

Is it possible to achieve 100% automated controls in a chemotherapy production unit?

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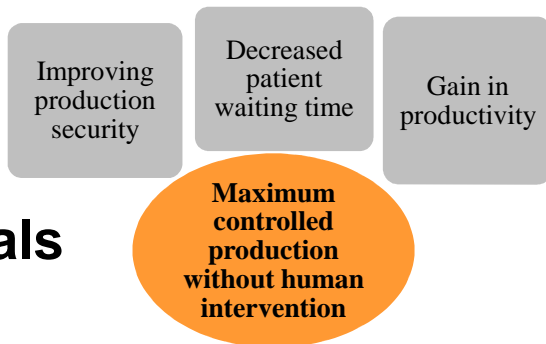
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Introduction

- **Reference method** : Gravimetric control (Cytocontrol® balances) and **vial recognition** (with barcode labeling) controlled by a **production assistant** (Chimio® software)
- Alternative : Double visual check

Goals



Methods

Production data over a period of 4 months
(September 1 to December 31, 2019)

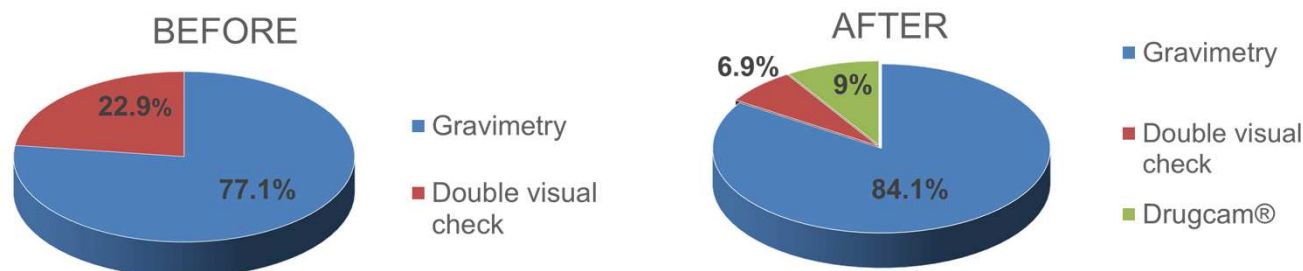
Review of the literature and collection of experience
feedback from centers practicing different control methods

1) Feasibility of extending our
reference method

1) Possibility of
implementing additional
methods

Results

Total of 16,339 preparations over the period studied



Extension of in-process gravimetric control to four cytotoxic drugs in the form of powders to be reconstituted representing 7.0% of our production (cyclophosphamide, ifosfamide, pemetrexed, vinblastine)

Acquisition of a Drugcam® workstation dedicated to **clinical trials** (6.6% of our production), products with **temporary authorization for use** (TAU, 0.6%) and **intrathecal preparations** (1.8%) : would increase automated controls to 93.1%

Discussion

- ✗ Analytical methods (QC Prep® and HPLC) were not retained : the constraints on our organization are too important
- ✓ **Extension of our reference method** : necessary optimization of the vial over-labeling circuit and their pharmaceutical release
- ✓ **Acquisition of a Drugcam® workstation** : would allow us to do away with the human intervention dedicated to double visual check + would improve quality and traceability. However, financial costs are to be anticipated, as well as the time required for implementation.
- ⚠ **6.9% of preparations remain in double visual check** : intra-vitreous, oral syringes, dilutions, complex non-computerized procedures and volumes to be withdrawn less than 1 milliliter