

ATMP's and microbiological related issues
Wednesday 23rd March 2022 (½-day meeting via Zoom)

Agenda (times advertised are in BST)

- 09.20 – 09.30** **Welcome**
Seb Hodgkin – Senior Director, Quality Assurance, Quell Therapeutics & Pharmig Committee Member
- 09.30 – 10.10** **Introduction to advanced therapies**
- Overview of what ATMP's are
 - State of the industry UK/EU/US
 - ATMP workforce - opportunities for Microbiologists
 - Overview of Catapult Manufacturing Facility covering
 - Issues of contamination control
 - Design consideration to minimise microbial contamination,
 - Cross contamination strategies in multi-product facility,
 - Managing EM for a shared facility,
 - Ensuring common cleaning and disinfection practices or material transfer
- Jon Halling – Quality Director, The Cell and Gene Therapy Catapult**
&
Stephen Ward - Chief Manufacturing Officer, The Cell and Gene Therapy Catapult
- 10.10 – 10.15** **Q&A session & changeover of speaker**
- 10.15 – 10.55** **Regulations associated with ATMP's and microbiology**
- UK (EU) Regulations with specific emphasis on Microbiology and Sterility Assurance
 - Part IV GMP for ATMP's
 - Annex 1
 - Differences with microbiology/sterility assurance between the two sections
 - Tissues and Cells Directive – HTA regs
 - Interaction between agencies
 - US considerations
 - Common Microbiological related inspection findings from ATMP manufacturers
 - GMO regs / Viral Safety considerations?
- Drew Hope – Consultant QP, ExMoor Pharma Concepts Ltd**
- 10.55– 11.00** **Q&A session**
- 11.00 - 11.15** **Virtual Break**
- 11.15 – 11.55** **Microbiological considerations for cell and gene therapies**
- Overview of cellular and gene therapies (ATMPs) and their manufacture and implication on Sterility Assurance
 - Differences and challenges compared to traditional pharmaceutical products
 - Materials – Starting and Raw Materials / Environment
 - Processing – Equipment / Open vs Closed / Scale Up and Scale Out
 - Env Monitoring and Aseptic Process Simulations
 - Personnel Considerations
- Seb Hodgkin – Senior Director, Quality Assurance, Quell Therapeutics & Pharmig Committee Member**

11.55 – 12.00	Q&A session changeover of speaker
12.00 – 12.40	Regulatory approval of three rapid microbiological methods for MACI® product release <ul style="list-style-type: none"> • Process Overview • Approved Rapid Microbiological Methods <ul style="list-style-type: none"> • Endotoxin • Mycoplasma • Sterility • USP Microbiology General Chapters John Duguid - Senior Director R&D, Vericel Corporation (USA)
12.40 - 12.55	Q&A Session and Open Floor Session
12.55 – 13.00	Chairs closing remarks

Please note: All information addressed by the speakers are of their own / company opinions. Pharmig is not responsible for any content presented at the meeting.

Pharmig also has the right to change the programme at any time due to unforeseen circumstances.

The voice of microbiology for 31 years: 1991 – 2022

BOOKING FORM

**ATMP's and microbiological related issues
Wednesday 23rd March (½-day meeting via Zoom)**

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 and microbiological related issues
Wednesday 23rd March – ½ day virtual meeting**

FEES

Member Fees Euro
Member Delegate - £320 / *€403

Non-Member Fees Euro
Non-Member Delegate - £520 / *€643

NHS Member Fees
Member Delegate - £180

NHS Non-Member Fees
Non-Member Delegate - £280

NOTE: * fee is higher to cover conversion rates

PAYMENT METHODS – please tick relevant box

Please raise an invoice to cover the delegate fee(s) £/€ _____

UK BACS Sort code 60 19 28 Account 80843867 £/€ _____

Wire Transfer Natwest Bank, 118 High Street, Slough, Berkshire SL1 1JH
SWIFT (BIC) NWB KGB2L Account 80843867
IBAN GB64 NWBK 6019 2880 843 867
£/€ _____

Please quote company approved purchase order no. _____ For £/€ _____

I/we wish to pay by credit card (Pharmig will contact you for details)

Please note: Due to these unusual times, and the need for Pharmig to ensure fees are received in a timely manner before the event, it will have the right to cancel a delegate's attendance unless alternative arrangements have been agreed in advance of the event(s) by both parties.

Email: info@pharmig.org.uk

Fax: +44 (0) 1920 871 156

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.

For those not familiar with Zoom – we will do a quick tour around the screen (it's all very straightforward) before starting the session on the afternoon of the 19th October 2021

Privacy Policy

By registering for these events, I accept the processing of my Personal Data. Pharmig will use my data for the processing of this order for which I hereby declare to agree that my personal data is stored and processed. Pharmig will only send information in relation to this order or similar events/publications/training courses etc. Pharmig may send your name and company only to other companies attending the same event in the form of an attendee list. Your full personal data will not be disclosed to third parties (see also privacy policy at <https://www.pharmig.org.uk/en/privacy-policy/>). You can ask for the modification, correction or deletion of my data at any time via an email to maxine@pharmig.org.uk

