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Analytical control of injectable preparations : take the time to analyze your activity

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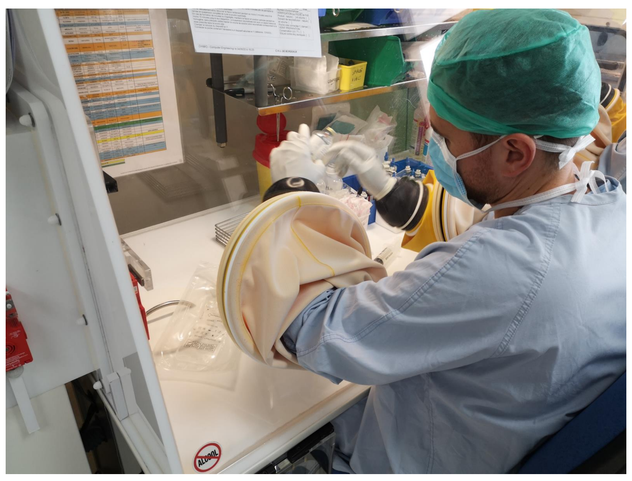
Good Practices Initiative (GPI)
Poster PC50214



Context:

WHAT WAS DONE ?

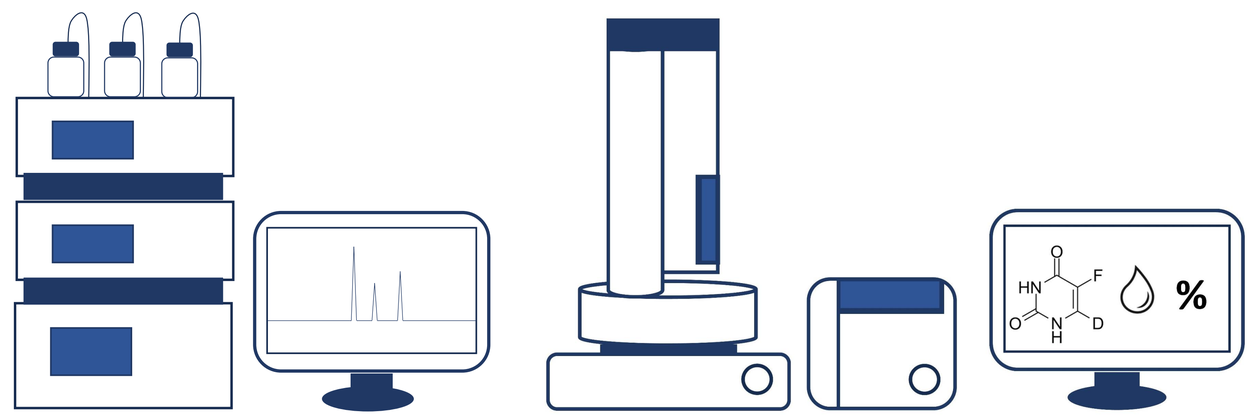
- **Injectable drug production unit, University Hospital**
- Production: ≈ **55,000 preparations/year (cytotoxic and monoclonal antibody/ bags and syringes)**
- For 15 years, implementation of **analytical control** (**identification and dosing**) as a post-process control method
- **HPLC-UV** and **UV-Raman spectrophotometry** (QCRX®)
- Around **one hundred assays/day** (50% of preparations produced, ≈ sixty different active substances are analyzed)

For the past 4 years, a monthly meeting has been devoted to monitoring the compliance of analytical assays for our preparations

WHY WAS IT DONE ?

It was essential to take **a step back from our control activity**, to:

- monitor and analyze assay compliance in detail,
- distinguish between preparation errors and errors linked to control equipment,
- detect upstream any deviations in assay methods or material damage.



HPLC-UV UltiMate™ 3000 (Thermo Scientific™) system
Cytotoxic analysis (bags and syringes)

QCRX (Icons Services)
Cytotoxic and Monoclonal Antibody analysis (bags)

HOW IT WAS DONE ?

Monthly-one-hour and multidisciplinary meetings

≈ 6 people including: senior and student pharmacists, pharmacy technician and a laboratory technician.

