



DBASM

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2013

Training Course Programme

The Health Sciences Training, Consultancy and Auditing Experts



Goodbye to all of this!

NSF DBA
Pharmaceutical Training, Consultancy and Auditing Experts

2 NSF-DBA Commits to a Digital Future

Over the years, our postal mailings have been a very effective way of communicating our courses to our clients and making you aware of the what, when and where of our course schedule. But now, all of that is coming to an end.

We have listened very carefully to the opinions of you, our clients, and the message coming through loud and clear is that the paper mailings have had their time. These very strong opinions, along with the environmental impact of sending paper, and of course the increasing cost of postage, has been on our minds for quite some time.

So, we have decided that we will no longer be sending out course information through the post!

Now, in order to communicate our courses to you, we will be using digital media to ensure you are kept completely up-to-the-minute on every aspect of NSF-DBA courses, both in Europe and across the world.

From now on we'll be emailing you details of our courses, so please keep an eye out to make sure our emails have permission to land in your inbox and don't disappear into the dreaded 'junk' folder. If you are in any doubt whether we have your correct email, please just take a minute to visit our website at www.nsf-dba.com where you can quickly and easily confirm it.

The course emails are directly replacing the paper brochures and so will be sent to you in plenty of time to allow you to secure your place on any of our courses. To make life that little bit easier, you'll be able to click through from our email directly to the relevant course pages on our website for all the details on venues, prices, tutors and full details on the course content to ensure it's right for you. Not only that, but from there you can book on to any course or download a booking form to complete and return to secure your place.



But that's not the end of our digital revolution, not by a long way!

In addition to making better use of email, we're also looking very closely at:

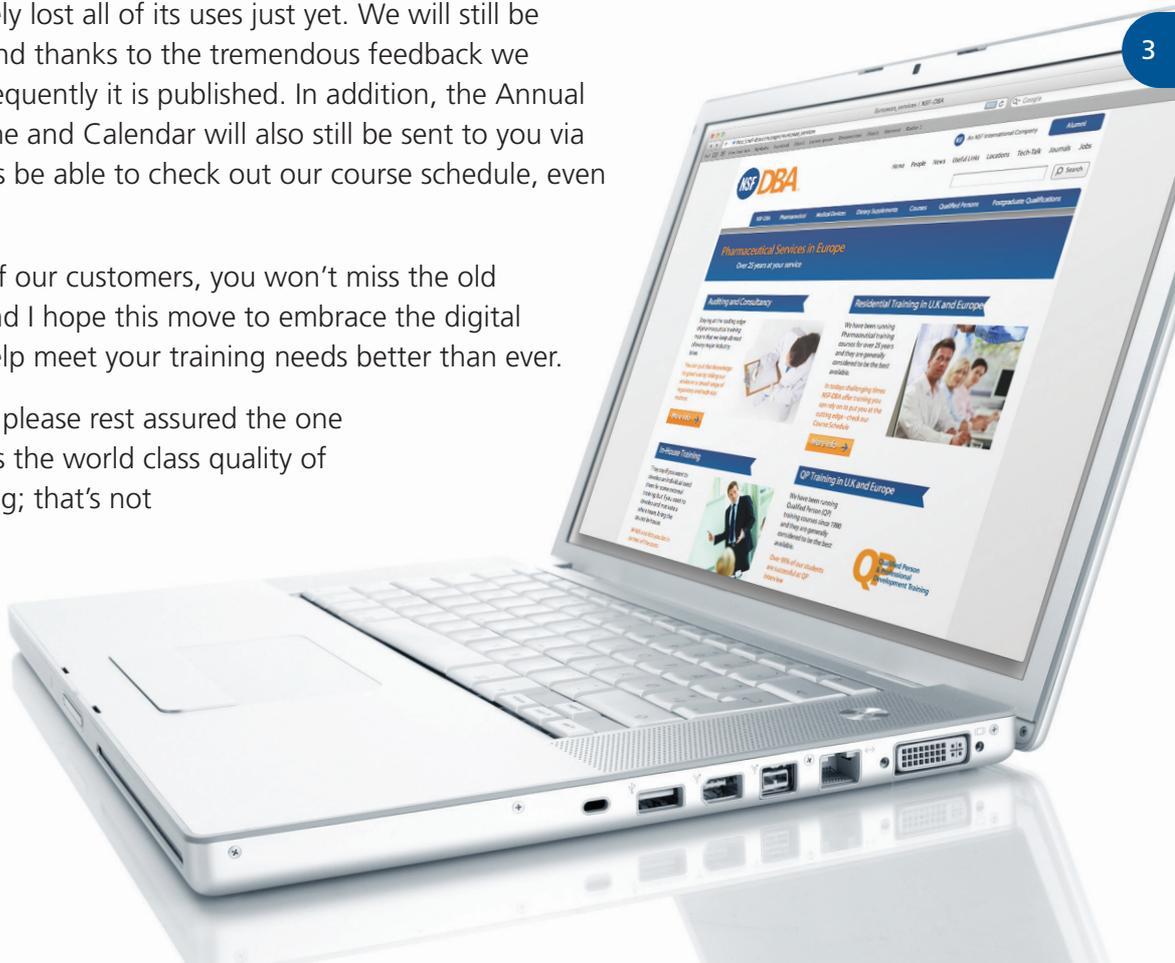
- Developing an NSF-DBA mobile app so you're always in touch with our courses as well as the latest pharmaceutical news even when you're out and about
- Using SMS messaging to ensure you don't miss course booking deadlines, but only if you want us to of course
- Developing the NSF-DBA website to improve your user experience and ensure value with every visit
- Launching an online payment facility to make booking simpler than ever

But paper hasn't completely lost all of its uses just yet. We will still be sending you the Journal and thanks to the tremendous feedback we may even increase how frequently it is published. In addition, the Annual Training Course Programme and Calendar will also still be sent to you via the post so you will always be able to check out our course schedule, even when you're offline.

