

The newsletter of the PQG's 'Pharmaceutical industry and Pharmaceutical suppliers Partners Team' bringing news on development and quality issues related to manufacture, use and supply of pharmaceutical starting and packaging materials

Note from the editor

Welcome to the 4th edition of the newsletter of the 'Partners team' of the PQG. There has been a lot of activity over the last 12 months with work in conjunction with other industry bodies and continuing promotion of Quality and GMP for Pharmaceutical materials. The main event for the group was a successful launch in London for the joint IPEC/ PQG GMP guide for Pharmaceutical excipients on February 7th this year, with additional excellent presentations from key speakers on topics important to supplier GMP and an update on the PQG supplier auditor certification and training scheme. A brief overview of each of the presentations is provided below. Full copies of the presentations are available on the members section of the PQG website.

Linda Nield

Latest!!

A new GMP guide for cosmetic ingredients has just been launched by the European Federation for cosmetic ingredients (EFfCI). Ian Moore of PQG helped develop this guide which is based on the IPEC-PQG excipients GMP guide. For further information see

www.EFfCI.com

PS 9004 : An explanatory Guide to the GMP requirements of PS 9000:2000 is now available to download from the IQA website

www.iqa.org/information/d2-15.shtml

IPEC/PQG Excipients GMPs guide Steve Moss

The joint international guide was developed through the collaboration of three organisations; PQG, IPEC Europe and IPEC Americas. PQG member Steve Moss (stephen.x.moss@gsk.com) described the process taken. This included selecting the most appropriate guidance from the source documents and comprehensive revisions to bring the guidance right up to date, followed by extensive consultation with many interested stakeholders. Kevin McGlue from IPEC Europe detailed the major improvements with the new guide, particularly the account taken of the different requirements for manufacture by continuous processing, as well as the easy to use structure and alignment with ISO 9001:2000. Kevin said, 'The new guide clearly differentiates appropriate guidance for excipients and should eliminate the need for multiple customers' requirements'.



left: Steve Moss, Kevin McGlue and Ashley McCraight

To obtain your copy of the PQG/IPEC Excipient GMP Guide, visit the PQG web site for an order form
The link is <http://www.pqq.org/publications/excipientsguide/index.php>

Update on EC Directive on Excipients

Following on from legislation for APIs, the European Commission intend to introduce a draft Directive in 2006, defining the requirements for GMP for manufacture of 'certain excipients'.

There has been extensive discussion between members of the Commission and EFPIA concerning which excipients should be controlled. At the recent PQG meeting Richard Andrews of the MHRA explained how a risk assessment process had been used. He went on to explain how several problems have originated from excipients. The current view is that the list of excipients will be limited initially to:

- ?? Animal derived excipients with a potential TSE risk
 - ?? Human/animal derived excipients with a potential viral contamination risk
 - ?? Excipients claimed to be sterile and used without further sterilisation in sterile products
 - ?? Excipients claimed to be endotoxin controlled/pyrogen free
- The Directive will contain GMP principles, which will draw on experience the PQG has gained working with IPEC on the recently launched joint guide.

To assess the implications of the proposals, the Commission and industry are working together to gather information from all manufacturers and users of excipients on the proposed list in an exercise planned to start in April. We will keep you informed of progress.

Ashley McCraight



Richard Andrews (MHRA)

IPAC-RS* GMP guide for suppliers of Inhalation Packaging materials Linda Nield

IPAC-RS supplier QC working group, a consortium of pharmaceutical inhaled product manufacturers and component suppliers has developed a GMP guide for the manufacture of components critical to the quality of inhaled drug products. Barbara Falco of Kos Pharmaceuticals and chair of IPAC-RS Supplier Quality working group gave an overview of the guideline, its development and proposed use.

The guide is based on the PQG quality guideline PS9000 with additional focus on key areas of particular concern for this group of products (e.g. metering valves, cans, pumps) such as extractables and leachables, change control and sub-supplier management and foreign particulate control. Publication is due Q2 2006 with launch workshops scheduled for June.

*International Pharmaceutical Aerosol Consortium on Regulation & Science.

PQG Supplier Auditor Certification and Training scheme

David Mogg – PQG Chairman

AUDITOR CERTIFICATION

This is covered by the PQG document 602: Pharmaceutical Supplier Auditor Certification Scheme 'The PS Scheme'. It has two grades of certification equivalent to IRCA QMS 2000 certification grades:

PS Auditor

PS Lead Auditor,

The PS Scheme is intended for Quality auditors who audit suppliers to the pharmaceutical industry. PQG 602 provides information and instructions additional to requirements laid down by IRCA 602 'QMS 2000'.

TRAINING COURSE CERTIFICATION

The International Register of Certificated Auditors (IRCA) and the Pharmaceutical Quality Group (PQG) have revised the criteria for approved training organisations to achieve certification of an ISO 9000:2000 series & Pharmaceutical Supplier auditor/lead auditor (PS) training course. See PQG website for current training organizations.

THE FUTURE

The PQG, together with the training organisations, will assure that the courses reflect ISO 15378 and IPEC – PQG as well as current regulatory requirements. There will be transitional period of the order of 12 months.

For Primary packaging material suppliers the route to certification is via ISO 15378 or PS 9000.

For Secondary (Print) suppliers, the route will continue to be PS 9000 alone.

The PQG web site provides more detailed information for pharmaceutical companies seeking both certified suppliers and certified auditors.

MORE INFORMATION IS AVAILABLE AT:

<http://www.pqg.org/publications/psseries/certsupp.php>

- Training Providers' details

<http://www.pqg.org/publications/psseries/auditors.php>

- Auditors' details

ISO 15378 – a new GMP Standard for Pharmaceutical Packaging Materials

Tony Harper

PQG partner team members Tony Harper and Roy Evans described the development process for this standard and an overview of a comparison of ISO 15378 and PS 9000.

ISO 15378:2006 Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP) was published in March 2006 and is now available from National Standards Bodies (in the UK, BSI www.bsi-global.com).

The process to have ISO 15378 adopted as a European (CEN) Standard (which automatically means a British Standard) is underway. The next stage should be the development of complimentary standards for Secondary Packaging Materials and Guidance.

Thanks are due to the members of the PQG who contributed to the development of ISO 15378, in particular, David Abraham, Ashok Chand, Roy Evans, Bill Hewlett, Afshin Hosseiny Jill Jenkins, Mike Shorten, Steve Taylor and John Turner.

And a Thank you!!...

Ashley McCraight who has successfully chaired the Partners team for a number of years is moving on to be vice president of the PQG. The new chair of the Partners team will be existing team member Steve Moss. Many thanks to Ashley for his commitment and enthusiasm to the team and all its activities – we wish both Ashley and Steve much success in their new roles.

The PQG will continue to provide new standards and monographs, assist suppliers, the industry and regulators apply consistent, agreed standards to areas of risk and increase its global role in influencing the establishment of standards and the reduction of risk to our customers.

How can I contact the PQG?

If you have any questions at all about the PQG, the Monographs or the Supplier Certification scheme you can contact us at :

info@pqg.org We respond quite quickly - as well as doing our day jobs!