Educational Program Europe
January – December 2016
Hello, and welcome to our Training Program for 2016

2016 marks our 30th year in the business of providing training to the pharmaceutical industry. We’re proud to be part of NSF, with all the benefits we can bring to our customers through the expertise and professionalism of our colleagues across the globe.

Although you may be more familiar with one of our former names, our values and commitment remain the same.

In our 30 years we’ve seen lots of changes in the industry; at the same time, we have grown and evolved, developing strong and lasting relationships with our client companies. We’re part of a much larger organization now, but fundamentally we’re the people you’ve always known: a group of professional individuals, passionate about working with you to deliver the best in medicine and healthcare for patients at every level. After all, those patients are our families, our friends, our responsibility.

This brochure showcases our program of public training courses – you can pick and choose the elements that match the needs of individuals in your organization. Remember though, if you want to deliver the same message to a larger group, it may be more time and cost effective for us to come to you. We can customize any of our courses to your needs, and in many cases deliver them in your own language – this is just one of the benefits that come with being part of NSF.

Contact us now and see how our history can help shape your future.
We apply our expertise in GMP gap analysis, risk management and expert training to ensure your staff know what they don’t know. We help them bridge the gaps, and learn the techniques to improve knowledge management for themselves. We focus on education, not training.

“Very good and in depth course, really thorough.”
Suzanne Moore, RB Healthcare, UK

“This course made me think outside of the usual pattern set by industry standards. It will help me find hidden root causes when solving problems.”
Ivor Kesic, Hospira Zagreb, Croatia

“Very dynamic, we could participate, good exercises”
Michelle Aprelin Alito, Crucell Holland, The Netherlands

Read on for more reasons why other people choose NSF, and details of all our public courses for 2016....
Our quality...

Our objective is to provide the best customized programs of education available. The best venues, the best tutors, the best course material, the best follow-up services. Although client feedback is always excellent we’re never satisfied with the quality of what we do. Each course is better than the year before.

“Really enjoyable. Presentations and material are excellent. Tutors are extremely knowledgeable. The learning techniques that were taught will be of great benefit.”
Adam Brown, Quantum Pharmaceutical

“The duration of the training was suitable, you didn’t have to rush. Very good with extra materials about the different subjects. Very good, understandable and experienced instructors.”
Jens Harry Jespersen, Statens Serum Institut

“Excellent update. Brief overview, well delivered as always.”
Anne Moore, Fleet Laboratories (DDD) Ltd

Our tutors...

Each tutor has in excess of 20 years’ experience. They understand your challenges and frustrations and ensure you leave each course with your questions answered, your problems solved and your frustrations removed!

“Best part of the course is the tutors’ knowledge and enthusiasm.”
Julie Hocking, BCM Specials

Our course content...

“Practical sessions were good and greatly facilitated understanding.”
Conrad Bosch, The Specials Lab

“I experienced the course as very balanced. Although the amount of information was substantial, the manner of the tutors made it easy to keep my attention to the presentations. The interaction with other attendees was really helpful”
Ruud Litjens, Sanquin Plasma Products

For more detailed information on any of our courses please contact us on +44 (0)1751 432999 or pharmamail@nsf.org
Your recommendations...

“Course was recommended by a colleague as very good and I was not disappointed. Very well structured, nice length of topics and delivered by very knowledgeable presenters making it very clear, with nice touch of humour. Really enjoyed it. Likewise would thoroughly recommend course. Thank you!”
Siobhan McKinney, Chesapeake Pharmaceutical & Packaging Ltd.

“NSF live up to their formidable reputation!”
Christopher Levick, Ipsen Biopharm

“Great overall outline of GMP. Enjoyed the course and the instructors. I would recommend it to all my colleagues at all levels.”
Stephanie Williams, Moorfield Pharmaceuticals

Value for money, time well spent...

Many of our clients keep coming back because they see the return on their investment. They leave with the knowledge and confidence to improve things in the workplace as well as improve their career prospects for the future.

“Instructors’ knowledge really showed, enjoyed the entire course and provided me with a good assessment of what I have learned in the IMP world.”
Damian Larrington, Allergan Europe

“Really enjoyed course – good mix of information and practical application.”
Arlene David, Scottish National Blood Transfusion Service
What can I expect?

Whichever course you select, we guarantee you will think differently afterward. We pride ourselves in providing education that adds value to your company and makes your life easier so you get a return on your investment. We want your experience to be educational, fun and career transforming. This is why so many of our clients come back time and again. Here’s what you will experience:

**Painless administration!**

From registration to payment – we keep it really simple. We also keep in contact with you every step of the way so you know what’s going on.

**Pre-course information to whet your appetite**

You will receive details of the venue, how to get there, and the educational program and objectives. We are also available to answer any questions you have.

**The course**

We believe you only learn if you’re having fun. We work hard to create a relaxed and informal environment so you feel at home straight away. Once you’ve got to know your fellow delegates we ask you about your own learning objectives and problems you want answers to. Our tutors then customize the course to ensure your personal needs are met in full. As for the tutors: well, our delegates tell us they are the best. ‘Experienced’, ‘extremely knowledgeable’ ‘inspirational’, ‘always approachable and available’ is the feedback we get. High levels of interaction, problem solving exercises and case studies all help to embed new skills and learning. You also leave with model answers to all case studies, comprehensive course notes, all the slides …and a smile on your face!

**After the course**

*(we see your attendance as just the beginning of our relationship)*

We send you pictures of the flip charts you generated from the problem solving exercises, which provide invaluable, additional learning. We want you to stay in touch with your fellow delegates, your new ‘network’. You will receive their email addresses and the group photograph to help. Access to free advice from our consultants, free webinars for selected courses and additional reference materials all help to round off the experience. You will also receive our free Journal, a ‘must read’.

For more information about our courses, contact pharmacour@nsf.org or visit our website at www.nsf.org.
What do I do next?

Our commitment is to YOUR career development, not only during a course, but afterwards as well. We are happy to answer any questions you may have, whether it’s related to the course you’ve just done or what your next steps should be. Frequently a delegate’s first question after a course is “That was great, but what should I do next?”

Our career path icons will help you select courses which would logically fit together, or which former delegates have linked and found useful. On the following page the courses are grouped together under these icons, and the icons are repeated at the top of each course listing for easy reference.

For example:

> If you’ve just completed Pharmaceutical GMP, you might want to consider Quality Management Systems as the next stage; GMP also meets the Prior Knowledge Requirements of the QMS Pharmaceutical Lead Auditor course.

> Some QP modules have a value to trainee QPs, as CPD for existing QPs, and as follow-up training for technical leaders/auditors throughout the industry.