I am sure that, like most of our customers, you won't miss the old paper course brochures and I hope this move to embrace the digital age means that we can help meet your training needs better than ever.

Despite all these changes, please rest assured the one thing that isn't changing is the world class quality of our pharmaceutical training; that's not up for negotiation!

Bob Pietrowski
Managing Partner



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

2013 Training Courses

15 – 18 January

Devices/Combination Products

York Marriott Hotel, York, UK

How to Audit

More and more companies are now developing products which are designated as medical devices or combination products (a combination of a medicine and a device). Auditors of these products need a working knowledge of both drug and device regulations. This course provides that knowledge.

Your Tutor James Pink

Course Fee £2400.00 plus VAT

21 – 25 January

Formulation & Processing Part 1

Hilton York Hotel, York, UK

QP

Once a new chemical entity has proved its potential in clinical studies, the challenge begins to formulate the compound into an effective medicine and to manufacture that medicine reliably so that safety, quality and efficacy are assured.

This module addresses the two important activities of formulation and processing and provides key information on...

- How the physico-chemical attributes of the drug and the therapeutic indication influence route of administration and dosage form
- Assuring bioavailability
- Methods of manufacture of the major dosage forms
- Factors affecting suitability for use of the major dosage forms

We will cover oral dosage forms – tablets, capsules, liquids

Your Tutors Mike Halliday
Pete Gough
Samantha Clack

Course Fee £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)

“The environment in which the course is run allowed me to develop a strong and effective network with other quality professionals which you can't put a price on!”

Ian Birch, Roche Pharma AG, Germany

30 – 31 January

QC Chemical Laboratories

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

How to Audit

Auditing the Quality Control (QC) laboratories can be a complex process. Key challenges include:

- What is important from the GxP and compliance perspective about QC laboratories, and why are they the focus of so much regulatory attention?
- How should I approach the auditing of QC laboratories?
- What standards are appropriate?
- How do I audit the integrity of laboratory data?
- How do I assess the precision and accuracy of analytical methodology?
- Is there anything new in the regulatory trends that I need to consider?

This course will attempt to answer all of these questions in a practical way so that delegates have materials they can use in their auditing work.

Your Tutors Pete Gough
Oona McPolin

Course Fee £1400.00 plus VAT



11 – 15 February

Pharmaceutical Packaging

York Marriott Hotel, York, UK

QP

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 module 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.

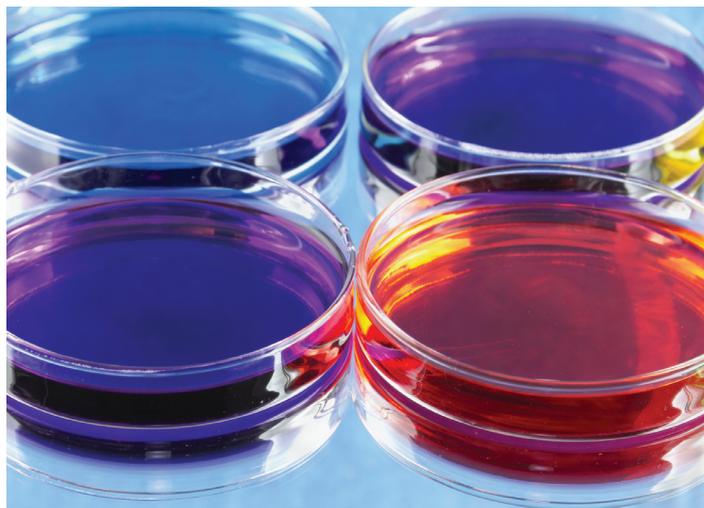
Your Tutors Mike Halliday
Erika Notman
Gary Rees

Course Fee £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)



Reserve your place today

tel: +44 (0) 1751 432 999



19 – 21 February

GMP for Biological and Biotechnology Products

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

This course is aimed at people who are new to the biotech industry or to QPs and auditors who are required to oversee or assess their production and control.

We will teach you:

- The major manufacturing processes for biotech products
- Key GMP and quality management issues
- What can go wrong and how risks can be controlled

Your Tutors Bob Pietrowski
Martyn Becker

Course Fee £1800.00 plus VAT

“Excellent overview of production of biotech products!”
Sandra Grote Beverborg, Organon, The Netherlands

20 – 21 February

Computer Systems

York Marriott Hotel, York, UK

How to
Audit

Computer systems and IT underpin the successful operations of all pharmaceutical and associated companies. They are everywhere in our activities and operations and so the potential audit scope is enormous. However, not all aspects of the systems in use in our regulated environment are GxP-relevant, although some are fundamental to the safety and protection of the patient.

It is important to be able to identify the real risks associated with the use of such systems and focus the attention of the auditor in these areas. This course will approach the auditing of computer systems and the IT Department from that perspective.

Your Tutor David Selby

Course Fee £1400.00 plus VAT

5 – 6 March



Risk-Based Decision Making for Quality Professionals and QPs

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

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 are 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!

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!

- Key point lectures will provide you with the most up-to-date information in each subject area
- You will then be given real life problems to solve in small groups. With the help of the tutors you will be asked to solve each one and make a risk-based decision

It is not what you know that matters. It is what you do with what you know that really matters. This course will improve your 'root cause' problem solving and decision making skills no matter what the situation.

Your Tutors Erika Notman
Gary Rees

Course Fee £1400.00 plus VAT

“Excellent insight into problem solving and assessing risk. Buzz groups challenging, backing up the theory. Great learning environment”

David Harvey, Reckitt Benckiser Healthcare, UK



2013 Training Courses

11 – 15 March

Formulation & Processing Part 2

Hilton York Hotel, York, UK



This course focuses on sterile dosage forms, inhalation products and topical products. The production of sterile products is highly demanding and much of the course is devoted to the facility and control issues which impact product quality and patient safety for sterile products. The course will review...

