

Hospital Aseptic Compounding Cleanroom Facilities

1st December 2017, Connolly Memorial Hospital

REGISTRATION: 07:45 - 08:30

Session #1 (08:30) - Opening, Introduction and Background, Bill O'Reilly Estates Mgr, Connolly Hospital and Brendan Redington, HSE Estates Quality & Standards
Background introductions by Chairpersons highlighting the importance of aseptic compounding and the challenges of Chemotherapy and CIVAS supplies and availability.

Session #2 (09:00) - Guidance on Aseptic Compounding Facilities in Hospitals, Aisling Collins, Assistant Pharmacy Director, Co Chair H-PIC/S, St James Hospital
Aisling will give a Pharmacist's perspective on the Issues and challenges of setting up a new Aseptic Compounding Unit at Saint James Hospital.

Session #3 (09:45) - HBS Estates Hospital Aseptic Cleanrooms Guidance Template Brendan Redington, HSE Estates Quality & Standards
New Guidance document with Check lists on how to specify the critical requirements and performance acceptance criteria.

KEYNOTE, #4 (10:30) – CASE STUDY in Aseptic Compounding – St James Hospital
Niall McElwee, Estates Manager, Aisling Collins, Dept. Head Pharmacy
St James Hospital transferred ACU operations in 2016 to a new modular facility.

Session #5 (11:30) – Role of C&Q in getting to Certification and GMP Compliance
Conor Murray, GMP Consultant
Commissioning and Qualification is a key tool to manage the process from User Requirements through to Detailed Design, to Construction documents and then Construction through to Certification and finally compliant Start Up.

LUNCH BREAK 12:00 - 13:30

Session #6 (13:30) – PANEL DISCUSSION
Moderators, Conor Murray, ICS and Brendan Redington, HSE
Topics include regulatory licensing requirements, the role of QP (Qualified Person), Isolators vs Biosafety cabinets, Ballrooms vs Separate Compounding rooms, CSTDs (Closed System transfer Devices), Radiopharmacies and Cleaning and Decontamination.

Workshop Session, #7 (14:30)

- #1 – ACU Operations using CSTDs (Closed System Transfer Devices) in Isolators**
- #2 – Selection of Isolators vs Biosafety Cabinets & background Cleanroom Environment**

Closing Session (15:30) – Overview & Final Q&A