The choice is yours – you can do any of the courses in any order, but the icons will guide you towards a coherent set of skills which will help you in the workplace.

Remember that we’re on hand to help with your decision. Our tutors are always happy to talk to individuals about their personal requirements and make suggestions about best ways forward.

Our Career Path Icons

- Active Pharmaceutical Ingredients/Excipients
- Qualified Person Training (EU)
- Audit/Self-Inspection
- Quality Management Systems
- Biopharmaceuticals/Biotechnology
- Risk Management
- Clinical Trials/Investigational Medicinal Products
- Senior Management
- Good Manufacturing Practice
- Statistics
- Laboratory Management/Quality Control
- Sterile Products
- Pharmaceutical Law/Regulatory Affairs
- Supply Chain and Distribution
- Pharmaceutical Manufacturing

For more information about our courses, contact pharmacourses@nsf.org or visit our website at www.nsf.org.
# Our Training Courses by Topic

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Reserve your place today [pharmacourses@nsf.org](mailto:pharmacourses@nsf.org)
Qualified Person Training

There are 12 modules in our QP Series – these are open to trainee QPs, and to those wanting top quality CPD. The program runs over two years; the modules taking place in 2016 are listed below.

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Active Pharmaceutical Ingredients (QP Module)

About This Course
This course gives a unique insight into the regulatory expectations associated with producing both chemically synthesised APIs and biological/biotech APIs. Delegates will practice interpretation of the key API regulations and see them in operation during visits to two API manufacturing facilities.

This course fulfils the requirements of the Qualified Person Study Guide. The course also provides insight and expertise on managing global API supply chains, vendor quality assurance and ‘how to audit’ API facilities.

Benefits
As API supply chains become ever more diverse and cost pressures more acute, the pharma manager needs a keen appreciation of risk factors, design, control and monitoring of API sources. This course allows delegates to manage risk across a range of API processes, indicating the most appropriate and proportionate actions to take to mitigate any areas of concern.

It provides practical guidance on the key responsibilities of the Qualified Person when approving a GMP declaration, how to meet 2004/27/EC, how to manage change of API source, how to audit and how to provide oversight of remote or contract manufacturing capabilities.

Course Outline
This course includes:
> Comparison and contrast of chemically and biologically produced API facilities to EU and US regulatory requirements
> How GMP is implemented across the key production processes from critical starting material or seed lot onwards
> Common sources of GMP non-conformance and adulteration or misbranding risks
> Vendor assurance, management of supply chains and auditing of facilities by QA or QPs (including API GMP declarations) – scope, execution and follow-up of audits
> Visits to state of the art facilities and discussions with onsite pharma professionals

Other information
Note that this course can be tailored to suit your operation and brought on-site.

Your Tutors
John Johnson
Peter Monger

A-Z of Sterile Products Manufacture

About This Course
This course is one of our ‘best sellers’ and is fully subscribed year on year.

Why A to Z? We cover everything from Air changes to Z values! Utilizing a range of team based exercises, videos, models and team challenges, we make sure every delegate has a grounding in the principles and practice of sterile processing. In addition, we present the key EU and US regulations, how industry interprets them and how the Inspectorate audits to them! More than half of the course is devoted to tackling common industry concerns, identifying and mitigating risks. Our tutors are expert in this field and have the ‘scar tissue’ that comes from working in this challenging area of pharma manufacturing. Bring along your concerns and take away practical knowledge that helps you to enhance the quality and safety of your formulations (and reduce costs).

This course is a useful supplement to your Qualified Person training – adding detail and science to your knowledge.

Benefits
Quality assurance of sterile products, even with 21st century automation, often depends on the education, decision-making and behaviors of people. This course explores how our knowledge can make or break a steriles supply chain and how the correct design, effective validation, and proportionate science based controls determine our ability to control product quality.

This course is highly interactive. We bring the ‘factory into the room’ via models, videos, props and scenario based exercises so that delegates learn perspective when dealing with common quality issues. They will bring back a proportionate risk based approach to identifying and mitigating risks. We help them see what to do and why, and what to avoid and to what benefit (quality, delivery and cost).

Other information
Note that this course can be tailored to suit your operation and brought on-site, and makes up a suite of related courses.

Your Tutors
John Johnson
Darren Jones
Richard Funnell

Date/s Location/s
12-16 September 2016 Newcastle upon Tyne
18-21 April 2016 Manchester
3-6 October 2016 Amsterdam

Reserve your place today e pharmacourses@nsf.org
Data Integrity Defined

About This Course
Data integrity is a ‘hot topic’ for both EU and FDA regulatory inspectors. Problems with data integrity which have resulted in vigorous regulatory actions such as import bans and recalls have been identified at finished product and API development and manufacturing sites around the globe. The consequences of receiving a citation for a data integrity problem can be catastrophic!

This course is designed to provide you with an overview of what is meant by data integrity so that you understand how to comply with the expectations of regulatory authorities and build a robust data management system.

What You Will Learn
> What is meant by ‘data integrity’
> The current EMA, FDA and MHRA expectations for data integrity
> A review of common data integrity examples for paper and electronic systems
> How to try to distinguish between genuine errors and fraudulent activity
> The importance of company culture in building a robust data management system

Who Should Attend
This course is essential to anyone who operates within a pharmaceutical quality system or who conducts audits of pharmaceutical manufacturers or their suppliers.

Your Tutors
Pete Gough, who has over 40 years’ experience with data management and laboratory quality systems
Darren Jones, who is a former MHRA Inspector

Data Integrity in QC Chemical Laboratories

About This Course
Quality Control (QC) laboratories provide the data upon which critical decisions, such as batch release and the stability of product, are based. If the laboratory data is incorrect then decisions may be wrong with potentially disastrous consequences for companies and patients. Unfortunately, a significant proportion of recent regulatory inspection issues with data integrity have related to data generated by QC laboratories.

This course is designed to provide you with the necessary skills and understanding of how chemical QC laboratories should manage the generation, analysis, reporting and storage of data. It will also ensure that you can include checking for evidence of both effective data management and data fraud during chemical QC laboratory audits.

What You Will Learn
> The elements that make up an effective data management system within a QC laboratory
> How each element of the QC laboratory management system should support data integrity:
  ♦ Documentation
  ♦ Sampling and sample management
  ♦ Laboratory equipment
  ♦ Analytical methods; validation, verification and transfer
  ♦ Chromatography and integration
  ♦ Out of Specification and Out of Trend results
> How to audit QC laboratories to ensure compliance with data integrity expectations

Who Should Attend
This course will be ideal for personnel who work within a chemical laboratory or who wish to learn how to conduct comprehensive audits of QC chemical laboratories.

