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 → Increased risk of errors
  - ➢ Desire to **improve the SECURITY** → Introduction of a **terminal** **analytical control**

OBJECTIVE

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

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 questionnaire
- Analysis of answers : pharmacists and pharmaceutical technicians

RESULTS

✓ **14** molecules validated in routine with 4 monoclonal antibodies

✓ 2 types of NC :

⊗ **No match** :
The molecule or concentration is not identified

⊗ **Fail** :
The concentration is outside the acceptance threshold +/- 15%

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)

DISCUSSION

❑ Absolute NC rate = 5% >> 1,3% [1] → Ordering NCs in **« explainable NCs » VS « unexplainable NCs »**
- Explainable NCs (n = 33) = selection product error, incorrect/omitted homogenization, incomplete sample
- Unexplainable NCs (n = 13) → 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?
- To provide assistance to interpret ourselves artefacts such as microbbubles ?

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

CONCLUSION

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

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

Limit : funding sustainability ?

Prospect : Reassessment planned in 1year