

THE QUALIFIED PERSON

18 & 19 April 2012, Conf. No. M4-8412



Application to Register

Please PRINT your details:

Title First Name.....
(Dr, Mr, Mrs, etc)

Family name

Position

Department.....

Company

Company VAT No.

Address

.....

City Post Code

Country.....

Tel No.

Fax No.....

E-mail

Secretary's Name

Payment by either: VISA MASTERCARD AMEX

Card No.

Card Security No.

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 / AMEX

Expiry date...../.....

- Cheque enclosed payable to Management Forum Limited
- Bank transfer on receipt of invoice

+44 (0) 1483 730008
Management Forum Ltd
www.management-forum.co.uk
E-mail: registrations@management-forum.co.uk

If you have NOT received confirmation seven days after registering, please contact Registration Department.

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
If you do not wish to receive selected third party mailings please contact nick@management-forum.co.uk

MANAGEMENT FORUM LTD., 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK
Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008
Website: www.management-forum.co.uk

Registration Information

Dates
18 April 2012 Start: 09.30 – Finish: 17.00
19 April 2012 Start: 09.00 – Finish: 16.30

Registration & Coffee
18 April 2012 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembbrandt@sarova.co.uk
Subject to availability, a limited number of
bedrooms have been reserved at the hotel at
a special rate. **All bookings should be made
directly with the hotel or online at
www.sarova.com/rembrandt, quoting promo
code 'manforum'.**

Directions
Opposite V&A Museum. Nearest Underground
station: South Kensington. Map available on
Website under Hotels and Venues.

Fee
£1,250 + VAT if applicable. The fee includes
course documentation as well as mid-session
refreshments and lunch. Invoice and
confirmation will be forwarded to you.

Conference No. M4-8412

Discounted Rates
Available on application for personnel from non-profit
making organisations and registered charities.
Group discount available on request

Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee
of £75. 7/14 days prior to the Seminar: 50% of the
fee. Fewer than 7 days or if no notification received:
Registrant liable to pay FULL seminar fee.

**NB: Cancellations must be received in writing by
registrations@management-forum.co.uk.**
In the event of circumstances beyond its control,
Management Forum reserves the right to alter the
programme, the speakers, the date or the venue.

**For Promotional Opportunities email:
vicki@management-forum.co.uk**

New Programme

THE QUALIFIED PERSON

A two day practical training course providing up-to-date and detailed
guidance for current and future QP's to fulfil their duties successfully

Benefits in Attending:

- **Understand** the Role of the QP within the
Legal and Regulatory Framework
- **Keep Abreast** of the Recent Regulatory
Changes for QPs
- **Discover** the Role of the QP in the Supply Chain
- **Improve** Your Risk Management and Decision
Making Processes
- **Know How to Develop and Manage Contracts**
- **Take Away** Practical Advice on Batch Release
Processes
- **Be Prepared** for Audits and Regulatory
Inspections

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With
Dr Afshin Hosseiny, Managing Director, Tabriz Consulting, UK
Sue Mann, Managing Director, Sue Mann Consulting Ltd, UK

You can register online at www.management-forum.co.uk
or by phone on +44 (0)1483 730071, fax 730008



18 & 19 April 2012
The Rembrandt Hotel, London



BENEFITS IN ATTENDING:

In this highly competitive industry, the past few years has seen the responsibilities of the Qualified Person become more in the spot-light and key to company success. Manufactures need to ensure their personnel are fully up-to-date with the latest GMP, regulatory and legal requirements. QPs need to broaden their knowledge, consider numerous issues and learn techniques to overcome the challenges in their many areas of responsibility. This course has been specifically designed to clarify the roles of the QP, ensure compliance with GMP and regulatory requirements and provide practical advice on how to fulfil the role successfully.

WHO SHOULD ATTEND

- Qualified Persons and those preparing to become a QP
- QA Managers
- QC Professionals/Executives
- Regulatory Compliance Managers
- Production Managers
- Supplier/Contract Managers
- Supply Chain Managers
- Quality Auditors
- Business Executives
- All personnel who need to understand the role of the QP and how the QP is best placed within the organisational structure.

SPEAKERS

Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Limited, formerly Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline, provides consultancy services to the companies within the pharmaceutical and biotechnology supply chain. He is a QP via permanent provision with detailed working knowledge of European and FDA regulatory requirements with over 20 years of experience of auditing pharmaceutical manufacturing sites across Europe and USA, as well as preparation for and fronting of EU and FDA regulatory inspections. Afshin is a member of the UK standards committee for development of the ISO GMP standards for packaging components. He is an acknowledged expert in quality management system for pharmaceutical supply chain, he is currently advising companies on developing and validating Cold Chain Supply process.

Sue Mann, Managing Director of Sue Mann Consultancy Ltd has extensive experience in the Pharmaceutical Industry, spanning 30 years, principally in Quality Assurance, and also in Clinical Trials supply, Technical Management and production support. Sue has worked for many types of company, including multinational, national, CMO, Japanese and virtual; latterly as Vice President of International Quality Assurance at Shire Pharmaceuticals. Here Sue was responsible for all quality, GMP and related aspects for both development and marketed products. Sue has also spent over 12 years in total as a QA/GMP consultant, providing Quality System support, Quality, GMP and technical training, Regulatory inspection support and auditing around the world. She is a Pharmacist, a Qualified Person and is also a QP Assessor, working on behalf of the UK MHRA, representing the Royal Pharmaceutical Society.

A Certificate of Attendance for Professional Development will be given to each participant who completes the course

Day One

18 April 2012

- **Welcome and Introduction**
- **The Legal and Professional Duties of the Qualified Person**
 - Role of the QP within EU Legislation and Regulatory Framework
 - Professional duties of a QP
 - QP as owner of the Quality System
 - What are the qualities of a good QP
- **Recent Regulatory Additions and Challenges for QPs**
 - EU GMP Guide Chapter 1
 - EU GMP Guide Chapter 4
 - Directive 2011/62/EU
 - EU Guide to GDP
- **Workshop 1: How Can a QP Discharge Their Duties Without Reviewing and Signing Every Piece of Paper?**
- **Role of the QP in the Supply Chain**
 - Regulatory expectations
- **Workshop 2: Role of the QP in the Supply Chain**
 - Defining the supply chain for your products
 - Identifying key activities
 - Defining roles and responsibilities

Day Two

19 April 2012

- **Risk Management and Decision Making by the QP**
 - What is risk in the GMP environment
 - Risk assessment and risk evaluation (ICH Q9)
- **Quality Management System for the Pharmaceutical industry**
 - ICH Q10, how can the QP influence implementation of ICH Q10
- **Workshop 3: Batch Release and Decision Making on Non Compliance Issues**
- **Role of the QP in Supplier Selections and Approval**
 - Supplier selection process
 - Contract manufacturers
 - Role of the QP in developing and managing contracts
- **Audits and Regulatory Inspections**
 - Internal audits
 - External audits (supplier/contract manufacturers)
 - Preparing for Regulatory inspections