- Cleanroom design and control
- Environmental monitoring – EU and FDA requirements
- Pharmaceutical water systems
- Kinetics of sterilisation and sterilisation technology
- Filtration and filter integrity testing
- Lyophilisation
- Media fills
- Inhalation products
- Topical products and dermal route of administration

Formulation challenges are reviewed for each product type. Case studies are presented for group discussion and learning. It is an ideal in-depth course for those involved in the production, oversight and control of sterile products and inhalation products.

Your Tutors Graham Clapperton
Martin Lush
Erika Notman
Mike Russell

Course Fee £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)

“More than met my requirements in learning about parenterals/sterile products and the associated areas around this. My knowledge before this was minimal and so has helped improve greatly this knowledge gap, very enjoyable.”

Adam Haigh, Perrigo UK Ltd, UK



11 – 12 March

Deviation and CAPA Systems – Best Practices

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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' (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.

Your Tutors Stewart Green
Terry Snape

Course Fee £1400.00 plus VAT

13 – 15 March

Human Error Prevention

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Human error is often thought to be the cause of many product recalls, customer complaints, batch rejects, deviations and adverse audit findings. In most cases, however, human error is not the root cause, just a convenient excuse.

The good news is that such costly and risky mistakes can be prevented. The objective of this course is simple – to provide you with very practical advice and guidance on how to significantly reduce so called 'human error'.

Error reduction will potentially save you £millions and improve your regulatory compliance. Don't allow yourself to fall behind your competitors!

Your Tutors Stewart Green
Darren Jones

Course Fee £1800.00 plus VAT

“Relevant, well researched, well presented content.”
Shirley Mutch, Genzyme, Ireland

Reserve your place today

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25 – 28 March

Sterile Products Manufacture

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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!

Your Tutors Stewart Green
Terry Snape

Course Fee £2400.00 plus VAT

“Excellent discussions and case studies, helped very much to put into perspective theory and practice and how to tackle often ambiguous situations.”

Andrew Schmid, Roche, Switzerland

26 March

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

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

This short course will keep you right up-to-date with the latest changes to EU and FDA pharmaceutical regulations and the latest proposals for future changes.

Additionally, we will provide practical advice on how best to comply!

Your Tutor Pete Gough

Course Fee £700.00 plus VAT

8 – 12 April

Quality Management Systems

Hilton York Hotel, York, UK



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 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!

This course will provide you with answers to some really tough questions.

Your Tutors Liz Allanson
Martin Lush
David Selby

Course Fee £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)

“It has been a really interesting week. I obtained several good ideas that I expect to implement now and later in my company. The approach for continuous improvement is a concept essential for the future.”

Javier Castañeira, MSD Animal Health, Spain

“It was good to learn more about the QMS (Q10) now I have some tools to go back to our company and change things and get senior management involved.”

Nicole Booden, Netherlands Vaccin Instituut, The Netherlands

15 – 18 April

Pharmaceutical GMP

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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!

- 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 course

Your Tutors Liz Allanson
Mike Halliday
Peter Monger

Course Fee £2400.00 plus VAT





2013 Training Courses



13 – 17 May

Pharmaceutical Microbiology

York Marriott Hotel, York, UK



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.

Your Tutors Martin Lush
Erika Notman
Mike Russell

Course Fee £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)

“Very helpful in realisation of the significant role micro can play in manufacturing processes and not just at the final product and environmental monitoring areas.”

Bertie Craig, Newcastle University, UK

14 May

Free Seminar for Prospective QPs and Sponsors

York Marriott Hotel, York, UK



Since 1990, NSF-DBA and the University of Strathclyde have collaborated to present a structured modular course designed for people wishing to become a QP.

This course is now recognised as the most successful and main route to QP education in the UK and increasingly in Europe.

Please attend this Free Seminar if:

- You are planning to train to become a QP
- You are interested in maximising your technical knowledge and value to your organisation
- You are responsible for QP training or technical development
- You want to know more about sponsoring a QP

Your Tutor Mike Halliday

Please Note: This seminar is open to sponsors and prospective sponsors of candidates currently studying or planning to study with NSF-DBA or any other training provider.

Best Practice for the Analytical Laboratory

Manchester Marriott Victoria & Albert Hotel, Manchester, UK



13 – 14 May

Analytical Methods: Documentation, Validation & Transfer

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.

This course aims to give you an overview of current best practices for the development, documentation, validation and transfer of analytical methods for use in QC laboratories. It is also designed to provide you with practical advice and detailed guidance on analytical method validation, based on the ICH Q2 guideline and on pharmacopoeial method verification, based on USP general chapter 1226.

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.

Your Tutors Pete Gough
Oona McPolin

Course Fee £1400.00 plus VAT

“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

Reserve your place today

tel: +44 (0) 1751 432 999

15 May

Investigating Out of Specification Results

The way a company responds to Out of Specification (OOS) results is a key part of GCLP, which first came to prominence in 1993, following the Barr case. However it is an area of GMP that companies still fail to meet regulatory expectations.

In October 2006 the final version of the FDA OOS Guidance was published. In late 2010, the UK MHRA published the first guidance on this subject by a European authority. This course will compare the US and UK guidance.

The adequacy of the investigations that should take place following the generation of an OOS result and the release/reject decision that must subsequently be made, is seen as a key measure of the overall integrity and probity of a pharmaceutical company.

The recent quality system guidance, such as ICH Q10 and FDA Process Validation, means that inspectors are now focusing much more on trend analysis. Every company will inevitably generate OOS and Out of Trend (OOT) results at some time, so this is an area of GMP compliance that cannot be ignored.

