



## Launch of PS 9000:2011

### A Revised Standard for Pharmaceutical Packaging Materials Incorporating Good Manufacturing Practice (GMP)

to be launched on 14<sup>th</sup> September 2011

at The Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN

#### Why you should attend

This event brings together a team of high profile speakers with a wealth of experience from the Pharmaceutical Industry, their Suppliers, Regulators (MHRA) and Industry bodies (IPAC-RS). The speakers will be sharing the updated requirements and guidance from the PS 9000:2011 Standard and its applicability to suppliers and the Pharmaceutical industry in ensuring appropriate Good Manufacturing Practice within the supply chain for packaging materials.

#### About the Standard

The quality of packaging materials is a critical factor in assuring the safety and efficacy of medicines. The PS 9000 Standard establishes a baseline of GMP applicable for suppliers to the Pharmaceutical industry. As regulations change for the Pharmaceutical industry and their products, also the requirements for all aspects of the supply chain change in order to assure product quality and patient safety.

The CQI's Pharmaceutical Quality Group in partnership with Pharmaceutical industry, suppliers and IPAC-RS (International Pharmaceutical Aerosol Consortium on Regulation and Science) has developed the next generation of the well established PS 9000:2001 Standard. This updated version of the Standard is based on the ISO 15378 framework, and delivers a quality management system with updated and enhanced additional requirements, together with guidance, reflecting Good Manufacturing Practice in the supply of pharmaceutical packaging materials.

The objective of the revised Standard is to provide updated requirements and guidance for all pharmaceutical packaging materials whether primary, secondary, complex or for suppliers of print origination. The Standard has been developed as a downloadable pdf document which can be navigated and focused according to the packaging material area of interest, together with the relevant requirements and guidance. The Standard will also be available as a hard copy document. The updated Standard provides the requirements for supplier certification against the revised requirements and is of use by suppliers to develop and implement an enhanced Quality Management System and for auditors and representatives from the Pharmaceutical industry to audit suppliers or to work with suppliers in developing and implementing enhanced standards of GMP.

#### Who should attend

Quality, Technical, R&D, Manufacturing and Procurement personnel from Suppliers and Pharmaceutical Industry. Suppliers to include primary (including complex and components), secondary, printed materials & artwork origination. Auditors from industry or certification bodies.

#### How to book

Bookings open 18<sup>th</sup> July 2011 via [www.pqg.org/events](http://www.pqg.org/events)

Cost is £180 inc VAT for PQG members and £225 inc VAT for non-members this includes:

- a copy of the interactive, electronic Standard and speaker presentations
- buffet lunch and refreshments

## Conference Programme – 14<sup>th</sup> September 2011

<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
09:30	<b>Registration and refreshments</b>	
10:00	<b>Chairman's introduction</b>	<b>Norman Randall</b> Consultant & PQG Webmaster
10:05	<b>Introduction</b> <ul style="list-style-type: none"> <li>• PQG / Partners / Projects</li> <li>• Introduction to PS 9000 certification scheme &amp; transition arrangements</li> <li>• Training</li> </ul>	<b>Justin Ahern</b> QP/ QA Manager, Teva UK Limited
10:30	<b>PS 9000:2011 Standard</b> <ul style="list-style-type: none"> <li>• Driver for revision (ISO 15378 gaps &amp; technology)</li> <li>• Project team + IPAC-RS</li> <li>• Benefits</li> </ul>	<b>David Abraham</b> Group Business Improvement Manager, TAG: Worldwide
11:00	<b>PS 9000:2011 – what has changed?</b> <ul style="list-style-type: none"> <li>• Content – key changes</li> <li>• Format</li> </ul>	<b>Colin McEnaney</b> Supplier Quality Manager, Sanofi - aventis
11:40	<b>Regulatory perspective - MHRA</b> <ul style="list-style-type: none"> <li>• Importance of standards for suppliers of primary and secondary pharmaceutical packaging materials</li> <li>• Potential problems with supply of packaging materials and the impact on safety &amp; efficacy of medicines</li> <li>• Regulatory developments in this area</li> <li>• Value of the revised PS 9000 which communicates the appropriate levels of GMP at the suppliers as expected by the pharmaceutical industry.</li> </ul>	<b>Mark Birse</b> Group Manager, Inspections (GMP/GDP), Medicines and Healthcare products Regulatory Agency (MHRA)
12:15	<b>Questions</b>	
12:30	<b>LUNCH</b>	
13:45	<b>A QMS for Pharmaceutical Origination</b> <ul style="list-style-type: none"> <li>• A structured approach to Pharmaceutical Origination</li> <li>• Benefits of using PS 9000 in an Artwork Studio</li> </ul>	<b>Suzanne Ivory</b> QA Manager, Perigord Group
14:10	<b>Primary and Complex Components</b> <ul style="list-style-type: none"> <li>• Use for Primary Packaging Materials</li> <li>• Incorporation of IPAC-RS / complex requirements into PS 9000:2011</li> <li>• Benefits to suppliers and the Pharmaceutical industry</li> </ul>	<b>Barbara Falco</b> Consultant / IPAC-RS
14:35	<b>Supplier perspective - Secondary packaging</b> <ul style="list-style-type: none"> <li>• Benefits to suppliers and the Pharmaceutical Industry</li> <li>• Benefits of dual certification to PS 9000 and ISO 15378</li> </ul>	<b>Arne Hoffmann Christiansen</b> Quality Systems Manager, Strålfors Identification Solutions
15:00	<b>Pharmaceutical Industry Position</b> <ul style="list-style-type: none"> <li>• Benefits in consistency, reduced audits, short-listing suppliers</li> <li>• Fit with other schemes</li> </ul>	<b>Ian Williams</b> Associate Director - Quality Wockhardt
15:25	<b>Questions</b>	
15:45	<b>Refreshments and close</b>	