

Background

The French GMP (Good Manufacturing Practices) enforce:

- ❖ validation of the aseptic process using simulation with a culture media
- ❖ valued formation of the pharmacy technicians

These two independent and complementary requirements seem to combine themselves in a global test that could authorize the pharmacy technicians throughout the entire injectable anti-cancer preparation process

Materials and methods

10 pharmacy technicians in charge of 6 aseptic filling global tests (n = 60):

- 1) Preliminary physical and chemical decontamination of equipment
- 2) Preparation and sterilisation of inox baskets containing the Media Fill Test kit (MFT, KLERKIT®) and preparation Medical Devices
- 3) Media Fill Tests preparation with gravimetric control (figure 1)

The 60 MFT were randomly integrated to our preparation activity
 One Growth Promotion Test (EZ-ACCUSHOT®) was performed in each isolator

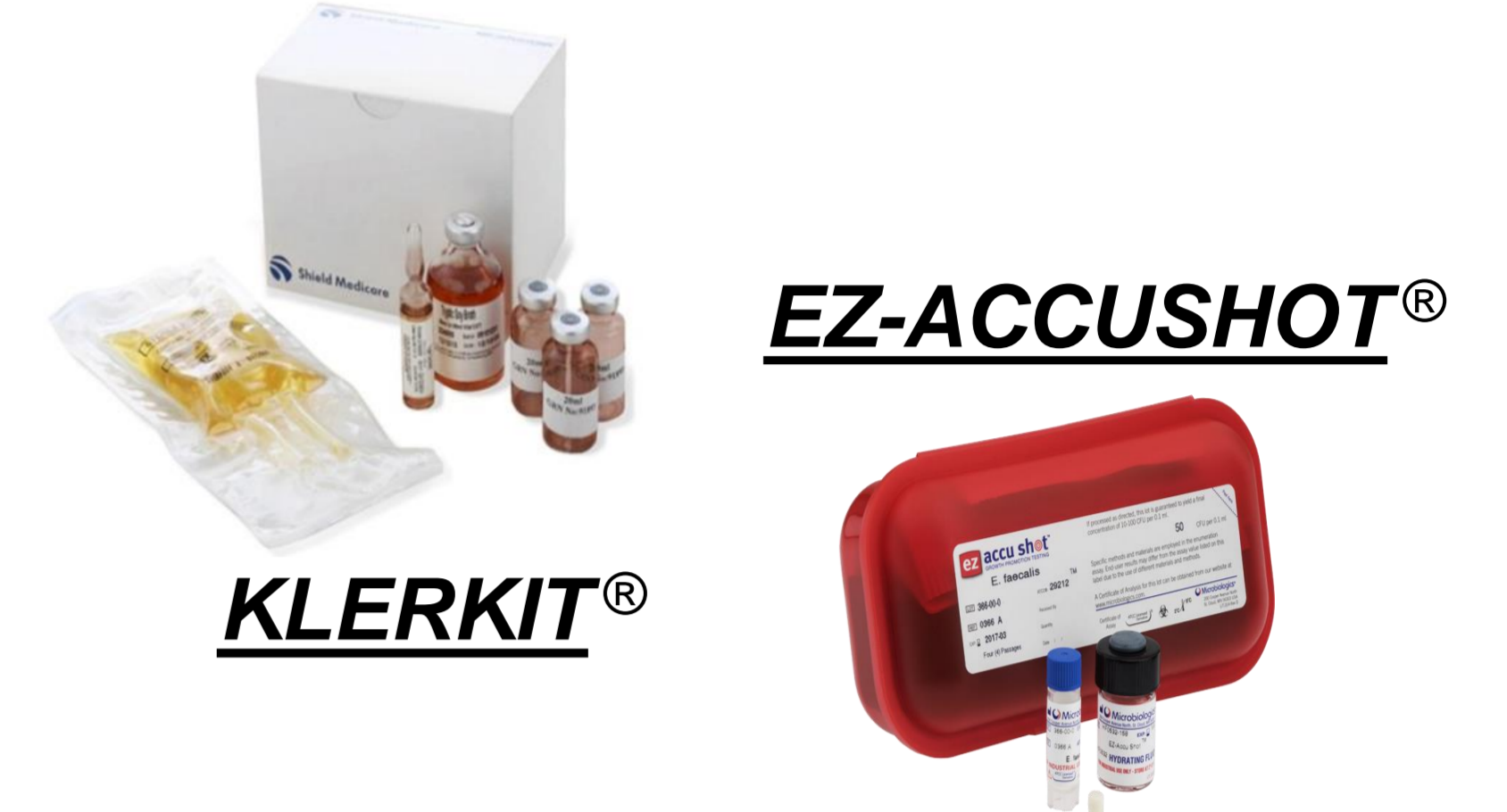
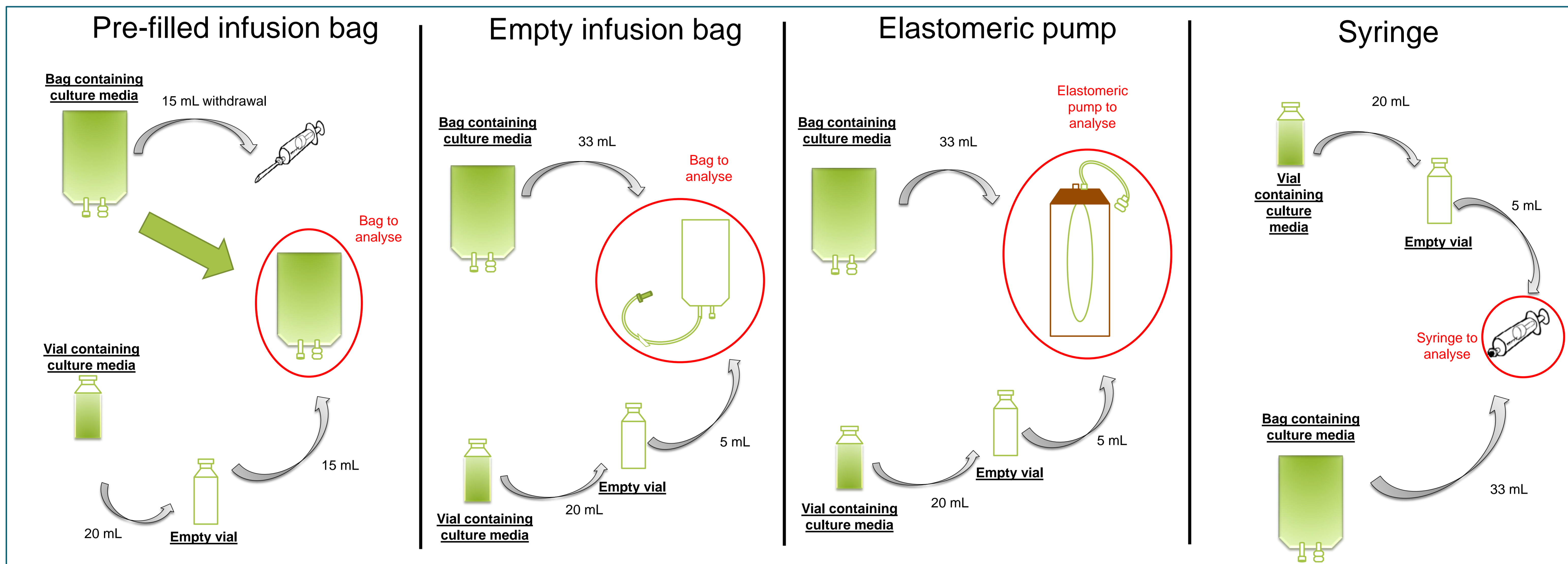


Figure 1 : description of the 4 types of computerized chemotherapy preparations associated with a gravimetric control of each step



The evaluation criteria were :

- Preparation without mistake on the computer assisted gravimetric control
- Preparation without microbiological contamination
- Proper use of preparation medical devices controlled by a pharmacist

Results

GROWTH PROMOTION TEST

	Isolator 1	Isolator 2	Isolator 3	Isolator 4	Isolator 5
Growth promotion test	√	√	√	√	√

Global ASEPTIC FILLING TEST

	Pharmacy technician (n = 6 aseptic filling global tests per technician)									
	1	2	3	4	5	6	7	8	9	10
Gravimetric mistakes	No	No	No	No	No	No	No	No	No	No
Microbiological contamination	No	No	No	No	No	No	No	No	No	No
Proper use of medical devices	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Conclusion

After these simulations by MFT, all pharmacy technicians were qualified. More than the validation of the aseptic process, the integration of all the variables defining our preparation process (especially the computer-assisted preparation, the gravimetric control and the proper use of medical devices) permitted us to use the MFT as an instructive tool which allows the pharmaceutical technician authorisation. This tool will be spread out in the formation of newcomers and also for the On-Call pharmacists who could potentially prepare chemotherapies out of opening hours.