

## BACKGROUND :

- ❑ The production of chemotherapy has increase (over 20% the last 3 years) → ↗ patients waiting time
- ❑ To **optimise our preparation time** and **reduce patients waiting time** we would like to **anticipate** any preparations

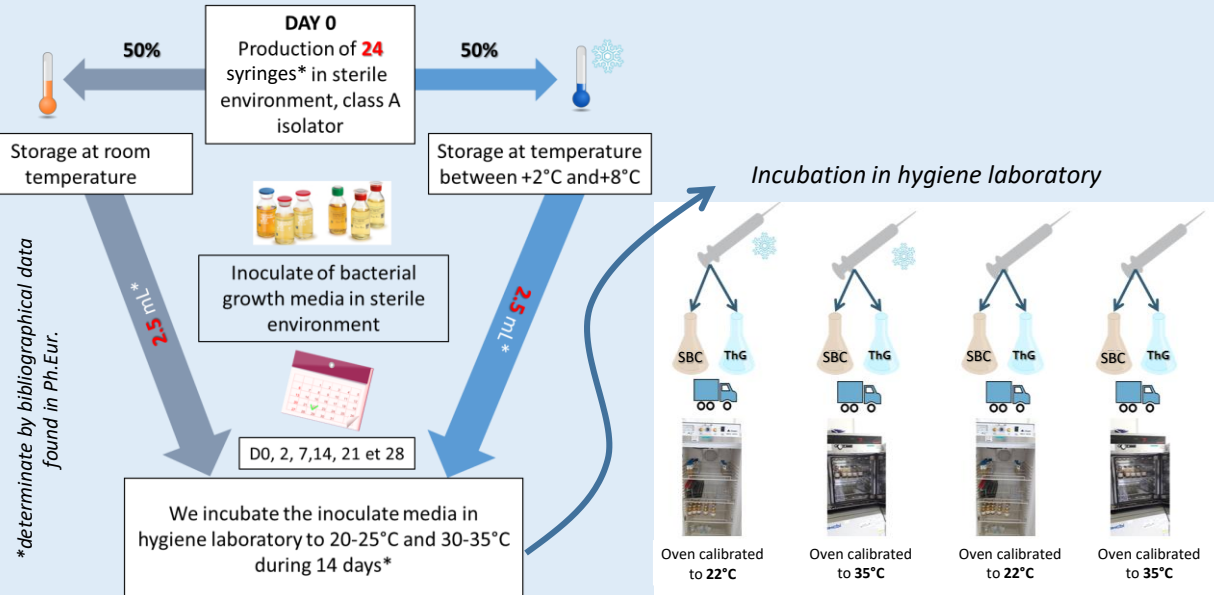
## PURPOSE:

- Qualification of the microbiological stability in our final assembly.

## MATERIALS & METHODS :

- ❑ Guidelines : **European Pharmacopoeia** (Ph.Eur.) 10th Edition, chapter 2.6.1 sterility, test for sterility of the production to be examined

- Elaboration of the **study plan** :



## RESULTS :

### Method validation tests:

- ❑ Fertility test :
  - Soya-bean casein digest medium (SBC) : **positive** in 48h
  - Fluid thioglycollate medium : **positive** in 24h
- ❑ Sterility test :
  - SBC : **stay negative\***
  - Fluid thioglycollate medium : **stay negative\***

\*after 43 days of incubation

### Results after 14 days of incubation (see Table 1)

■ Absence of bacterial growth

■ Presence of bacterial growth

We observe the absence of a bacterial growth 14 days after the beginning of incubation also for syringes which has stored during **28 days**.

## CONCLUSION & PERSPECTIVES :

- ❑ Microbiological integrity of our propylene syringes after handling is valid for **28 days**
- ❑ Realization **Media Fill Test** (MFT) will specify our results to follow the Gerpac guidelines (May 2020) → anticipate preparations in this final assembly, such as subcutaneous doses of trastuzumab.

Day of incubation	N° of medium	storage at room T°				storage at 4°C					
		SBC		Fluid Thioglycollate		SBC		Fluid Thioglycollate			
		22°	34°	22°	34°	22°	34°	22°	34°		
		Day of positivity (if it's positif)				Day of positivity (if it's positif)					
17/03/2021	1										
	2										
	3										
	4										
	5										
	6										
	7										
	8										
	9										
19/03/2021	10										
	11										
	12										
	13										
	14										
	15										
	16										
	17										
	18										
24/03/2021	19										
	20										
	21										
	22										
	23										
	24										
	25										
31/03/2021	26										
	27										
	28										
	29										
	30										
	31										
	32										
	33										
	34										
07/04/2021	35										
	36										
	37										
	38										
	39										
	40										
	41										
14/04/2021	42										
	43										
	44										
	45										
	46										
	47										
	48										

Table 1 : detection of a bacterial growth 14 days after the beginning of incubation