PERFORMANCE QUALIFICATION OF ROBOTIC SYSTEM FOR CYTOTOXIC DRUGS PREPARATION IN A FULLY GMP COMPLIANT HOSPITAL PHARMACY

E. Kytö[1], P. Suonvieri[1], G. Moroni[2], M. Federici[2]

[1] Tyks Hospital Pharmacy, Turku, Finland

[2] Loccioni, Ancona, Italy

25th Congress of European Association of Hospital Pharmacists

23-28 March 2021
VIRTUAL MEETING

Abstract number: 3PC-063
ATC code: L01 – Cytostatics

BACKGROUND AND IMPORTANCE

The robotic system APOTECAchemo for automated preparation of cytotoxic drugs ensures reduced occupational exposure to toxic substances and aseptic working conditions. The most critical operations are performed by a robotic arm and the operator's intervention is limited to un-/loading materials in a rotating warehouse through an un-/loading area enclosed within a laminar airflow barrier (Figure 1).

In European hospital pharmacies which comply with Good Manufacturing Practice (GMP), the performances of the robot have to be assessed by GMP qualification to confirm that the technology meets the set quality standards.

Figure 1: APOTECAchemo system

AIM AND OBJECTIVES

The aim of this study was to evaluate microbiological performances and environmental conditions during fully-automated preparation with APOTECAchemo in a Grade B cleanroom. In TYKS hospital pharmacy performance qualification of APOTECAchemo was performed in 2020.

MATERIALS AND METHODS

Effectiveness of laminar airflow retention was checked by potassium iodide (KI)-discus test in the un-/loading area of APOTECAchemo robot (Figure 2).

Validation of the aseptic preparation: media-fill simulation tests performed on three consecutive days in two shifts each. In total, 240 products (180 infusion bags, 30 syringes, 30 elastomeric pumps) were automatically filled with single/double strength tryptic soy broth in lieu of drug products (Figure 3). Media-fill products were visually inspected for turbidity after 14-day incubation.

Microbiological environmental controls: performed by passive-air sampling (settle plates), surface sampling (contact plates/swabs), and active-air sampling, taken for each shift (Figure 4). In addition, microbiological samples were taken from the operator at the end of each day. The number of colony-forming-units (CFU) per plate were counted and identified.

Environmental monitoring: during compounding of the media-fills particle counters were present in both working and loading area. Humidity and temperature were also monitored.

Figure 2: KI-discus test

Figure 3: Media-fill test

RESULTS

Effectiveness of laminar airflow retention: the results of the KI-discus test lay far below the acceptance limit, demonstrating the effectiveness of laminar airflow in preventing the escape of particles from the internal areas of the robot.

Validation of the aseptic preparation: none of 240 media-fills showed turbidity after incubation indicating no contamination with microorganisms.

Microbiological environmental controls: mean CFU on contact/settle plates was <1 in all locations sampled. Most of the CFU were identified as skin-related micro-organisms, such as *S.epidermidis* and *S.hominis*. Samples taken from the operator were within Grade B limits.

Environmental monitoring: particles during compounding of media-fills were within grade A-limits. Humidity and temperature were within set limits.

Location	Mean CFU/settle plates	Mean CFU/contact plate
Working area	0	0
Warehouse area	0.1	0.2
Loading area	0.8	0.3

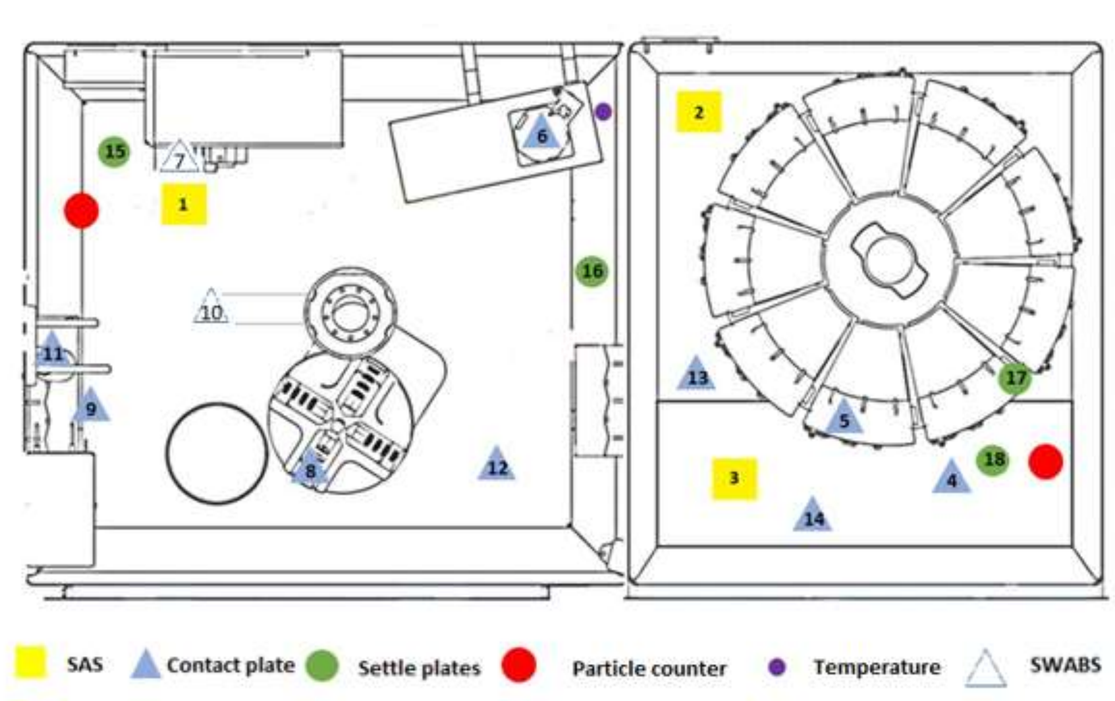

Figure 4: Locations of microbiological monitoring

CONCLUSIONS AND RELEVANCE

Extensive media-fill tests and environmental monitoring during fully-automated preparation with APOTECAchemo revealed well-controlled aseptic procedure and adequate sterility level, thereby complying with the quality standards set by the hospital pharmacy.

Turku University Hospital

erkka.kyto@tyks.fi