Following points are presented:

- Number of assays and their nature (1st assay or 2nd assay following a 2nd sample);
- Number of non-compliant assays. Limit: +/- 15% of the target concentration
- Overall compliance rate
- Analysis of rejected and destroyed preparations/investigation into the causes of non-compliance (e.g. solvent/molecule/dosage error)

=> **Corrective action** may then be taken, e.g. early maintenance of equipment, quarantine of analytical methods and research into the causes of drift, implementation of new dosing methods. => **Feedback** is then given to the whole team.

Analysis data

Month	Mars	April	Mai	June	July	August	September	October	November	December	January
Total analyses	1727	1717	1497	1503	1656	1598	1588	1816	1626	1596	**1862**
Total Non-compliant assays	96	51	83	92	53	48	77	97	73	78	**116**
Compliant after rep 1 or 2	51	32	54	52	36	38	63	72	42	58	**66**
Compliant after HPLC	4	2	1	1	1	2	3	3	3	0	**6**
Destructed preparations	18	6	6	13	1	7	5	6	10	5	**14**

Example of overall analysis of activity by month on QCRX

Molecule	Total number of analysis	Overall compliance rate	Number of preparations dosed	Compliance rate after 1st dosage	Compliance rate after HPLC dosage	Number of REP 1	Number of REP 2	Compliance rate after REP	Destruction of bags	Molecule forcing
Idarubicine	10	40.0	6	66.7	0	2	1	0.0	2	0
Cyclophosphamide	121	71.1	94	77.7	0	21	5	50.0	8	56
Vincristine Sulfate	90	72.2	67	74.6	0	17	4	71.4	2	5
Docetaxel	17	82.4	15	93.3	0	1	1	0.0	1	4
Etoposide	6	83.3	5	80.0	1	0			0	0
Fludarabine	82	86.6	71	84.5	0	11		100.0	0	0
Carboplatine	129	90.7	117	90.6	0	11		100.0	0	0
Vinblastine Sulfate	18	94.4	17	94.1	0	1		100.0	0	1
Rituximab	111	94.6	105	94.3	0	6		100.0	0	3
Doxorubicine	62	95.2	60	93.3	0	4	1	60.0	1	41
Ganciclovir	103	98.1	101	100.0	0	0			0	0
Bevacizumab	236	98.3	232	98.3	0	4		100.0	0	5
Fluorouracile	529	98.7	522	99.0	5	0			0	1
Busulfan	18	100.0	18	100.0	0	0			0	0
Cetuximab	18	100.0	18	100.0	0	0			0	0
Dacarbazine	33	100.0	33	100.0	0	0			0	0
Daunorubicine	15	100.0	15	100.0	0	0			0	3
Etopophos	7	100.0	7	100.0	0	0			0	0
Gemcitabine	6	100.0	6	100.0	0	0			0	0
Irinotecan	59	100.0	59	100.0	0	0			0	1
Nivolumab	70	100.0	70	100.0	0	0			0	13
Oxaliplatine	2	100.0	2	0.0	0	2		100.0	0	0
Pemetrexed	96	100.0	96	100.0	0	0			0	0
Trastuzumab	10	100.0	10	100.0	0	0			0	10
Vinorelbine Base	13	100.0	13	100.0	0	0			0	0
Cisplatine	1	100.0	1	100.0	0	0			0	0
TOTAL	1862		1760	95.1	6	80	12	71.7	14	143

Example of detailed analysis by molecule and review of compliance rate on QCRX

WHAT AS BEEN ACHEEVED ?

These monthly meetings have enabled us to **anticipate analytical drifts** and reinforce our team's compliance to this type of control. They also enable us to **limit the downtime of dosing methods** and the need for double visual checks, a potential source of errors.

WHAT IS NEXT ?

The aim is to eventually increase the proportion of analytical control to over 50% of preparations produced.

This will involve the introduction of new dosing methods for preparations usually controlled by double visual inspection, and the acquisition of additional equipment.

Share our experience

PC50214