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.

Your Tutor Pete Gough

Course Fee £700.00 plus VAT

“**Good interactive style of passing information. Sufficient detail on the course notes. Good balance between information and time allowed.**”

Mahboob Rehman, Intertek ASG, UK

16 May

Ongoing Stability Testing

In June 2006 the EU implemented a change to Chapter 6 of the EU GMP Guide to add the requirement that the stability of marketed products be monitored according to a continuous programme that will detect any stability issues.

ICH Q7 GMP for APIs also requires that “at least one batch per year of API manufactured should be added to the stability monitoring programme and tested annually to confirm stability”.

This course is designed to help you understand and meet the EU GMP expectations in an effective and efficient manner that will add value to your business.

You will receive detailed guidance on what is required for a compliant ongoing stability programme and how to analyse the data that is produced.

Your Tutor Pete Gough

Course Fee £700.00 plus VAT

20 – 24 May

Effective Pharmaceutical Audits and Self-Inspections

Manchester Marriott Victoria & Albert Hotel, Manchester, UK



Faced with industry and regulatory pressure, NSF-DBA was actively encouraged to successfully redesign an existing, popular course and reintroduce it with the **first and only** International Pharmaceutical Quality Management Systems Auditor/Lead Auditor Qualification. The course, certified by IRCA (www.irca.org), the world's largest international certification body for auditors of quality management systems, meets the requirements of the new Pharmaceutical Quality Management System. The course has been specifically designed to provide delegates with education, understanding and development to meet today's pharmaceutical pressures, including the auditor skills and toolbox of auditing techniques needed by the successful pharmaceutical lead auditor. Given the course focus, content and delivery of EudraLex Volume 4 Chapters 1 to 9, ICH Q10 as the combined QMS, the team at NSF-DBA sees this as the first truly certified GMP auditor training course available globally today.

Your Tutors Liz Allanson
Mike Halliday
David Selby

Course Fee £2600.00 plus VAT

“**Very useful for a newcomer to the field of auditing. The buzz groups and role play were very helpful. Both presenters/tutors were excellent in their presentation of the topics, with genuine examples. Obvious that they both are experienced in this field/subject matter!**”

Shivani Patel, Merck (Pty) Ltd, South Africa



21 May

Bulk Biotech Operations

York Marriott Hotel, York, UK

How to Audit

This short course is designed to prepare you to conduct your first audit of bulk biologics manufacture. We will outline the general process, indicate quality critical steps and provide you with the key questions to ask (and answers to expect!) when auditing facilities, cell banking, cell cultivation, harvesting, purification steps, cleaning, environmental control, bioburden management, QC activities and much more.

Your Tutor Terry Snape

Course Fee £700.00 plus VAT



2013 Training Courses

22 May

Sterile Filling Operations

York Marriott Hotel, York, UK

How to Audit

We will be running this highly interactive course with the objectives of:

- Reminding auditors of the key legislation and guidance around auditing sterile operations
- Developing audit plans and agendas for sterile audits that work
- Working through case studies and audit observations to discuss severity ranking and references to support the findings

Your Tutor Darren Jones

Course Fee £700.00 plus VAT

4 June

Manufacture and Control of Investigational Medicinal Products

York Marriott Hotel, York, UK

How to Audit

It is a challenge for the industry and for auditors to know where GMP audits end and where GCP audits begin. In fact there is no clear dividing line. There is a great deal of overlap between GMP and GCP and this needs to be understood.

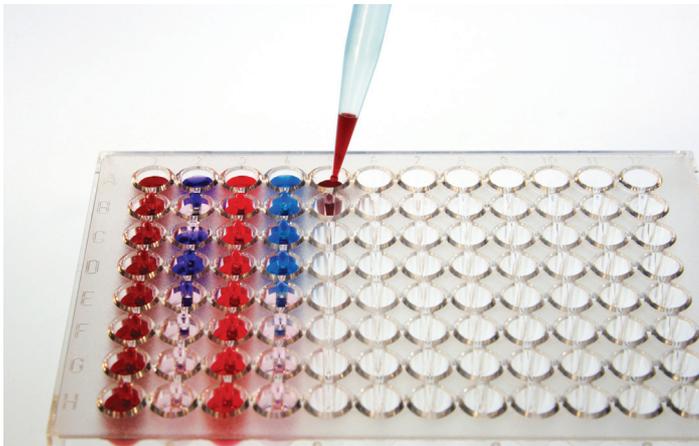
Auditors faced with performing their own internal audits or audits of contractors handling IMPs have many questions:

- What are the key differences between commercial operations and IMP operations?
- How do I know what is the correct approach to auditing IMP facilities?
- How do I assess the significance of any findings?
- How much do I need to know about the IMP itself?
- Do I need to know about GCP?

This one-day course will attempt to answer all of these questions in a practical way so that delegates have materials they can use in their IMP auditing work.

Your Tutor Darren Jones

Course Fee £700.00 plus VAT



6 – 7 June

QP Alumni Meeting

York Marriott Hotel, York, UK

QP

By Invitation Only

The annual meeting organised by the NSF-DBA QP Alumni Association, where former NSF-DBA trainees gather to discuss topics of key importance to practising QPs.

A meeting for QPs, organised by QPs!

Your Tutors Liz Allanson
Mike Halliday

Meeting Fee £450.00 plus VAT



10 – 13 June

Risk-Based Decision Making in Sterile Products Manufacture

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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 and which require decisions which are...

- Scientifically justified
- Based on an objective and realistic assessment of RISK
- In compliance with regulatory requirements and expectations
- GOOD for your business!

This unique course is designed to help YOU to do all these things!

