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South Africa!

Practical Application of Quality Risk Management

Practical guidance for the
pharmaceutical, biopharmaceutical
and active pharmaceutical
ingredient industries

Wednesday 23 to Friday 25 February 2011
Glenhove Conferencing Facility,
Johannesburg, SA

NSF **DBA**
25 YEARS OF EXCELLENCE

About This Course

Risk management has become the latest hot topic in pharmaceutical quality.

The ICH Q9 guideline on “Quality Risk Management” was approved in November 2005 and has been implemented in the EU, Japan and USA. It is Annex 20 of the EU GMP Guide.

You are already making risk-based decisions every day! This course is designed to assist you in understanding exactly what formal Quality Risk Management is, how to implement it and provide you with the skills to make the right decisions; this will add value to your business and meet the developing regulatory expectations. It will help you move away from “fire fighting” to proactively manage risks.

The background and content of ICH Q9 will be explained by a member of the Expert Work Group who drafted the guideline.

Industry experts will explain how Quality Risk Management can be used in real life, practical situations.

What You Will Learn

- What is in ICH Q9/EU Annex 20 and how it can be used to improve business performance
- How to decide on the appropriate level of Quality Risk Management
- A structured Quality Risk Management process and how it can be applied to a wide range of situations
- The most common Risk Assessment techniques (e.g. Risk Ranking, FMEA and HACCP) and how they may be used in a pharmaceutical context
- How to document Quality Risk Management in a way that will add value to your business and meet regulatory expectations
- How leading practitioners are already using Quality Risk Management in the pharmaceutical industry

Who Should Attend

The course is essential for anyone wishing to improve their decision making by using formal risk management techniques. It is also for quality management and technical staff who need to understand Quality Risk Management and how to effectively implement it to meet the developing regulatory expectations. This will include Qualified Persons, other Quality Personnel, Laboratory, Engineering, Development, Validation, Technical Support and Production Staff.

Course Outline

The background to the new science and risk-based regulatory paradigm.

- ICH Q8 on Pharmaceutical Development
 - Quality by Design
- ICH Q10 on Pharmaceutical Quality Systems

ICH Q9 Guideline on Quality Risk Management

- What it says and what it means
- Impact on regulatory expectations

A detailed Quality Risk Management process, based on ICH Q9/EU Annex 20

- How to implement it
- How to integrate with existing Quality Management Systems

The key focus will be on how to apply risk management tools and techniques in a variety of pharmaceutical situations such as:

- Validation planning
- Complaints, deviations and other troubleshooting
- Audit planning and preparation
- Microbial and cross-contamination control
- Supplier and contractor management
- Documentation design and control
- Planning preventative maintenance
- Day-to-day decision making

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 including a tutor-led panel session will provide delegates with an opportunity to have their specific questions answered.



Dr Allan Thomas, DPharm, MPS NSF-DBA South Africa

Allan is a former Professional Services Director as well as Marketing Director at North-West University. He has been associated with the Pharmaceutical profession in executive positions for over 20 years. He has experience in Manufacturing, QA, R&D and Technology Transfer in several sites in SA, the EU, USA and Canada and has been involved in teaching Pharmaceutical GMP for over 10 years.



Mr Peter Monger, CChem, FRSC NSF-DBA UK

Peter is a chemist by profession and a Fellow of the Royal Society of Chemistry. He has over 30 years' experience in the pharmaceutical industry of both APIs and drug products where he held QC and QA positions in both primary and secondary manufacturing sites. Before joining NSF-DBA in 1996, Peter was a Principal Medicines Inspector with the UK Medicines Control Agency (now the MHRA), where he spent nine years, and had specialist responsibility in the areas of sterile product manufacture and APIs.

What Previous Attendees Said About This Course

“Good course, the teamworks really helped you to understand the different tools and possibilities as well as showing the potential pitfalls you might face when implementing Quality Risk Management in your company.”

Annette van Utteren, Synthon B.V., Netherlands

“Teamworks provided very positive learning by doing; a lot of fruitful discussions both within and outside the classroom. The pragmatic approach, humour included.”

Inger Kvitvang, Pharmaq AS, Norway

“A very good course. It will bring the quality in our company to an even higher level.”

Michael van der Kuylen, Nobilon International BV, Netherlands

“Good balance between lectures and team exercises.”

Krisztina Aust, GSK Biologicals KTF, Hungary

Booking Form

Practical Application of Quality Risk Management

Course Code QRMZA

Wednesday 23 to Friday 25 February 2011

Glenhove Conferencing Facility, 52 Glenhove Road, Melrose Estate, Johannesburg, 2196

Please reserve me a place on this course...

First/only delegate attending: R6760-00 Additional delegate(s) from same site: R5408-00

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

Excludes: Any hotel accommodation and dinners

Course begins at 09.00 on Wednesday and finishes at 16.00 on Friday

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"/>				
<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"/>

Payment Information:

Payment must be made 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 equivalent to half the course fee. Cancellations within 10 working days of the course start date will not be refunded. If a Purchase Order number is necessary to effect payment of an invoice, please provide below.

By credit card:

Credit Card No Expiry Date

By bank transfer:

Bank:	National Westminster Bank PLC, Pickering	Sort Code:	60-16-30
Account Number:	50144499	Account Name:	David Begg Associates (York) Ltd
IBAN Code:	GB38NWBK60163050144499	SWIFT (or BIC) Code:	NWBKGB2L

Authorised Signature	<input type="text"/>	Purchase Order number	<input type="text"/>
Date	<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 Glenhove Conferencing Facility is centrally located in Johannesburg and close to the very popular Melrose Arch Complex with its superior hotels and dining facilities.

The Glenhove Conferencing Facility is the headquarters of the Southern Gauteng branch of the South African Pharmaceutical Society.

For assistance in finding accommodation please contact the Course Convener, Dr A J Thomas on ajt@dba-global.com



The courses will be held in the ultra-modern Upper Glenhove meeting room which can comfortably seat 80 persons. Acoustics in the room are excellent as is the standard of catering facilities provided. For further information please visit the conference centre's own website at www.glenhove.co.za or email them at glenhove@glenhove.co.za

Catering

On each of the course days, mid-morning tea plus snacks will be served at approximately 10.00 with afternoon tea served at 15.00. At lunchtime you can enjoy an appetizing finger buffet served in the foyer.

After each day's activities a closed bar service will be available, chargeable to your account where relevant.

Special Dietary Requirements

If you have any special dietary requirements, please contact the conference management at:

52 Glenhove Road
Melrose Estate
2196
PO Box 2467. Houghton, 2041
Tel: 011 442-3601
Fax: 011 442-3678

4 Easy Ways To Book Your Place

- **By phone: +44 (0) 1751 432 999 or +27 (0) 714999614**

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 fax: +44 (0) 1751 432 450 or +27 (0) 86 568 1887**

You can find further details about us and our courses online and either register online or download a booking form and fax or mail it to us.

- **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 for that course once they are available.

- **Online: www.nsf-dba.com**

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Map to Venue

