NUI Galway
OÉ Gaillimh

REMEDI

Centre for Cell Manufacturing Ireland

ADVANCEMENT OF PATIENT CARE BY DEVELOPING NEW CELLULAR THERAPIES

www.nuigalway.ie/stem-cells

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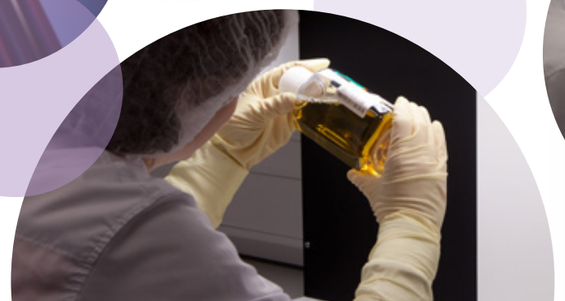
IRELAND'S FIRST CENTRE FOR STEM-CELL MANUFACTURING

The Centre for Cell Manufacturing (CCMI) at NUI Galway is the first and only approved facility on the Island of Ireland to manufacture Advanced Therapeutic Medicinal Products such as stem cells for use in human clinical trials. Authorisation was obtained from the Health Products and Regulatory Authority (HPRA) – (Irish Regulator) in 2013.

Cellular therapy is not a technology of the future; it is having an impact now, with thousands of ongoing clinical trials using stem cells as the preferred treatment option.

CCMI is currently manufacturing hMSCs for a clinical trial to treat Critical Limb Ischemia. This trial will treat at least nine patients over the period 2015 to early 2017. There are three further clinical trials in the pipeline in 2016/2017; 1. ADIPOA-2: Autologous Adipose Derived Stem Cells (ASCs) for the treatment of osteoarthritis 2. Nephstrom: Allogeneic hMSCs for the treatment of diabetic kidney disease 3. Visicort: hMSC in Corneal transplant.



GMP MANUFACTURING AND TRANSLATIONAL RESEARCH FACILITY

The Centre for Cell Manufacturing Ireland (CCMI) is a 250m² (2,700ft²) state of the art cleanroom, housed in the National Centre for Biomedical Engineering Sciences (NCBES) at NUI, Galway. The facility manufactures human adult stem cells (hMSCs) for use in clinical trials, bridging the gap between the Regenerative Medicine Institute (REMEDI)'s research programmes and the clinic.

CCMI is a versatile cell manufacturing facility with standout clean room features including two independent parallel production suites, each consisting of 3 processing rooms, certified to EU GMP grade A/B, allowing the aseptic production of multiple batches of advanced therapeutics. Each of the two suites is capable of clinical grade manufacturing of cellular therapy products and small molecules for therapeutic applications. The cleanrooms are served by custom-designed HEPA filtered air and a dedicated carbon dioxide supply. An on-site Liquid Nitrogen generation plant allows the controlled freezing and cryogenic storage of clinical grade products.

The facility is staffed by dedicated highly skilled personnel and has implemented a Quality Management System (QMS) to ensure full compliance with EU legislation for manufacture of cell based IMP. There are dedicated QC testing laboratories for batch release testing, including flow cytometry (immunophenotyping) and karyotyping, as well as microbiological and environmental monitoring.

MEET THE TEAM

PROF. TIMOTHY O'BRIEN - Director of REMEDI. Professor O'Brien established the Regenerative Medicine Institute at NUI, Galway (REMEDI). The focus of the Institute is to exploit the synergies between the technologies of gene delivery and stem cell biology to promote organ regeneration and repair. The principal initial disease targets of the Institute are ischaemic cardiovascular disease and osteoarthritis.

PROF. FRANK BARRY - Scientific Director of REMEDI. Researcher in the therapeutic application of adult stem cells, especially mesenchymal stem cells (MSCs) from bone marrow.

ANDREW FINNERTY - CCMI General Manager. Andrew has 30 years experience in the pharmaceutical manufacturing industry having worked for Warner Lambert, Schering Plough, Organon and Merck Sharpe and Dohme. He has worked extensively in the areas of quality, development, validation and production. He has significant experience in the areas of aseptic manufacturing and operational management. He has a degree in Biochemistry and an MBA.

MAGS DESMOND - CCMI Quality Manager. Mags has 10 years experience working in the medical device, pharmaceutical and biotech fields. She has previously worked for Glaxo Smithkline and Boston Scientific. Her background is in microbiology and she has significant experience in the areas of quality control, manufacturing, quality assurance and compliance.

LISA O' REILLY - Stem Cell Technologist. Lisa has over 5 years experience in GMP cell processing. Her background is in Microbiology and she has been working in CCMI for 5 years as both a quality associate working in Microbiology, Environmental Monitoring and Document Control and a stem cell technologist working in aseptic manufacturing. She has a BSC in Microbiology.

MIRIAM HOLOHAN - CCMI Qualified Person. Miriam has spent over 25 years working in the Pharmaceutical and Medical Device Industry. Her background is primarily as a Qualified Person and in Quality Assurance Management, Miriam has a Higher Diploma in Applied Science and a Masters in Pharmaceutical Sciences. She has extensive experience in all aspects of pharmaceutical manufacturing including project management and providing Technical and Regulatory support.

TATIANA DOROSHENKOVA - CCMI Quality Control Scientist. Tatiana has experience in GMP cell processing. Her background is in optimisation and validation of the methods for stem cell selection, expansion, animal- and xeno-free medium formulation for production of clinical grade adult human stem cells. She has extensive experience in stem cells quality testing, flow cytometry and pre-clinical work. She has a Masters in Regenerative Medicine and is a Winner of SFI/TIDA Commercialisation Pitching Performance 2014.

AOIFE DUFFY - CCMI Production Manager. Aoife has over 10 years experience in GMP cell processing. Her background is in quality assurance, compliance, stem cell production, process optimisation and aseptic manufacturing. She has a Masters in Molecular Medicine and a Higher Diploma in Quality Assurance.

SIOBHÁN STACK - Stem Cell Technologist. Siobhán has 15 years of experience in the medical device field with expertise in mammalian tissue culture. Proficient in GMP/GLP and complying to high quality standards and systems throughout her career. Her qualification is an MSc in Biomedical Science. She joined the CCMI team early 2014.

GEMMA O' BRIEN – Stem Cell Technologist. Gemma has over 10 years experience in cell culture and is directly involved in the aseptic manufacturing of stem cells for use in clinical trials and all quality aspects surrounding the manufacturing process. Gemma is a graduate of NUI Galway where she obtained a Degree in Biomedical Science and a Masters in Neuropharmacology."