

The logo for PHSS (Pharmaceutical & Healthcare Society) features the lowercase letters 'phss' in a white, sans-serif font on a dark blue background.

over 25 years of advancing
pharmaceutical and
healthcare sciences



The Chartered Quality Institute
PHARMACEUTICAL QUALITY GROUP

EU GMP ANNEX 1 DRAFT REVISION INSIGHT

Joint PHSS & PQG Conference - Discussion

12th March 2018: Woodland Grange, Leamington Spa

Following the revision of EU GMP Annex 1 for Sterile Medicinal product manufacturing the PHSS: Pharmaceutical & Healthcare Society and PQG: Pharmaceutical Quality Group are joining together to host a discussion on the revision with the regulatory authorities.

The revision of Annex 1 will impact all in sterile medicinal product manufacturing and those sectors where Annex 1 applies: Advanced therapies and Hospital pharmacy aseptic services.

The MHRA are invited to join the discussion with the PHSS & PQG on the impact of the Annex 1 revision and discuss focus group comments that are in preparation for submission to the EMA.

The Conference will also host exhibitors that have technologies and services that support sterile and therapeutic product manufacturing and aseptic processing.

AGENDA: ANNEX 1 CONFERENCE

Start 10am - 12th March 2018

Key note presentation: Regulatory perspective on EU GMP Annex 1 consultation document.

10.00am - 11.00am: Andrew Hopkins MHRA GDMP Expert: Head of EU GMP Annex 1 EMA/PICS/WHO revision working group.

Presentation: Pharma industry perspective on EU GMP Annex 1 consultation document.

11.00am - 12.00pm: Ian Symonds GSK Head, Aseptic Strategy and Intelligence, Pharma Ops, Global Function representing the PHSS & PQG Annex 1 Focus group preparing comments from the Pharma Industry on the revised Annex 1 draft/ consultation document.

12.15pm - 12.45pm: Overview-listing of PHSS-PQG Comments to be submitted to the EMA presented by discussion facilitators covering each of the Annex 1 chapters providing an insight to the type and extent of PHSS-PQG comments.

12.45pm - 2.00pm: Lunch break / viewing exhibition / networking

2.00pm - 3.15pm: Discussion Session 1.

Facilitators Neil Wayman: AstraZeneca UK, Chairman of PQG: Pharmaceutical Quality Group and Una Hearty Pfizer Ireland: representing the PHSS Annex 1 focus group. Discussion format:

- Discussion on prepared/ selected questions on key concerns and comments on Annex 1 revision. Facilitators will introduce the questions with background information and open up discussion to the conference audience.
- Discussion with open questions from the conference audience with responses from the MHRA and Pharma Industry representing the PHSS Annex 1 focus group.

3.15pm - 4.30pm: Discussion Session 2.

Facilitators Mike Davies: GSK UK Director, Aseptic Strategy & Intelligence Pharma Ops Global Functions, Co-leader of PHSS Aseptic processing and Bio-contamination special interest group & member of PHSS Annex 1 focus group.

James Drinkwater: Chairman of PHSS, F Ziel GmbH Head of GMP Compliance, Co-leader of PHSS Aseptic processing and Bio-contamination special interest group & PHSS Annex 1 focus group and member of PQG.

- Discussion on prepared/ selected questions on key concerns and comments on Annex 1 revision. Facilitators will introduce the questions with background information and open up discussion to the conference audience.
- Discussion with open questions from the conference audience with responses from the MHRA and Pharma Industry representing the PHSS Annex 1 focus group.

Conference Close & Thanks 4.30pm: PHSS & PQG Chairman

Venue: Woodland Grange, Leamington Spa

Fees: Members of PHSS or PQG: £250 plus VAT

Non-Members: £350 plus VAT

Bookings via PHSS or PQG websites
with booking administration by the PHSS