



6.7.8 Octobre 2021



THÉMATIQUE : ISOLATOR AND ACCESSORIES SINGLE USE

SOCIÉTÉ : JCE BIOTECHNOLOGY

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WHY DEVELOP A SOLUTION SINGLE USE ISOLATOR FOR ASEPTIC FILLING (FILL AND FINISH)

**THE IMPLEMENTATION OF SINGLE USE TECHNOLOGY FOR THE DEVELOPMENT OF
PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES IS GROWING UP**

LOTS OF UNDENIABLES ADVANTAGES:

- **READY TO USE**
- **NO CLEANING TO VALIDATE**
- **NO BIOCONTAMINATION TO VALIDATE**
- **INVESTMENT STUDIED**
- **TRAÇABILITY A TO Z**
- **OPTIMIZATION OF PRODUCTION**

HIGHT FLOW DISTRIBUTION IN THE ISOLATOR

ADVANTAGE : MAINTENANCE OF ASEPSIS, HIGHT PRODUCTION
TO CONSIDER: MAINTENANCE, CLEANING, CROSS CONTAMINATION,
BIODÉCONTAMINATION, RÉSIDUE AGENT H2O2





THE CONCEPT :DISPOFillSYSTEM®

URS* : FILL AND FINISH UNIT UNDER A DISPOSABLE ISOLATOR ALLOWING THE FILLING AND PACKAGING OF ALL MODELS OF VIALS AND PREFILLED SYRINGES WITH HIGHT ADDED VALUE INJECTABLE LIQUID DERIVED FROM BIOTECHNOLOGY AS DESCRIBED IN ATMP (ADVANCE THERAPY MEDICINAL PRODUCT) CGT (CELL GENE THERAPY) AND NANO MÉDECINE

TARGET :

- **SOLUTIONS DÉDICATED TO BIOTECHS AND CDMO**
- **FILLING CAPACITY 5/10000 PER DAY VIALS 2R À 30R SYRINGUES 0.5 À 5 ML**
- **FILLING AND CAPPING UNDER UNIDIRECTIONAL LAMINAR AIR FLOW CLASS A 0.45m/s**
- **SLEEVES FOR ARMS OF OPERATORS AND ROBOTS**
- **FACILITATE MAINTENANCE BY DEPORTING ALL MECHANICALS ELEMENTS AS FAR AS POSSIBLE**
- **REMOVAL OF CLEANING AND QUALIFICATION BY A READY TO USE VALIDATED**
- **NO DÉCONTAMINATION AND NO RESIDUE VAPOR H2O2**
- **NO RISK OF CROSS CONTAMINATION**
- **POSSIBILITY OF INERT ATMOSPHERE**
- **CONTINUOUS CONTROL PARTICLE AND BIO COLLECTOR**
- **MANUFACTURING AND QUALIFICATION ACCORDING GMP/ BPF /EMA**

