NUI Galway
OÉ Gaillimh

CCMI
Centre for Cell Manufacturing Ireland

2nd Annual workshop on GMP Manufacturing, Scale-Up and Challenges of ATMPs

Glenlo Abbey Hotel, 13th and 14th November 2019

Based on the success of our first GMP Manufacturing, Scale-Up and Challenges meeting held in Galway in 2018, we are pleased to announce our second annual meeting of this event, add in here, in association with our sponsors Cook Regentec, Mylteni Biotec and VivaBioCell.

Advanced Therapeutic Medicinal Products (ATMPs) are at the forefront of regenerative medicine to solve the unmet need of patients. Rather than a typical pharmaceutical manufacturing process, manufacturing of ATMPs can be complicated and challenging. How the manufacturing process is designed and controlled directly correlate with the safety and efficacy in patients and also correlates to inputs such as starting and raw materials. Characterization of the ATMP during all stages of development, whether process or analytical, is crucial for compliance and producing a safe product.

During this meeting we will explore the current ATMPs being manufactured, from MSCs, CAR-T, NK- Cells and viral vectors. The aim of this meeting is to unravel the different manufacturing methods currently used in the manufacture of these ATMPs, as well as exploring the option of scale-up for the manufacturing process. Traditional cell culture based methods of tissue culture vessels will need to advance to large scale bioreactors in order to meet the need for ATMPs. We will discuss the challenges the industry faces regarding both manufacturing and scale up as well as regulatory requirements and experiences from our array of expert speakers. At the end of this workshop, the attendees will have a greater understanding of the manufacturing process involved in ATMP manufacturing, the scale-up and expansion possibilities available for large scale manufacturing as well as identifying potential challenges and risks involved in the manufacturing of ATMPs.

For further information contact:
aoife.duffy@nuigalway.ie

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AGENDA DAY 1

8.30-9.00	Registration
9.00-9.15	HPRA Speaker
9.15-9.45	Francessco Dazzi, Kings College London
9.45-10.15	Richard Day, University College London
10.15-10.45	Lise Geissert, NantBioscience
10.45-11.15	Benjamin Gysi, Takeda
11.15-11.30	Coffee
11.30-12.00	Shirley O Dea, Avectas
12.00-12.30	Lior Raviv, Pluristem
12.30-13.00	Bart Vaes, ReGenesys
13.00-13.30	Enda Shevlin, Cellectis
13.30-14.30	Lunch
14.30-15.00	Michael O'Dwyer, Onkimune
15.00-15.45	Aileen KirkPatrick, GSK
15.45-16.00	Coffee
16.00-16.45	Owain Millington, TC BioPharma
16.45-17.30	Mark Lowdell, Autolomous
17.30-19.30	Drinks Reception
19.30	Dinner

AGENDA DAY 2

9.30-12.30	Workshop

Please register at http://clr.ie/128562

Early Bird before September 30th: **€1,250 per attendee**

Early Bird before September 30th: **2 or more from one company €1,000 per attendee**

After September 30th: **€1,500 per attendee**

After September 30th: **2 or more from one company €1,250 per attendee**

See website for hotel booking information

COOK® REGENTEC

MACS Miltenyi Biotec

ViaBioCell

CCMI
Centre for Cell Manufacturing Ireland

For the first time in Ireland, the Centre for Cell Manufacturing (CCMI) has been established at NUI Galway and licensed to manufacture stem cells for use in human clinical trials. CCMI currently operates on the third floor of the Orbsen Building. It comprises of a 250m2, within which there are two parallel production suites, each consisting of 3 production room. Each of the two suites is capable of clinical grade manufacturing of cellular therapy products. CCMI has a full Quality Control Laboratory for safety testing e.g. sterility and endotoxin, and functional testing such as flow cytometry, as well as its own microbiology laboratory. The facility manufactures human adult stem cells (hMSCs) for use in clinical trials, bridging the gap between REMEDI's research programmes and the clinic. CCMI is accredited under EU GMP and was granted a manufacturing authorization by the Health Products Regulatory Authority (HPRA) - formerly the Irish Medicines Board (IMB) in 2013 for the manufacture human mesenchymal stem cells, enabling the manufacture of clinical grade Advanced Therapy Medicinal Products (ATMPs) for clinical trials.