Your Tutors Gary Rees
Terry Snape

Course Fee £2400.00 plus VAT

“Excellent insight into problem solving and assessing risk. Buzz groups challenging, backing up the theory. Great learning environment.”

David Harvey, Reckitt Benckiser Healthcare, UK

“The course has helped me to identify and map a clear process for decision making and assessing the risk of a deviation and the risk of the decision made.”

Suzanne Smyth, Janssen-Cilag, Ireland

Reserve your place today

tel: +44 (0) 1751 432 999



10 – 13 June

Modern Approaches to Process Validation

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

In January 2011, the FDA published their Guidance for Industry on Process Validation, which includes requirements for process design, design of facilities, the qualification of equipment and utilities, process qualification and continued process verification after product launch. Significantly, the FDA requires this new process validation approach for existing marketed products, as well as new products.

In March 2012 the EU published a concept paper that proposes a revision to the CHMP Note for Guidance on Process Validation along similar lines to the new FDA guidance, and EU GMP Annex 15 is also going to be revised.

Both the FDA and EU are now requiring a more scientific, risk-based approach to process validation. It is no longer simply a one-time event where three batches are manufactured and then tested, around the time of filing a regulatory submission, which alone adds very little real value to the company or to patients.

This course will focus on the modern approaches to process validation, including the design of facilities and the qualification of equipment and utilities. We will explain how process validation must link to patients' needs and the regulatory requirements and will explain how tools, such as risk management, statistics and change management, are used to accomplish this. We will show how this modern approach can add real value to your business and provide better protection to patients.

Your Tutors Bruce Davis
Line Lundsberg

Course Fee £2100.00 plus VAT

“Thoroughly enjoyed this course. Have learned some invaluable information that I am looking forward to sharing with my QA colleagues. Thank you to Line, Bruce and David for helping to benefit the future validation activities we plan to execute on our site.”

Lindsay Jones, Eli Lilly & Co, UK

10 – 13 June

GMP for Clinical Trials Manufacture and Supply

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

The implementation of Directive 2001/20/EC has brought profound changes to the way clinical trials are conducted in the EU and equally important changes to the way IMPs are manufactured and controlled.

Few people within the pharmaceutical and healthcare sectors would question the wisdom of greater uniformity of approach to the conduct of clinical trials in Europe, but the application of the directive is proving to be a significant challenge to manufacturers of clinical supplies...

- What 'standard' of GMP is appropriate at the various clinical trial phases?
- Validation – how much, how soon?
- What exactly is a Product Specification File?
- In the case of split manufacture, whose QP should release?
- What is the role of the QP when IMPs are imported?
- Where does GMP end and GCP begin?
- How do QPs deal with comparators?

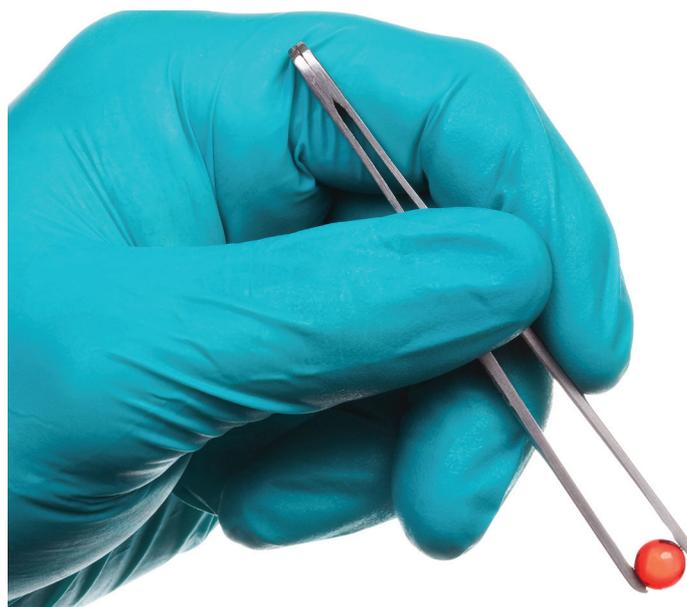
All of these questions and many more will be addressed in this intensive four-day training course.

Your Tutors Liz Allanson
Mike Halliday
Darren Jones

Course Fee £2400.00 plus VAT

“I found the course really valuable at setting the scene and covering the current issues relevant to GMP for IMP manufacture and supply. The opportunities to discuss in open forums common areas of interest and experiences between delegates and guest speakers was most helpful.”

Peter Jones, Oxford Biomedica, UK



2013 Training Courses

17 – 20 June

Active Pharmaceutical Ingredients



Durham Marriott Hotel Royal County, Durham, UK

The quality of a medicine depends in no small part on the quality of its ingredients, and in particular the active.

Thus, the QP and other key professionals in dosage form manufacture must have a thorough understanding of how the manufacture and control of the active and its supply chain may influence the fitness for use of the finished product.

This is recognised by the regulators, especially in Europe where the adoption of Directive 2004/27/EC has put the responsibility for assuring the quality of the active firmly on the shoulders of the dosage form manufacturer, with certain expectations specifically for the QP.

This course is designed to provide you with the knowledge and understanding to fulfil your responsibilities.

Your Tutors Peter Monger
Susan Rocca
Terry Snape

Course Fee £2560.00 plus VAT (First delegate)
£2048.00 plus VAT (Additional bookings from same site)



19 June

Implementation of Falsified Medicines Directive: Anti-Counterfeit Safety Features

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

The current complexity of the global supply chain now presents many challenges and threats to the quality of medicines and the ability of pharmaceutical companies to deliver them at the right time and the right price to the patient. Counterfeiting of medicines is a lucrative opportunity for organised crime, and is growing at an alarming rate globally. The course will review the trends over the last ten years, the initiatives of the global security network, and the current regulatory requirements. It will also discuss existing and emerging technology to protect the patient and the reputation of the pharmaceutical industry from this ever increasing threat.