Your Tutors
Pete Gough, who has over 40 years’ experience with data management and laboratory quality systems
Oona McPolin, who is an expert in laboratory data analysis
Free QP Seminar for Prospective QPs & Sponsors

About This Free Seminar
With credibility as the top trainer of Qualified Persons since 1990, NSF and the University of Strathclyde have collaborated to bring a unique modular training program to the global pharmaceutical industry.

Your Chance To …
> Have all your questions answered
> Fully understand the path to QP
> See the exceptional and unique reference material available to delegates
> Meet with the NSF QP support team to have individual questions answered
> Meet former delegates, sponsors, a current or former QP assessor
> See a course in action – meet current QP delegates
> Talk about the free gap analysis

Benefits of the NSF QP program
> MSc level training with an industrial perspective
> Access to world class tutors and experts
> Develop individuals to be the best QP they can be – confident, knowledgeable decision makers
> More than meets the requirements of the UK QP study guide
> This training is so valuable it is used across Europe and globally
> A course that gives you the time to grow to be the best
> Complete education documentation building to a full library of lifelong reference materials across the QP modules
> Gap analysis and gap analysis tools to create your own personalized experience and training plan
> Honest feedback – is QP training right for you?
> Personal tutor system: always contactable
> Non-technical QP skills training
> Viva prep sessions
> Revision interview: a chance for you and your sponsor to confirm with the experts if you are ready to apply for assessment
> Guidance with the application form

Who Should Attend
> Potential QPs hungry for information about the best training to become an effective QP
> Sponsors seeking guidance on selection and supporting QPs through the QP development process

Your Tutor
Mike Halliday

GMP for Biological and Biotechnology Products

About This Course
This course reflects the emerging importance of innovative biopharmaceuticals in the world healthcare market. Growth often outstrips regulation, so learn how a bioprocessing unit remains in step with a rapidly transforming set of regulatory expectations, make certain your quality system evolves and ensure perpetual GMP inspection readiness for your facility. Regulatory action and discontinuation of supply can cause catastrophic revenue losses in this high risk sector, so how can you assure supply, reduce GMP risks, reduce product losses and improve yields? This course shows how – using case studies, team based exercises and discussion of common causes for concern.

If you are a trainee QP in this field, this course is a useful supplement to your Qualified Person training plan.

Benefits
Delegates will gain insight into the identification, interpretation and mitigation of risk across a typical bioprocessing train, ensuring that proportionate oversight is applied to the areas of highest risk. Using illustrations of how the regulatory expectations are interpreted in practice, delegates will be able to critique and modify their quality system to suit the biotech sector. Also delegates will sharpen their skills on 'how to audit' bioprocessing facilities, manage contracted out processes and tackle common GMP non-conformances.

Course Outline
> EU and US regulatory expectations, industry best practice and the QMS across biofacilities and various bioprocesses
> Design, management and monitoring of biopharma clean rooms
> GMP expectation associated with the control of seed lots, expansion, cultivation, harvest, purification and viral assurance
> GMP expectations associated with in process, stage and drug substance QC testing
> How biosimilars are manufactured and the key challenges involved
> How to audit biopharma facilities to reduce risk – scope, execution and follow-up of the audit

Your Tutors
John Johnson
Roger Guest

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<td>York</td>
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<td>Manchester</td>
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Human Error Prevention

About This Course
If you think human error is the real cause of your quality problems then think again! It isn’t. Human error is only the symptom, never the cause. It is the starting point of your investigation, never the conclusion.
Over the last 5 years delegates from over 245 companies and from at least 4 regulatory agencies have attended this course. All have gone away with very practical tools and techniques to help reduce so-called ‘human error’. Remember, error reduction will potentially save you millions and protect you from severe regulatory action. You will go away with the tools needed to reduce errors, protect your business and drive continuous improvement.

What You Will Learn
> Best industry practices: how the best companies gain regulatory and commercial advantage from reducing human error
> The psychology of human error: why do we all make mistakes?
> That human error is only the start of any investigation, never its conclusion
> The anatomy of problems and mistakes and why these are due to multiple contributing factors, never a single root cause!
> How to design processes and procedures to reduce human error
> Practical guidance on how to drive out complexity at every level…. for good
> How to build in reliable ‘system safeguards’ to detect mistakes early on
> How to ‘error proof’ processes and procedures

Your Tutors
Martin Lush
Darren Jones

Investigational Medicinal Products (QP Module)

About This Course
On this highly interactive course you’ll learn from former IMP expert instructors, QPs and current consultants, focusing on quality systems and the GMP/GCP interface from the Qualified Person or quality leader’s perspective. We look at the QP’s duties and the challenges presented when it comes to protecting trials, volunteers and patients.

Benefits
> Explains the new regulations and requirements of the QP
> More than meets the QP study guide requirements for IMPs
> Essential training for QPs or others in clinical trials supply
> MSc level training with a real industrial perspective
> Access to tutors with credibility who bring years of knowledge in IMP, MHRA and consulting to explain and answer your own questions
> Talk to expert tutors to understand what the regulators and inspectors look for
> A chance to prepare for and improve your next inspection or IMP audit
> Essential for those auditing IMP operations on behalf of a QP
> Clearly defines QP duties
> Explains IMPs and FMD, validation
> We don’t just train you to pass a viva – we take the time to prepare you to excel
> Our detailed educational documentation, which grows into a lifelong reference library.
This course can be brought on-site to reach a wider internal audience of QPs and those who support QPs.

Your Tutors
Liz Allanson
Darren Jones
Richard Funnell
Managing Cost of Poor Quality
Combining business excellence and GMP compliance

About This Course
As a leader in your organization, you are tasked with one distinct priority. That priority is to detect and tackle business risk and utilize the right resources to mitigate that risk to an acceptable level. Our highly acclaimed NSF courses associated with ICHQ9 quality risk management deal with the former, but how do you ensure that you are clear on what resources you need, where they are expended and whether you are getting a return for that cost? Inadequate placement of finite and often diminishing resources is often cited as a root cause for failure to follow cGMP, regulatory citation, and acts as a barrier to business growth. Companies compete for the best staff but then how are those staff developed, deployed and kept engaged with meaningful, value-adding tasks? One of the chief reasons for staff turnover is a lack of personal development and at the heart of this is often the fact that the individual's skills have been misplaced or misused. So as a leader, how do you ensure your biggest asset (and cost) is best deployed?

What You Will Learn
Studying the reasons for poor quality and being able to quantify the cost of adverse situations and defaults begins with the process of using the language your Board members understand – bottom line cost. And taking care of the bottom line and ensuring the organization seeks to detect, quantify and minimize costly defaults or non-value adding activities is crucial to your company’s long term business plan.

