations to audit API manufacturers, suppliers of key excipients and packaging materials and contracted out laboratory services. This course covers the skills and processes necessary to perform effective external audits and follows the processes described in ISO 19011 – the international standard for auditing. The course focuses on the specific standards used by external suppliers to the pharmaceutical industry – EU GMP Part II, PS9000 and 9100, GCLP and ISO 17025. Several elements of Quality Management Systems (ISO 9001) are explored in detail, which helps build knowledge and confidence in this universally recognised standard, on which many of the above are based.

This course is suitable for people who have already undertaken some auditing (usually internal auditing) and now wish (or are required) to perform external audits; it is also useful for QPs and managers who are concerned with supplier auditing. Delegates will learn and practice how to plan, execute, report and close-out external audits including writing non-conformity reports.

QMS Auditor/Lead Auditor Training – designed for Auditors in the Pharmaceutical Industry

Successful completion of this intensive five day course provides the delegate with a qualification in auditing that is recognised by the International Register of Certified Auditors and the Pharmaceutical Quality Group. The course is focused on ISO9001 and the specific GMP standards that have been developed for the supply of packaging and excipient materials to the pharmaceutical industry. ISO9001 is covered in detail and this will enable pharmaceutical auditors to converse in the language that is universally used by its suppliers. It has had continuous IRCA accreditation since its establishment in 1999 and has a very high success rate.

The course is aimed at QA, QC and purchasing professionals from pharmaceutical companies, suppliers and third party certification bodies. It is also highly recommended for Qualified Persons as part of their continuous professional development and is suitable for people who have been doing some auditing already (perhaps internal auditing and/or supported external audits) or have now been asked to take the lead in external supplier audits.

Preparing For a Regulatory Inspection

Regulatory inspections are a requirement in the pharmaceutical industry, and a successful outcome is of paramount importance to every company. All aspects of the facility and Quality System in operation can be subject to detailed review.

This course provides practical guidance on how to prepare for a regulatory inspection and examines the different approaches taken by various inspectorates, e.g. those in the EU and the US FDA. It will help improve understanding of the mechanics and dynamics of the inspection process. All pharmaceutical personnel who could become involved in preparation activities for a regulatory inspection and those participating in the actual inspection will benefit from this course

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:

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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.