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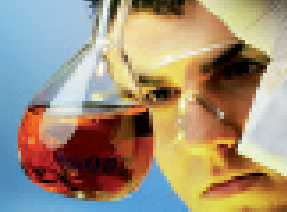
The Pharmaceutical Training Experts

How to Simplify and Improve Your Batch Record Review Process

Monday 19 and Tuesday 20 April 2010

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

About This Course



Your primary objective is to manufacture safe and effective medicines and release them to your customers and patients as soon as possible.

Whether involved in the release of fully licensed products, batches for clinical trials or those from third party manufacturers (including a growing number of virtual companies), the challenges are considerable. Your Batch Manufacturing Record and Product Release process must be simple, quick, effective and legally compliant. This course will give you practical and essential advice on how to achieve these challenging objectives.



What You Will Learn

- How to meet the **regulatory requirements** for BMR reviews and product release procedures (EU and USA)
- How to incorporate **Quality by Design** into your BMRs
- How to **simplify** your BMR to improve the **speed and effectiveness** of your review process
- How to **reduce the size** of your BMR by including only quality critical data
- How to achieve a **simple and effective review** process for contract manufacturers, CROs, virtual companies and other third parties
- **Practical tools and techniques** to help you make the right product release decisions, particularly those really tough ones when you feel isolated, vulnerable and alone!!

Who Should Attend

This course is for anyone involved in the review and approval of BMR and Product Release. This will include Qualified Persons, Consultants or Contract QPs, QP delegates and trainees and QA/Manufacturing personnel responsible for BMRs. This course is a must for anyone interested in simplifying their BMR and PR procedures for:

- Fully licensed medicines
- Products from third party and contract manufacturers
- Products destined for clinical trials

Reserve your place today

email: courses@DBA-global.com

Course Outline

Batch Manufacturing Record Review and Product Release Procedures

- Regulatory demands and expectations – now and in the future
- Best industry practices – find out how the best companies improve the speed and effectiveness of their review process

Your Batch Manufacturing Records, Structure and Contents

- Design and layout – how to keep things simple to help reduce BMR ‘errors’
- BMR content – what data must be included and what can be excluded to reduce BMR size and complexity
- How to link your BMR review to your change control system to ensure you only release fully compliant products!

The Batch Manufacturing Record Review and Approval Process

- Who must review what and how
 - Operator/Analyst
 - Production Manager/Supervisor
 - QP Delegate
 - QP (whose responsibilities can and cannot be delegated!)

Product Release Decision Making

- Practical tools and techniques to help with the really tough product release decisions
- QP discretion – what does this mean and how far can you legally go?
- How to measure the effectiveness of your BMR review and approval process

Your Tutors



Martin Lush

David Begg Associates, UK

Martin is Senior Partner with DBA and has worked in the Pharmaceutical Industry for over 30 years. He has extensive experience of helping companies to improve the efficiency of their batch record review processes.



Stewart Green

David Begg Associates, UK

Stewart has spent many years in senior QA management and during that time has reviewed thousands of batch records. He has also overseen the re-modelling of documents to make them easier to fill in and easier to review effectively.

What previous attendees said about this course

These are just some of the comments we have received and are typical of the kind of feedback we've come to expect after a DBA course.

"Great course. Loved every minute and learnt lots"

Sylvia van Gaal-Versteeg, Intervet, The Netherlands

"Course provided me with the tools I need to simplify my batch records"

Jean-Louis Delmotte, Merck Serono SA, Switzerland

"Course was worthwhile and enjoyable, like every DBA course!"

George Scott, GlaxoSmithKline

"Brilliant course which will help with our Green Belt Project to stream line our batch records"

Clare Watson, MedImmune

Booking Form

How to Simplify and Improve Your Batch Record Review Process

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Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Please reserve me a place on this course...

First/only delegate attending: £1320.00 Plus VAT at the prevailing rate

Additional delegate(s) from same site: £1056.00 Plus VAT at the prevailing rate

Includes: Includes: tuition, comprehensive course notes, attendance certificates, 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 Tuesday

Please write clearly in BLOCK CAPITALS

Mr/Mrs/Miss/Ms/Dr First Name Surname

Job Title Company

Full Site Address

Post Code

Delegate Tel No Delegate Fax No Delegate Email

Accommodation: I require accommodation (please tick box) YES NO See *Hotel Accommodation section for details*

Please indicate any special needs (dietary/accommodation):

To guarantee your accommodation reservation, credit card details must be supplied (please write clearly)

Card Number Expiry Date

Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address below. Settlement must be received at least 10 working days prior to the course start date. A VAT invoice will be provided. VAT Reg No GB 927 3679 85. Under UK law all applications are subject to VAT irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. Cancellations within 25 working days of the course start date are subject to charges (see Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

Purchase Order number

Authorised Signature Date Cheque enclosed

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. David Begg Associates reserves the right to make any changes which may become necessary.

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The Venue

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The Manchester Marriott Victoria & Albert Hotel stands on the banks of the River Irwell, near the city centre but convenient for Manchester Airport (19km), the city's Piccadilly rail station (3km) and the UK's motorway networks. Recently lovingly restored, this Grade II listed building bears many modern features. The hotel has its own car park and the Living Well Health Club with pool, gymnasium, sauna and steam room is just a few minutes from the hotel. Also nearby are the Imperial War Museum North West, Lowry Museum and Manchester's three theatres. A few minutes' walk takes you to the city's main shopping and eating district.

- David Begg Associates has a block booking of bedrooms at the Manchester Marriott Victoria & Albert, at the specially negotiated bed and breakfast rate of £107.22 (plus VAT at the prevailing rate) per delegate per night.
- The nights of Sunday 18 and Monday 19 April 2010 inclusive will usually be reserved.
- Accommodation should only be reserved through us using the Booking Form. Credit card details must be provided to ensure this reservation is kept for you. Please do not contact the hotel directly as this could cause duplicate reservations.
- 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.
- Where at all possible, your booking for accommodation should be received six weeks before the course start date. Places on the course will be available after this time but we cannot guarantee bedroom or rate availability.
- Where no indication is made on the Booking Form, no accommodation will be reserved by us.

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.

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.

**Booking your place
couldn't be easier!**

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