ATMP Isolator Technology

Facing challenges of today’s advanced therapy environment

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01 About Us

Personal
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Personal

Dr.-Ing. Dureid Qazzazie

Professional development, Switzerland

Sales Manager Europe, Valtria Swiss AG, Volketswil (Zürich), since 2022

International Sales Manager, Bioengineering AG, Wald (Zürich), 2021
Global Product Manager, SCHOTT PHARMA, St. Gallen, 2020
Global Product Manager, SKAN AG, Allschwil (BL), 2017 – 2019

Academic career, University of Freiburg, Germany

Doctorate studies, Nanotechnology Engineering (Dr.-Ing.), 2013 – 2017
Research and development of novel hybrid nanomaterials for use as catalytic electrodes in fuel cell applications

Master‘s studies, Microsystems Engineering (M.Sc.), 2010 – 2012
Bachelor‘s studies, Microsystems Engineering (B.Sc.), 2006 – 2010

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COMPANY PROFILE

INTERNATIONAL EXPERIENCE

- Projects carried out by the team in more than 15 countries: Multicultural management

20 YEARS OF EXPERIENCE

- A team with 20 years of common experience
- More than 300,000 m^2 of clean rooms designed and installed

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OUR SERVICES:
EPCMQ
ENGINEERING • PROCUREMENT
CONSTRUCTION • MANAGEMENT • QUALIFICATION
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02 Introduction

Challenges of ATMP manufacturing
Regulatory aspects

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Introduction

Challenges of ATMP manufacturing, some premises

At hospital environment, research teams are responsible for manufacturing, controlling and releasing of products.

Fundamentally, ATMPs are characterized by being injectable preparations.

This type of product(s) cannot be subjected to any type of terminal sterilization.

Aseptic processing

The performance of sterility test is challenging.

Normally there is a high level of human intervention in the manufacturing.

The manufacturing process must be controlled. It is the only way to achieve the absence of external microbiological contamination in the final product; which could compromise the health of patients.

Challenges of ATMP manufacturing

With these premises, what do you think in terms of risk?

Chance of occurrence

Severity

Detectability

Challenges of ATMP manufacturing

CCS (Contamination Control Strategy). The goal is to implement the highest level of protection for the process that will finally imply safety for patients.

Challenges of ATMP manufacturing

Using closed systems, such as isolators for production directly implies working under completely sterile, hermetic and controlled environment.

Regulatory aspects

GMP

Good Manufacturing Practice for Advanced Therapy Medicinal Products, 22 May 2018

EU GMP Annex 1

Manufacture of Sterile Medicinal Products, 22 August 2022

03 Isolator Technology

Definition
Main features
Accessories

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Definition

The definition of “isolator”, and the most appropriate for ATMP environment according to the glossary of the new GMP Annex 1 (Sterile) (22-08-22 edition):

The isolator is *“An enclosure capable of being subject to reproducible interior bio-decontamination, with an internal work zone meeting grade A conditions that provides uncompromised, continuous isolation of its interior from the external environment (e.g. surrounding cleanroom air and personnel).”*

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Main features

Closed surrounding

Safe and totally separated from the environment and personnel, with capacity to maintain grade A inside.

Controlled pressure

Controlled positive or negative pressure inside, to be reached with automatic leak test capacity.

HEPA-filtered ventilation system

Unidirectional air flow, with integrated automatic H_2O_2-decontamination system.

Accessories

Complete separation

For complete separation from process and personnel, all operations inside of the isolator are carried out using gloves, remote handling systems or robotic systems.

Transfer systems

For the entry and exit of materials, automated H_2O_2-decontamination airlocks are used or sterile transfer systems, such as RTP ports or split valves.

„Liner“ system

For waste material, a “continuous liner” type systems are usually used for the removal of used waste or dirty materials.

04 Case Study

Isolator system for production
of Mesenchymal cells

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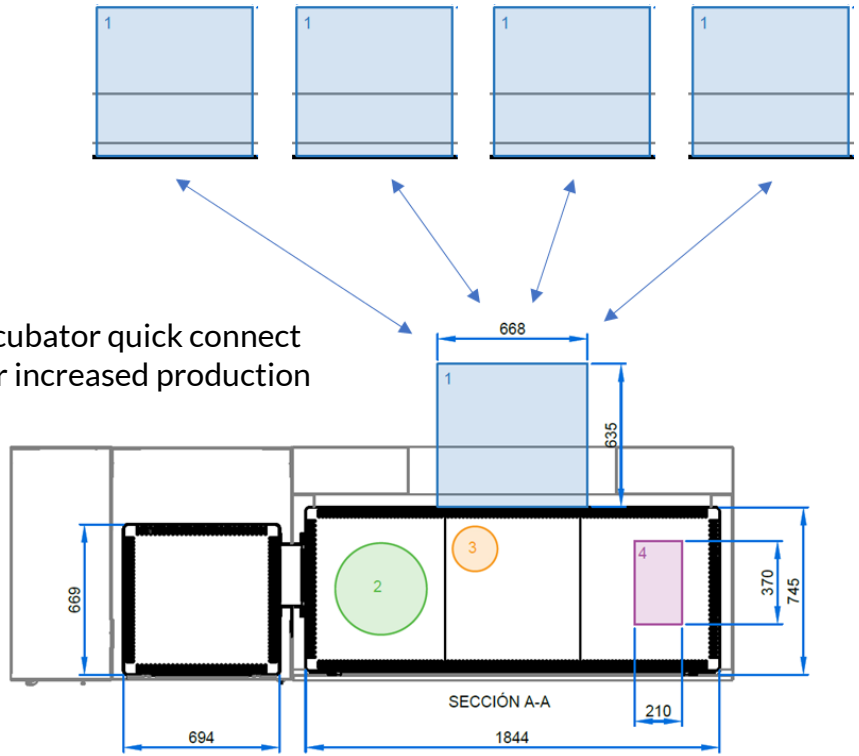
Case Study

Isolator system for production of Mesenchymal cells

Mobile incubator quick connect system for increased production



1) CO_2 Incubator
2) Centrifuge
3) Agitator
4) Microscope

Case Study

Isolator system for production of Mesenchymal cells

05 Conclusions

Conclusions

Isolator Technology for ATMP manufacturing

The production of ATMPs has high risk of contamination.

The production of these medicines under closed systems, such as isolator technology solution system, directly implies working under completely sterile, hermetic and controlled environment.

Despite the reticence of users towards isolator technology application, the key decision-makers and scientists must be aware of the risk involved in aseptic production with lots of human intervention.

State-of-the-art technologies are available to be used in the ATMP production under isolator, such as integration of laboratory equipment, mixed-reality to guide users, and robotization to minimize human intervention.

Compared with traditional clean rooms, the application of isolator technology significantly reduces energy consumption, hence, also enabling reduced operation cost.

THANK YOU!

Do you have any question?

CONTACT US!

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Added value to your projects