3PC-036 RISK ANALYSIS OF THE PHARMACEUTICAL CIRCUIT FOR INJECTABLE CHEMOTHERAPIES AFTER IMPLEMENTATION OF DRUGLOG ®

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INTRODUCTION

As part of a quality assurance approach, a **UV-visible spectrophotometer** (Druglog®) has been installed in 2021 in the cytotoxic reconstitution unit (CRU), enabling pre-release analytical control. This new stage has led to a new risk analysis usingthe **FMECA method** (Failure Modes, Effects and Criticality Analysis). **The aim** was to **evaluate** the entire injectable chemotherapy **process** compared with an initial FMECA carried out in 2016 in order to assess the added value of the DrugLog®tool.

2016
First FMECA

2021
DrugLog ® installation

2023
Second FMECA

MATERIAL & METHOD

June - September 2023

Multidisciplinary team
2 pharmacists, 1 resident, 1 pharmacy technician

Six working meetings

Update failure modes (FM) identified in 2016 to finish at 97 FM in 2023 (i.e +20FM) → Development of a criticality scale → Calculation of a criticality index (CI) for each FM → Classification of different criticalities into 3 categories

Criticality index						
		Frequency				
		1	2	3	4	5
Severity	1	1	4	9	16	25
	2	2	8	18	32	50
	3	3	12	27	48	75
	4	4	16	36	64	100
	5	5	20	45	80	125
		1	2	3	4	5
		Detectability				

$$CI = FxSxD$$

F : frequency
S : severity
D : detectability

Criticality index rating	
Light	IC < 25
Moderate	25 < IC < 75
Severe	> 75

RESULTS

70 FM common to both years, divided into **10** categories

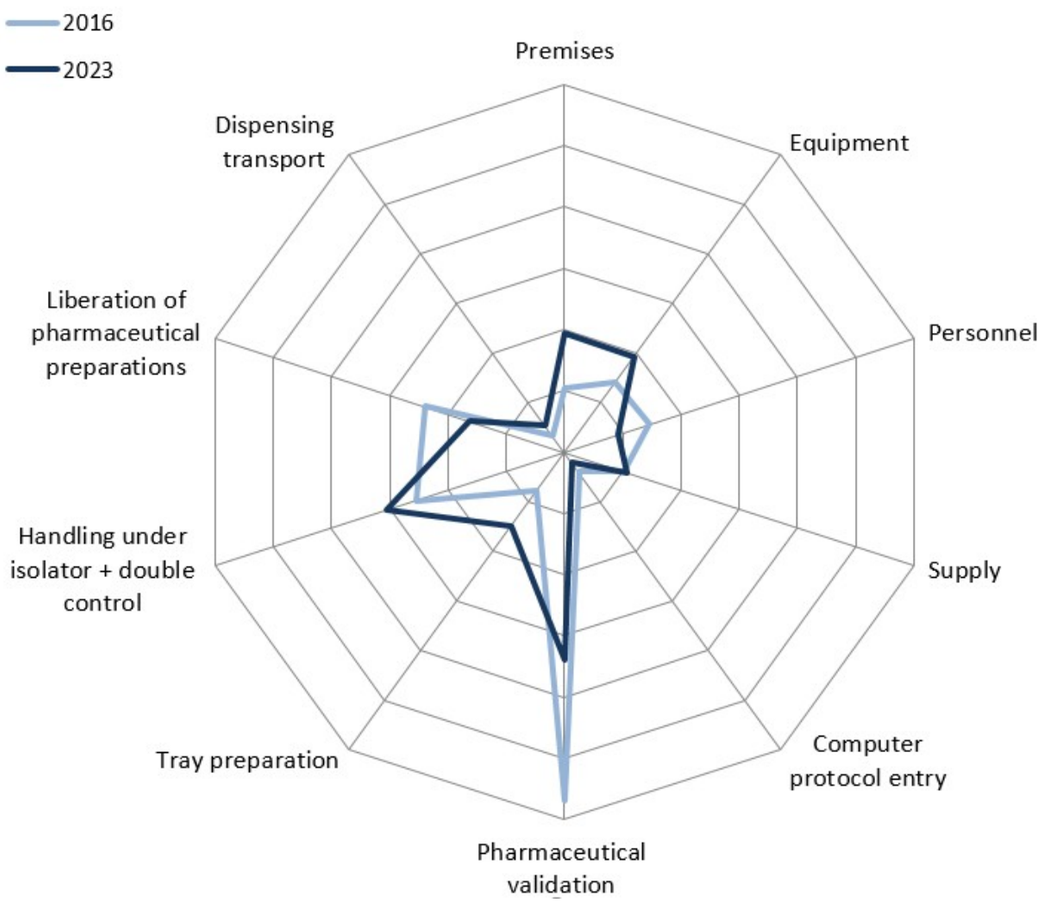

Figure 1 : *Breakdown of cumulative criticality indices (CCI) between 2016 and 2023*

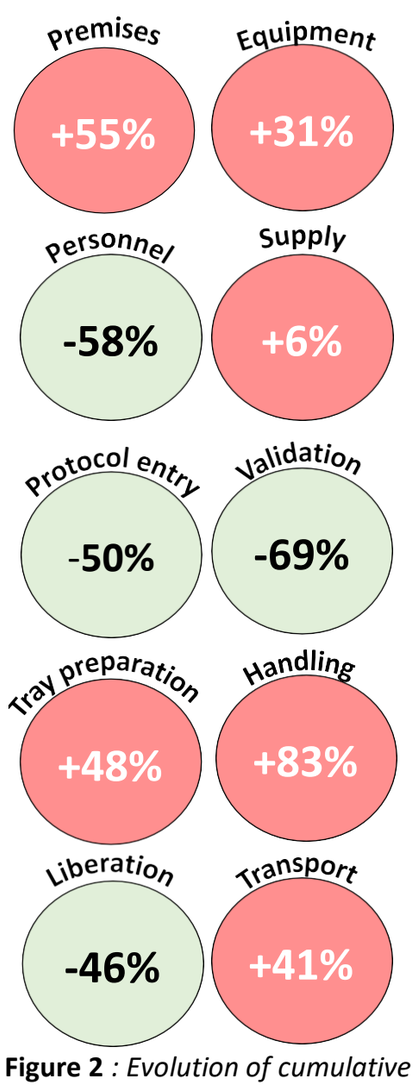

Figure 2 : *Evolution of cumulative criticality index by categories*

	2016	2023
Light	63	68
Moderate	7	2
Severe	0	0

Table 1 : *Comparison of the 70 failure modes between 2016 and* 2023

CCI_{2016} : **806**
CCI_{2023} : **809**

Figure 3 : *Comparison of cumulative criticality indices between 2016 and 2023*

DrugLog ® analysis
Identification of 18 FM
100% of the 18 FM are low of criticality

CONCLUSION & DISCUSSION

DrugLog ® allows a liberation more reliable with qualitative and quantitative assay. Indeed comparison of FMECA highlight an improvment of our practices in the area of liberation. However, not all molecules are dosed on DrugLog (antibodies, clinical trials, etc.), which means that double-checking must be maintained for certain preparations.
Major changes had been made since the first FMECA, such as the introduction of double validation when entering computer protocols, which explains the significant improvements.
The increase in criticality in certain categories is explained by ageing equipment and premises (currently being renewed), as well as by the increase in production (+25% in 6 years) and the specificities of molecule preparation.