Using a mixture of real life examples, COPQ tools and interactive case studies, the course is pivotal in helping you develop a strategy that drives organizational change, business excellence and cost reduction, whilst ensuring no risks to cGMP or product quality.

Your competitors know that their best (and costliest) asset is people; and ensuring accurate and agile staff deployment (alongside the prevention of concerns on yield, batch disposition and market withdrawal) is central to running a long term, successful pharma business.

Your Tutors
John Johnson
Frank Dollard

Date/s Location/s
10-11 November 2016 Manchester

Medicinal Chemistry & Therapeutics (QP Module)

About This Course
Originally designed for the QP, this course is essential knowledge for Qualified Persons and all those working with pharmaceuticals. Demystify the reference material, from patient information leaflets to data sheets. This intensive course will provide you with an understanding, and break through the terminology.

> How the body works – what goes wrong – how therapies work
> Covering the most commonly prescribed therapeutics on the market today
> 5 days of interactive, detailed, case study based education
> Essential knowledge to help understand reference material and make decisions, covering cross contamination risk, product risk, patient risk, quality and operator risk and facility design

Benefits
> The body, how it works and what goes wrong, from cells to key body physiology
> Major therapeutic areas: central nervous system, heart, respiratory tract, inflammatory disease, GI tract
> Drug therapy – receptors, autonomic nervous system and other drug targets
> Cleaning and risk based cross-contamination avoidance
> More than meets the QP study guide requirements
> MSc level training with a real industrial perspective
> Essential training for QPs and those considering the patient’s needs
> Access to expert tutors from one of the top schools of pharmacy in the UK
> Delegate presentations of currently marketed products
> Your questions answered
> We don’t just train you to pass a viva – we take the time to prepare you to excel
> Our detailed educational documentation, which grows into a lifelong reference library

This course can be brought on-site to reach a wider internal audience of QPs and those who support QPs.

Your Tutors
Mike Halliday
Chris Prior

Date/s Location/s
14-18 November 2016 York

Reserve your place today e pharmacourses@nsf.org
Modern Process Validation

About This Course
EU and US expectations for process validation and equipment qualification have changed dramatically in the past 5 years. The 2011 FDA and the 2014 EU CHMP Guidance on Process Validation, and the 2015 EU GMP Annex15 have all introduced a new approach to process validation and equipment qualification.

Join us on this course to ensure that you understand the very latest requirements for the design, execution, assessment and reporting of process validation studies, and learn how process validation can bring added value through product quality assurance.

We will look at modern approaches to process validation, looking fundamentally at the whole validation concept as defined in recent EU and FDA guidance. We will explain how process validation must link to patients’ needs and the regulatory requirements, using tools such as risk management, statistics and change management to accomplish this. We will show how this modern approach can add real value to your business and provide better protection to patients.

You will also learn how to apply these concepts to existing processes with beneficial results.

What You Will Learn
> Practical application of the new FDA and CHMP Process Validation Guidance and the revised Annex 15
> How validation activities link the patient’s needs to the product and the associated manufacturing process
> The new EU and FDA regulatory expectations for process validation, including qualification and validation requirements
> How to develop a strategy for process understanding for both new and existing products that will link to process validation
> How to plan, design, execute and document qualification and validation activities
> The tools that can be used during process validation; e.g. risk assessment and statistical tools

Course Outline
> The concept of process validation
> Modern regulatory expectations
> How to gain process understanding
> Process performance qualification
> Facility design and qualification of equipment and utilities
> Change management

Your Tutors
Bruce Davis
Line Lundsberg

Date/s Location/s
7-9 June 2016 Manchester

Pharmaceutical GMP

About This Course
Pharmaceutical legislation requires initial and ongoing training in Good Manufacturing Practice (GMP).

This course covers key sections of the ever changing EudraLex Volume 4 to provide a thorough understanding of the essentials of GMP.

Benefits
Europe’s most popular GMP course!
> Tutors with real credibility and experience to bring GMP to life with examples and real life stories
> Hundreds of delegates each year attend our public and on-site versions of this highly popular course
> This course repeatedly achieves the highest customer satisfaction level of any of our courses, with 95% of delegates rating it ‘very good’ or ‘excellent’
> This course meets the entry level GMP training requirement for our very popular Pharmaceutical Quality Management Systems Auditor/Lead Auditor Training Program
> Very interactive and a fun approach to gaining a good working knowledge of a broad subject
> Training designed to reach all learning styles and preferences
> Bring your questions and have the free consultancy of tapping into great experience from helpful tutors
> Fantastic detailed reference material to take away and to become instantly useful
> A great start to careers as auditors, QP, senior leaders and decision makers
> Delegates often move on to the modular QP, MSc level program
> Latest updates provided
  * Essential to new starters and those in the first 5 years
  * Ideal for experienced staff changing roles to work in a GMP environment
  * Experienced staff benchmarking current trends

This course can be brought on-site to reach a wider internal audience.

Your tutors will be drawn from the following:
Liz Allanson
Rachel Carmichael
Mike Halliday

Date/s Location/s
4-7 April 2016 Manchester
21-24 November 2016 Amsterdam

† +44 (0) 1751 432 999  w  www.nsf.org/info/pharma-training
Pharmaceutical GMP Audits and Self-Inspections
(An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)

About This Course
This highly interactive course takes the form of a mock or virtual audit. It assumes experience and working knowledge of GMP guidelines in the region where the auditor is working (EudraLex Volume 4 or US CFR 21), or previous attendance at an NSF Pharmaceutical GMP course.

Benefits
We all face increasing pressure to audit more with less. This course provides…

> A toolkit of auditing skills designed by pharmaceutical auditing experts for Pharmaceutical Quality Management System Auditors
> Expert advice/experience and clinics for your auditing concerns
> The GMP context for Pharmaceutical Quality Management System Lead Auditors
> Tutors with credibility; they include very highly regarded former inspectors and Pharmaceutical Lead Auditors with a wealth of experience
> Superb success rate for students
> Unparalleled support and reference material for delegates
> Personal assigned tutor to maximize your learning experience and exam opportunity
> Essential guidance for auditors of suppliers, contractors, CMO, service providers, outsourced activities and self-inspectors
> Essential education and development for QPs, those auditing on behalf of QPs and external and internal auditors wishing to improve
> Essential training for those who need to demonstrate suitable experience and training to inspectors
> This course meets the training requirements for the IRCA (www.irca.org) Certification of Pharmaceutical Quality Management Systems Auditor/Lead Auditor (PQMS)

This course can also be brought on-site to reach a wider internal audience.

