GOOD MANUFACTURING PRACTICE AND CHEMOTHERAPY PREPARATION: A CASE STUDY ON IMPLEMENTATION OF A ROBOTIC SYSTEM IN A DANISH HOSPITAL PHARMACY

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25th Congress of European Association of Hospital Pharmacists

23-28 March 2021
VIRTUAL MEETING

GPI number: PC10223

WHAT WAS DONE?

A robotic system for aseptic preparation of cytotoxic drugs was implemented in the pharmacy-based cleanroom (Grade C), fully-compliant with *Good Manufacturing Practice* (GMP) regulations. Specific organisation allowed the integration of APOTECAchemo into the pharmacy workflow, thereby steadily improving the robot productivity.

HOW WAS IT DONE?

- A multidisciplinary team defined 228 User Requirements Specification (URS) addressed in the tender and associated to GMP regulations to assess that the technology complied with the intended purpose.
- APOTECAchemo passed through all the qualification stages: Design Qualification (DQ), Factory-Acceptance Testing (FAT), Installation Qualification (IQ), Site-Acceptance Testing (SAT), Operational Qualification (OQ), Performance Qualification (PQ).
- The implementation of the robot was evaluated in terms of doses prepared, active ingredients processed, and percentage of the total production compounded. Data were taken from the management software and examined from June 2019 to September 2020.

