2013 – 2014
Educational Programme
Welcome to our Pharma/Biotech Educational Programme covering the courses we offer in Europe between September 2013 and July 2014.

We aim to try to give continual and advanced visibility of our courses to allow individuals and companies to plan ahead in line with their budget cycles. In addition to this brochure we will give you visibility of our courses via e-cards and our website www.nsf-dba.com

Our business continues to grow, both geographically and in the breadth and depth of services we can offer you in Consulting, Auditing and Education/Training. We now have established a growing team in the non-English speaking European markets and are in the process of integrating Becker & Associates, an expert US consultancy firm, and IPEA (International Pharmaceutical Excipient Auditing), into our business.

Importantly, on 2 January 2014 we will become NSF Health Sciences, comprising three business units: Pharma/Biotech, Medical Devices, and Dietary Supplements.

So whilst the NSF-DBA logo will disappear, we are committed to continuing to provide the same high quality in our services as we move forward in this exciting transition.

The Pharma/Biotech sector continues to face unprecedented levels of change as a result of both the economic and regulatory environments we face. The need for a ‘Pharmaceutically’ well educated and motivated workforce at all levels, that understands not just the ‘Whats’, but also the ‘Whys’, has never been higher.

In addition to our ‘core’ courses and our premier, industry-leading QP programme, we are continuing to add courses in areas of increased Industry focus such as Auditing and Supply Chain topics to allow you to keep current, and continue to develop as Pharmaceutical Professionals.

An increasing number of our clients today are asking us to run courses, either individual courses or a series of courses, in-house at their facilities – please contact us if this is of interest to you.

Please note that whilst historically many of you know us as a ‘Training’ company, this is only a part of our business. We also provide high quality Consultancy and Auditing services to many clients (see pages 24 and 25).

As your resources get increasingly stretched we are able to complement your own activities in these areas, often as a ‘fresh pair of eyes’. Our expert Auditors, positioned around the world, can undertake individual audits, a portion of, or your full audit programme on your behalf. This approach is acceptable to regulators when credible Third Party Audits are performed using competent Auditors with Pharmaceutical understanding. An increasing number of clients are asking us to do this. Our expert Consultants can help you develop a modern Quality Management System, as well as providing expert technical advice across a wide range of Pharma/Biotech areas.

I hope you find this brochure useful and will continue to work with us, or try us out if you haven’t done so far, as we all seek to ensure the development and supply of high quality medicines to patients around the world.

Please contact us if you have any questions, or suggestions as to how we can continue to improve our services.

Best regards

Neil Wilkinson

President, NSF Health Sciences Pharma/Biotech
Global Capabilities, Local Service – Expansion without Compromise

NSF Health Sciences Division – Three New Companies to Serve Three Critical Industry Sectors

The NSF Health Sciences Division has undergone an internal reorganisation to enable us to better serve our three main customer sectors: the pharmaceutical and biopharmaceutical industries, medical devices and the dietary supplements industry. The Health Sciences Division now consists of three customer-focused companies:...

Our services of consulting, auditing, certification, education and analytical support remain unchanged, as does the quality of service we provide to our clients worldwide, but from now on it will be easier for you to find the services you require and connect with the experts you need to speak to. We are committed to providing you with an improved client relationship and a class-leading service.

Skilled and Experienced Personnel

As we expand our services overseas, we continue to provide the best quality of experts we can find. Many of our trainers come with extensive industry experience and want to impart that knowledge to maintain and improve standards. We understand that you attend courses or commission consultancy work to learn about latest regulations or to get advice, questions answered and your problems solved. Our in-depth customer research suggests that we are helping you to make the difference you need both for the individual and for the organisation to develop and grow.

Valuing the Customer

Listening to the voice of the customer remains the heart of our business. As part of a recent reorganisation, we’ve assessed what our customer needs are in this industry and made some strategic changes to streamline our business and provide optimal support to you. Our Client Liaison team, headed by Anne Davies is listening.

In the office at Kirkbymoorside we have a team of skilled staff who are involved in the day-to-day logistics of the business. Firstly, the team ensures that the right technical expert listens and understands the customer needs and secondly, by using well-oiled processes to ensure the training course materials, whether open or in-house, are put together to provide all the information you need to fully participate and enjoy the training experience.

If you are a budding QP, a trainee QP or even an experienced QP, you will no doubt come across our dedicated administrator, Stella Pearson-Smith, who takes care of the QP programme. Stella is available for any queries you may have.

Our Training Style

At NSF-DBA we believe that training should be informative, involving, participative, relevant and above all FUN! Every one of our training courses, whether open or in-house, maximises participation and involvement by providing a balanced mix of lectures, tutorials and participative team based learning.

Attention to your Needs

We understand that you need more out of a training course than just the classroom experience. In today’s business climate you need to keep in touch with the office, which is why we choose venues with excellent in-room broadband connectivity and fully serviced business centres.

Similarly we know that after a hard day you need to relax, so we ensure that our hotels are comfortable, provide all the services you demand and are conveniently located for relaxation pursuits such as ‘retail therapy’, a range of varied dining, as well as cultural pursuits.

Post Course Service

At the end of our course, you will be on first name terms with your tutors and know they are accessible, at no charge, for further guidance when you return to work and put in practice what you have learnt.

Our aim is to ensure that you leave one of our courses eager to attend another.

For more information call +44 (0)1751 432 999, email mail@nsf-dba.com or visit our website at www.nsf-dba.com
### Our Training Courses by Topic

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**Audit/Self-Inspection**
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**Biopharmaceuticals/Biotechnology**
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**Clinical Trials/Investigational Medicinal Products**
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Reserve your place today  
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Qualified Person Training

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Supply Chain and Distribution

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About This Course

Virtually all patient and business critical decisions made by Qualified Persons and other quality professionals are in some way made on the basis of data provided by an analytical laboratory. It is, therefore, of paramount importance that this data is accurate and can be relied upon. Hence, it is essential that these decision makers understand the basis of the analytical techniques used and their respective strengths and weaknesses.

This module seeks to provide a foundation of knowledge which will enable Qualified Persons and others to judge analytical data, ask relevant questions to aid interpretation and know when to call for additional data/advice. This knowledge is also essential when auditing laboratories.

The module is designed for delegates with a scientific educational background who wish to obtain a broader knowledge of Good Control Laboratory Practice (GCLP). The module may also be suitable for analytical chemists who are new to the pharmaceutical industry.

For delegates who already have a deeper knowledge of analysis and testing there will be opportunities to discuss issues with the course tutors.

What You Will Learn

Laboratory Management
• Principles of GCLP/laboratory management
• Handling atypical results (e.g. OOS/OOT results)

About This Course

Quality Control (QC) laboratories perform a vital role within Good Manufacturing Practice. They provide the data upon which critical decisions, such as batch release and the stability of products, are based. If the laboratory data is incorrect, then decisions may be wrong, with potentially disastrous consequences for companies and patients.

