

PS 9000-2011 in the Pharmaceutical Supply Chain

10 & 11 May 2012, Conf. No. M5-8212



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To Register

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Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008
Website: www.management-forum.co.uk

Registration Information

Dates

10 May 2012 Start: 09.30 – Finish: 17.00
11 May 2012 Start: 09.00 – Finish: 16.30

Registration & Coffee

10 May 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. M5-8212

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.

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PS 9000-2011 IN THE PHARMACEUTICAL SUPPLY CHAIN



Standards for Pharmaceutical Packaging Materials and Components: New Requirements and Implications

Benefits in Attending:

- **Understand** the fundamentals of the standards and its implications on working practices
- **Prepare** for implementation in your company
- **Plan** how to develop a PS9000:2011 system
- **Clarify** management and quality unit roles
- **Take away** techniques for product supply evaluation and product security
- **Discover** key areas for measurement and analysis

Members of



Pharmaceutical Quality Group

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With

Dr Afshin Hosseiny, Managing Director, Tabriz Consulting, UK

David Abraham, Chairman PQG Partner's Team and Project Leader in the Development of the Updated PS 9000:2011 Standard

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



10 & 11 May 2012
The Rembrandt Hotel, London



INTRODUCTION

The new PS9000:2011 standard specifies GMP requirements and guidance within a quality management system (QMS) for suppliers of packaging materials and origination/artwork to the pharmaceutical industry. The standard has been developed to assist medicinal product manufacturers and their suppliers in their understanding of their respective responsibilities in producing materials of the requisite quality, in order that the final product is fit for purpose.

This training course has been developed to assist users in understanding the additional requirements and the key role of PS 9000 in the pharmaceutical supply chain. Key elements of the revised standard and its implications on working practices will be addressed and practical advice will be provided to prepare for implementation in your company facility.

The course will encompass both theory and practical workshop activities bringing a fully interactive learning experience.

WHO SHOULD ATTEND

- Suppliers of packaging materials and origination/artwork to the pharmaceutical industry
- Qualified Persons, QA Managers
- QC Professionals/Executives
- Regulatory Compliance Managers
- Production Managers
- Supplier/Contract Managers,
- Supply Chain Managers
- Quality Auditors

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 25 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 and is a regular speaker at Pharmaceutical industry conferences in Europe and the USA. Afshin is visiting lecturer at the London Metropolitan University.

David Abraham, is an experienced quality professional and has a strong background in the print and packaging sector, which has seen him working with the Pharmaceutical and Healthcare industry for over 15 years, developing and implementing both quality management systems and the application of GMP processes. David is a chairman of the PQG partner's team, as well as being the project leader in the development of the newly updated PS 9000:2011 interactive document. He has been a key representative and contributor in a number of projects, at national, European and international level in the development of standards and guidance documents for the industry including the PS9004, ISO 15378, EN15823 Braille on packaging for medical products and the 2001 edition of PS 9000.

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

Day One

10 May 2012

- **Welcome**
- **Introduction to PS 9000**
 - Background overview
 - The journey and development process
 - Role of PS in the supply chain
 - Future expectation
- **Industry Positions**
 - Pharma expectations
 - Supplier prospective
 - Trades and bodies
- **Fundamentals of the Standard**
 - ISO 9000 Relationship
 - Key requirements
 - Applications of the standard
- **Understanding the Standard**
 - Navigating the document
 - Terms and Definitions
 - Using annexes and Bibliography
- **Preparing for Implementation**
 - Gap analysis exercise
 - Risk assessments
- **Developing a PS 9000:2011 System**
 - Scoping
 - Mandated requirements
 - Workshop exercise

Day Two

11 May 2012

- **Key Elements for a PS 9000 Quality Management System**
 - Requirements and guidance
 - Interactive workshop
- **Management and Quality Unit Roles**
 - Requirements and guidance
 - Interactive workshop
- **Resource Management**
 - Training
 - Infrastructure & environmental conditions
 - Guidance
 - Interactive workshop
- **Product Realisation**
 - Product supply evaluation
 - Specification & communication
 - Change control
 - Product security
 - Interactive workshop
- **Key Areas for Measurement and Analysis**
 - Requirements and guidance
 - Interactive workshop
- **Annex A-F (Key Points and Applications)**