



ATMP's and Microbiological Related Issues
Thursday 16th May ½ day virtual meeting
13.00 – 17.15 (BST)
Via Zoom

The manufacturing of ATMP's provides unique challenges to contamination control. Many products are manufactured at a very small scale, over multiple days using a combination of open and closed processes, with many manual steps and often, due to their natures as living cellular products, without a sterilisation step. Viral vectors are used to provide the genetic material that creates, for many products, the ability to find the clinical target cells and allow the ATMP product to perform it's intended function.

The need for specially designed facilities and processes for viral vectors and final product is critical to allow for flexibility in being able to operate multiple overlapping different products. In all cases a comprehensive and well considered Contamination Control Strategy (CCS) is needed to bring together the many controls needed to ensure products are microbiologically controlled and free from contamination.

This virtual meeting will focus on microbiological challenges associated with the manufacture of these fascinating and life changing group of products with a focus on CCS for facilities, viral vector and final product manufacturing both in Europe and US as well as the particular challenges around operator qualification.

The meeting will start by setting the scene related to growth of the ATMP industry and potential skills gap.

This virtual meeting is targeted to those working with ATMP's/Biologics or those who wish to learn more about these products. It will be of interest to microbiologists, quality control and quality assurance professionals responsible for risk-based decision making, as well as manufacturing personnel who want to upskill their microbiological knowledge around current hot topics in the manufacture of ATMP's.

Current draft agenda

- 13.00 – 13.05 **Introduction**
Seb Hodgkin – Senior Director QA, Quell Therapeutics (Pharmig Committee Member and Meeting Chair)
- 13.05 – 13.30 **Setting the scene: The growth of the ATMP industry**
 - UK opportunity
 - Impact of higher-automation on QC
 - The skills gap / employment opportunities for Microbiologists/QC professionals**Stephen Ward PhD - Chief Manufacturing Officer, Cell and Gene Therapy Catapult**
- 13.30 – 13.40 Q&A and changeover of speaker
- 13.40 – 14.20 **Facility design considerations when building a multi-product facility important for CCS for ATMP's**
 - The key facility & operational design considerations when designing a multiproduct ATMP facility
 - How the design considerations translate to the build out of the CCS
 - Making the CCS an operational process.**Gillian Lewis – Associate Director - QP, eXmoor Pharma**
- 14.20 – 14.30 Q&A and changeover of speaker
- 14.30 – 15.10 **Special considerations for CCS for viral vector manufacturing**
 - Brief intro about Adaptimmune (who we are what we do)
 - Vectors and GMPs
 - Adaptimmune's approach to generating CCS
 - Considerations with sterilising filtration, sterility testing, closed systems**Jennifer Rawsthorn - Quality Lead, Adaptimmune**
- 15.10 – 15.30 Q&A – mini break - and changeover of speaker
- 15.30 – 16.10 **Annex 1 aseptic process simulation challenges for operator qualification in CGT**
Marija Pesic – Sterility Assurance Manager, CGT facility, Lonza, Netherlands
- 16.10 – 16.20 Q&A and changeover of speaker
- 16.20 – 17.00 **CCS for ATMPs – A US perspective**
A US based presentation covering what is currently stated and expected by the FDA. Hints & tips and similarities and differences between current US and EU expectations described in Annex 1 and EU GMP Part IV
Marsha Steed – Founder & President, Steed MicroBio LLS & USP Microbiology Expert Committee Member
- 17.00 – 17.15 Q&A and close of virtual meeting



BOOKING FORM

ATMPs & Microbiology Related Issues

Thursday 16th May (½-day meeting via Zoom)

13.00 – 17.00 (BST)

Company: _____

Address: _____

Contact name if different from the delegate: _____

Tel: _____ Email: _____

DELEGATE 1
Surname: _____ First Name: _____

Job Title: _____ Email: _____

DELEGATE 2
Surname: _____ First Name: _____

Job Title: _____ Email: _____

ATMPs & Microbiology Related Issues

Thursday 16th May 2024

FEES

Member Fees	Please Tick	Non-Member Fees	Please
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Member Delegate - £350/ *€415	<input type="radio"/>	Non-Member Delegate - £450 / *€550	<input type="radio"/>

NHS Member Fees	Please Tick	NHS Non-Member Fees	Please
Tick			
Member Delegate - £200	<input type="radio"/>	Non-Member Delegate - £300	<input type="radio"/>

NOTE: * fee is higher to cover conversion rates

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INFORMATION ON FEES & PAYMENTS

Where possible fees must be paid in advance in order to attend the virtual conference. This can be done via credit card payment OR by an approved company purchase order number

INFORMATION ON ZOOM SET UP

Once you have sent back your registration form and payment (please see info of fees and payments above), Pharmig will add you to the Zoom list and will send out an email which will include the Zoom link and additional information.

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