



## Fundamentals of Stem Cell Therapy Manufacture

Stem cell therapy is an area of increasing investigation and investment as a treatment option for patients with a previously unmet clinical need.

This training programme, presented as a collaboration between the Centre for Cell Manufacturing Ireland (CCMI) and NIBRT, will cover all aspects of stem cell therapy manufacture. It will allow trainees to gain hands on experience of cell vial thaw, initial seeding, expansion and cryopreservation as well as the associated equipment required to carry out these tasks. In addition, trainees will gain insight into the morphology of stem cells and indications of cell culture contamination, allowing them to identify and troubleshoot potential issues.

### Key Topics Covered

- Cryopreservation
- Aseptic handling
- Seeding of cells
- Trypsinisation and expansion
- Harvest
- Aseptic filling of drug product

New course for November 2019

### Course Details

Dates:

- November 25<sup>th</sup> – 29<sup>th</sup>

Cost:

- €3500

### Who Should Attend?

This course is designed for those that have some knowledge of cell culture techniques but would like to specifically learn how stem cell therapy manufacture is conducted. This course would be ideally suited to graduates with a cell culture background or cell culture technicians from a biologics manufacturing setting.

### How to Register

Register at [www.nibrt.ie](http://www.nibrt.ie) or email [training@nibrt.ie](mailto:training@nibrt.ie)

### Useful links

[www.nuigalway.ie/stem-cells/](http://www.nuigalway.ie/stem-cells/)

[www.nuigalway.ie/remedi/](http://www.nuigalway.ie/remedi/)

[www.nibrt.ie](http://www.nibrt.ie)

### Lead Trainer Profiles:

**Name:** Aoife Duffy ([aoife.duffy@nuig.ie](mailto:aoife.duffy@nuig.ie))

**Role:** Production Manager, Regulatory Affairs and Training Manager

**Experience:** Aoife graduated with a BSc in Biochemistry and then completed an MSc in Molecular Medicine from Trinity College Dublin and a postgraduate Higher Diploma in Quality Assurance from NUI Galway. Aoife has over 18 years' experience in stem cell biology, ATMPs, GMP manufacturing of ATMPs, Quality Control and regulatory affairs. Aoife has been Production Manager at CCMI since 2010. In 2013, Aoife played an essential role in getting the regulatory license for the first approved stem cell manufacturing facility in Ireland to produce clinical grade ATMPs. Since then Aoife has successfully led technical transfer, process development and clinical trial approvals for 4 clinical trials in Ireland and across Europe (one of which went through the VHP submission process) for various different ATMPs for different disease indications (critical limb Ischemia, osteoarthritis, diabetic Kidney Disease), with over 20 patients treated. In addition,

she is currently developing a newly funded product for a novel immune cell-based therapy for oncology and is developing the production and clinical trial strategy for first in human trials of this product in Ireland

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**Name:** Adam Pritchard ([adam.pritchard@nibrt.ie](mailto:adam.pritchard@nibrt.ie))

**Role:** Senior Bioprocessing Trainer

**Experience:** Adam received a M.Sc. in Neuroscience from Trinity College Dublin in 2010. He was awarded a Trinity College Postgraduate Studentship to conduct a research Ph.D. in Molecular Neuropharmacology within the Physiology department. During this time, he undertook a placement in Novartis, Basel, relating to drug discovery in the field of neuro-inflammation. Adam's expertise ranges from cell culture and cellular signalling to protein and immune-based assay techniques. Adam joined NIBRT in 2014 and his role focuses on training in upstream processing with a particular emphasis on cell culture techniques and technologies.

The Centre for Cell Manufacturing Ireland (CCMI) was launched at NUI Galway in 2014 and is the first facility on the island of Ireland to be licensed to manufacture cultured stem cells for human use in clinical trials. CCMI currently manufactures cell therapy products for four 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 Advanced Therapy Medicinal Products (ATMPs) in the treatment of conditions such as critical limb ischemia (CLI), diabetic kidney disease, transplant rejection and osteoarthritis in the knee.

For the first time in Ireland, the Centre for Cell Manufacturing 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 250 Square metre area, within which there are two parallel production suites. Each of the two suites is capable of clinical grade manufacturing of cellular therapy products. 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 GMP facility will also be used for the GMP expansion-production of NK cells, including human umbilical cord derived NK cells. CCMI will work closely with Galway University Hospital and the Clinical Research Facility in sourcing cord blood supplies and the ultimate translation of cancer cell therapies into clinical trials. 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 and they also organise information seminars and workshops in the cellular manufacturing field.

The National Institute for Bioprocessing Research and Training (NIBRT) is a global centre of excellence for training and research in bioprocessing. NIBRT is located in a world class facility in Dublin, Ireland. Our mission is to support the biopharmaceutical industry by providing a unique learning experience for trainees in an environment that replicates the most advanced industrial bioprocessing facility. In parallel, we also undertake leading edge research in key areas of biopharmaceutical manufacturing in collaboration with industry and academia.