

## Impact of a Process Deviation Working Group in an Aseptic Compounding Unit

St. James's Hospital  
Dublin  
Aoife Lucey  
Senior Pharmacist, Aseptic Services

### Introduction (1)

- The Aseptic Compounding Unit (ACU) is a sterile manufacturing unit responsible for the production of chemotherapy
- There are a number of steps in the manufacturing process

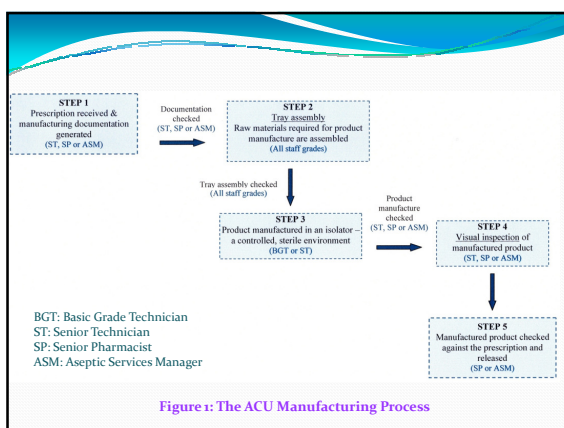


Figure 1: The ACU Manufacturing Process

### Introduction (2)

- A process deviation (PD) describes any event in the manufacturing process that has the potential to impact on the quality of the manufactured product

#### Tray Assembly Errors

A tray assembly error is the incorrect assembly of raw materials required for product manufacture

#### Visual Inspection Fails (VIFs)

Products manufactured in the ACU are inspected for signs of precipitation, leaks and particles

- In Quarter 1 of 2008 PDs at **tray assembly** and at **visual inspection** resulted in costly drug loss. As a result, a number of education initiatives were undertaken and in June 2008 the ASM established a PD Working Group comprising of a representative of all staff grades

The aims of the group were to:

- Trend and assess all PDs
- Investigate potential root causes of PDs
- Discuss and agree corrective or preventative actions (CAPAs)
- Communicate CAPAs to all staff
- Assess the impact of CAPAs

### Methodology

- Trending of all PDs was undertaken on a monthly basis  
Details of:
  - the *type and frequency* of PDs
  - the *drug* noted in the PD
  - the *personnel* involved in the PD
  - the *cost* and the *appropriateness* of drug loss associated with the PD
- These trends were evaluated at the PD Working Group meeting
- Potential root causes of the PDs were discussed and CAPAs were proposed and agreed
- Implementation plans were agreed by the PD Working Group and documented in meeting minutes
- Reports were generated for each staff member that detailed PDs that related to them
- The impact of the CAPAs were assessed at the following monthly/quarterly meeting

### Results

- The cost of tray assembly errors reduced by 99.4%, from €5,779.86 in Quarter 1 to €34.80 in Quarter 4 of 2008
- Implementation of CAPAs resulted in a reduction in the cost of drug loss due to visual inspection fails (VIFs)

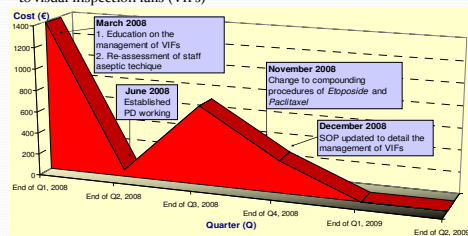


Figure 2: Impact of CAPAs on the cost of Visual Inspection Fails

## Conclusion

- The PD Working Group has been effective in identifying and implementing changes in the ACU manufacturing process that have resulted in reduced unnecessary drug loss
- A systematic approach to assessing PDs, with input from all staff grades, significantly strengthens the identification and implementation of CAPAs

Thank you!