Your Tutors
Learn from some of the most experienced auditors in the industry. Tutors will be drawn from:

Mike Halliday
David Selby
Liz Allanson

Darren Jones
Rachel Carmichael

Date/s Location/s
1-5 February 2016 Manchester
16-20 May 2016 Manchester
19-23 September 2016 York
31 October – 4 November 2016 Amsterdam

Pharmaceutical Law & Administration (QP Module)

About This Course
Pharmaceutical law and administration is a key foundation knowledge requirement for all Qualified Persons – this is clearly spelled out in European Directives and Regulations. The QP must ensure that relevant laws are being complied with; therefore, a thorough understanding of the laws and legal processes within Europe and beyond is essential. This is equally true for other pharmaceutical technical managers.

Benefits
> A deep and detailed understanding of:
  ♦ Why we have medicines laws and what they seek to achieve
  ♦ The laws and legislative processes within the EU which impact on medicinal products, and hence the role of the QP
  ♦ The UK medicines legislative framework
  ♦ US and other international pharmaceutical legislation
  ♦ Other relevant laws and guidelines
> Fulfill the requirements of the Qualified Person Study Guide
> Our QP education is considered the most comprehensive and professional in existence today, with a UK viva pass rate of 96% and a QP alumni group available to former students to maintain their knowledge in this area
> We don’t just train you to pass a viva - we take the time to prepare you to excel

Course Outline
European Medicines Legislation
> EU Directives and Regulations affecting medicines
> Organization and function of EMA
> Importation into the EU and distribution within the EU (wholesale dealing)
> Powers of the licensing authorities and adverse licensing reports

UK Medicines Legislation
> MHRA and VMD

Other Relevant Legislation
> US legislation and FDA
> International Conference on Harmonization (ICH)
> PIC/S
> Medical devices

Your Tutors
Liz Allanson
Rachel Carmichael
Pete Gough

Plus a guest speaker from the MHRA

Date/s Location/s
17-21 October 2016 York

Reserve your place today e pharmacourses@nsf.org
Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel

About This Course
Pharmaceutical legislation and regulatory authority guidance are continually changing. These changes to legislation and guidelines, and the interpretation of them, can have significant implications for companies. Many changes require detailed planning to implement and failure to do so can result in serious compliance problems.

This is the continuation of a very successful series of one-day seminars that are designed to form part of your Continuing Professional Development.

What You Will Learn
The current interpretation of recent and proposed changes to:
- EU legislation; Directives and Regulations
- EU GMP; Chapters and Annexes
- International guidance
  - ICH, PIC/S, WHO
- US legislation and FDA guidance
- UK MHRA requirements and processes

Who Should Attend
- Quality Assurance personnel, in particular Qualified Persons
- Other technical/managerial personnel responsible for the manufacture and testing of APIs and medicinal products

Your Tutors
Rachel Carmichael
Pete Gough

Pharmaceutical Packaging (QP Module)

About This Course
Why is packaging still the greatest source of recalls?
As a QP you must understand your risks, vulnerabilities and obligations and keep current with changing legislation and requirements.

This interactive course covers all important aspects of the packing process, from selection of suitable components, pack design, packing processes and their associated GMP and QMS challenges. This course provides a detailed review of the supply chain from starting components to patient. Design your ideal packing department and then get inspected! Take back to your workplace ideas for improvement.

Led by highly experienced industry experts and QPs and current consultants with support from academic staff from one of the UK’s top schools of pharmacy.

Key industry speakers and essential site visits down the supply chain.

Benefits
- Learn how to avoid the recalls experienced by others
- Find out what the regulators worry about
- GMPs explained in a pragmatic and cost effective way
- Understand what is changing in legislation, expectation and requirements; keep up to date
- FMD, serialization and implementation
- More than meets the requirements of the QP study guide
- MSc level training with a real industrial perspective
- Essential training for the QP
- Essential training for those suffering recalls related to packing operations
- Access to tutors with credibility and years of knowledge
- Your questions answered by knowledgeable, friendly and approachable tutors and guest speakers
- Clearly defines QP duties and challenges
- Numerous interactive scenarios, team works, buzz groups and discussions
- Practice decision making for the QP and Quality leader and packing supervisor and manager

We don’t just train to pass a viva – we take the time to prepare you to excel.

Our detailed educational documentation grows to a lifelong reference library.

This course can be brought on-site to reach a wider internal audience of QPs and those who support QPs.

Your Tutors
Samantha Clack
Erika Notman
Gary Rees

Date/s Location/s
7 April 2016 Manchester
4 October 2016 Manchester
18-22 January 2016 York

Scan this code to view our courses online

+44 (0) 1751 432 999 www.nsf.org/info/pharma-training
QP Alumni

A Family of QPs – 10th Annual QP Alumni Meeting

About This Course
The NSF QP Alumni is a not for profit body run by past delegates for the benefit of QPs, to provide Continuing Professional Development and a forum for discussion, exchange of ideas and support.

Membership (currently at some 390) is by invitation only, and available to those delegates classed as core delegates for the QP training program. This is typically those who have attended 4 or more QP modules.

Benefits
> Annual meeting including CPD and an opportunity for networking and benchmarking with fellow QPs
> Meeting with regulators and opinion leaders
> Sharing best practice
> Debating the impact of new legislation
> Influencing strategies for regulators, QPs and the industry
> Legal updates
> Technical updates
> Qualifying CPD
> Soft skill enhancement

Date/s Location/s
9-10 June 2016 York

QP Practical Module (QP Module)

About This Course
In today’s pharma world it is a challenge for QPs and prospective QPs to gain a functional understanding of the equipment and processes used to manufacture and test today’s dosage forms.

This course provides hands-on experience for trainee QPs wishing to gain better understanding of what really happens in manufacturing and testing.

Share knowledge with industrial and academic experts, solve real life QP problems.

Benefits
> Totally practical, hands-on lab based training at one of the top schools of pharmacy in the UK
> MSc level training with a real industrial perspective
> Understanding the ‘why’ behind the pharma industry processes
> Getting closer to products than is possible in a GMP environment
> Find out what’s really important for your starting materials; use this knowledge to help with your risk based supplier management programs

Course Outline
> Sterile Products
> Tablets
> Bioprocessing: from raw materials to final product
> Analysis

We don’t just train you to pass a viva – we take the time to prepare you to excel.

Your Tutors
Oona McPolin
Erika Notman

Date/s Location/s
9-13 May 2016 Glasgow

Reserve your place today e pharmacourses@nsf.org
**Quality Management Systems (QP Module)**

**About This Course**

The quality of your products depends on the quality of your people and the effectiveness of the Quality Management System. Properly functioning, your QMS should be your Business Management System and should drive continuous improvement and cost saving.

As Qualified Persons (QPs) and quality professionals, you can’t certify or release products and stay in business unless your QMS is in control.