Your Tutor Gary Rees

Course Fee £700.00 plus VAT

“Excellent course – and much needed to address the growing problems in this area.”

Darren Smithies, Fujifilm Diosynth Biotechnologies UK Ltd, UK

18 June

Implementation of Falsified Medicines Directive: Supply Chain Assurance

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

The current complexity of the global supply chain now presents many challenges and threats to the quality of medicines and the ability of pharmaceutical companies to deliver them at the right time and the right price to the patient. The EU Falsified Medicines Directive and the revised EU GDP Guideline seek to address a number of these issues and to improve the security of the supply chain, in a more integrated way. The course will cover the requirements for the manufacturer, packager, QP/QA department, distribution network, brokers, and wholesaler dealers. It will also seek to identify and discuss the practical implications to all the stakeholders in the supply chain.

Your Tutor Gary Rees

Course Fee £700.00 plus VAT

“Helped identify gaps in our supply chain and the weaknesses/homework. Good to hear it from people with a wealth of experience.”

Ashlene Leonard, Abbott Ireland Ltd, Republic of Ireland

11 – 12 July

Good Distribution Practice

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

For many years, regulatory agencies have demanded that temperature sensitive products be stored and distributed under conditions which maintain the safety and efficacy of those products to the patient. This has led to ‘cold chain’ best practices and guidelines.

Maintenance of the cold chain is essential for products such as vaccines and other biopharmaceuticals. The effectiveness of the cold chain is a major area of concern during regulatory inspections and adverse inspection observations are common.

More recently, however, regulators have broadened the emphasis of temperature control to include all products where defined temperature bands exist, including ‘room temperature’ or ‘ambient temperature’ products.

This course is designed to help you avoid regulatory criticism and to assure the quality of your products from factory to patient.

Your Tutors Liz Allanson
Darren Jones
Gary Rees

Course Fee £1400.00 plus VAT

Reserve your place today

tel: +44 (0) 1751 432 999



22 – 25 July

The Role & Professional Duties of the Qualified Person

York Marriott Hotel, York, UK

The principal objective of this course is to emphasise how QPs 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.

Your Tutors Pete Gough
Darren Jones
Erika Notman

Course Fee **£2560.00 plus VAT** (First delegate)
£2048.00 plus VAT (Additional bookings from same site)

16 – 17 September

**Deviation and CAPA Systems – Best Practices**

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

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' (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.

Your Tutors Stewart Green
Terry Snape

Course Fee **£1400.00 plus VAT**



16 – 19 September

Mathematics & Statistics

York Marriott Hotel, York, UK

The introduction of the EU requirement for product quality reviews, together with ICH Q8, Q9 and Q10, 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 is designed for delegates who have little or no experience in the application of statistical techniques.

The provision of useful information is essential to the QP and other professionals in helping them to:

- Understand the reliability and accuracy of data
- 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

Your Tutors Pete Gough
George Gettinby

Course Fee **£2560.00 plus VAT** (First delegate)
£2048.00 plus VAT (Additional bookings from same site)

“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

17 September

Free Seminar for Prospective QPs and Sponsors

York Marriott Hotel, York, UK

Since 1990, NSF-DBA and the University of Strathclyde have collaborated to present a structured modular course designed for people wishing to become a QP.

This course is now recognised as the most successful and main route to QP education in the UK and increasingly in Europe.

Please attend this Free Seminar if:

- You are planning to train to become a QP
- You are interested in maximising your technical knowledge and value to your organisation
- You are responsible for QP training or technical development
- You want to know more about sponsoring a QP

Your Tutor Mike Halliday

Please Note: This seminar is open to sponsors and prospective sponsors of candidates currently studying or planning to study with NSF-DBA or any other training provider.

2013 Training Courses

18 – 20 September



Human Error Prevention

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

Human error is often thought to be the cause of many product recalls, customer complaints, batch rejects, deviations and adverse audit findings. In most cases, however, human error is not the root cause, just a convenient excuse.

The good news is that such costly and risky mistakes can be prevented. The objective of this course is simple – to provide you with very practical advice and guidance on how to significantly reduce so called 'human error'.

Error reduction will potentially save you £millions and improve your regulatory compliance. Don't allow yourself to fall behind your competitors!

Your Tutors Stewart Green
Terry Snape

Course Fee £1800.00 plus VAT

“The most useful course I've ever been on. I wish my colleagues had been here as well.”

Flemming Mørch Hansen, Bavarian Nordic, Denmark

23 – 27 September

Effective Pharmaceutical Audits and Self-Inspections

York Marriott Hotel, York, UK



Faced with industry and regulatory pressure, NSF-DBA was actively encouraged to successfully redesign an existing, popular course and reintroduce it with the **first and only** International Pharmaceutical Quality Management Systems Auditor/Lead Auditor Qualification. The course, certified by IRCA (www.irca.org), the world's largest international certification body for auditors of quality management systems, meets the requirements of the new Pharmaceutical Quality Management System. The course has been specifically designed to provide delegates with education, understanding and development to meet today's pharmaceutical pressures, including the auditor skills and toolbox of auditing techniques needed by the successful pharmaceutical lead auditor. Given the course focus, content and delivery of EudraLex Volume 4 Chapters 1 to 9, ICH Q10 as the combined QMS, the team at NSF-DBA sees this as the first truly certified GMP auditor training course available globally today.

Your Tutors Liz Allanson
David Selby

Course Fee £2600.00 plus VAT

“One of the best training courses I have ever been to!! The mix of lectures, teamworks and presentations was very good and gave a lot of opportunities to practise and discuss with other participants. Very competent trainers.”

