

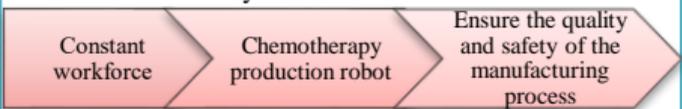
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Introduction and objective :

Increase of activity in the cytotoxic pharmaceutical unity related to :

- Development of patient's care in day hospital
- Diversity of molecules



Robot **qualification** → evaluating **biocontamination**

- ➔ Microbiological environmental controls
- ➔ Media fill Test (MFT)

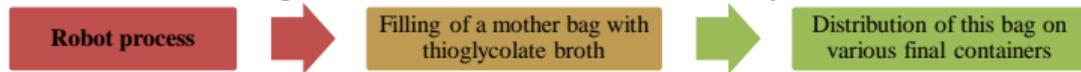
Results:

- Microbiological environmental controls:
 - ➔ Active air samples: **negative**
 - ➔ **Very** low inoculum observed on sedimentation agar plates and swabs but disappeared after surface cleaning
 - ➔ Identified germs: microorganisms of the skin flora
- **No turbidity** on the 81 preparations during the 14 days of incubation
- **No germ** present during final seeding

Matérials and methods:

Microbiological environmental controls :

- **Sampling plan for critical areas of the robot enclosure:**
 - Air → Aerobiocollector, sedimentation agar plates
 - Surface → swabs
- Samples collected over 5 days (including the 3 days of MFT)
 - In the morning after cleaning, during and after the activity



Media fill test* :

- **3 cycles per day during 3 days** → *1 cycle = 3 syringes, 3 empty bags, 3 infusors*
- **Incubation** of finished products: 7 days at 25°C then 7 days at 35°C
- Visual control during 14 days: **turbidity** research (= microbial growth) and comparison to controls
- Seeding of final containers: check **sterility**

** Before realization of the MFT, a fertility test had been performed on the same batch of thioglycolate broth*



Conclusion and discussion:

- No contamination observed during the MFT
- Results of environmental controls → importance of respecting the aseptic handling process for all robot operators
- Additional robot qualifications: analytical dosages and chemical contamination tests
- Maintenance of the **efficiency, safety and quality** of the robot: periodic validation by MFT once a year or evaluation of the operator's ability to maintain sterility during manufacturing operations