

BSI Conference

Cleanrooms and Contamination Control for Healthcare and Pharmaceuticals- Update on Standards, Regulations and Best Practice

26 June 2008

ICO Conference Centre, London

The one-day conference was attended by around 50 persons and was chaired by Gordon Farquharson. The workshops planned for day two were cancelled.

Seven speakers presented over three sessions on the day.

Gordon Farquharson started the “Regulatory and Standards Information” session with a discussion of the ISO 14644 series of standards and key changes in the latest version of Annex 1 of the EUGMP released in February 2008.

Tim Eaton completed the session with a look at practical issues for pharmaceutical cleanroom manufacturing.

Andrew Tweedie, representing S2C2, started the second session “Key Issues” with an examination of the current biocontamination standards (ISO14698), followed by concerns and proposed changes to these standards.

Tim Triggs followed with a review of HEPA filtration test methods, examining the differences between them and giving some practical views on how to achieve satisfactory testing.

Next Tim Eaton examined risk management of contamination during cleanroom manufacturing. He considered the fundamental mechanism of contamination transfer, sources and routes of contamination, giving an overall assessment for general cleanroom areas.

Dr Thomas Treutler completed the session by giving a very interesting wee presentation on contamination issues from nanotechnology in healthcare and pharmaceuticals. He highlighted the importance of both, protecting the workforce against possible healthrisks, and the need to protect patients by avoiding cross-contamination with materials whose impact is not completely understood.

The last session on “Practice Update” was presented by Conor Murray who looked at a case study on design and construction of a hospital pharmacy cleanroom in Ireland. He used a series of pictures of the facility to highlight and discuss the issues.

The final presentation of the conference was given by Joyce Bowler who presented a case study on the effective application of airborne cleanliness in orthopaedics. Joyce covered the development of ventilation from conventional to laminar flow. She also produced some colourful pictures and highlighted what infection control teams are required to know in this area.