BIOCHEMICAL ENGINEERING

UCL

MBI Modular training for the bioprocess industries

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Vaccine Bioprocess Development and Commercialisation

18 – 20 June 2024

MBI Training Programme

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Welcome to the MBI Vaccine Bioprocess Development and Commericialisation module.

This module is an end-to-end course that seeks to instruct in the various stages of vaccine development and commercialisation. As many vaccines are administered to healthy individuals the regulatory requirements shape development unlike any other biopharmaceutical.

Module Leader

Stefanie Frank, UCL
Stacy Springs, MIT
Barry Buckland, BiologicB

Expert Speakers

Martina Micheletti, UCL
José Castillo, Qantoom Biosciences
Sarah Gilbert, Pandemic Sciences Institute, Oxford
Hao Chen, Merck
Barry Buckland, BiologicB
Stacy Springs, MIT
Lee Smith, GreyRigge Associates
Ingrid Kroman CEPI
Derek O'Hagan, GSK
David Robinson, Bill & Melinda Gates Foundation
Giada Mattiuzzo, MHRA
Sabine Gaillard, Sanofi
Kumar Namdev, Sanofi
Keith Chidwick, Accord Healthcare
Marija Sajic, MHRA
Brendan Wren, London School of Hygiene and Tropical Medicine

MBI Training Agenda

Tuesday, 18 June 2024

9.15am
Registration

9.45am
Introduction to UCL and the MBI Training Programme
Stefanie Frank and Olivia Festy, UCL

10.00am
Introduction to Vaccine Bioprocess Development
Barry Buckland, BiologicB.LLC

Following a survey of the main different vaccine technology platforms examples will be given for specific case studies. Gardasil® vaccine for prevention of cervical cancer is a great example of a Virus Like Particle (VLP) vaccine. Rotateq® vaccine for prevention of Rotavirus infection is an example of a live virus vaccine. Flublok quadrivalent is a protein-based vaccine for protection against Influenza. For protection against COVID-19 both the Moderna mRNA vaccine and the Pfizer mRNA vaccine are great examples.

11.00am
An international academy-industry partnership to advance sustainable vaccine manufacturing
Martina Micheletti, UCL

Abstract

12.00pm
Break

12.20pm
Lessons from the MIT Consortium on Adventitious Agent Contamination in Biomanufacturing
Stacy Springs, MIT

Abstract

1.20pm
Lunch

2.15pm
From serendipity to success – the development of a recombinant glycoconjugate vaccine technology platform
Brendan Wren, London School of Hygiene and Tropical Medicine

This lecture will describe the origin of the production of recombinant glycoconjugate vaccines developed through the functional characterization of an N-linked OTase general glycosylation system from the enteric pathogen Campylobacter jejuni. It will describe how these basic studies were used to re-constitute the glycosylation system in E. coli, which allowed for the first time the production of recombinant glycoproteins through a process termed Protein Glycan Coupling Technology (PGCT). Producing glycoproteins in E. coli has multiple applications, the major application of PGCT is in the construction of affordable recombinant glycoconjugate vaccines. To date, the technology has been used to produce novel recombinant Campylobacter, Streptococcus pneumoniae, Francisella, Burkholderia pseudomallei, E. coli, Shigella, Brucella, Group A, Group B Strep, Brucella and Salmonella glycoconjugate vaccines. These have been shown to be protective and some are in clinical trials. I will describe the applications and limitations of PCGT for the construction of low-cost recombinant glycoconjugate vaccines in three areas; (i) designing novel vaccines against pathogens where no current vaccine exists (eg Group A Strep), (ii) improving existing glycoconjugate vaccines (eg pneumococcal vaccine), and (iii) producing affordable glycoconjugate vaccines for the veterinary market (eg poultry).

3.15pm
Role of Standards in Vaccine Development and Testing
Giada Mattiuzzo, MHRA

Standards are an important tool in every stage of vaccine development, from initial research and preclinical studies to clinical trials and release on the market. Written standards provide recommended criteria and guidelines for the development and distribution of vaccines, including manufacturing processes, formulation, potency, purity, and stability. This presentation will mainly focus on physical standards, or reference materials, which are

required to evaluate the immunogenicity and quality of vaccines. There is a hierarchy of standards based on traceability, with the WHO International Standard being the highest order of standards and the primary calibrant. The use of reference materials and reporting results relatively to a common standard enhances reproducibility and comparability of the results within the same laboratory. Calibration of the in-house reference material against the WHO International Standard and/or sharing of the same reference material allows for harmonisation of data among different laboratories globally, through the use of the same unit system, usually the International Units. Having a common language when evaluating the immune responses elicited by vaccines among clinical trials increases comparability of the results, improve confidence during the regulatory evaluation of the data, and also may lead to the identification of correlate of protection.