Kicki Garheden Fredriksson, Octapharma AB, Sweden

24 – 25 September

Risk-Based Decision Making for Quality Professionals and QPs

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

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 are 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!

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!

- Key point lectures will provide you with the most up-to-date information in each subject area
- You will then be given real life problems to solve in small groups. With the help of the tutors you will be asked to solve each one and make a risk-based decision

It is not what you know that matters. It is what you do with what you know that really matters. This course will improve your 'root cause' problem solving and decision making skills no matter what the situation.

Your Tutors Graham Clapperton
Mike Russell

Course Fee £1400.00 plus VAT

7 – 10 October



Sterile Products Manufacture

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

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!

Your Tutors Stewart Green
Darren Jones

Course Fee £2400.00 plus VAT

Reserve your place today

tel: +44 (0) 1751 432 999

8 October

How to Perform Effective Product Quality Reviews

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

It is a legal requirement in the EU to produce a regular Product Quality Review. Chapter 1 of the EU GMP Guide lists the 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.

Your Tutor Pete Gough

Course Fee £700.00 plus VAT

“The course was great and met all my objectives and will most certainly help me implement a satisfactory PQR into our quality system.”

Ian Snowball, Fujifilm Diosynth Biotechnologies UK Ltd, UK

9 October

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

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

This short course will keep you right up-to-date with the latest changes to EU and FDA pharmaceutical regulations and the latest proposals for future changes.

Additionally, we will provide practical advice on how best to comply.

Your Tutor Pete Gough

Course Fee £700.00 plus VAT



14 – 17 October

GMP for Clinical Trials Manufacture and Supply

Park Hotel Amsterdam, Amsterdam, The Netherlands

The implementation of Directive 2001/20/EC has brought profound changes to the way clinical trials are conducted in the EU and equally important changes to the way IMPs are manufactured and controlled.

Few people within the pharmaceutical and healthcare sectors would question the wisdom of greater uniformity of approach to the conduct of clinical trials in Europe, but the application of the directive is proving to be a significant challenge to manufacturers of clinical supplies...

- What 'standard' of GMP is appropriate at the various clinical trial phases?
- Validation – how much, how soon?
- What exactly is a Product Specification File?
- In the case of split manufacture, whose QP should release?
- What is the role of the QP when IMPs are imported?
- Where does GMP end and GCP begin?
- How do QPs deal with comparators?

All of these questions and many more will be addressed in this intensive four-day training course.

Your Tutors Liz Allanson
Darren Jones
Mike Russell

Course Fee £2400.00 plus VAT

21 – 25 October

Pharmaceutical Law & Administration

Hilton York Hotel, York, UK



Pharmaceutical law and administration is a key foundation knowledge requirement for all 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.

This extremely popular module is designed to ensure that, in an increasingly changing world, you have 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 Act and legislative framework
- US and other international pharmaceutical legislation
- Other relevant laws and guidelines

Your Tutors Liz Allanson
Samantha Clack
Pete Gough

Course Fee £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)

2013 Training Courses

29 – 31 October



Good Autoclave Practice

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

This course provides you with all you need to know about working with autoclaves. This equipment is fundamental to contamination control and requires an understanding of what the regulators consider to be Good Autoclave Practice. Come along to discuss the practicalities of...

- Choosing the right autoclave for your business
- Validation steps required to release into production
- Designing validation cycles for your use
- Ongoing performance monitoring to maintain equipment – fit for purpose

In addition we will discuss what to do when your cycle fails and training of operators.

Your Tutor Peter Monger

Course Fee £1800.00 plus VAT

“I now understand what happens inside an autoclave and what to do when things go wrong!”

James Walsh, BioReliance, UK

4 – 8 November



Effective Pharmaceutical Audits and Self-Inspections

Park Hotel Amsterdam, Amsterdam, The Netherlands



Faced with industry and regulatory pressure, NSF-DBA was actively encouraged to successfully redesign an existing, popular course and reintroduce it with the **first and only** International Pharmaceutical Quality Management Systems Auditor/Lead Auditor Qualification. The course, certified by IRCA (www.irca.org), the world's largest international certification body for auditors of quality management systems, meets the requirements of the new Pharmaceutical Quality Management System. The course has been specifically designed to provide delegates with education, understanding and development to meet today's pharmaceutical pressures, including the auditor skills and toolbox of auditing techniques needed by the successful pharmaceutical lead auditor. Given the course focus, content and delivery of EudraLex Volume 4 Chapters 1 to 9, ICH Q10 as the combined QMS, the team at NSF-DBA sees this as the first truly certified GMP auditor training course available globally today.

Your Tutors Liz Allanson
Mike Halliday
David Selby

Course Fee £2600.00 plus VAT

“A really excellent course! It was one of my most active and intensive weeks but I do not regret it at all.”

Tomasz Zawislak, Pharmatiqa Consultants, Poland

11 – 14 November



Quality Aspects of the CTD

Hilton York Hotel, York, UK

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 involved 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.

Your Tutors Liz Allanson
Pete Gough

Course Fee £2400.00 plus VAT

12 – 13 November

Pharmaceutical Quality Systems: Best Industry Practice

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

How good is your Pharmaceutical Quality System (PQS)? Will it comply with the requirements and expectations of ICH Q10? Will it satisfy the ever-increasing demands of the regulatory agencies? How does your PQS compare with the 'best in class'? As regulatory criticism of quality systems reaches unprecedented levels you have a duty to ensure your PQS is 'fit for purpose'. This is a tough call. Do too much and your PQS becomes unaffordable and complex. Do too little and you risk regulatory criticism destroying your business. This invaluable seminar will help you strike the right balance by sharing 'best industry practice'. For each element of the PQS we will:

- Remind you of the minimum regulatory requirements – focusing on the facts and dispelling the myths!
- Outline the key elements of 'best practice' – how others achieve competitive advantage
- Describe how best practice can be implemented effectively
- Show you how to 'close the gap' and make your PQS compliant, cost effective and 'future proof'

Your Tutors Martin Lush
Stewart Green

Course Fee £1400.00 plus VAT

“Highly knowledgeable and friendly tutors. Will definitely attend another DBA course.”

