

www.nsf-dba.com

Pharmaceutical GMP

“Europe’s Most Popular GMP Course!”

Monday 28 November to Thursday 1 December 2011

Amsterdam Marriott Hotel,
Amsterdam, The Netherlands



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 seven years, nearly 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"

Delegates on a previous GMP course said:

"I found this course very interesting and useful. To me GMP is a new topic, which will be very important in my work as a future QP. Although the department wasn't very big, I think it was very useful to me to hear about all the different topics involving GMP. I want to thank the tutors for all the information they've given us. They did it in a very enthusiastic way and they have a lot of knowledge! Thanks and I'm looking forward to another DBA course!"

Roumaynes Schepers, Sandoz

"The standard of Lecturers/Presenters was excellent, very impressed with the quality and completeness of the material covered"

Gerard Kemmy, Covidien

"Really great tutors answering all our questions. Absolutely nice mix of lectures and buzz group working. The course had great content (for starters) and was very well presented"

Hans-Juergen Franke, B Braun

"Complete overview on GMP – that was what I was looking for. Regained my motivation to continue working in QA"

Markus Schoester, Novartis

"It is a fun and relaxed way of knowing much more about GMP"

Elma Snjyder, Solvay

"Lecturers were very knowledgeable and presentation style was very good"

Nick Hodgson, Genzyme

Course Outline

A clear comparison of EU and FDA GMP requirements ...

- Areas of agreement
- Critical differences

Up-to-the-minute information on new GMP initiatives and regulations ...

- FDA's cGMP for the Twenty-First Century
- Changes to EU GMP regulations:
 - Product Quality Review
 - Ongoing Stability Testing
 - Reference samples and retention samples
- ICH Q9: Quality Risk Management

Practical advice on dealing with the 'difficult areas' of GMP ...

- Change Control
- Deviations
- Assessing the effectiveness of training

An understanding of how GMP is influenced by ...

- Premises
- Processes
- Products
- Procedures
- People

An appreciation of the critical GMP issues for ...

- Solid dosage forms
- Sterile products
- Liquids/semi-solids
- Packing operations
- Computers

A panel discussion session to explore **YOUR** specific GMP problems

Your Tutors



Liz Allanson
NSF-DBA, UK

Former manager of the UK MHRA's GMP inspection team.

Liz has a thorough understanding of EU and US GMP regulations.



Mike Halliday
NSF-DBA, UK

Former Associate Director, Global Audit and Compliance, Wyeth Europa.

Mike is experienced in interpreting EU and US GMP regulations in a practical manner.



Samantha Clack
NSF-DBA, UK

Samantha is a current Qualified Person with experience as a QA Manager and in corporate QA auditing.

An Ideal Mix of Lectures, Discussion and Team Tasks

Like all NSF-DBA courses, this course will provide ample opportunity for discussion and debate.

Teamwork exercises will encourage participation and reinforce the messages of lectures and tutorials.

Delegates will learn from each other as well as from the tutors and will definitely feel 'involved' in the learning process!

Booking Form

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Please reserve me a place on this course...

First/only delegate attending: £2275.00 Plus VAT at the prevailing rate (*where applicable – see note below*)

Additional delegate(s) from same site: £1820.00 Plus VAT at the prevailing rate (*where applicable – see note below*)

Includes: tuition, comprehensive course notes, attendance certificate, lunches and refreshments

Excludes: all hotel accommodation and dinners (see Hotel Accommodation section)

Course begins at 09.00 on Monday and finishes at 15.00 on Thursday

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate; however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT PROVIDED THAT valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

VAT ID No.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT.

Mr/Mrs/Miss/Ms/Dr <input type="text"/>	First Name <input type="text"/>	Surname <input type="text"/>
Job Title <input type="text"/>	Company <input type="text"/>	
Full Site Address <input type="text"/>		
		Post Code <input type="text"/>
Delegate Tel No <input type="text"/>	Delegate Fax No <input type="text"/>	Delegate Email <input type="text"/>
Please indicate any special dietary needs <input type="text"/>		

Sterling cheques, payable on a UK bank to NSF-DBA Ltd, for the full invoiced amount (net of ALL bank charges) should be attached to this Booking Form and sent to NSF-DBA Ltd at the address below. A VAT invoice (if applicable) will be provided (VAT Reg No. GB 927 3679 85). Payments can also be made by bank transfer online (our company bank details are included on our invoice). Settlement must be received at least 10 working days prior to the course start date. Cancellations within 25 working days of the course start date are subject to charges (see Course Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

<input type="text"/>	Purchase Order number <input type="text"/>	
Authorised Signature <input type="text"/>	Date <input type="text"/>	Cheque enclosed <input type="text"/>

To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number

The programme and other information contained in this brochure are correct at the time of printing and are published in good faith. We reserve the right to make any changes which may become necessary.

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The Venue

The Amsterdam Marriott Hotel is among the superior hotels in Amsterdam, it offers an ideal location across from the Leidseplein's fine shopping, dining and entertainment. As a guest, you'll find well appointed guest rooms with high speed internet to keep you in touch. A well equipped fitness room will help keep you in shape. Fine dining awaits in their two restaurants.

Marriott
AMSTERDAM



Hotel Accommodation

- We have a block booking of bedrooms at the Amsterdam Marriott Hotel, at the specially negotiated bed and breakfast rate of €189.00 per delegate per night. This rate does not include any local taxes which may be applicable.
- As part of our improvements to the booking process, we have arranged for an online booking service with the hotel and details of how to make your accommodation booking will be included in your course joining instructions (issued to you at the time of booking). Alternatively you will be able to make a telephone booking directly with the hotel. If you need any help or guidance with the accommodation booking process, please contact our course administration team.
- Your account with the hotel should be settled at check out.
- Any charges made by the hotel as a result of you not taking up your reservation for any reason will remain your responsibility, therefore please ensure you are aware of the hotel's cancellation policy.
- Whilst places on the course will be available, we would also ask you to ensure that your booking for accommodation is made at least six weeks before the course start date as the hotel cannot guarantee bedroom or rate availability after this time.

To Book on this Course

- Fax the completed and signed form from this brochure to our Course Administrator. Your place will then be confirmed by post and a course fee invoice will be issued.
- Provisional bookings can be made via our website, in the Training Courses section. Online reservations must be confirmed by the completion of a Booking Form (pdf brochure and Booking Form files can be downloaded via the website).
- Make sure you write a Purchase Order number on the Booking Form if this is necessary for settlement of our invoice.
- Reserve a place by telephone or email (contact details are on the Booking Form), confirming as above.

Course Cancellations

Written cancellations with a full refund will be accepted up to 25 working days before the start date of the course. A cancellation fee of 50% will be payable for cancellations received between 10 and 25 working days before the start of the course. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.