

Introduction

In 10 years, the production unit has seen its activity double with the preparation of 40 400 chemotherapies in 2022. Pending a capacity expansion, it has been decided to implement a dose-banding (DB) network within the production.

- To analyze molecules and doses to be standardized
- To carry out an impact analysis in order to anticipate and assess changes before the implement of DB

Method



CHOICE OF BANDED DOSES
Assistance tool Excel® (GERPAC)

Choice of molecules
6 criteria: number of preparations/years, stability, cost, first molecule in protocols, frequently discarded molecules, 60% of needs covered by the maximum production of 5 DBs



CHANGE CONTROL

Impact analysis - SWOT analysis
Impact rating based on 3 criteria: **blocking**, **troublesome**, **acceptable**

Discussion-Conclusion

The change control process has made it possible to map the impacts resulting from the deployment of DS within the unit, and to guarantee control and coordination of the changes made.

The Gantt chart enables to organize, plan and prioritize the implementation of corrective measures.

The method « Change control » a successful project implementation thanks to a priori risk management, despite major organizational changes.

This method can be reiterated whenever there is a change in practice.

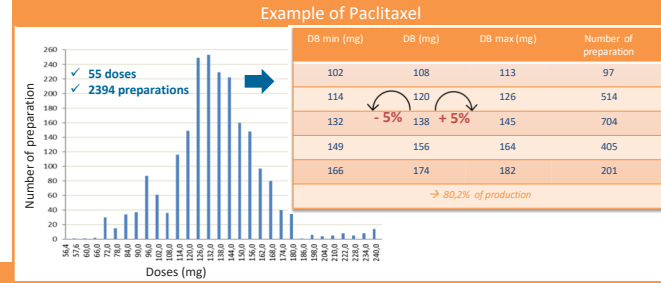
Résultats

1
Molecules

5 molecules selected
out of 12 studied:

- ✓ Oxaliplatine
- ✓ Paclitaxel
- ✓ Irinotecan
- ✓ Gemcitabine
- ✓ 5FU

25% of the annual production

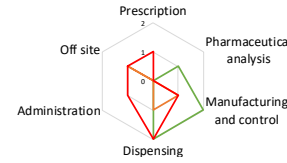


2
SWOT

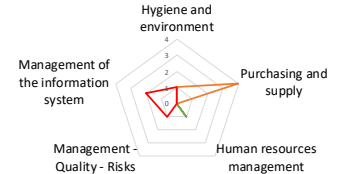
Highlighting of 25 impacts :

- 5 rated **acceptable**
- 9 rated **troublesome**
- 11 rated **blocking**

Level of impact on the production process



Level of impact on the supporting process

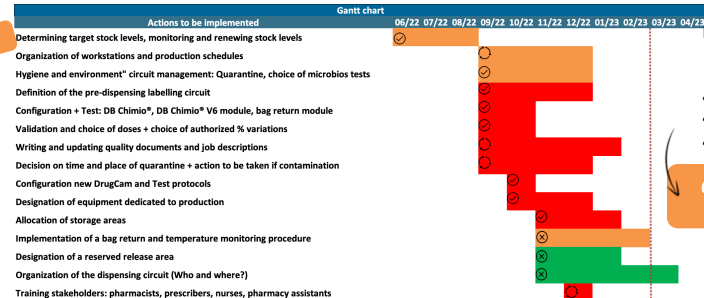


Stage of dispensing : circuit on bag relabeling

Stage of manufacturing and control : equipment availability, procedure to follow in case of a microbiological contamination, storage

Management of the information system : tests and configuration of the business software

3
GANTT



Highlighting of 15 correctives measures on identified impacts:

- 2 on **acceptable**
- 4 on **troublesome**
- 9 on **blocking**

6 of 9 on blocking impacts have been completed

- ⊗ Not started stage
- ⊙ Finished stage
- ⊘ In progress stage