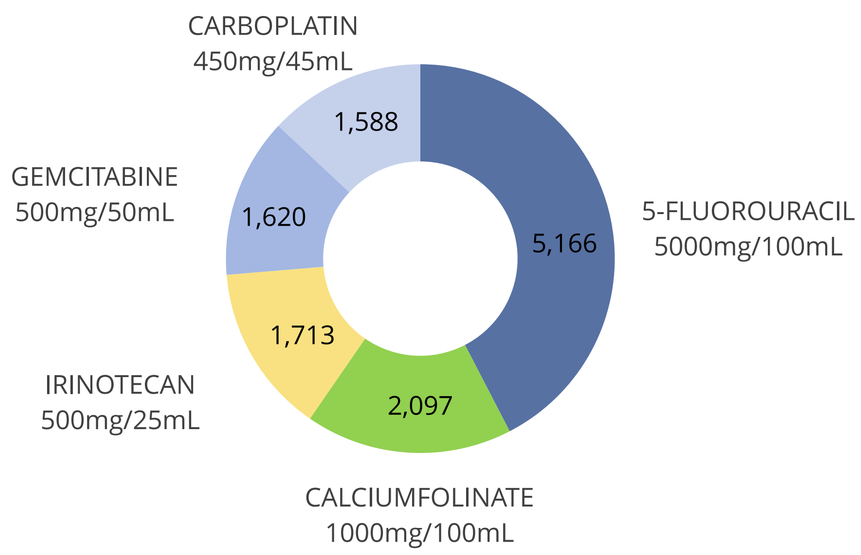


Fig 1 Active ingredients covering 58% of the total production

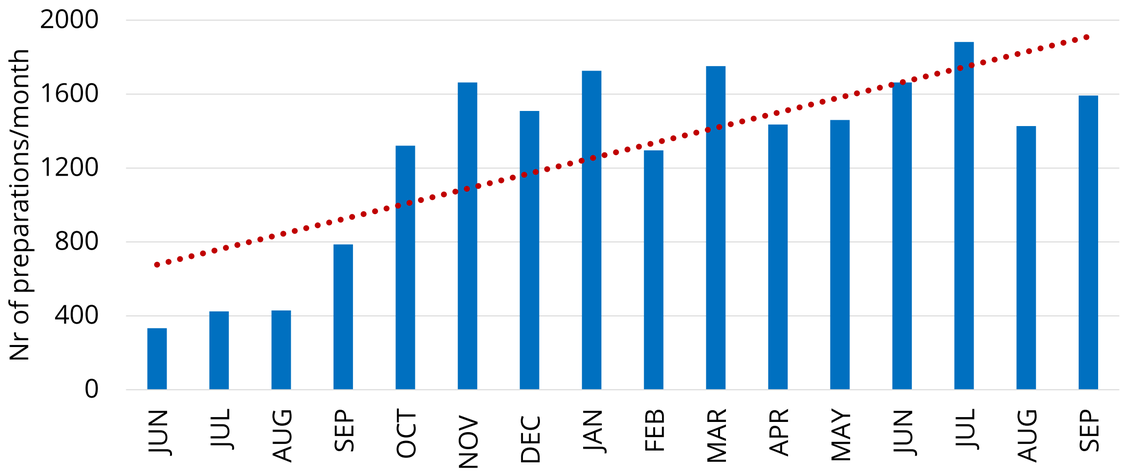
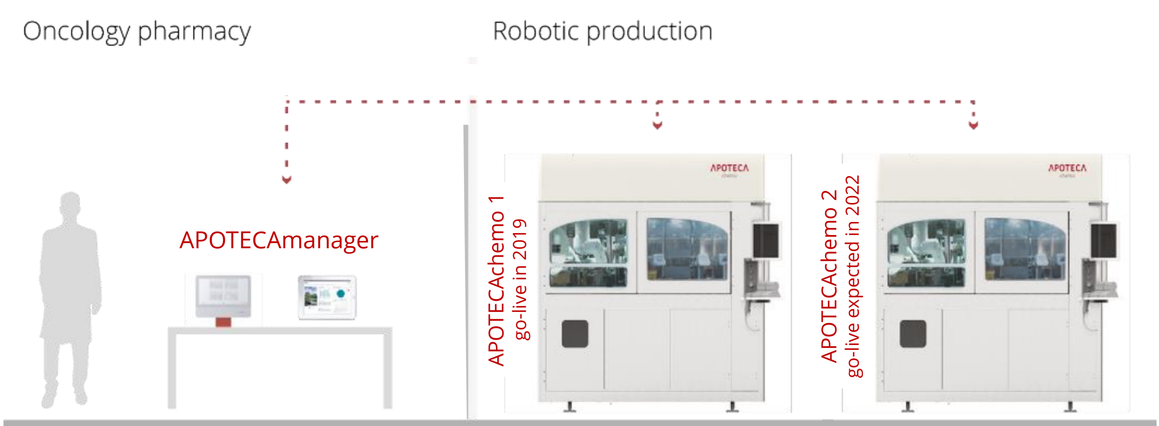


Fig 2 Ramp-up of APOTECAchemo productivity since the go-live



WHY WAS IT DONE?

In 2017, the hospital pharmacy has started a project for automated chemotherapy preparation aimed at managing the increasing workload, while ensuring highest level of quality and the safety of healthcare workers.

In Denmark, the authorities expect hospital pharmacy preparation to be GMP compliant. To achieve the best implementation of APOTECAchemo, go-live was preceded by a thorough qualification process and followed by robot performance evaluation in a GMP-pharmacy.

WHAT HAS BEEN ACHIEVED?

GMP qualification process

- Completed in 13 months (April 2018-May 2019)
- APOTECAchemo fulfilled the set requirements in accordance with GMP regulations and went live in May 2019

Implementation (from Jun 2019 to Sep 2020)

- 20,968 doses were prepared with the robot
- 18,242 infusion bags (87%), 2,726 elastomeric pumps (13%)
- 21 active ingredients processed
- 58% of the total production covered by 5 active ingredients (irinotecan, 5FU, Ca-folinate, gemcitabine, carboplatin) (Fig.1)
- +39%: average monthly production with APOTECAchemo (from 963 doses/month in 2019 to 1,582 doses/month in 2020) (Fig.2)
- The percentage of the total production operated by APOTECAchemo rose from 20,9% (2019) to 46,4% (2020)

WHAT NEXT?

APOTECAchemo robot was successfully implemented in a fully GMP-compliant hospital pharmacy, thereby enabling the automation of the preparation process and the reduction of the manual operations. Through the evaluation performed, the hospital pharmacy decided to install a second robotic system to further enhance the automated production

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