BioProcess International Academy

MANUFACTURING PRACTICES FOR CELL & GENE THERAPIES

30 November - 10 December 2020

New LIVE Online Course

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COURSE OVERVIEW

The Cell & Gene Therapy industry is a rapidly growing area of medicine. However, although both cell and gene therapies offer a regenerative approach to treat disease, their modes of action and individual manufacturing techniques are largely different from one another.

Over 6 sessions, this course will take you on a deep dive into the different product types that exist under the Cell & Gene Therapy umbrella, then compare key manufacturing principles. You will consider aspects such as viral vector vs. non-viral vector genetic manipulation methods in gene and gene-modified cell therapies, EU & US expectations when working with cells, and the importance of cryogenics to safeguard and transport your product to the patient.

LIVE ONLINE COURSES

Gain real time access to a subject matter expert delivering online training in a structured virtual classroom environment.

What is a Live Online Course?

Live online courses are a new interactive and engaging education tool designed to provide training in real time with access to a subject matter expert (trainer). By using webinar technology, a virtual classroom is created providing direct contact with the trainer so you can ask questions, clarify complicated theories and fully understand the topic area.

A live online course is broken down into manageable sessions that are delivered online at set times, providing a structured learning pathway for delegates. All sessions are recorded and uploaded to our virtual learning environment where you will have unlimited access to the materials for a month.

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LIVE ONLINE COURSES

What are the benefits of studying a live online course?

- **Engagement & interaction**

All learning content is delivered in real time with our expert faculty, enabling you to have direct contact with the trainer during each session via live Q&A.

- **Structure & convenience**

Bitesize sessions are delivered at set times meaning there is minimal disruption on your day to day function.

- **Cost-effectiveness & accessibility**

No travel or accommodation costs required for your team to attend training. The course can be studied from any location, all that you need is an internet connection.

- **Speed & flexibility**

Live online courses are fast to organise and deliver meaning your team cam be upskilled quickly. Revisit materials as often as you like for a month after the course, as everything is recorded and hosted on our virtual learning environment.

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MEET THE TRAINER

Dr. Olivier Negre

Olivier Negre, PhD developed his expertise in preclinical research, bioassays, and drug development through more than 20 years of experience in biotherapies. After working on recombinant vaccines with Bioprotein Technologies, he joined bluebird bio (formerly Genetix Pharmaceuticals) and contributed for 14 years to the development of the first approved gene therapy for beta-thalassemia (ZyntegloTM). From preclinical studies to marketing authorization, he served as Senior Scientist / Team Leader in France and Director translational Research in the USA. He is currently, co-founder and Partner at Biotherapy Partners, acting Chief Development Officer of a biotech company, participant in HEC Challenge+ programme, board member of the French Society of Gene and Cell Therapy, expert of the Cure Sickle Cell initiative (NIH), Associated Personnel at the Boston Children's Hospital and active member of the think-tank Gene and Cell Therapy Institute (G&CTI).

Olivier graduated from ENSTBB engineering school and earned a PhD in cell and molecular biology from Paris Diderot University. He contributed to several patents and scientific publications in the field of gene and cell therapy (e.g. Nature 2010, Blood 2011, Stem Cells 2013, Current Gene Therapy 2015, Human Gene Therapy 2016, New England Journal of Medicine 2017, New England Journal of Medicine 2018, Science Translational 2019, Molecular Therapy Methods & Clin Dev 2020).

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SESSION 1 AGENDA - 2PM GMT, 30TH NOVEMBER

Understanding Cell & Gene Therapies and the differences between them

- Important definitions between cell therapy, gene-modified cell therapy and gene therapy
- Ex vivo vs in vivo gene therapy
- Autologous vs allogeneic products
- Example products, including NK cells, Stem Cells, CAR T
- Brief overview of the manufacturing process in cell vs gene therapies

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SESSION 2 AGENDA - 2PM GMT, 2ND DECEMBER

Deep dive into Cell Therapy manufacturing processes

This session will provide a detailed overview of the manufacturing processes of Cell Therapies, with the delegate being able to easily understand key processes. An emphasis on raw material collection should be covered.

- Understand that autologous cell therapy includes receiving starting material obtained via apheresis from the patient and allogeneic from a donor. Understand that ex vivo culture is required, with details on how this is achieved, before patient infusion.
- Understand that gene-modified cell therapies have an additional modification step, where gene transfer or gene editing changes the cell phenotype (such as with CAR T) before infusion.
- Understand that genetic modification can be achieved via means other than viral vector technology: naked DNA, CRISPR/CAS9 and electroporation

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SESSION 3 AGENDA - 2PM GMT, 4TH DECEMBER

Deep dive into Gene Therapy manufacturing

This session will provide a detailed overview of the manufacturing processes of Gene Therapies, with the delegate being able to easily understand key processes. An emphasis on raw material collection should be covered.

- Understand that Gene therapy is designed to genetically modify cells to compensate for abnormal genes or to make a beneficial protein
- Understand how the corrective gene is maintained
- Understand the rational to use different methods to genetically modify cells including viral and non-viral vectors
- Ex vivo vs in vivo gene therapy
- Germ line vs somatic

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SESSION 4 AGENDA - 2PM GMT, 8TH DECEMBER

Understanding best practices for working with cells

This session will highlight the practices which need to be adopted when working with genetically modified cell lines to produce cell and gene therapies.

- Guidelines on good manufacturing
- Practice EU vs US regulations
- Cell collection, culture, modification, storage, infusion
- Air quality – understanding that contamination can occur via airborne particles and aspects such as air filtration and particle counting needs to be measured
- Quality control and drug product release
- Identity, Viability, Microbiological Sterility
- Sterility testing of cell therapy products

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SESSION 5 AGENDA - 2PM GMT, 9TH DECEMBER

The importance of cryogenics

This session will show that some raw materials and final products need to be cryogenically frozen for storage and transportation and will highlight important factors to consider for this process.

- Definitions
- Why is it important – inadequate freezing can result in a direct loss of potency which costs money and compromises patient safety
- Products frozen at -130 degrees
- Selecting the best cryoprotective agent and rate-controlled freezing protocol
- GMP management of a cold space – logistics and distribution

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SESSION 6 AGENDA - 2PM GMT, 10TH DECEMBER

Logistical considerations

Understand, particularly in the context of cell-based therapies, the role that patient locations and timeframes play in delivering therapies for use.

- Supply chain considerations: cell lines, plasmids, tissue culture materials – where are they coming from, how is quality ensured?
- Transportation and storage – where is the modification taking place in relation to the patient.
- Should there be a satellite site for modification steps?
- Quality tests times may exceed the shelf life of the drug products which may be released at risk – what are the ethical and regulatory guidelines concerning this
- The importance of working with hospital staff to ensure efficiency

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For information contact our training consultants

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