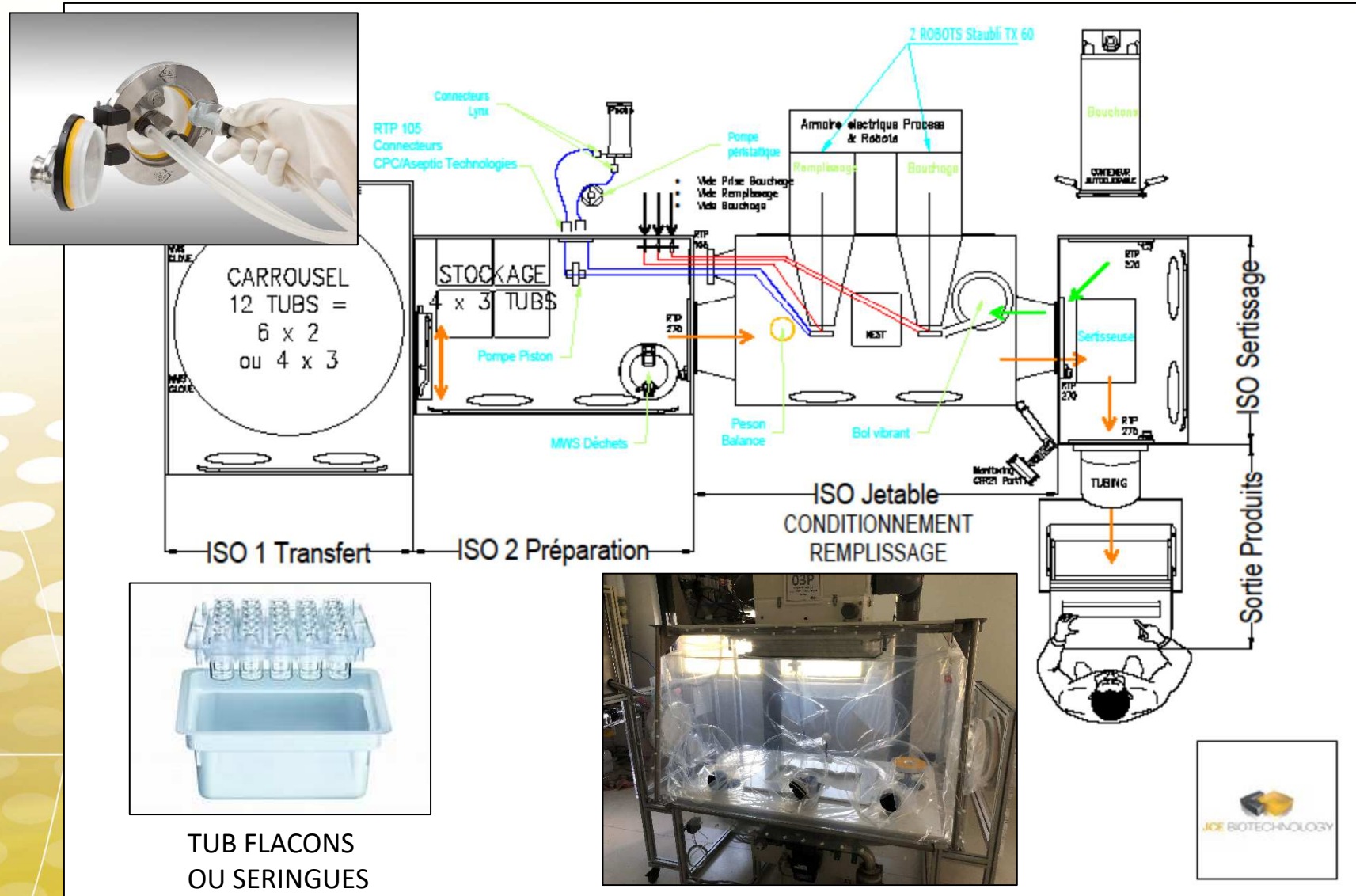
***USER REQUIREMENT SPECIFICATION**



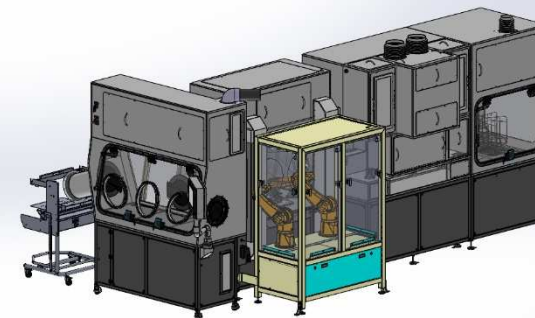
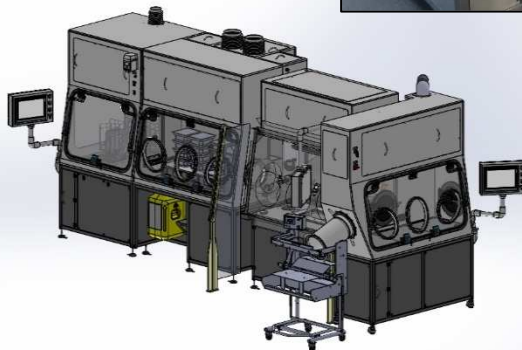
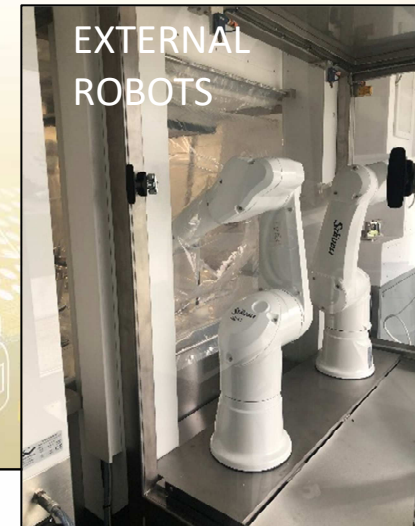
DISPOFILLSYSTEM® SOLUTION CHARACTÉRISTIQUES

