In-process gravimetric control coupled with vial recognition and dematerialization of chemotherapy production: an option to promote the autonomy of operators and the safety of chemotherapy preparations

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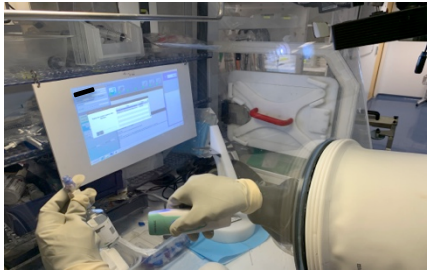
Goals:
The dematerialization of the production with gravimetric control in process started in 2010 in our unit (> 50,000 preparations / year).
Initially used for quantitative control and anticipated production, we have recently extended gravimetric control to daily production and quality control (identification of the active substance by barcode scanning of the vials).
The aim of this work is to present a feedback on this important transition in the dynamics of our unit.

Methods:
- The **manufacturing data extracted from Chimio® software** and the **opinions of the operators evaluated by a questionnaire** were compared before and after this extension over one-year periods.
- A **4-weeks prospective study** completed these data.



Gravimetric process:
Manual production is carried out using a **production assistant** controlled by Chimio® software integrating :
- **Gravimetric control in process** (Cytocontrol® weighing scales),
- **Vial recognition** (with barcode labelling),
- **Traceability of manufacturing steps** archived as a report.

Results:

	UNTIL March 2018	AFTER March 2018
Workstations equipped	**2**	**4**
Number of preparations per day (gravimetric process)	**> 40**	**> 100**
Annual productivity / Percentage of pharmaceutical interventions / Percentage of weighing errors	**7,108 / 0.6 % / 4.0 %**	**20,667 / 0.4 % / 7.6 %**
Percentage of in-process controlled preparations (considering our automated production (20%))	**40 %**	**70 %**
Average wait times for our adult day hospital center	**68 min**	**65 min**
Opinions of the operators (N=24)	***"slow and impractical"***	***"time efficient, safe, in favor of autonomy and quite practical"***

Discussion-Conclusion:

Advantages:
Gravimetric control in process has **increased our quality level with an optimization of our production**.

Disadvantages:
Interventions have increased (management of technical problems and nonconformities); **Computer dependence**, **workstation clutter**, **vial labeling** and **batch number management**.

Limits at the Curie Institute:
Non-recognition of reconstitution and dilution **solvents**;
Preparations requiring **reconstitution** or **small volumes** (< 1mL) **and complex preparations** (clinical trials, *per os*) **remain excluded**.

Perspectives of evolution:
Include the **identification of solvents**, **solve recurring computer problems** and **add the products to be reconstituted**.

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