On day 0, 56 infusion bags were produced in a positive air pressure isolator (Isocyt Freja; Getinge). Half of them were stored at room temperature and the other half at 4°C.

Twenty mL samples were taken and inoculated on day 0, 2, 7, 14, 21, 28 and 42 under laminar flow at the pharmacy. This volume represents 10% of the final volume of the bag according to the 2.6.1 chapter of sterility test of the European Pharmacopoeia 9.7.

Liquid medias used at the hygiene laboratory were thioglycolate and trypticase. Fertility and sterility of these medias were checked. American Type Culture Collection strains were used to test the fertility of these medias.

Liquid medias were incubated at the hygiene laboratory for 14 days at 22°C and 34°C. The positivity of the liquid medias was observed by the appearance of a turbidity, visible to the naked eye.

Results Fertility and sterility controls were validated. After 14 days of incubation, no microbiological growths were observed. The main limit of this study was the decision to use one media per bag, to avoid accidental contamination at sampling time.

According to a previous study¹ carried out in our medical centre, the majority of the centres that use dose-banding, have only achieved a chemico-physical stability study. Since sterility control cannot be performed systematically, it seemed important to us to prove the microbiological stability of these preparations.

Conclusion This preliminary study proves the sterility of chemotherapy bags after 28 days of storage. It allows dose-banding in order to shorten waiting periods for dispensation.

REFERENCE AND/OR ACKNOWLEDGEMENTS

<http://www.gerpac.eu/etat-des-lieux-des-pratiques-du-dose-banding-en-france>

No conflict of interest.

3PC-023

A RISK ANALYSIS METHOD TO EVALUATE THE IMPACT OF A CHEMOTHERAPY COMPOUNDING WORKFLOW MANAGEMENT SYSTEM ON CANCER PATIENTS' SAFETY

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Background The implementation of technology for chemotherapy compounding is recommended by several organisations to improve patient safety. However, a careful evaluation of their benefits and risks is needed.

Purpose To evaluate the safety before and after the implementation of an image-based volumetric compounding workflow software system (PhocusRx), and stratification of residual risks to drive future developments.

Material and methods Setting: chemotherapy compounding pharmacy unit of a 1300-bed tertiary teaching hospital provided with a Computerised Prescription Order Entry program, online pharmacy validation and online printing of compounding order sheets. In the before phase, quality control was made by a pharmacy technician who verified starting products, number of vials used, aspects of the final product and label accuracy.

Design: comparative risk analysis of the chemotherapy compounding process before and after the implementation of PhocusRx, according to the Failure Modes, Effects and Criticality Analysis (FMECA) method.

Measurements: the failure modes were defined and their criticality index (CI) calculated on the basis of the likelihood of occurrence, potential severity for patients and detection probability. CI of the before and after phases were compared, and new measures were proposed.

Results In the pre-implementation phase, the sum of CI of 16 identified failure modes was 1999. After PhocusRx implementation, 21 failure modes were identified and the CI was reduced to 668 (a 67% reduction). According to the compounding subprocess, the material preparation CI was reduced by 46% (318 vs 171), the drug production by 76% (1411 vs 341) and the quality control by 48% (126 vs 240). The five failures modes exclusively detected after the implementation of the robot were associated with very low CI (CI <30).

After PhocusRx implementation, the failure modes with the highest CI reduction were: wrong vehicle type (−96.7%); incorrect label (−96%); forgotten bag preparation (−83.3%); incorrect drug packaging (−80%); incorrect drug measure (−77.8%); and incorrect drug (−75%).

High-priority recommendations defined were: improving barcode identification of the starting products vials and process improvements in the image-based quality control.

Conclusion PhocusRx implementation has increased the safety of the compounding process in the pharmacy department. FMECA is a useful method for evaluating the impact of compounding technology implementation and identifying further improvement strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-024

THE VALIDATION OF CONTROL METHOD: THE GRAVIMETRIC ANALYSIS IN CYTOTOXIC DRUG PREPARATION

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Background Our production unit realises more than 35 000 cytotoxic drug preparations per year in an isolator chamber (IC). The control method is done by in-process gravimetric analysis coupled with scan identification, led by software with interactive instructions. The balances are certified once a year, yet outside the IC. Indeed, turbulent airflow could impact the scales' measurements. The accepted errors percentages are a function of the volumes weighted.

Purpose After software development and setup, we need to validate this control method with the two components: the weighing scales and the software.

Material and methods For the weighting scales, a qualification was made inside and outside the IC with standard weights. For the validation the tests performed were fidelity, accuracy and eccentricity. Then, a comparison to visual control was performed to evaluate the bias of the balance. Six syringes with different volumes were made and then verified by a third person. Next, they were weighed 15 times to obtain the total error. For the software, a method is being developed to analyse the specificity and the sensitivity. For the specificity,