- **FLEXIBLE ISOLATOR PU 300µm**
- **Ready to use installation < 1 hour**
- **Integrated HEPA H14 PE up and down**
- **Recycling ventilation with unidirectionnal laminar air flow 0.45 m/s**
- **Manufacturing control: Cleaning, Airtightness, particle counting Class A and Emery test**
- **Double packaging under ISO 8 Class D or ISO 7 Class C**
- **Gamma stérilized à 25 Kgy**
- **Connecting sleeves of the double Staubli robots (filling and capping)**
- **Single use RTP Beta for transfert sterile components and filling liquids with external péristaltic pump**
- **Tubing and accessories single use,**
- **Incinérable after use**

DISPOFillSYSTEM® SOLUTION DIAGRAM

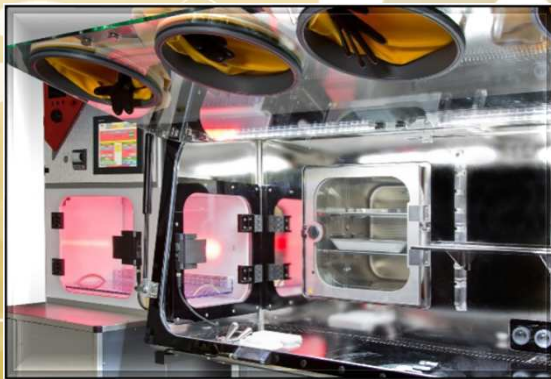


VIEW OF THE DISPOFILLSYSTEM®



CELL THERAPY UNDER ISOLATOR

- **CONVENTIONAL ISOLATOR INTEGRATING CO₂ INCUBATOR AND CENTRIFUGE**
- **VALIDATION AND QUALIFICATION OF CLEANING PROCEDURES**
- **VALIDATION AND QUALIFICATION OF BIODECONTAMINATION PROCEDURES**
- **RISK OF CROSS CONTAMINATION**
- **PROBLEMATIC AIRTIGHTNESS ON CONNECTED DEVICES (CENTRIFUGE AND INCUBATOR)**
- **COMPLEXITY FOR MAINTENANCE**