4.15pm
Break

4.35pm
How mRNA complemented the bioprocessing industry of viral vaccines; and what the future holds

José Castillo, Qantoom Biosciences

This presentation delves into the transformative journey of viral vaccine bioprocessing, tracing its evolution over recent decades and spotlighting the profound impact of COVID-19 on vaccine manufacturing methodologies, particularly through the advent of mRNA vaccine technologies.
We will begin with a comprehensive overview of traditional viral vaccine production and the technological strides that have shaped the landscape of immunization.
This segment aims to provide a solid foundation in understanding the key biological and engineering principles that have governed vaccine development historically.

5.35pm
Close

MBI Training Agenda

Wednesday, 19 June 2024

9.00am
Introduction to (GMP) Vaccine Manufacture and Validation
Daniel Bracewell, UCL

This lecture will examine vaccine manufacturing by exploring the commonalities between the diverse product types seen in the sector. Attention will be given to the importance of the product's specifications in process design. Before examining common features of importance to process understanding in upstream, downstream and formulation areas. We note how the regulatory perspective on process validation has evolved before concluding how the issues we have discussed relate to several of the vaccine products discussed in this course.

10.00am
Process Development Challenges of Novel Vaccines - Example of a new rabies vaccine in Sanofi
Sabine Gaillard, Sanofi

After a short introduction on vaccination and Sanofi Pasteur, the talk will focus on the main vaccine development challenges, using as example the process development and scale-up for a new rabies vaccine, from lab-scale to industrial scale batches.

11.00pm
Break

11.20am
Challenges in the development of the Oxford AstraZeneca Covid vaccine
Sarah Gilbert, Pandemic Sciences Institute, Oxford

The 2014 outbreak of Ebola virus disease in West Africa highlighted the lack of preparedness for combating infectious disease outbreaks. Since 1976, vaccine development had proceeded slowly and no candidate vaccines had progressed further than phase I trials. Ebola is only one of many known viruses with the potential to cause outbreaks. With the support of the WHO in identifying priority pathogens, and the formation of CEPI to provide funding, vaccine development was initiated with the aim of having vaccines available in readiness for future disease outbreaks. 'Disease X', to represent a disease caused by a previously unknown pathogen, was also considered. In the first days of 2020, the first 'Disease X' outbreak, caused by a virus later named SARS-CoV-2 occurred. Vaccine developers found ourselves attempting to put into place plans that were at an early stage of development, had not been funded and had not therefore been tested. Rather than working to produce a vaccine which could then be deployed in the 'outbreak area' we found ourselves attempting to develop a vaccine against a novel pathogen that was causing a pandemic whilst we ourselves were in the grip of that pandemic with every aspect of our work affected.

12.20pm
QbD in Vaccine Development
Lee Smith, GreyRigge Associates

Abstract

1.20pm
Lunch

2.15pm
Workshop: Strategies for commercial specifications for vaccines - product quality requirements and process analytics
Lee Smith, GreyRigge Associates; Stefanie Frank, UCL, Aadil El-Turabi University of Oxford; Stephen Morris, UCL; Barry Buckland, BiologicB.LLC; Stacy Springs, MIT

Abstract

4.15pm
Break

4.35pm
Advancing Global Health: The Role of Vaccine Bioprocessing and Commercialisation
David Robinson, Bill & Melinda Gates Foundation

Abstract

5.35pm
Close

6.30pm
Dinner

MBI TRAINING AGENDA

Thursday, 20 June 2024

9.30am
Vaccine Technology - Current Issues and Future Challenges
Hao Chen, Merck

Abstract

10.30am
mRNA presentation
Kumar Namdev, Sanofi

Abstract

11.30am
Break

11.50am
Designing and building the next generation of vaccine adjuvants
Derek O'Hagan, GSK

Adjuvants are vaccine components that enhance the magnitude, breadth, and durability of the immune response. Since its introduction in the 1920s, insoluble Alum remained the only adjuvant licensed for human use for the next 70 years. However, since the 1990s, a further five adjuvants have been included in licensed vaccines. Yet, the molecular mechanisms by which adjuvants work remains only partially understood. A revolution in our understanding of the molecular pathways of activation of the innate immune system through pattern recognition receptors (PRRs) has allowed a mechanistic understanding of adjuvants. The intervening period has witnessed many conceptual advances, including the notion that tissue damage, different forms of cell death, and metabolic regulators and nutrient sensors, can all profoundly activate the innate immune system and adaptive immunity. Also, recent advances in the use of systems biology to probe the molecular networks driving immune response to vaccines in humans is revealing new mechanistic insights and providing a new paradigm for the vaccine discovery-development process. I will discuss the emerging concepts in adjuvant science, and highlight how our expanding knowledge about innate immunity and systems immunology are revitalizing the science and development of adjuvants.

12.50pm
Lunch and Research Showcase

1.50pm
Regulatory Perspectives and Future Directions Panel Discussion

Keith Chidwick, Accord Healthcare
Adam Hacker, CEPI
Marija Sajic, MHRA
Anissa Cheung, FDA

3.20pm
Global Vaccine Preparedness to Respond to Future Disease Outbreaks
Ingrid Kroman, CEPI

Abstract

4.20pm
Close

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