

Preliminary hazard analysis applied to a chemotherapy compounding robot

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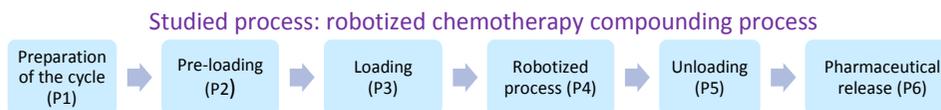
Aims

- Implementation of the robot Kiro Oncology® (Grifols, Spain) in June 2016
- 23% of the preparations** have been performed using the robot
- A Preliminary Hazard Analysis (PHA) was carried out in our unit to **identify specific risks about robotized chemotherapy compounding process**

Method

- Multidisciplinary working group**
 - Pharmacists (3)
 - Pharmacy technician (1)
 - Grifols technician (1)
- 6 meetings between February and May 2020
- Identification of **priority situations (PS)**
- Definition of a **risk plan** and scenarii associated
- 2 scales were defined (severity degree of hazard and possibility of occurrence of hazard)
- Evaluation of **initial and residual criticality**
- Implementation of **corrective actions**

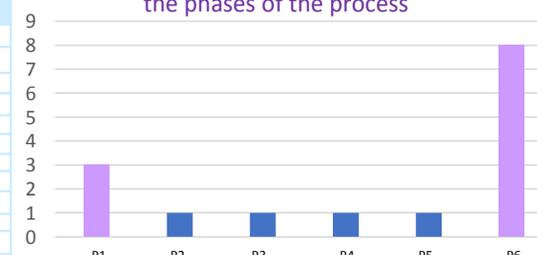
Résultats



Hazard mapping

Generic dangers	Specific dangers	Hazardous events
Organisational	Management of the production	No communication
		No prioritization
		No management of the cycle
		No management of the material
Human	Human resources	Inadequate training
		No technician available
	Operator	Over-confident
		Interruption of work
Technical	Equipment	Failed equipment
		Management of alarms
		Computer bug
Environmental	Environmental incident	Power cut, fire, natural disaster...

Breakdown of the scenarios according to the phases of the process



The phases with most of the dangerous situations were preparation of the cycle and pharmaceutical release of the preparations

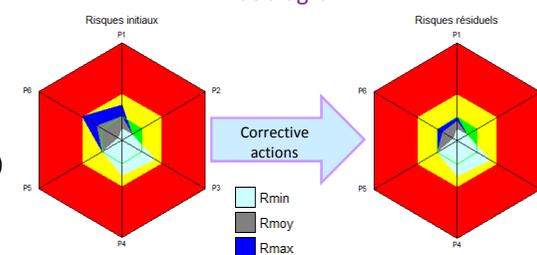
Severity degree

Severity degree	Category	Index	Consequences
G1	Minor	1	No impact on the preparation
G2	Significant	2	Preparation detected as non compliant by the robot
G3	Serious	3	Preparation detected as non compliant by the pharmacist
G4	Critical	4	Preparation detected non compliant just before the administration
G5	Disastrous	5	Preparation undetected non compliant and administered

Criticality matrix

		Gravité				
		1	2	3	4	5
Vraisemblance	5	2	2	3	3	3
	4	1	2	2	3	3
	3	1	1	2	2	3
	2	1	1	1	2	2
	1	1	1	1	1	2

Risk mapping by phases according to the Kiviat diagram



Main corrective actions proposed

Set up immediately:

- Optimization of the back label "to be validated" affixed to the preparation if a problem occurred during automated cycle: checklist to identify the problem
- Implementation of **preparations quarantine**
- Real-time validation** of pending preparations by the quality pharmacist

To be programmed (require greater efforts in terms of human and financial resources) :

- Bidirectional interfacing** between CHIMIO® software and that of the robot (KiroLink®)
- Improvement of drugs recognition in addition to the **datamatrix system**
- improvement of the IT management of **alarms**

- 12 PS identified
- 15 scenarii developed
- After proposing 11 corrective measures, 87% of scenarii became acceptable as it was

Discussion/Conclusion

This step is crucial for the installation of an equipment like the robot Kiro®. This PHA shows that robotization does not exclude the difficulty of controlling risks linked to the human factor. Despite the corrective actions, 2 scenarii were still critical with a residual criticality of level 2 (tolerable risk under control), which means that the associated corrective actions couldn't reduce the criticality in level 1 (acceptable risk as it is). For these scenarii, the risk reduction measures are part of an action plan to manage their implementation and keep risks to a minimum.