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Now in
South Africa!

Preparing for the Future:

Successful Implementation of
ICH Q8, 9 and 10

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



About This Course

A quality vision for the future state of pharmaceutical development and manufacturing was agreed between industry and regulators at ICH in 2003.

"A harmonised pharmaceutical quality system applicable across the lifecycle of the product emphasising an integrated approach to quality risk management and science."

This led to, and steered, the development of ICH guidelines Q8/Q8R (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality System) over the period 2003-2008.

Now that the guidelines are complete we are moving into the implementation phase of the journey to modernise industry and regulatory approaches towards a more science and risk-based way of operating.

If successful, implementation of Q8, 9 and 10 should deliver benefits for all stakeholders.

This course will provide an understanding of why the guidelines are important, their content, their practical use and real case studies of the benefits of implementation.

Expert speakers from industry and the regulators have been invited to present their views on the guidelines and implementation.

Whilst technically ICH guidelines provide guidance, they are accepted by regulators and 'strongly recommended'. It is therefore essential that individuals and companies are fully aware of their impact and the potential competitive advantages of implementing them.

What You Will Learn

- Why the industry needs to change
- The intent of Q8, 9 and 10 and how they fit together
- Fundamentals and practical uses of Q8, 9 and 10
- Tools and techniques to support implementation
- Implementation case studies – real examples and business benefits from industry
- The regulators' viewpoint

Who Should Attend

- Personnel involved in the development and manufacture of API and dosage forms – both small and large molecules
- Managers wishing to understand the impact of Q8, 9 and 10 and the opportunities they present
- Personnel involved in the design, maintenance and operation of quality systems, both at sites and corporately
- Regulatory Affairs professionals supporting regulatory filings and inspection activities
- Qualified Persons/Quality professionals

Course Outline

- The need for change
- Fundamentals of Q8, 9 and 10
- Practical use of Q8, 9 and 10
- Tools and techniques to aid implementation
- Industry case studies and business benefits
- The reality of implementation
- Preparing for the future
- Viewpoint of key regulators

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

'Great stuff'

Steve Engels, Merck Serono,
Switzerland

'Tutors very open and knowledgeable. Fun to work with and listen to'

Jos Van Vugt, Schering-Plough,
Netherlands

'I especially found the case studies useful to see how other companies have implemented the guidelines'

Lorna Wark,
Controlled Therapeutics Ltd, UK

'Excellent, experienced tutors'

Kieran Madigan,
Merrion Pharmaceuticals, Ireland

Booking Form

Course Code ICHZA

Preparing for the Future: Successful Implementation of ICH Q8, 9 and 10

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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"/>				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