So ensuring the integrity of the data produced by QC laboratories is essential, and a key component in providing data integrity is the validation of the test methods.

This year we have extended our previous one-day course to a two-day course that provides a more detailed explanation of how analytical methods are validated, enabling a full understanding of method performance characteristics and associated statistics, and how they are applied to the techniques used for analysing drug related samples. This knowledge will enable informed interpretation of the regulatory guidance on validation, namely ICH Q2 (R1) and guidance from FDA and EMA on bioanalytical methods.

Many organisations encounter difficulties when they attempt to transfer methods from one laboratory to another. This course will provide you with strategies and approaches to ensure success in this complex area.

What You Will Learn

After attending this course you will be able to:
• Understand the purpose of analytical method validation
• Define the parameters used for method validation, i.e. validation characteristics
• Generate a validation protocol including relevant acceptance criteria
• Interpret the results of validation using appropriate statistics
• Understand best practice for analytical method transfer

Your Tutor

Oona McPolin, Mourne Training Services, UK

This is complex material, however, the tutors explained the contents in an understandable way. Most importantly they point the direction for looking for information and references.

Qian Cai, Apatech, UK
Deviation and CAPA Systems – Best Practices

About This Course
How good is your Deviation and CAPA system… or are you at RISK?
• Can you guarantee your deviations will never happen again, or are costly repeat incidents common?
• Do you use every incident as a learning opportunity for ‘Continuous Quality Improvement’, or are deviations closed to get the batch released?
• Do you really identify root cause, or just conclude ‘Human Error’ for most incidents?
• Does your system efficiently ‘triage’ or prioritise incidents based on risk, or do you treat every incident the same… which is costly and dangerous?!
• Can you report, investigate and resolve deviation incidents in hours, or only within the unacceptably long ‘30 days’?
• Years after the incident, can you accurately reconstruct the history of the event from the report, or are you left guessing in front of a frustrated inspector?

Your Deviation and CAPA system is a crucial part of your Quality System. It should protect your patients against poor quality medicines and drive Continuous Quality Improvement by stopping inefficient, wasteful and often dangerous practices. This course is not just about how to conduct a root cause investigation, it is much, much more.

What You Will Learn
• How to use your deviations to drive down costs and reduce complexity
• How to make ‘repeat’ incidents a thing of the past!
• How to apply structured, risk-based decision making tools and techniques to ensure that every incident is investigated to root cause in a consistent and thorough manner
• How to report, investigate and resolve incidents within hours
• How to ‘triage’ or prioritise deviations
• How to make sure that your deviation reports provide an accurate history of events!

Who Should Attend
This course will be invaluable to anyone involved in the review and approval of batch manufacturing records, and the investigation of deviations, out of specifications, customer complaints, product recalls or any unplanned quality incident.

Your Tutors
Stewart Green
Terry Snape

Dates: 16-17 September 2013 | Location: Amsterdam Marriott Hotel, Amsterdam, The Netherlands
28-29 April 2014 | Location: Renaissance Manchester City Centre Hotel, Manchester, UK

Effective Pharmaceutical GMP Audits and Self-Inspections (An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)

About This Course
Supply chain assurance is the key topic in our industry today. From starting material to patient, pharmaceutical companies are expected to be able to demonstrate control. Increasingly that means audit or justify why not!
Regulators’ expectations for the quality of audits and their work continue to increase. This course will prepare you to perform your best audit ever. During 2014 we expect to reach our 500th trained auditor in this new challenging and demanding course.

What You Will Learn
You will develop a toolbox of auditor skills from planning to execution and follow-up.
This course provides the training required for the IRCA certified Pharmaceutical Quality Management System auditor and lead auditor certificate (satisfactory completion of the course exam and post course audit experience are required to gain certification).

Who Should Attend
• Those who audit and are audited!
• This course has been used to train PIC/S inspectors
• Those engaged in self-inspection activities

Your Tutors
Mike Halliday
Martyn Becker
Liz Allanson
Darren Jones

I would strongly recommend this course to anyone who performs pharmaceutical compliance auditing. I was very impressed with the instructors, their presentation and interpersonal skills were especially good.
Paul J Siciliano, Patheon Pharmaceutical Services, USA

Dates: 23-27 September 2013 | Location: York Marriott Hotel, York, UK
4-8 November 2013 | Location: Park Hotel Amsterdam, Amsterdam, The Netherlands
17-21 March 2014 | Location: Renaissance Manchester City Centre Hotel, Manchester, UK
19-23 May 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK
Free Seminar for Prospective QPs and Sponsors

About This Course
Since 1990, NSF-DBA and the University of Strathclyde have collaborated to present a structured modular course designed for people wishing to become Qualified Persons. This course is now recognised as the most successful and main route to QP education in the UK and increasingly in Europe.

Who Should Attend
Those who are:
- Planning to train to become a QP
- Interested in maximising their technical knowledge and value to their organisation
- Responsible for QP training or technical development
- Interested in gaining a vocational MSc, Postgraduate Diploma or Certificate

Or want to know more about sponsoring a QP

This is your opportunity to...
- Get an overview of the route to becoming a QP and the structure and content of the modules
- Have 1:1 discussions with NSF-DBA tutors and the QP Administrator
- Understand the vital role of the sponsor
- Find out what the assessors expect from candidates and sponsors
- Listen to presentations from…
  - A former QP delegate about their experiences of QP training
  - An assessor from one of the Joint Professional Bodies
  - An active sponsor who has successfully mentored a number of trainee QPs
- Experience part of a QP module and ask questions of the tutors and current QP delegates over lunch

Your Tutor
Mike Halliday

Dates: 17 September 2013 | Location: York Marriott Hotel, York, UK
12 November 2013 | Location: Cheshunt Marriott Hotel, Broxbourne, UK
11 March 2014 | Location: York Marriott Hotel, York, UK

GMP for Biological and Biotechnology Products

About This Course
The development of new biopharmaceuticals and biotechnology products promises to bring about a revolution in global healthcare. However, the manufacture and control of such products brings with it special concerns and challenges which, if inadequately addressed, could jeopardise product quality and patient safety.

If companies are to be successful in this highly important arena, it is essential that staff at all levels clearly understand...
- The risks and challenges associated with biopharmaceuticals manufacture and control
- The rapidly changing international regulatory demands and expectations for these products
- How these requirements can be translated into a practical, effective and cost-efficient quality management system

All these issues and more will be addressed in this introductory three-day training course.

Who Should Attend
This course is not for experienced staff! It is primarily intended for those people with less than three years’ experience of working in the manufacture and control of biopharmaceuticals and biotech products for commercial and clinical trial use, and those looking to learn the fundamentals of GMP and Quality Management for these products.

