



How to Perform Effective Product Quality Reviews

Tuesday 4 October 2011
Manchester Airport Marriott Hotel,
Manchester, UK

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 Q7a, 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

- The regulatory requirements for medicinal products and Active Pharmaceutical Ingredients in the EU and USA
- The data that should be included in a Product Quality Review and what may be excluded
- Statistical techniques to enable you to analyse and interpret data effectively
- 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
- Approval
- Review of data

of Product Quality Reviews for medicinal products or Active Pharmaceutical Ingredients.

This will include...

- Qualified Persons
- Other quality personnel
- Laboratory staff
- Validation and technical staff
- Production staff
- Support specialists
- Regulatory Affairs professionals

Course Outline

Periodic Product Reviews

- What they are and why they are important
- Current regulatory expectations:
 - EU GMP Chapter 1
 - US CFR 21
 - ICH Q7a
- Data requirements

Data Analysis Techniques

- Control charts
- Process capability
- Linear regression

Why not combine this with Pharmaceutical Legislation Update?

On Wednesday 5 October we shall be running a seminar which offers an ideal opportunity to speak to experienced tutors and to delegates who are in similar roles.

Why not stay an extra night and attend both these courses?

Data Interpretation

- How to identify trends in, and draw conclusions from, data

Product Review Reports

- How to present the information
- How to document conclusions

Acting on the Information

- How to make the exercise add value to your business

Discussion and Working Groups

A significant proportion of the course will be devoted to group work, where delegates have the opportunity, through case studies, to put theory into practice.

Additionally, discussion periods will provide delegates with an opportunity to have their specific questions answered.



Peter Smith
NSF-DBA, UK

Peter is a former Specialist Principle Medicines Inspector with the UK medicines inspectorate. He also has extensive senior management experience within the pharmaceutical industry.



Pete Gough
NSF-DBA, UK

Before joining NSF-DBA, Pete held numerous senior management positions within the pharmaceutical industry, culminating in his role as Senior Quality Consultant in Eli Lilly's Global Quality Systems division.

What Previous Attendees Said About This Course

"Great content and delivery – even a few 'light bulb' moments on the maths!!"

Paul Thomas, Penn Pharmaceutical Services Ltd, UK

"Course was very good. Emphasis on data assessment was great, with a brief outline on the regulations and writing skills. Good balance."

James Valentine, Pfizer Biotech Campus

"The course has given me a better direction in the handling of PQR and the application of the knowledge gained will definitely be a good foundation to move forward in this area."

Anita Van Der Laan, Norbrook Laboratories Ltd, Northern Ireland

"The course has helped identify improvements that can be made to our current process."

Mark Fox, Rosemont Pharmaceuticals Ltd, UK

"Enjoyed the practical application and the statistics to measure whether process is capable and in control."

Blanaid Dixon, Servier Industries, Republic of Ireland

Booking Form

How to Perform Effective Product Quality Reviews

Tuesday 4 October 2011

Manchester Airport Marriott Hotel, Manchester, UK

Please reserve me a place on this course...

First/only delegate attending: £695.00 Plus VAT at the prevailing rate (*where applicable – see note below*)

Additional delegate(s) from same site: £556.00 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 and finishes at 16.00

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

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 Manchester Airport Marriott Hotel is just five minutes by courtesy bus from the airport terminal buildings and railway station. Transport will also be available, free of charge, at the close of the course to take you from the hotel to your terminal building.

Situated adjacent to the M56 motorway, it is also easily accessible by road. With its comfortable bedrooms, swimming pool and fitness room, the hotel is an excellent place to relax as well as learn.



Hotel Accommodation

- We have a block booking of bedrooms at the Manchester Airport Marriott Hotel, at the specially negotiated bed and breakfast rate of £106.38 (plus VAT at the prevailing rate) per delegate per night.
- 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.