> How to handle supply chains of increasing complexity
> How to do more with less
> Your questions answered
> Simplify your QMS to improve speed and flexibility

This highly interactive course will enable you to decide if your QMS is fit for purpose and working well, or if not, what to do about it!

**Benefits**

> More than meets the requirements of the QP study guide
> MSc level training with a real industrial perspective
> Essential training for the QP
> Essential training for anyone who owns part or all of the QMS
> Invaluable oversight for senior leaders
> Defining what is a QMS and what is covered by the QMS
> Confirming it is fit for purpose and working well
> Sharing industry norms and best practices
> Access to tutors with credibility, drawing on years of knowledge to answer your questions
> Interactive scenarios, QP problems to solve, team works, buzz groups and discussions
> Practice in decision making
> Meet the requirements of Annex 16 and other key EudraLex chapters and annexes

We don’t just train you to pass a viva – we take the time to prepare you to excel.

Our detailed educational documentation grows to a lifelong reference library.

This course can be brought on-site to reach a wider internal audience of QPs and those who support QPs.

**Your Tutors**

David Selby
Liz Allanson
Rob Hughes

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<tr>
<th>Date/s</th>
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<tr>
<td>14-18 March 2016</td>
<td>York</td>
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**Rapid Change Control**

**Pure and Simple**

**Your Challenges**

> Your world is changing every day. New products, procedures, equipment, ways of working. Change, change and more change!
> To survive, your change control system must be simple, fast and effective. A slow, bureaucratic and complex system is not good enough. The longer your change control SOP, the more dangerous it is. More than 5 pages? Think again
> If your change control system approves everything it’s not working
> If your change control system takes longer than 30 minutes to review and approve a routine (non-regulatory) change, it’s simply not good enough
> Research confirms that up to 80% of ‘approved’ changes fail to deliver any lasting benefit
> Your business depends on hundreds of third parties. Do you sleep easy at night confident their change control system is fit for purpose?
> The change control systems of third parties are rarely audited (challenged) rigorously enough
> Getting people enthused and motivated about change control!

**What You Will Learn: The Solutions You Will Leave With!**

> How to review and approve changes within minutes, not hours
> How to use your change control system to STOP unnecessary change so you can focus on the 20% of changes that matter
> How to ensure that approved changes are implemented correctly and add value
> How to control change with your third parties so you can sleep easy at night
> How to audit change control systems properly
> The measures you can use to prove your system is working
> How to make people smile with enthusiasm when they talk about change control!

**Who Should Attend?**

Change control is a key business system that must be owned by all. This course will appeal to anyone who interfaces with your change control system. Manufacturing and Engineering, QA and QC, Regulatory and those involved in auditing and managing third parties. Whether involved in the manufacture of licensed products or those destined for clinical trials, this course is for you.

**Your Tutors**

Rob Hughes

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<tr>
<th>Date/s</th>
<th>Location/s</th>
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<tbody>
<tr>
<td>30 June – 1 July 2016</td>
<td>Manchester</td>
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† +44 (0) 1751 432 999  www.nsf.org/info/pharma-training
Risk-Based Decision Making for Quality Professionals and QPs

About This Course
This course focuses on how to make the right quality decision in tough situations with limited information, short deadlines, and high pressure.

Utilizing a range of scenarios across the common pharma dosage forms, the course is jam-packed with real-life GMP non-conformances, product quality concerns, customer complaints, change control requests, ‘uncontrolled’ variations, potential market actions and field alerts – helping you to see how to make more effective risk-based decisions at your workplace.

Life is rarely black and white, and it is those situations in the grey zone where your powers of risk identification, risk assessment, prioritization, execution and post-event verification are really tested.

Taking a structured approach to decision-making is critical in proposing the best ‘next steps’ and on this course you will spend time practicing a proven approach, evaluating your decisions and learning how to deal with a range of issues that challenge the quality attributes of pharma products.

Benefits
Hindsight tells us that the wrong decision (or no clear decision!) at the wrong time can make or break a company or its supply chain. Some scenarios may only present themselves once or twice in a career, so attending this course concentrates a range of tough scenarios into two intensive days where we present some proven tools and then work alongside you to resolve several typical product quality issues. We help you to see bias and distractions, help you to see the issue through fact and assumption; and help you to develop for yourself tools and expertise that ensure your decision making is well founded.

Poor decision making costs money, destroys reputation and erodes confidence. Make sure your team use the right tools and approach, regardless of the situation being faced.

Course Outline
> Tools and techniques given for effective decision making
> Use of risk registers, FMEA, HACCP, is/is not – all useful but how do you decide which to use for which scenario?
> Decision making checklists and process flows for you to take back to the workplace
> How to turn data into useful information

Your tutors will be drawn from the following:
John Johnson
John Wilkinson
Darren Jones

Date/s Location/s
27-28 September 2016 Manchester

Further dates and venues to be confirmed.

Risk-Based Decision Making in Sterile Products Manufacture

About This Course
Our course is jam-packed with real-life GMP non-conformances, product quality concerns, customer complaints, change control requests, ‘uncontrolled’ variations, potential market actions and field alerts – helping you to see how to make more effective risk-based decisions at your workplace.

Making sterile products is a risky business. When things go wrong making the right decision is tough. The data you rely upon is usually imprecise and often too late. High count from a water system? Settle plate failure in class 100? HVAC pressures lost? Particulates in product? BI failure on autoclave revalidation? Media fill failure? One day any one of these could be insignificant. On another day either could trigger a costly batch rejection, or even a product recall. This course will transform your decision making abilities so you always make the right call.

Benefits
This course has all the benefits of Risk-Based Decision Making for Quality Professionals and QPs but focuses specifically on sterile products manufacturing, and is intended primarily for experienced pharma professionals in this area.

Course Outline
> Tools and techniques given for effective decision making
> Practice, practice, practice with expert tutors on hand
> Scenarios include OOS investigations, excursions in WFI testing and cleanroom environmental monitoring, elevated pre-filtration bioburden results, anomalies in sterile garment monitoring, media fill non-conformances, process time excursions, issues on visual inspection, validated settings/loading patterns not respected during sterilization (and many more!)

Other Information
Note that this course can be tailored to suit your operation and brought on-site.

Your Tutors
John Johnson
Darren Jones

Date/s Location/s
20-22 June 2016 Manchester

Further dates and venues to be confirmed.

Reserve your place today e pharmacourses@nsf.org
### Statistics for Ongoing Process Verification – Analyzing and Trending Data

#### About This Course
New EU and US GMP process validation guidance is emphasizing the need for ongoing/continued process verification by the trending of data, e.g. EU GMP Annex 15, ICH Q10 and the US guidance on process validation.