Your Tutors
Stewart Green
Terry Snape

What You Will Learn
- Current EU and US regulations and expectations for the manufacture of biopharmaceuticals for commercial and clinical trial use
- Key GMP compliance issues for the different stages of the manufacturing process…
  - cultivation
  - QC
  - downstream processing
  - shipping
  - fill and finish
  - key issues of importance to the Qualified Person

Date: 18-20 February 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Excellent overview of production of biotech products!
Sandra Grote Beverborg, Organon, The Netherlands
GMP for Clinical Trials Manufacture and Supply

About This Course
Companies in the EU have been required to comply with the Clinical Trial Directive for almost 10 years now, and yet Regulatory inspections still uncover critical non-compliances. These deficiencies often relate to inadequate Quality Systems, which are not robust or effective enough to manage the GMP/GCP Interface areas in Clinical Development, thus jeopardising the results of the trials and putting patients at risk.

What You Will Learn
The specific requirements and areas of Regulatory focus for the manufacture of Clinical Trial Supplies are explained and discussed in this course.

Questions such as:
• Does the Falsified Medicines Directive apply to Clinical Supplies?
• How much validation is required and how soon?
• How can the QP ensure effective blinding when the sponsor determines the study design and protocol?
• What GMP implications will there be for the new Clinical Trial Regulation in 2016?

are not straightforward and require those involved to fully understand the risks and regulatory implications. Our team of highly experienced tutors, including ex-MHRA GMP inspectors, will discuss the answers to these questions and explain the pitfalls and weaknesses still seen in many companies manufacturing and supplying clinical materials.

This popular course will build on the success of previous years and cover all the information necessary to fully understand the GMP requirements and supply issues associated with Clinical Trials.

Your Tutors
Liz Allanson
Darren Jones
Mike Russell

Date: 14-17 October 2013 | Location: Park Hotel Amsterdam, Amsterdam, The Netherlands

Good Autoclave Practice

About This Course
A comprehensive course on the practicalities of...
• Autoclave selection
• Cycle design
• Equipment qualification
• Cycle validation
• Ongoing performance monitoring and management

What You Will Learn
Current Regulatory Issues, Standards and Best Industry Practice for Steam Sterilisation
• EU and US expectations compared and contrasted

Microbiology of Sterilisation
• The conditions needed to kill microbes
• The kinetics of sterilisation (Fo, D and Z)

Steam
• Steam quality testing
• Causes and consequences of steam quality problems

Moist Heat Cycle Types
• Applications, advantages and disadvantages

Good Validation Practices
• DQ, IQ, OQ, PQ

Biological Indicators
• Selection and quality control
• Use and abuse of BIs

Life after Validation
• Planned preventative maintenance and calibration
• Change control

Good Autoclave Practices
• Training of operators
• Management of failed cycles
• Measuring and monitoring performance

Your Tutor
Peter Monger

Date: 29-31 October 2013 | Location: Amsterdam Marriott Hotel, Amsterdam, The Netherlands
About This Course
This course is designed to give existing auditors, who have no ‘bio’ background, sufficient exposure to some of the specific issues involved in biologics and biotech processing to allow them to approach a biologics/biotech audit with confidence. GMP requirements of both EMA and FDA (CBER) are addressed. The course is ideal for delegates who have either previously attended NSF-DBA’s IRCA certified Pharmaceutical Quality Management Systems Auditor/Lead Auditor course, or who already have a good understanding of the basic principles and practices of auditing and wish to expand their technical understanding to biologics/biotech GMPs. The course can also contribute to registered auditors’ and lead auditors’ professional requirement for continuing professional development (CPD).
This course will also be ideal for manufacturing and quality personnel already working in a biologics/biotech facility who wish to undertake effective self-inspection.

What You Will Learn
- How to develop an audit aide-mémoire for risk-based auditing of bulk bio manufacturing
- A structured approach to an audit that will address both EMA and FDA expectations

Date: 21 February 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

About This Course
Auditing of API manufacturers is receiving increasing scrutiny from European regulators primarily as a result of recent issues around counterfeiting of medicines such as the well-known Heparin scandal. In the European Union the responsibility for GMP conformity for the medicinal product lies with the Qualified Person of the holder of the marketing authorisation, and this includes GMP at the site of API manufacture. Since January 2013 the situation has become even more challenging for the MAA holder as the Qualified Person has to declare that they are satisfied with GMP controls within the whole of the supply chain, which includes the supply chain of the API manufacturer(s) used by that MAA holder.

European Union inspection bodies will therefore be placing even more scrutiny on the audits carried out for your companies to allow this declaration around the supply chain.

What You Will Learn
- Increase confidence in conducting API audits
- Understand how to report observations and respond to corrective action plans
- Reasonable expectations for environmental and in-process monitoring for bio facilities
- Risk-based prioritisation of activities to be audited when time presses (doesn’t it always?)
- Practice, in a non-threatening situation, in classification of bio facility audit observations

Who Should Attend
Auditors wishing to develop technical skills in auditing chemical API operations. This course will provide useful Continuing Professional Development for auditors expanding their areas of focus.

Your Tutor
Susan Rocca

Date: 21-22 November 2013 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK
How to Audit – Key Excipients

About This Course
Many experienced auditors find they have to audit areas which they are unfamiliar with; in addition, experienced auditors should always be seeking opportunities to keep up-to-date through continuing professional development. As part of our ‘How to Audit’ series, providing hands-on practical courses for auditors who wish to improve skills and develop areas of expertise, we are delighted to announce that the ‘How to Audit – Key Excipients’ course will be run by Peter Monger, a former MHRA inspector and extremely experienced auditor. The course is designed to provide practical help and guidance to those engaged in the auditing of excipients.

What You Will Learn
New directives and expectations place increasing pressures on companies to audit the entire supply chain of starting materials including excipients.
Peter will be running this highly interactive course with the following objectives:
- Remind auditors of the key legislation and guidance around auditing excipients, GMP, IPEC, ISO 9000
- What is the role of EXCiPACT™?
- How to construct an audit plan or agenda that works
- Working through case studies and audit observations to discuss the severity ranking and references to support findings
- What to do when time on site is limited, shared or impossible

Who Should Attend
Auditors wishing to develop technical skills in auditing chemical API operations. This course will provide useful Continuing Professional Development for auditors expanding their areas of focus.

Your Tutor
Peter Monger

Date: 19-20 November 2013 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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How to Audit – QC Chemical Laboratories

About This Course
This course is designed to provide existing auditors with the necessary technical detail to enable them to effectively audit a Quality Control (QC) chemical laboratory to ensure that both EU and FDA GMP requirements are met. It is ideal for delegates who have either previously attended NSF-DBA’s IRCA certified Pharmaceutical Quality Management Systems Auditor/Lead Auditor course or who already have a good understanding of the basic principles and practices of auditing and wish to expand their technical understanding of good QC laboratory practice. The course can also contribute to registered auditors’ and lead auditors’ professional requirement for continuing professional development (CPD).

This course will also be ideal for personnel who work within a QC chemical laboratory and who wish to learn how to conduct comprehensive self-inspections.

