

# IMPLEMENTATION OF A TERMINAL ANALYTICAL CONTROL IN CYTOTOXIC RECONSTITUTION UNIT (CRU)

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### **INTRODUCTION - CONTEXT**

- No staff dedicated to this activity (rotation of the entire team : pharmacists and pharmaceutical technicians)
- Visual inspection in place : double check by pharmacists in production and release
- +8% production activity over the year 2022 for 6 530 preparations/year  $\rightarrow$  Increased risk of errors
  - > Desire to improve the SECURITY -> Introduction of a terminal analytical control

### **MATERIALS & METHODS**



CALIBRATION OF CURVES by supplier : by groups of speciality/solvent (without discrimination of monoclonal antibodies)

10 to 20 samples required by molecule(pharmaceutical lab)/solvent

#### **ANALYSIS OF THE FIRST RESULTS** : internet plateform

- From November 2022 to May 2023
- Analysis of non-conformities (NC)

**EVALUATION OF THE DEVICE** : Writing of a satisfaction guestionnaire

Analysis of answers : pharmacists and pharmaceutical technicians

### RESULTS

- 14 molecules validated in routine with  $\checkmark$ 4 monoclonal antibodies
- 2 types of NC : ~
  - No match : The molecule or concentration is not identified Fail :

**OBJECTIVE** 

 $(\mathbf{x})$ 

(X)

The concentration is outside the acceptance threshold +/- 15%

Validate the routine use of the qualitative and quantitative control by UV-visible spectrometry DrugLog<sup>®</sup> (Pharmacolog) for the release of preparations in our CRU



n = 869 samples Total number of NC = 46

#### %NC over the study period = 5%

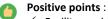
Questionnaire of 10 items of 5 choices (very satisfied to completely dissatisfied) n = 15 participants

> Assigned average = 15,2/20 (min-max : 9-17/20)

## CONCLUSION



This quality control is an ASSET in securing the circuit of injectable chemotherapies



- ✓ Facility, rapidity and fiability of this quality control currently integrated in routine
- ✓ Reactivity from the supplier

Limit : funding sustainability ?

**Prospect** : Reassessment planned in 1year

### DISCUSSION

- □ Absolute NC rate = 5% >> 1.3% [1]  $\rightarrow$  Ordering NCs in « explainable NCs » VS « unexplainable NCs »
  - Explainable NCs (n = 33) = selection product error, incorrect/omitted homogenization, incomplete sample
  - Unexplainable NCs (n = 13)  $\rightarrow$  systematic re-manufacturing

### → This rate drops to 1,5%

- Writing of a guide available to the pharmacist : detailing necessary steps to take before concluding a true NC
- Discuss areas for improvement with the supplier :
  - Addition of a color code to distinguish molecules already validated from those being calibrated ?
  - Import of absorbance curves on the internet plateform? ٠
  - To provide assistance to interpret ourselves artefacts such as microbbubles ? ٠

1)Alexandre Exquis, Evaluation d'un automate (spectrophotométrie UV) pour le contrôle qualité des chimiothérapies produites en pharmacie hospitalière, Master en pharmacie, Genève, 2015