CCMI currently manufactures cell therapy products for 4 ongoing clinical trials in Galway and other centres around Europe i.e. VISICORT, Critical Limb Ischemia, NEPHSTROM and ADIPOA2. Human Mesenchymal Stem Cells are being used in these trials as ATMPs in the treatment of conditions such as Critical Limb Ischemia (CLI), Diabetic Kidney Disease (DKD), corneal transplant rejection and osteoarthritis in the knee.

CCMI will also be used for the GMP expansion-production of NK cells, including human umbilical cord derived NK cells. This project will allow CCMI the opportunity to develop for the first time manufacturing capacity for NK cell therapy for cancer, which has the potential to deliver transformative cell therapies to patients on academic led clinical trials at a fraction of the cost of current approved cell therapies for cancer.

In addition CCMI conducts training for Scientists and Production personnel in cellular manufacturing.

Miltenyi Biotec

Company profile: Miltenyi Biotec provides products that advance biomedical research and cellular therapy. Our innovative tools support research from basic to translational research to clinical application. Our 30 years of expertise includes immunology, stem cell biology, neuroscience, and cancer. Miltenyi Biotec has 2,500 employees in 28 countries.

What will Miltenyi show at the Workshop: Miltenyi Biotec will present a live demonstration of the CliniMACS Prodigy T-cell Transduction process for manufacture of CAR T cells as a showcase of ATMP manufacture. This is followed by characterisation of the cells using the CAR T cell express modes on the MACSQuant flow cytometer. In this workshop, the user will understand how the Prodigy utilises technology to achieve the various complex stages of CAR T production, whilst maintaining a closed and sterile system for product administration to patient.

Cook Regentec

Company profile: Cook Regentec is focused on developing research and clinical tools to advance regenerative medicine therapies from the lab to the patient. Our team originated at Cook Medical, a medical device company that has worked with researchers and physicians for more than 50 years to develop more effective therapeutic tools. Cook Regentec's starting range of products includes cellular growth media, as well as tools to package, store and recover cells in cryopreservation.

What will Cook show at the Workshop: Cook Regentec will focus on two key aspects for manufacturing of carT therapies:

- The maintenance of less differentiated T cell phenotype in CAR T cells has been extensively explored by many groups using various methods (sorting or drug treatment). We demonstrate that simple replacement of traditional FBS or human AB serum with human platelet lysate can achieve same goal with potent anti-tumor effect in both in vitro and in vivo experiments;
- Live demonstration of Cook's CellSeal platform for closed system storage of intermediate and final product. This will include hands on experience of vial fill & finish/thaw/retrieval and a live webinar demonstrating high throughput fill/finish device.

VivaBioCell

Company profile: VivaBioCell develops, manufactures and commercializes automated bioreactors to support ATMP manufacturing for innovative and regenerative medicine therapies. Our Mission is to encourage the diffusion of cell therapies through automation of the cell manufacturing process. Our products aim at improving process efficiency by increasing productivity, scalability and standardization, while reducing risks and costs. VivaBioCell is part of NantCell, Inc., a subsidiary of Nantworks, LLC.

What will VivaBioCell show at the Workshop: VivaBioCell will present a live demonstration of NANT 001 and NANT XL Automated Cell Culture Systems for manufacturing of Mesenchymal Stem Cells. During the workshop, users will understand the key features of both bioreactors and disposables, such as live cell imaging, remote monitoring and automated protocol customization, and how the systems are flexible enough to support expansion of both adherent or suspension cells. Case Studies of AD-MSCs and NK cells automated expansion and characterization will be presented as well.