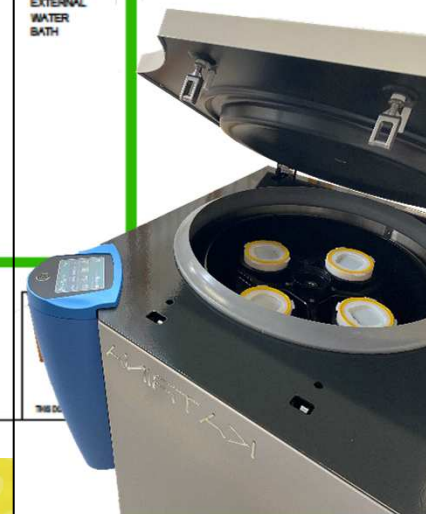
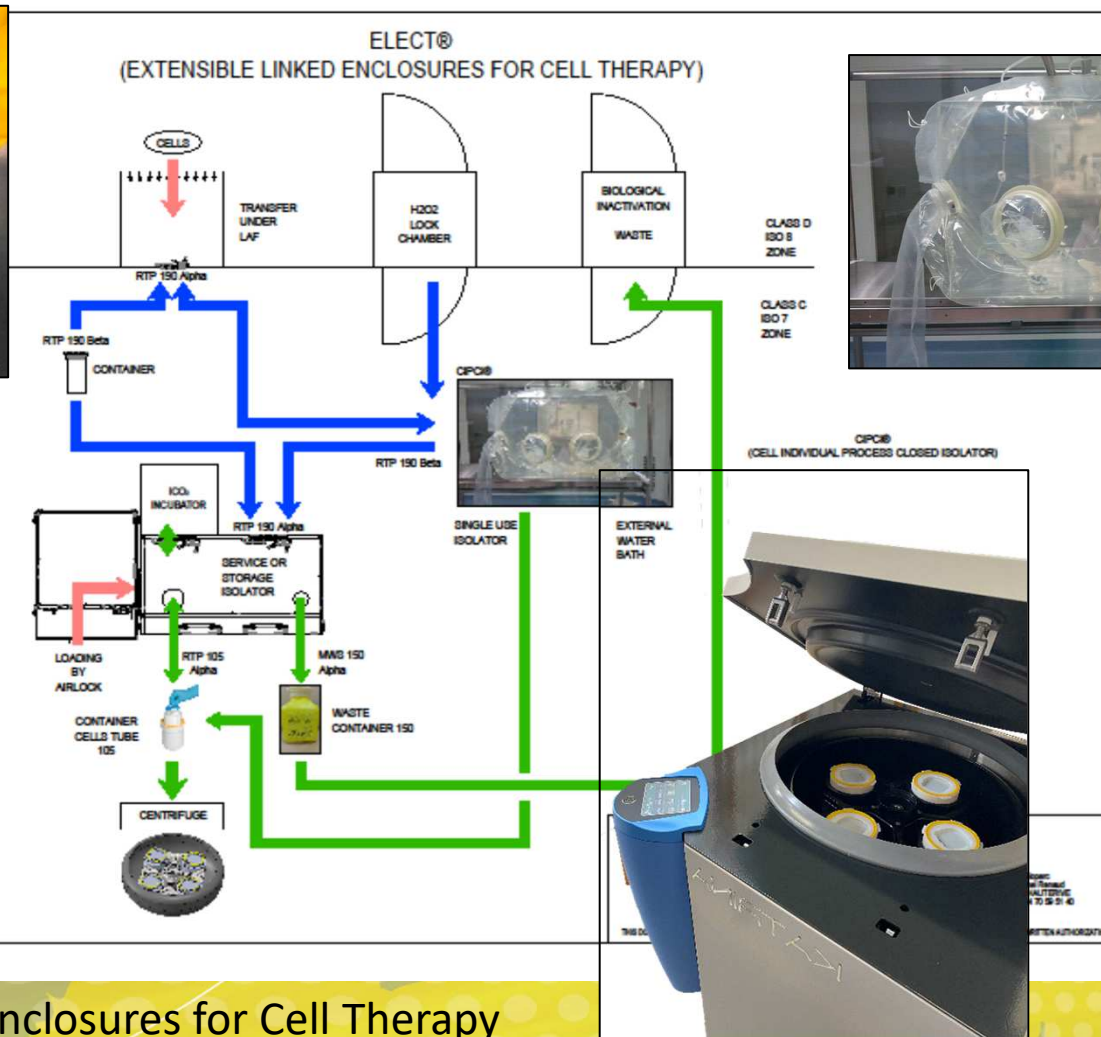


ELECT® FOR CELL THERAPY

SINGLE USE ISOLATOR AND CONTAINER FOR THERAPEUTICS PREPARATIONS

DESIGN AND ADAPTATION ACCORDING YOUR PROCESS

NO CROSS CONTAMINATION VALIDATED ACCORDING GMP/BPF



Elect® :Extensible Linked Enclosures for Cell Therapy



THANKS FOR YOUR ATTENTION

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Gerpac Presqu'île de Giens October 2021