What You Will Learn
- Why it is important to audit QC laboratories
- How to plan QC laboratory audits
- The critical areas to focus on during the audit of a QC laboratory
- How to classify QC laboratory audit observations
- To develop an audit aide-mémoire for auditing QC laboratories

Your Tutors
Pete Gough
Oona McPolin

Date: 30 April-1 May 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

"An interesting and informative course that provides a practical approach on the application of GMP and IPEC guidance when performing audits of excipient suppliers. The course was very interactive and the course tutors provided good examples and were extremely knowledgeable."
Kirsteen Scott, Eisai Manufacturing, UK

"Very informative and friendly course. I found it very beneficial and great start to a new compliance job."
Tamara Alani, GlaxoSmithKline, UK
How to Audit – Sterile Products Manufacture

About This Course
The manufacture of sterile products is perhaps the most hazardous of all pharmaceutical production activities – failures can and sometimes do result in patient harm and death. That is why auditing of sterile filling operations is essential and why it is important that the auditor has the right knowledge and experience to conduct the audit with skill and professionalism.

This short, focused course is designed to help auditors with little or no direct experience of auditing sterile filling operations to know where the risks lie, what questions to ask and how to assess whether or not processes are under control.

What You Will Learn
• What makes sterile products special
• An overview of relevant GMP guidance
• The quality critical steps in sterile filling and how to ensure these are under control
• How to plan an audit of sterile filling
• How to assess the effectiveness of environmental monitoring programmes
• The key questions to ask
• What answers to expect!

Date: 4 April 2014 | Location: Renaissance Manchester City Centre Hotel, Manchester, UK

Your Tutor
Darren Jones

How to Perform Effective Product Quality Reviews

About This Course
On 1 January 2006 the EU implemented a change to Chapter 1 of the EU GMP Guide to add the requirement to produce a regular Product Quality Review. This listed numerous criteria which should form part of that review.

The FDA has long required product reports to be submitted for licensed products and ICH Q7, GMP for Active Pharmaceutical Ingredients, also requires that “processes should be periodically evaluated to verify that they are still operating in a valid manner”.

This course is designed to assist you and your company in producing Product Quality Reviews which meet these GMP expectations in an efficient manner that will add VALUE to your business as well as compliance to your operations.

What You Will Learn
• How to decide if a process is in control, capable and still valid
• How to produce Product Quality Review reports which add value to your business and meet all regulatory expectations

Who Should Attend
This course is for anyone involved in the…
• Design
• Preparation
• Review
of Product Quality Reviews for medicinal products or active pharmaceutical ingredients.

Your Tutor
Pete Gough

Date: 8 October 2013 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Help with understanding of importance of statistical analysis in PQRs
Tammy Frost, Dermal Laboratories, UK

Course Duration | 1 day
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
Stewart Green Terry Snape

Date: 18-20 September 2013 | Location: Amsterdam Marriott Hotel, Amsterdam, The Netherlands
28-29 October 2013 | Location: Milan Marriott Hotel, Milan, Italy
30 April-2 May 2014 | Location: Renaissance Manchester City Centre Hotel, Manchester, UK

Investigating Out of Specification Results

About This Course
This course is designed to provide you with practical advice on how to investigate OOS results and make appropriate decisions, which will meet Regulatory expectations and add real value to your business. The recent quality system guidance, such as ICH Q10 and the FDA Process Validation, means that inspectors are now focusing much more on trend analysis. Every company will inevitably generate OOS and OOT results at some time, so this is an area of GMP compliance that cannot be ignored.

What You Will Learn
• The Barr case history
• What the October 2006 FDA OOS Guidance says and what it means
• What the 2010 MHRA Guidance says and what it means
• How to assess the quality of the data generated by your laboratory
• The relationships between OOS, OOT and other atypical results
• How to identify OOT stability results
• How to conduct effective OOS and OOT investigations and interpret the results
• What to consider when making batch release decisions

Who Should Attend
Laboratory personnel who need to be able to identify and investigate OOS and OOT results.
Quality Assurance personnel, particularly Qualified Persons, who have to make decisions based upon the results from OOS and OOT investigations.

Your Tutor
Pete Gough

Date: 2 May 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK
Investigational Medicinal Products

About This Course
Companies in the EU have been required to comply with the Clinical Trial Directive for almost 10 years now, and yet Regulatory inspections still uncover critical non-compliances. These deficiencies often relate to inadequate Quality Systems, which are not robust or effective enough to manage the GMP/GCP Interface areas in Clinical Development, thus jeopardising the results of the trials and putting patients at risk. The QP role is essential to ensure that the Quality System and GMP aspects of this interface are fit for purpose. The QP cannot perform an effective role if it is not!

What You Will Learn
The specific requirements and areas of Regulatory focus for the manufacture of Clinical Trial Supplies are explained and discussed in this course.

Questions such as:
• What are my duties as a QP working with IMPs?
• Does the Falsified Medicines Directive apply to Clinical Supplies?
• How much validation is required and how soon?
• How can the QP ensure effective blinding when the sponsor determines the study design and protocol?

What GMP implications will there be for the new Clinical Trial Regulation in 2016? are not straightforward and require those involved to fully understand the risks and regulatory implications. Our team of highly experienced tutors, including ex-MHRA GMP inspectors, will discuss the answers to these questions and explain the pitfalls and weaknesses still seen in many companies manufacturing and supplying clinical materials.

This popular course will build on the success of previous years and cover all the information necessary to fully understand the GMP and QP requirements and supply issues associated with Clinical Trials.

Your Tutors
Liz Allanson
Darren Jones

Very useful course. A whole new world has been opened. It also changed a wrong perception that IMPs follow lower GMP and are less complex. Thank you.

Nuno Furtado, Baxter Healthcare, UK

Date: 16-19 June 2014 | Location: York Marriott Hotel, York, UK

Mathematics & Statistics

About This Course
The introduction of the EU requirement for Product Quality Reviews, ICH Q8, Q9, Q10 and Q11, and new guidance from both the FDA and EU on Process Validation, which includes ‘continued process verification’, all mean that the Pharmaceutical Industry and the Regulatory Authorities are becoming increasingly aware of the benefits that statistical techniques can provide and the vital information that can be obtained by trend analysis. This module assumes that delegates have little or no experience in the application of statistical techniques and will demonstrate how simple statistical tools can be used to turn data into useful information.

What You Will Learn
How to:
• Understand the reliability and accuracy of data and information arising from samples taken from a population
• Monitor and detect adverse trends before a process goes out of control
• Assess the capability and reliability of a process
• Understand the interaction of process parameters via experimental design
• Maintain regulatory compliance

What GMP implications will there be for the new Clinical Trial Regulation in 2016? are not straightforward and require those involved to fully understand the risks and regulatory implications. Our team of highly experienced tutors, including ex-MHRA GMP inspectors, will discuss the answers to these questions and explain the pitfalls and weaknesses still seen in many companies manufacturing and supplying clinical materials.

This popular course will build on the success of previous years and cover all the information necessary to fully understand the GMP and QP requirements and supply issues associated with Clinical Trials.

