Impact of a process deviation working group in an aseptic compounding unit

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Objective:
Assess the impact of the PD working group in the ACU in SJH.

Background:
The Aseptic Compounding Unit (ACU) in St. James's Hospital (SJH) manufactures sterile chemotherapeutic agents for cancer patients. The manufacturing process involves 5 steps i.e. generation of documentation; tray assembly; compounding; check on the compounded product and product release. To ensure appropriate quality and safety standards a checking procedure is incorporated into each step. If a checking procedure fails it is recorded as a process deviation (PD). The immediate impact of the PD on the quality of the product is assessed and appropriate action taken. However, prior to June 2008 each PD was reviewed in isolation by the Aseptic Services Manager (ASM). There was no forum for reviewing and investigating trends in process failures or personnel training issues highlighted by the recorded PDs. In June 2008 a PD working group was set up. The group comprised of a basic grade technician, a senior technician, 2 senior pharmacists and the ASM. The role of the working group is to assess, review, control and communicate manufacturing errors and to identify and implement corrective or preventative actions.

Methods:
1. The PD working group met each month to review the documented PDs. Corrective or preventative actions identified were feedback to the ACU staff.
2. Quarterly reports were generated that detailed the trends identified, the actions taken and the impact of the actions on reducing the error rate.

Results:
- A downward trend in the frequency of errors in areas targeted by the PD working group was recorded. For example, in the first quarter (Q1) of 2008 there were 7 tray assembly errors. The cost incurred was €5,779.86. This was reduced to 3 tray assembly errors in Q4, with an associated cost of €34.80.
- The incidence of visual inspection failures reduced due to a) changes in the manufacturing process of certain drugs and b) assessment of individual technician compounding technique. There was an associated reduction in cost of waste.
- Product manufacturing worksheets were amended to incorporate changes in the checking produces that reduced the risk of checking procedure failures.

Conclusions:
The PD working group has been effective in identifying and implementing changes to the manufacturing process that improved quality by reducing the error rate. Currently, the PD reporting system is being expanded to incorporate all errors, not only those relating to failed checks. It is hoped that the data collected from the new system will further enhance the quality and safety of the manufacturing process.