Dan Winfield, Moorfields Pharmaceuticals, UK

Reserve your place today

tel: +44 (0) 1751 432 999

15 November

Practical Implementation of Quality by Design: Regulatory Submissions

Hilton York Hotel, York, UK

Although the pharmaceutical industry is now investing more heavily in PAT and some companies are working towards implementation of QbD principles in their manufacturing processes, there is only limited guidance from the main regulatory agencies about how information in support of this should be provided within a submission.

This course looks at the regulatory implications and practicalities of preparing the Quality Section of a CTD file to introduce QbD concepts into new and existing submissions.

Your Tutor Bruce Davis**Course Fee** £700.00 plus VAT

18 – 22 November

Analysis & Testing

Hilton York Hotel, York, UK



A fundamental part of the QP's release decision is the review and interpretation of analytical data. It is therefore essential that the QP understands the basis of the analytical techniques and their respective strengths and weaknesses.

This module seeks to provide a foundation of knowledge to enable the QP to judge analytical data, to be able to ask relevant questions to aid interpretation and to know when to call for additional data/advice.

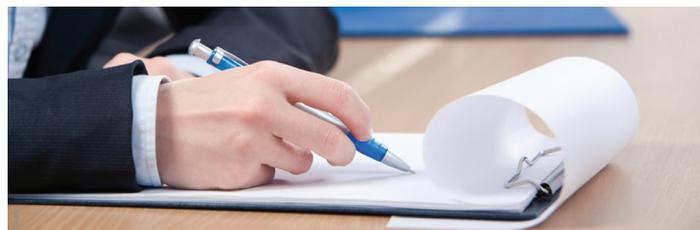
The module is designed for delegates with a scientific educational background who wish to obtain a broader knowledge of Good Control Laboratory Practice (GCLP). The module may also be suitable for analytical chemists who are new to the pharmaceutical industry.

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

Your Tutors Pete Gough
Oona McPolin
Terry Snape**Course Fee** £3200.00 plus VAT (First delegate)
£2560.00 plus VAT (Additional bookings from same site)

“Overall another excellent and very enjoyable course. I learnt a lot in a short time.”

John Horry, Reckitt Benckiser, UK



19 – 20 November

Key Excipients

How to Audit

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

New directives and expectations place increasing pressures on companies to audit the entire supply chain of starting materials including excipients. This new course will cover key legislation and guidance around auditing excipients, GMP, IPEC, ISO 9000, and discuss the role of EXCiPACT™. We will work with case studies and audit observations to discuss the severity ranking and references to support findings.

Your Tutor Peter Monger**Course Fee** £1400.00 plus VAT

21 – 22 November

Chemical API Manufacture

How to Audit

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

The quality of any medicine depends on the quality of the API. We will show you what process 'critical control points' to focus on and what questions to ask about the manufacture and control procedures that can have a direct impact on the purity, potency and stability of the API.

Your Tutor Susan Rocca**Course Fee** £1400.00 plus VAT

25 – 28 November

**Pharmaceutical GMP**

Park Hotel Amsterdam, Amsterdam, The Netherlands

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!

- 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 course

Your Tutors Liz Allanson
Samantha Clack
Mike Halliday**Course Fee** £2400.00 plus VAT



Auditing



In-House Training

For team training that makes a real difference, don't come to us – let us come to you.

On your premises, we can make the course fit precisely with your priorities for content, duration, target audience and timing – and ensure everything ties in directly with the day-to-day working lives of the attendees:

- Course materials will be based on your company's products and procedures
- Case studies will reference the real-life experiences of your people
- Confidential and sensitive issues can be discussed openly and confidentially

18 In-house training works well because everyone is exposed to the same material at the same time – and that translates into quick changes and improvements across the board – efficient and cost-effective.

Five Steps to Bespoke In-House Training

1. We discuss the course programme with you – objectives, target audience, locations and timing
2. We provide a draft proposal and programme for you to review
3. We listen to any feedback and change the programme accordingly
4. We deliver the programme
5. We gather and discuss feedback from course attendees and stakeholders and plan any follow-up actions as appropriate

Third Party Audits

Let us help you to find the ideal contractor by performing audits on your behalf. We have all the expertise needed; we can compare what we find with what is available elsewhere; a third party is more likely to be open with us than with you; and there are fewer concerns over confidentiality.

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.

For more information call +44 (0)1751 432 999, email mail

Services

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 the altering areas of non-compliance and vulnerability
- Staff coaching in the type of questions which are likely to be asked during the inspection and how best to answer them
- Sound, practical support and advice in the run-up to the real inspection

EU Readiness for FDA Inspection

We have a great deal of experience in preparing EU clients for inspection by the FDA and, thanks to our work with US clients, an in-depth knowledge of what is required. But our EU-based operation lets us demonstrate several advantages over American consultancies offering the same service:

- Practical experience of how the FDA carries out overseas inspections (many US consultancies only deal with US-based investigations)
- The ability to bridge linguistic, cultural and philosophical gaps between EU countries and US inspectors; an area where misunderstandings can occur
- Our European presence reduces our costs in comparison to those of US consultants – and makes us more accessible during final preparations

Consulting and Troubleshooting



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.

4 easy ways to book your place

By phone

+44 (0) 1751 432 999

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 email

courses@nsf-dba.com

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.

By fax

+44 (0) 1751 432 450

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

Online

www.nsf-dba.com

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

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