Your Tutors
Pete Gough
Professor George Gettinby, Department of Statistics and Modelling Science, University of Strathclyde, Glasgow, UK

Tutors did a great job of explaining basic concepts so we could apply them to more complex problems/concepts. I feel like I have learned how to use many tools to turn data into information so I can go back and learn more about our process control and capability.

Laura Matthys, Reckitt Benckiser Healthcare, UK

Date: 16-19 September 2013 | Location: York Marriott Hotel, York, UK

Reserve your place today t: +44 (0) 1751 432 999
Modern Approaches to Process Validation

About This Course
This course will look at the modern approaches to process validation, including the design of facilities and the qualification of equipment and utilities. It will start by looking fundamentally at the whole validation concept, why validation makes sense and what the objectives are. The course will explain how process validation must link to patients’ needs and the regulatory requirements. It will explain how tools, such as risk management, statistics and change management, are used to accomplish this. It will show how this modern approach can add real value to your business and provide better protection to patients. It will also show how these concepts can be applied to existing processes with beneficial results.

What You Will Learn
• How validation activities link the patients’ needs to the product and the associated manufacturing process
• The modern 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; eg risk assessment and statistical tools
• Practical application of the new FDA Process Validation Guidance

Who Should Attend
This course will be invaluable to anyone who is already familiar with the ‘traditional’ approach to process validation and would like to learn more about the new paradigm. This is likely to include:
• Process development
• Technical support
• Validation
• Quality Assurance
• Qualified Persons

Your Tutors
Bruce Davis
Line Lundsberg

Date: 9-12 June 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Pharmaceutical GMP

About This Course
It is a legal requirement that all staff receive regular training in Good Manufacturing Practice. This course is designed to provide you with up-to-date knowledge of new and impending GMP regulations and current ‘hot topics’.

Europe’s Most Popular GMP Course!
• In the last eight years, over 1000 delegates from all over Europe have attended this very 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 now forms an entry level GMP training requirement for our very popular Pharmaceutical Quality Management Systems Auditor/Lead Auditor Training Programme
• This highly interactive course involves considerable delegate participation throughout

This Course Will Cover…
• Why we have GMP
• EudraLex Volume 4
• A clear comparison of EU and FDA GMP requirements
• Up-to-the-minute information on new GMP initiatives and regulations
• Practical advice on dealing with the ‘difficult areas’ of GMP
• A panel discussion session to explore YOUR specific GMP problems

Who Should Attend
• New starters in the industry in their first 1-5 years
• Experienced staff changing roles to work in a GMP environment
• Experienced staff benchmarking current trends

Your Tutors
Mike Halliday
Liz Allanson
Samantha Clack
Darren Jones

Dates: 25-28 November 2013 | Location: Park Hotel Amsterdam, Amsterdam, The Netherlands
7-10 April 2014 | Location: Renaissance Manchester City Centre Hotel, Manchester, UK

Course Duration 4 days
Course Duration 4 days
Pharmaceutical Law & Administration

**About This Course**
Pharmaceutical law and administration is a key foundation knowledge requirement for all Qualified Persons (QPs). This is clearly spelled out in the relevant article of European Directives 2001/82/EC and 2001/83/EC and in the current UK Qualified Person Study Guide. The QP must ensure that the relevant laws are being complied with. Thus, a thorough understanding of the laws and legal processes, within Europe and beyond, is essential. This is equally true for other pharmaceutical technical managers.

**What You Will Learn**
- 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

**Your Tutors**
Pete Gough  
Liz Allanson  
Darren Jones

**Date:** 21-25 October 2013  |  **Location:** Hilton York Hotel, York, UK

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Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel

**About This Course**
The Qualified Person and other technical personnel need to be informed and aware of pharmaceutical legislation. Changes in legislation and guidelines, and the interpretation of them, can have significant implications for the individual and their company. 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 reality and interpretation of recent and new EU legislation
- Changes to EU GMPs
- An update on ICH and other international initiatives
- USA changes to legislation and FDA guidance
- UK updates

**Who Should Attend**
Although designed primarily for Qualified Persons, these seminars provide rapid, efficient updates on issues of direct relevance to technical personnel in a broad variety of roles, including:
- Quality Management
- Production
- Engineering
- Regulatory Affairs
- Research & Development

**Your Tutor**
Pete Gough

**Dates:** 9 October 2013  |  **Location:** Manchester Marriott Victoria & Albert Hotel, Manchester, UK  
15 October 2013  |  **Location:** Milan Marriott Hotel, Milan, Italy  
26 March 2014  |  **Location:** Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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Has brought all my previous knowledge and experience together to bring clarity on subject matter. Would be hugely beneficial for anyone working in QA. Brought to life with real examples.

Julia Hocking, Boots Contract Manufacturing, UK

Has brought all my previous knowledge and experience together to bring clarity on subject matter. Would be hugely beneficial for anyone working in QA. Brought to life with real examples.

Julia Hocking, Boots Contract Manufacturing, UK

At a time of unprecedented change and more to come, this was an excellent course to highlight these changes to help check that I hadn’t missed anything and what this means to the industry. I am not alone!

Carol Sandercock, Helena Biosciences Europe, UK
Pharmaceutical Microbiology

About This Course
Microbiological contamination of products and processes continues to be a major concern to the industry and its regulators. The potential impact of such contamination can be catastrophic. Put simply, microbial contamination can kill your patients and your business! This course, for non-biologists and microbiologists, is designed to provide you with the knowledge, confidence and decision making risk assessment skills to prevent this happening. You will learn:

- The basic characteristics of all microorganisms found in your pharmaceutical environment, how they get there and how you can remove them
- How you can sample, isolate, count and identify these microorganisms
- How to prevent contamination of your products and processes using practical risk management and risk assessment tools and techniques
- How to interpret microbiological data in order to make the right ‘risk-based’ decisions – decisions that will satisfy the regulators, protect your patient and improve your operational efficiency

This Course Will Cover...
- Microorganisms: Understanding your ‘Enemy’!
- Microbiological Methods: ‘How to’ Guidance
- Microorganisms and your Products, Procedures and Plants

Date: 28 April-2 May 2014 | Location: Amsterdam Marriott Hotel, Amsterdam, The Netherlands

Your Tutors
Mike Halliday
Erika Notman

Gavin Halbert

Pharmaceutical Packaging

About This Course
Despite advances in technology, quality problems with packaging still continue to occur. Print origination and packaging processes continue to be a major reason for product recall! This course has been carefully designed to cover all important aspects of the packaging process, from selection of suitable components, pack design, packaging processes and their associated GMP challenges, through the supply chain to the patient.

The course includes visits to a wholesaler and a pharmacy, with input from printed packaging component suppliers.

This Course Will Cover...
- Packaging Components
- Pack Design
- The Packaging Process
- Regulatory Aspects
- The Route to the Patient
- Concerns for the QP

Who Should Attend
The course is designed to provide the necessary understanding of packaging materials and the packaging process to enable the Qualified Person to carry out his/her duties with knowledge and professionalism. Equally, the course will be of value to staff involved in Packaging Development, Packing Operations, QA and QC.

