

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

PQG Partners Team – your chance to influence

At the end of last year we asked the PQG membership for feedback on a long list of potential projects. The responses have been very helpful for the Partners team in developing a priority list of activities to focus on and identify some interested people to help with these. There were also some topics for other groups within in the PQG to work on. The priority Partners projects are:

1. Risk management guidelines for pharmaceutical suppliers
2. IPEC/PQG excipients audit guide [in progress]
3. PS 9100 Part 1 revision/Audit standard for excipients
4. ISO 15378 adapted for secondary packaging materials, & guidance
5. Common questionnaire for pharmaceutical suppliers

Now it's your chance to get involved with these projects, developing guidance for pharmaceutical industry and its suppliers. You can learn what other companies are doing and help shape the future of the industry!

If you would like any further information or would like to help with one of these projects, please contact Steve Moss Stephen.x.moss@gsk.com.

Origination / Artwork briefing

The Institute of Packaging's Pharmaceutical Packaging Forum have set up a sub-group to develop guidance in the production of electronic origination / artwork for medicinal products and medical devices.

The current draft covers all the key stages from artwork brief through to generation, proofing, and reprographic production. Information on counterfeiting, auditing, risk management, change control and validation are also amongst the additional guidance included.

PQG members who wish to contribute to the development of these guidelines, please contact Tony Harper: TonyHarper@aol.com

Update from IPAC-RS

IPAC-RS (international Pharmaceutical Aerosol Consortium on Regulation and Science) recently held a seminar and second workshop in the USA targeting Pharmaceutical manufacturers who make inhalation and nasal products and their suppliers. The GMP guideline takes the PS9000 application standard as developed by PQG and has additional guidance for this speciality area. The guideline has been well received by all groups, including by FDA representatives. The value of PS9000 as the source document has been well acknowledged.

Linda Nield is the PQG/IPAC-RS representative.

For further information on IPAC-rs and the guide please visit www.ipacrs.com.

Keep in touch with Braille standard

The UK have spearheaded the development of standards to support EU legislation requiring Braille in the labelling of medicinal products and the provision of patient information in alternative formats. The UK will publish a Draft for Development, DD264:2007, in 2-3 months.

At the European level, CEN are drafting a requirements and guidance Standard for Braille on the packaging and a separate Technical Report containing guidance on alternative formats for patient information. Drafts for public comment are anticipated in 2007.

To support these standards, a University research project has been developed to determine the minimum Braille dot height that enables blind and visually impaired people to identify their medicines. Funding is required (~£50,000) and is being sought from stakeholders. The research is expected to be started in Q2/2007 for completion in Q4/2007.

For further information please contact Tony Harper: TonyHarper@aol.com

Presentation marks Roy Evans' contribution to PQG Partners

The Partners team would like to say a huge 'Thank you' to Roy Evans who has been an active and enthusiastic member of the Partners team for very many years, and has decided that it is time to enjoy a well deserved retirement. Roy (left in picture) was presented with a thank you gift at the December PQG committee meeting by Ashley McCraight, PQG chairman. Roy brought a great amount of experience and energy to the group and was instrumental in developing the PS series application standards and guidance and associated training and awareness.



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!