The pharmaceutical industry has historically under-utilized statistical data analysis techniques that have been used extensively in many other industries to drive product and process improvement. It is still too often true to characterize the pharmaceutical industry as being data rich but information poor.

Performing the necessary statistical calculations is now relatively simple with a variety of software packages being available to do the ‘number crunching’. However, in order to obtain maximum benefit from the use of these sophisticated statistical software tools it is also vital that the outputs are correctly interpreted.

This course will provide you with the essential understanding of several fundamental statistical tools for analyzing data and enable you to understand what the output from these tools is telling you about your product or process. This, in turn, will give you powerful information that you can use to demonstrate ongoing/continued process verification and to drive quality improvement.

#### What You Will Learn
- How to visualize data
- The concept of statistical confidence
- The common statistical process control tools; such as control charts, process capability and linear regression, that enable ongoing process verification
- How to use statistical software and interpret the outputs
- Where these simple tools and techniques can be used to add value: e.g. to provide ongoing/continued process verification, in Product Quality Reviews, etc.
- Case studies from pioneers who are already using these tools to good effect

#### Your Tutors
Pete Gough  
Chris Harris

#### Date/s Location/s
- **11-12 October 2016**  
  Manchester

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### The Role & Professional Duties of the Qualified Person (QP Module)

#### About This Course
The role and duties of the QP are constantly changing and the revision of EU GMP Annex 16 introduces some significant new expectations. It is, therefore, essential that QPs keep up to date. This course covers these new challenges in detail to help you understand them and their impact.

Of paramount importance is the QP’s ability to focus on the broad issues of managing quality and to bring these issues together in a cohesive way when making decisions to certify medicinal products, so throughout the course you will have the opportunity to test your skills via interactive ‘release or reject’ scenarios.

The course will also include a simulation of a typical UK QP assessment interview as conducted by the three professional bodies.

#### Benefits
- Provides aspiring QPs and other pharmaceutical quality professionals with the knowledge and understanding they need of the QP’s legal duties
- Demonstrates how the QP must work with others to ensure that those duties and responsibilities are performed in the best interests of the company, the patient and society
- Will help you to understand how the QP should work in tandem with professionals in other departments, and will stress the non-technical ‘people’ skills that are essential to being a good QP

#### Course Outline
- The QP’s legal and professional duties
  - Including a detailed review of the revised Annex 16
- QP Code of Practice
- Proposed and recently implemented EU legislation and guidance
- Product certification/release criteria
- Role of the QP in complex manufacturing scenarios
- How to be an effective QP
  - Influencing skills, assertiveness and leadership
- Routes to becoming a QP across the EU and the UK assessment procedure
- Links with other stakeholders

#### Your Tutors
Pete Gough  
Erika Notman

#### Date/s Location/s
- **25-28 July 2016**  
  York
Course Fees

Our prices represent excellent value for money. Our courses are highly interactive and the tutors are on hand throughout to answer your questions, so you’ll be ready to put what you’ve learnt into practice. You will also be provided with comprehensive course materials, which will be an essential reference tool when you return to work.

Please note the separate table for our QP course prices.

### Standard Course Fees

<table>
<thead>
<tr>
<th>Course Duration</th>
<th>2016 Prices</th>
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<tr>
<td>5 days</td>
<td>£2810 per delegate</td>
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<tr>
<td>4 days</td>
<td>£2600 per delegate</td>
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<td>3.5 days</td>
<td>£2240 per delegate</td>
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<tr>
<td>3 days</td>
<td>£1950 per delegate</td>
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<td>2 days</td>
<td>£1500 per delegate</td>
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<td>1 day</td>
<td>£750 per delegate</td>
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### Qualified Person Training Fees

<table>
<thead>
<tr>
<th>Course Duration</th>
<th>QP Series Prices</th>
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<tr>
<td>5 days**</td>
<td>£3350 per delegate</td>
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<tr>
<td>4 days</td>
<td>£2680 per delegate</td>
</tr>
<tr>
<td><strong>except QP Practical Module</strong></td>
<td>£3530 per delegate</td>
</tr>
<tr>
<td>QP Alumni – 2 days</td>
<td>£475 per delegate</td>
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Please note that all prices are in Sterling and VAT is payable where applicable. Please refer to our website, www.nsf.org/info/pharma-training, for full booking terms and conditions.

Discounts of up to 50% are available
If you are booking 2 or more delegates onto the same course, contact us for details.

Reserve your place today email pharmacourses@nsf.org, call +44 (0) 1751 432 999 or visit www.nsf.org/info/pharma-training
Providing you with Solutions across the Product Life Cycle

Whilst being well known as a respected training organization, we also provide a full service of consultancy and auditing. Consultancy can range from answering one question, through to major remediation projects, supporting companies through significant regulatory actions. Auditing can range from contract supplier audits to mock regulatory inspections and audits.

Our objective is to provide you with the best customer service available and to help you achieve your goals. We act in your long term best interest based on good science, expert experience and common sense. We care about our clients, which is why over 87% come back for more.

Education and Certification

Many companies now seek formal certification as an outcome for certain specific training. Through our strategic alliances with key independent third parties, we can bring internationally recognized, independently certified training to your staff on your site:

> Lead Auditor in Pharmaceutical GMP – successful delegates can apply to IRCA for certification as a Lead Auditor
> Internal Auditor – leading to IRCA Certified Internal Auditor for successful delegates; two to three day courses tailored to your needs
> Pharmaceutical Quality and GMP MSc – modular training recognized by the University of Strathclyde which can lead to master’s, diploma or certificate-level postgraduate degrees

See overleaf for detail on some of our most successful on-site courses. If you can’t see exactly you need, we can develop and tailor a course to suit your operational requirements.
YOUR MEDICINES ARE ONLY AS GOOD AS YOUR PEOPLE: THE BENEFITS OF AN ON-SITE TRAINING COURSE

Finance Director:
“What happens if we train these people and they leave?”

CEO:
“What happens if we don’t and they stay?”

Over the last 30 years, NSF Health Sciences (previously David Begg Associates) has become the leader in providing customized education courses. Our objective is simple. Our courses change the way people think and, in doing so, provide an immediate return on investment. For example, fewer rejects, better compliance, better decisions and simpler and faster systems.