Date: 20-24 January 2014 | Location: Hilton York Hotel, York, UK

Your Tutors
Erika Notman
Gary Rees

Good mix of lectures, group sessions and industrial visits. The visits were an excellent opportunity to see how the theory of the course is put into practice in real industrial situations.
Matt Young, Aptuit, UK

Excellent course. Found the visits particularly beneficial as that provided good variation and offered ‘real’ examples of theory covered.
Tristram Evans, Biotec Services International, UK
Pharmaceutical Quality Systems: Best Industry Practice

About This Course
How good is your Pharmaceutical Quality System? Will it comply with the requirements of ICH Q10? Will it satisfy the ever increasing demands of global regulatory agencies? With increasing levels of Warning Letters and the like is your PQS at risk? How does your PQS compare with the best in class?

Over the last 25 years NSF-DBA has audited many thousands of quality systems, some bad, many good. We have also looked at how those in the aviation, micro-electronics and automobile industries manage quality. From this research we have identified industry best practices for quality management systems. By sharing these, this course will help you to strike the right balance between compliance and effectiveness, and achieve operational excellence.

Would You Like Answers To The Following?
• How can we achieve operational excellence?
• How do we successfully implement ICH Q10?
• What do the regulators expect?
• What does a simple and efficient PQS look like?
• How can we get our PQS to do more with less?
• How do we simplify our PQS?

Who Should Attend
Anyone interested in having a pharmaceutical quality system that is compliant and cost effective!

Your Tutors
Martin Lush
Stewart Green

Date: 12-13 November 2013 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Qualified Persons Training – Practical Module

About This Course
One of the greatest challenges facing the prospective QP is gaining a practical understanding of the equipment and procedures used to manufacture and test the broad range of dosage forms produced by the pharmaceutical industry. It is still true to say that the majority of candidates who fail at interview do so because they do not display a practical knowledge of the pharmaceutical manufacturing and testing procedures and their key vulnerabilities.

This module aims to assist the prospective QP by providing basic practical experience in these areas for the major dosage forms. This cannot take the place of practical experience in your company’s manufacturing areas and laboratories, but does provide “hands-on” experience for a broad range of products and expert tuition from pharmaceutical specialists using the modern facilities of the University of Strathclyde’s School of Pharmacy which are used for research and teaching in Pharmacy and Biomedical Sciences.

As with all NSF-DBA QP training modules there will be many scenario questions to challenge prospective QPs.

This Course Will Cover…
• Sterile Products
• Tablets
• Analysis
• Bioprocessing: from raw materials to final product

Who Should Attend
This course is open to delegates participating in our QP programme. We also welcome students from other QP training courses whose syllabus does not provide practical tuition, but as places will be strictly limited, early booking is strongly recommended.

Your Tutors
Mike Halliday
Oona McPolin
Erika Notman

Date: 12-16 May 2014 | Location: Strathclyde University, Glasgow, UK

Reserve your place today t: +44 (0) 1751 432 999
About This Course
The NSF-DBA 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 and exchange of ideas.

Why This Training Will Benefit YOU
- Networking with European QPs and fellow professionals
- Meeting with regulators and industry leaders
- Benchmarking and sharing best practice
- Debate and discussion of new legislation and its cost-effective implementation
- Review and development of influencing strategies
- Legal updates
- Technical updates
- Qualifying CPD

Who Should Attend
This course is by invitation only and is restricted to those delegates who are classed as ‘cores’, that is, they have attended four or more QP modules.

Date: 5-6 June 2014 | Location: York Marriott Hotel, York, UK

Quality Aspects of the CTD

About This Course
The ever-increasing complexity of obtaining approval for drug products requires that companies provide high quality registration applications. To achieve this objective, it is essential that personnel in Regulatory Affairs, Research & Development, Manufacturing and Quality Assurance understand regulatory requirements and work together as an effective team. The ICH Common Technical Document (CTD) has brought the possibility of a global dossier many steps closer. This emphasises the importance of getting it right first time.

NSF-DBA and Regulatory Resources Group have once again combined their complementary skills to present this well proven and successful course which is designed to provide attendees with a clear understanding of the regulatory process and technical data requirements for registration and subsequent manufacture of medicinal products. Although this course will primarily focus on EU aspects, consideration will be given to corresponding aspects in US submissions.

What You Will Learn
- Data requirements for new and established products
- CTD summary documents
- Role of the EU expert
- EU marketing authorisation procedures
- EU clinical trial applications
- Post approval changes (variations)
- GMP inspections
- Role of the EU Qualified Person

Your Tutors
Pete Gough
Liz Allanson
Shaun Stapleton, Regulatory Resources Group
Helen Erwood, Regulatory Resources Group

Date: 11-14 November 2013 | Location: Hilton York Hotel, York, UK

Overall a very interesting and beneficial course – covers a wide range of information in detail
Louise Griffin, Almus Pharmaceuticals, UK

e: courses@nsf-dba.com w: www.nsf-dba.com
About This Course
We all know that the quality of your products depends on the quality of your people and the effectiveness of your Quality Management System (QMS). In fact, as Qualified Persons (QPs) and quality professionals, you can’t release product and stay in business unless your QMS is ‘in control’. This is easier said than done. Supply chains are more complex than ever before and you are being asked to do more with less, and faster! It is not surprising that failures in QMS are a key reason for severe regulatory action in Europe and the USA.
This course will provide you with answers to some really tough questions.

What You Will Learn
• How to meet the ever increasing demands of global regulatory agencies, both now and in the future
• How to succeed when others have failed and implement ICH Q10 (Pharmaceutical Quality Systems) successfully throughout the product lifecycle
• Contractors and third parties – how to manage quality across your supply chain, no matter how complex

Your Tutors
Liz Allanson  David Selby

Date: 10-14 March 2014 | Location: York Marriott Hotel, York, UK

Risk-Based Decision Making for Quality Professionals and QPs

About This Course
The manufacture of medicines is easy – until something goes wrong. Important decisions have to be made quickly. These are rarely simple. There is never enough time, and important data and information is usually in short supply. To protect your patients and your reputation your decisions must be:
• Scientifically justified
• Based on an objective and realistic assessment of RISK
• In compliance with regulatory requirements and expectations
• GOOD for your business!

What You Will Learn
This course will provide you with the tools and techniques to make the right risk-based decision no matter how challenging the situation.
This is not a typical course where you are lectured to for hours on end. Most of the course will be spent working in small groups on common problems you face every day.

Your Tutors
Graham Clapperton    Gary Rees
Stewart Green        Mike Russell

Dates: 24-25 September 2013 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK
4-5 March 2014 | Location: Amsterdam Marriott Hotel, Amsterdam, The Netherlands
Risk-Based Decision Making in Sterile Products Manufacture

About This Course
Manufacturing sterile products is easy – until things go wrong! When things go wrong catastrophically, decision making is relatively straightforward. However, things are rarely so ‘black and white’. The biggest challenge facing anyone in sterile products manufacture is to deal with the ‘grey area’ problems which arise almost daily. The objective of this course is to help you improve your problem solving and decision making skills when presented with any situation associated with the manufacture of sterile products. The skills you learn could save your company $millions in rejected product!

