

# Best Practices for the implementation and use of the APOTECaChemo technology agreed by the German hospital pharmacy user group

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## Background and importance

The implementation of a robotic solution in the hospital pharmacy must be planned and structured with the aim of ensuring that automated and manual production complement each other efficiently and run in parallel. The definition of standards and best practices for the automated production of cytotoxic preparations facilitates the implementation of the technology while taking into account local peculiarities.

## Aim and objectives

During a two-day meeting in September 2018, the German APOTECaCommunity and technology experts with experience in robotic manufacturing of intravenous preparations were asked to define best practices for the optimal implementation and use of APOTECaChemo technology in German hospital pharmacies.

## Results

### WORKFLOW & ORGANISATION

- The selection criteria for preparations that should preferably be produced with APOTECaChemo are preparations with large volumes, preparations in bags and active ingredients that are frequently prescribed.
- The identification of the "drug days", i.e. main production days for individual active ingredients on which they are produced in large quantities, enables the optimal organization of automated production.
- In order to optimize automated production, all preparations containing the same active ingredient could be grouped together, taking into account a decreasing or increasing order of volume.

### PRODUCTION

- Optimum interconnection between technicians and the robot will increase the efficiency.
- The required starting material for automated production should be provided before it is displayed in the "loading list" on the APOTECaChemo screen. The management software "APOTECaManager" can be installed in the cleanroom as direct support for the technician.
- The dissolving of powder drugs and the compounding of preparations with liquid drugs should take place simultaneously

## Materials and Methods

Prior to the APOTECaCommunity meeting in September 2018 a survey with 24 statements and recommendations for the implementation and use of APOTECaChemo technology was sent to the participants. The 24 best practices were assigned to 4 categories: Workflow & Organization, Production, Roles & Responsibilities and Quality & Process Control. The survey participants were asked to evaluate the best practices considering their feasibility in German hospital pharmacies. Based on the results of the survey, the best practices were agreed or adapted during the meeting and further best practices were defined.



### ROLE & RESPONSIBILITIES

- Pharmacist**
  - Responsible for the workflow design with APOTECaChemo, which has to be established in addition to manual production
  - Responsible for the organization of the production activities and control of the compounded preparations
- Technician**
  - Manager of automated production and responsible for the robotic implementation
- Head of the pharmacy**
  - Evaluation of the new workflows and the quality of the defined procedures

### QUALITY & PROCESS CONTROL

Type of monitoring	Where			Mode and frequency
	Loading / unloading area	Carousel	Production area	
Particle Counting	x	x	x	* In operation: Continuous measurement in the production area is possible * At rest: at least every 6 months in all areas of the robot (during maintenance)
SAS	x		x	* In operation: every 3 months between dosing unit and scale (production area) * At rest: every 3 months between dosing unit and scale (production area) and in the loading area
Sedimentation plates / Contact plates	x	x	x	* Sedimentation plates: at least once a week with at least one plate in each area of the robot (in operation) * Contact plates: at least once a week with at least one plate in each area of the robot at the end of the production day
Fingerprints				* 1 time per week per operating PTA before changing gloves



## Conclusions and relevance

The best practices defined by the German APOTECaCommunity can be advantageously used by experienced users and especially by hospital pharmacies that are newly implementing the technology.