The benefits of us coming to you are considerable:

> Content is customized to meet your exact needs and requirements
> You leave with your problems fixed and your questions answered
> No travel or hotel costs
> No time away from home and family
> Less work disruption
> Everyone listens to the same message, creating real momentum for change
> Better return on your investment
> Ongoing support from NSF after the course

Here are some of our most successful on-site courses. For more information, please contact pharmamail@nsf.org or call +44 (0) 1751 432 999

LEADERSHIP, QUALITY CULTURE AND CHANGING GMP BEHAVIORS

> Quality Culture: How to create a culture that improves profit and compliance
> Changing GMP Behaviors: A simple five-step process
> Quality Systems – Best Industry Practices: Find out what the best companies do
> How to Change Quality Habits: Getting people to do the right thing, automatically
> How to Communicate with Senior Management: And not be ignored
> Managing Quality Across Cultures: Understanding the behaviors that drive the actions
> Vital Leadership Skills for the Pharmaceutical Professional: How to make a difference

CONTINUOUS IMPROVEMENT, ERROR REDUCTION AND SIMPLIFICATION

> Human Error – Causes and Prevention: 5 steps to improving human reliability
> Advanced Problem Solving: Taking your root cause investigations to another level
> Reducing Documentation Errors: Pure and simple
> The Art and Science of Simplification: How to remove deadly complexity
> Batch Record Simplification: How to reduce errors and speed up review time
> The Analysis and Trending of Data: Using your data to drive improvement

REGULATORY COMPLIANCE, INSPECTIONS AND DATA INTEGRITY

> EU GMP and Inspection Readiness: How to succeed on the day
> FDA GMP and Inspection Readiness: How to succeed on the day
> Thinking Under Pressure: How to make the right decisions no matter what
> Warning Letters: Causes and prevention
> Regulatory Crisis Management – Best Industry Practices: What to do when things go wrong
> Data Integrity: How to manage DI issues and prevent them in the first place
> Regulatory Update: What new regulations are coming and how to interpret them

For more information, please email pharmamail@nsf.org or call us on +44 (0) 1751 432 999.
> Pharmaceutical Law: A no nonsense, practical interpretation of pharmaceutical regulations

**PLANT AND UTILITIES**
> The A-Z of Pharmaceutical Water Systems: Everything you ever wanted to know
> The A-Z of HVAC Systems: Everything you ever wanted to know
> Good Autoclaving Practices: The control and management of your autoclaves
> GMP for Engineers

**MANUFACTURING PROCESSES AND SYSTEMS**
> The A-Z of Sterile Product Manufacturing
> Process Simulations and Media Fills: Best-in-class practices
> GMP for Biotechnology Products
> The A-Z of the Manufacture of Tablets and Capsules
> The A-Z of the Manufacture of Liquids, Creams and Ointments
> The A-Z of the Manufacture of Metered Dose Inhalers
> Pharmaceutical Packaging: Minimizing risk in this high-risk area
> Modern Approaches to Validation
> Computer System Validation: The essentials

**QUALITY SYSTEMS AND GMP**
> The A-Z of Quality Management Systems
> Pharmaceutical GMP: How to excel at the doing the basics
> Deviation and CAPA Systems: How to prevent repeat incidents – five easy steps
> Rapid Change Control: How to review and approve changes in minutes
> Customer Complaints – Management and Control: Best industry practices
> Product Recalls – Management and Control: Best industry practices
> Good Documentation Practices: How to create documents people can use
> Product Quality Review: Using data to drive continuous improvement
> The Cost of Poor Quality: Improving margin by reducing waste
> Annual Product Quality Reviews: Using APRs to drive continuous improvement

> EU GMP Requirements for Clinical Supplies Manufacture
> Good Distribution Practices: How to keep your product fit for purpose
> The Management and Control of Third Parties: Best industry practices
> Training Effectiveness: How to improve the effectiveness of your training programs
> Key Performance Indicators: Selecting measures that tell the truth and drive improvement

**QUALITY CONTROL AND LABORATORY ACTIVITIES**
> Good Control Laboratory Practices: The chemistry lab
> Good Control Laboratory Practices: The microbiology lab
> Out of Specification Investigations: Best industry and regulatory practices
> Ongoing Stability: Regulatory and best-in-class practices

**RISK MANAGEMENT AND RISK-BASED DECISION MAKING**
> Risk-Based Decision Making: How to make the tough decisions
> Risk-Based Decision Making in Sterile Product Manufacture

**CONTROL OF CROSS-CONTAMINATION (CHEMICAL AND MICROBIOLOGICAL)**
> Cleaning Validation: Science based, pragmatic, pure and simple
> Pharmaceutical Microbiology for the Non-Biologist: Demystifying the “black art”
> Risk-Based Approach to Environmental Monitoring: Getting the most from your EM program

**AUDIT AND SELF-INSPECTION**
> Effective Pharmaceutical Audits and Self-Inspections: Certified auditor course
> How to Audit – Bulk Biotech Operations
> How to Audit – Sterile Products Manufacture
> How to Audit – Data Integrity
> How to Audit – QC Chemical Laboratories
> How to Audit – Chemical API
> How to Audit – Computer Systems

For more information, please email pharmamail@nsf.org or call us on + 44 (0) 1751 432 999
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Venues used:
- Amsterdam Marriott Hotel, Amsterdam, The Netherlands
- Renaissance Manchester City Centre Hotel, Manchester, UK
- University of Strathclyde School of Pharmacy, Glasgow, UK
- Newcastle Marriott Gosforth Park, Newcastle, UK
- Hilton York Hotel, York, UK
- York Marriott Hotel, York, UK
- Newcastle Marriott Gosforth Park, Newcastle, UK
- Renaissance Manchester City Centre Hotel, Manchester, UK
- University of Strathclyde School of Pharmacy, Glasgow, UK

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**Training Course Calendar**

1. **Active Pharmaceutical Ingredients** ~ 4.5 days
2. **Human Error Prevention** ~ 3 days
3. **Pharmaceutical GMP Audits and Self-Inspections** (An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course) ~ 5 days
4. **Statistics for Ongoing Process Verification – Analyzing and Trending Data** ~ 2 days
5. **Risk-Based Decision Making for Quality Professionals and QPs** ~ 2 days
6. **Medicinal Chemistry & Therapeutics** ~ 5 days
7. **A-Z of Sterile Products Manufacture** ~ 4 days
8. **Managing Cost of Poor Quality** ~ 2 days
9. **Modern Process Validation** ~ 3 days
10. **QP Alumni** ~ 2 days
11. **Pharmaceutical Law & Administration** ~ 5 days
12. **Free QP Seminar for Prospective QPs & Sponsors** ~ 1 day
13. **Pharmaceutical GMP** ~ 3.5 days
14. **Free QP Seminar for Prospective QPs & Sponsors** ~ 1 day
15. **Pharmaceutical GMP Audits and Self-Inspections** (An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course) ~ 5 days

**Contact Information:**

- **Phone:** +44 (0) 1751 432 999
- **Website:** [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)
- **Email:** pharmacourses@nsf.org
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