What You Will Learn
You will be given the skills and, through practice, the confidence to deal with any situation and make the right risk-based decision no matter how challenging the scenario. For example:
• High environmental counts in a Class A (viable and non-viable)?
• Unexpectedly high pre-filtration bioburden counts?
• Momentary drop in temperature and pressure during autoclave cycle?
• Filling room occupancy higher than has been simulated during media fills?

Who Should Attend
This course is intended for staff with several years’ experience of sterile products manufacture and who are required to take decisions when things don’t go according to plan! Thus, the course will be of immense value to managers and supervisors in the following disciplines:
• Quality Assurance (including Qualified Persons)
• Production
• Quality Control
• Validation
• Engineering
• Quality Compliance

Your Tutors
Stewart Green  Darren Jones

About This Course
Sterile products manufacture represents the most hazardous activity (to the patient!) performed by pharmaceutical companies. This is why it attracts so much regulatory scrutiny!

Recent regulations and guidelines from EU (Annex 1) and FDA ‘Sterile Drug Products Produced by Aseptic Processing’ are confusing to many and very difficult – and expensive – to comply with in full.

This course is designed to help you comply with these and other documents in a way that is…

• Practical  • Scientifically sound  • Cost-effective

This is by far the most popular of our courses – hundreds of people attend it every year, either through this residential course or via courses run in their companies – and delegate feedback is excellent!

What You Will Learn
• Current EU and FDA requirements for…
  * design and qualification of cleanrooms

Who Should Attend
This course is intended for staff with several years’ experience of sterile products manufacture and who are required to take decisions when things don’t go according to plan! Thus, the course will be of immense value to managers and supervisors in the following disciplines:

Your Tutors
Stewart Green  Mike Russell
  Darren Jones

Excellent! Tutors brilliant on all aspects of the course. Content was extensive and explained accurately with ‘real-life’ examples.

Rebecca Bent, Eli Lilly & Co, UK

Dates: 23-26 June 2014 | Location: Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Sterile Products Manufacture

About This Course
Sterile products manufacture represents the most hazardous activity (to the patient!) performed by pharmaceutical companies. This is why it attracts so much regulatory scrutiny!

Recent regulations and guidelines from EU (Annex 1) and FDA ‘Sterile Drug Products Produced by Aseptic Processing’ are confusing to many and very difficult – and expensive – to comply with in full.

This course is designed to help you comply with these and other documents in a way that is…

• HEPA filter integrity test failure during requalification?
• Sterile filtration of solution takes longer than is permitted in the manufacturing instruction?
• Higher than normal reject rate during visual inspection?
• High microbial counts on hands of operator detected at exit monitoring?
• Unplanned deviation from approved steriliser loading pattern? …and many more

Who Should Attend
This course is intended for staff with several years’ experience of sterile products manufacture and who are required to take decisions when things don’t go according to plan! Thus, the course will be of immense value to managers and supervisors in the following disciplines:
• Quality Assurance (including Qualified Persons)
• Production
• Quality Control
• Validation
• Engineering
• Quality Compliance

Your Tutors
Stewart Green  Terry Snape

Dates: 7-10 October 2013 | Location: Amsterdam Marriott Hotel, Amsterdam, The Netherlands
31 March-3 April 2014 | Location: Renaissance Manchester City Centre Hotel, Manchester, UK
The Role & Professional Duties of the Qualified Person

About This Course
The principal objective of this course is to emphasise how the QP should conduct themselves in discharging their legal duties. Of paramount importance is the 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. Throughout the course, therefore, delegates will have the opportunity to test their skills via interactive ‘release or reject’ scenarios. The role and duties of the QP are constantly being added to and it is essential that QPs keep up-to-date with these new expectations. This course covers these new challenges in detail to help you understand them and their impact.

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

What You Will Learn
• The detailed legal and professional duties of the QP
• The QP Code of Practice
• Current challenges facing the QP
• EU legislation and its implications
• The role of the QP in complex manufacturing scenarios
• How to be an effective QP
• Links with other functional groups
• Product certification/release criteria
• Routes to becoming a QP across the EU and the UK assessment procedure
• The future of the QP role

Your Tutors
Pete Gough  Erika Notman

The course gave a really good insight into the role of the QP and what is expected. The real life views and experiences of the tutors and guest speakers were particularly useful. This course has firmed up why I originally wanted to become a QP.
David Bell, Reckitt Benckiser, UK

Date: 21-24 July 2014 | Location: Hilton York Hotel, York, UK

About NSF DBA

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 (Days)</th>
<th>5</th>
<th>4</th>
<th>3</th>
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QP Course Fees*

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<th>Course Duration (Days)</th>
<th>5</th>
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<tr>
<td>Current Series†</td>
<td>£3200</td>
<td>£2560</td>
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*Except Qualified Persons Training Practical Module – 5 days: £3380. †New series commences October 2014; price changes will apply.
QP Alumni – 2 days: £475
Please note that all prices are in Sterling and VAT is payable where applicable. Please refer to our website, www.nsf-dba.com, for full booking terms and conditions.

Reserve your place today e: courses@nsf-dba.com t: +44 (0) 1751 432 999 w: www.nsf-dba.com
In-House Educational Training

Bringing expert trainers to your door

At NSF Pharma/Biotech, in-house training is a premium client service offering. Customers, in some cases, have benefited from other NSF Pharma/Biotech services before expanding to NSF’s extensive range of educational resources. The majority of our in-house educational training courses are specifically designed to meet your company’s precise needs and are built in modular form. Once the number of modules have been determined, they can be conducted over a 12-24 month period. In-house training courses can vary in duration from half a day up to five days. The optimum attendance is 12 to 30 delegates to enable interactive learning.

Training is most effective when it is directly relevant to the activities performed by the attendees. Courses are therefore designed with you enabling your employees to immediately relate to the topic and pose relevant questions.

Our comprehensive range of professional in-house course topics includes:

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<th>Topic</th>
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<tr>
<td>Analysis &amp; Testing – cGMPs and Best Practices in Pharma Labs</td>
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<td>Deviation and CAPA Systems – Certification and Best Industry Practices</td>
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<td>Effective Pharmaceutical GMP Audits and Self-Inspections</td>
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<td>Investigational Medicinal Products</td>
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<td>Human Error Avoidance</td>
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<td>Risk-Based Decision Making in Sterile Products Manufacture</td>
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<td>Satisfying Regulatory &amp; Quality Requirements in Key Emerging Markets</td>
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<td>Supply Chain Assurance &amp; Anti-Counterfeiting</td>
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How it works

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>Discuss the course – aims, audience, location(s) and duration</th>
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<tr>
<td>STEP 2</td>
<td>Formal proposal submitted including draft course programme/costs</td>
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<tr>
<td>STEP 3</td>
<td>Feedback received, revisions made and final programme created</td>
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<tr>
<td>STEP 4</td>
<td>Training delivered, course materials provided and teamwork tasks distributed</td>
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<tr>
<td>STEP 5</td>
<td>Review of course undertaken and follow-up actions noted and shared</td>
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For more information call +44 (0)1751 432 999, email mail@nsf-dba.com or visit our website at www.nsf-dba.com
Auditing Services

Third Party Audits
Let us help you to find the ideal contractor by performing audits on your behalf. We have all the expertise needed; our highly trained and experienced auditors can work to your procedures and report formats as a virtual part of your audit team. A very cost-effective solution compared to the increase in overheads of a permanent member of staff.

We can carry out audits to any GMP standard for:

- Production
- Packing
- Testing
- Storage and distribution
- Engineering
- Computer software
- Water systems
- Autoclaves
- Raw material suppliers
- Other vendor and supplier services

We’ll provide a balanced detailed report highlighting:

- Company vulnerabilities
- Recommendations for remedial actions: short, medium and long term
- Overall recommendations about the contractor’s suitability for your needs

Benchmarking Audits
We deal with companies of every size worldwide, which puts us in a perfect position to measure your company’s facilities, procedures and practices against current industry norms.

We’ll give you an accurate view of your position in the marketplace along with practical advice on how to move forward.

Due Diligence Audits
We regularly help pharmaceutical companies, investment banks, venture capitalists and others in the process of due diligence for acquisitions, buy-ins, joint ventures and other investment projects.

We carry out an in-depth assessment of the regulatory compliance status of companies and/or projects by reviewing:

- The status of marketing approvals, applications etc
- Current complaints, adverse reactions etc – assessing vulnerability
- Current relationships with the major regulatory authorities
- The quality of staff in key technical positions
- The general levels of GMP compliance and investment needed to maintain GMP compliance in the short, medium and long term

Mock Regulatory Inspections
It is useful to prepare for an imminent inspection by carrying out one or two mock audits in the style of the regulatory body – FDA, MHRA, EMA, etc.

We’re often called on to conduct mock audits, after which we provide:

- An in-depth, impartial and professional assessment of your current state of compliance
- A detailed, prioritised action plan for altering the areas on non-compliance and vulnerability
- Sound, practical support and advice in the run-up to the real inspection
- Creating a WIN:WIN atmosphere during the inspection

Inspection Readiness
Our teams of experts working out of UK/EU and US offices bring a wealth of experience in preparing for successful regulatory inspections.

Cost-effective solutions can be found using local experts. In addition we can help with the problems, pitfalls and common misunderstandings encountered when FDA inspectors work outside America and European inspectors work outside Europe. Style and focus still have some differences.

For more information call +44 (0)1751 432 999, email mail@nsf-dba.com or visit our website at www.nsf-dba.com
Certified Auditor Training

Pharmaceutical Quality Management System auditor/lead auditor training course – meeting the training requirements for certification by IRCA

The course, launched in 2012, now attracts close to 200 delegates per year and interest continues to grow. The course can be run in-house or at public venues.

We use the new updated GMP standards, EudraLex, CFRs and PIC/S as the criteria for auditors working in our industry, with additional courses covering the practical application of ‘appropriate’ levels of GMP to excipients.

The auditor training course now really is a Pharmaceutical GMP auditor/lead auditor course providing a framework and toolkit of skills to enable new and experienced auditors to perform effective audits and self-inspections and also to demonstrate a level of competence to regulators and colleagues.

- This new course is built on a great history – over 25 years of auditor training
- Very experienced tutors, all of whom have audited in the pharmaceutical industry. Many have managed teams of auditors, and several are former Health Authority Inspectors
- Tutors are trained in specific educational skills to prepare them to deliver this highly interactive course
- Follow-on courses for auditor CPD and technical skills are available

What prior training or experience do I need to attend the course?

As this is a pharmaceutical industry-based course, a good working knowledge of pharmaceutical GMP is important – we teach you how to audit against GMP requirements; you should already be aware of the details of GMP. Ideally, therefore, we believe the trainee auditor should attend a comprehensive GMP training course (the NSF-DBA Pharmaceutical GMP course – see page 15 – is designed to complement and lead delegates into the course) or have about 2-3 years’ experience working in a GMP environment prior to attending.

What’s in it for the delegate?

Becoming a certified pharmaceutical auditor or internal auditor provides you with the skills to perform professional and insightful audits which will benefit your company and its patients and will satisfy the increasing demands of the regulators that auditors be appropriately trained. But more than this, there is evidence that the qualification can be important in your career development…

- Some professional GMP auditors go on to lead audit teams and departments
- Some professional GMP auditors go on to train as Quality Professionals/QPs using the knowledge and experience gained in auditing in their everyday decision making process
- Some professional GMP auditors go on to become senior leaders in their companies

Specialist Knowledge, Expert Advice

Because we’re at the leading edge of pharmaceutical training, we keep up-to-date with every major industry issue – and that means we’re the perfect source of advice and guidance on a wide range of matters, including:

- Implementation of cost-effective, compliant quality management systems
- Advice on legal and regulatory issues
- Assistance with responses to regulatory inspection reports, writing letters etc
- Advice on facility design, validation and operation
- Review of validation plans and completed studies

- Regulatory compliance for computers and automated control systems
- Specialist microbiological advice
- Specialist advice on water systems and autoclaving

Problem-Solving

When problems arise, the people most closely involved are not always able to find a solution. That’s when we can provide a clear and independent advice service to bring matters to a satisfactory conclusion.

We have a wealth of knowledge to troubleshoot and resolve problems with products, processes, equipment and systems.

il@nsf-dba.com or visit our website at www.nsf-dba.com
### Course Calendar 2013

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#### Venues used:
- Amsterdam Marriott Hotel, Amsterdam, The Netherlands
- Park Hotel Amsterdam, Amsterdam, The Netherlands
- Hilton York Hotel, York, UK
- York Marriott Hotel, York, UK
- Durham Marriott Hotel Royal County, Durham, UK
- Cheshunt Marriott Hotel, Broxbourne, UK
- Renaissance Manchester City Centre Hotel, Manchester, UK
- Manchester Marriott Victoria & Albert Hotel, Manchester, UK
- Milan Marriott Hotel, Milan, Italy

Reserve your place today  
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e: courses@nsf-dba.com  w: www.nsf-dba.com
Our phones are manned between 09.00 and 17.00 Monday to Friday. Outside these hours you can leave a message and one of our team will return your call as quickly as possible.

By phone
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Just drop us an email letting us know which course you are interested in and we will send you full details and a booking form.

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courses@nsf-dba.com

Once you've chosen your course online you can download your booking form and fax it through to our office to secure your booking.

By fax
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For further details about all of the courses we offer visit our website.

Online
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