

# AIM OF THE COURSE

Recent advances in the biopharmaceutical field (Cell and Gene Therapies, Vaccines and Biopharmaceutical Proteins) has increased the number of innovative human medicines for different diseases (e.g. cancer, auto-immune, infections).

Process development, scalability, and implementation of these innovative medicines is a main issue for different companies due to the lack of process knowledge, thereby delaying the commercial introduction of new medicines.

Experts from academia, industry, and regulatory agencies have joined forces and will present a program that addresses biopharmaceutical bioprocessing in depth, covering drug discovery, upstream/downstream processing, analytics, as well as regulatory and clinical perspectives. The focus of the course is on the design of innovative processes for cell therapies, gene therapies, vaccines, and biopharmaceutical proteins, complemented with examples of mammalian processes for biopharmaceuticals. A substantial part (ca. 40% of the time) will be dedicated to a case study, executed in teams of 4-6 participants.

This case study is about the design of a bioprocess for the production of a therapy from one of the four different fields. This includes the upstream/downstream process design and you will take into account the needed process analytics and an overall process economic evaluation. The team with the best design performance wins the Biopharmaceutical Bioprocessing prize. There are several guest lecturers from leading universities and companies in the bioprocess field, providing latest insights in technology innovations, cell lines and new bio-product categories, complemented with views from the industrial practice.





## **COURSE DESCRIPTION**

This one-week course is intensive and offers full-day programs. To ensure active participation by those attending, a combination of theoretical (lectures) and practical work (exercises, case study) is offered. Some online preparatory materials will be given to ensure all participants have access to have the same basic knowledge.

# **LECTURES**

The core lectures are mainly scheduled in the mornings and will focus on the following themes:

- Overview of the different therapies present in the field of Biopharmaceuticals
- Upstream and Downstream Process understanding needed for Biopharmaceuticals
- Scale-up processes and their scale up features
- Analytics, including process analytical technologies, needed to monitor the process development and product characterization

Invited lectures are scheduled on e.g. examples of successful bioprocesses, downstream processing, upstream processing, patient perspective, regulatory, drug development and economic aspects of bioprocessing.

## CASE STUDY

The case study will be developed in such a way that the lectures in the morning will give the information needed to develop the case study step by step in the afternoon. The course will be given in English.

## WHO SHOULD ATTEND?

The course is primarily aimed at academic and industrial professionals (MSc, PhD or equivalent experience) who seek for refreshing and broadening their know-how and practical insight in Biopharmaceutical Bioprocessing, to enable progress towards the development of human medicines. A background in e.g. bioprocess engineering, pharmaceutics or biochemistry and a basic working knowledge of the other disciplines is expected.



### **COURSE BOARD**

Michel Eppink
Marcel Ottens
Marieke Klijn
Bioprocess Engineering
Section Department of Biotechnology
Delft University of Technology
Delft, the Netherlands

#### TU DELFT

Cees Haringa Martin Pabst

## **COURSE COORDINATION**

Yvonne van Gameren
Jenifer Baptiste
BioTech Delft, Delft University of Technology
Department of Biotechnology
Delft, the Netherlands

### **LECTURERS**

Chris Klijn Genmab

Sophie van Tomme Sanofi

Evelyn van der Aa CCMO

Lenneke de Winter Polpharma Biologics

Jan Schouten Eef Dirksen Ingrid Overes Byondis

Bianca Consorti Bussamra Valentine Tuyishime J&J Innovative Medicine

Mathieu Streefland Galapagos

Dirk Martens
Wageningen University & Research

Silvia Pirrung Novo Nordisk

Mariken Segers Intravacc

Marc Bisschops Cytiva

Mariana Sao Pedro VectorY

Emile van den Akker Sanquin

Marcel Hoefnagel

Pauline Meij LUMC

# **PROGRAM**

### **MONDAY 15 SEPTEMBER 2025**

Theme: Drug discovery & cell line development

**08:45** Registration

**09:00** Introduction to the course

Michel Eppink

**09:10** Introduction to biopharma products & business *Michel Eppink* 

10:15 Drug discovery

Chris Klijn

**11:15** Patient perspective

Sophie van Tomme / Evelyn van der Aa

**12:15** Group picture & Lunch

**13:00** Cell line Development Lenneke de Winter

**14:00** Lab automation for screening

Jan Schouten
15:00 Case study

**16:30** Group presentations

18:15 Social event

## **TUESDAY 16 SEPTEMBER 2025**

Theme: Upstream processing

09:00 Basics of bioreactor processes

Marieke Klijn

**10:00** Protein production

Bianca Cosorti Bussamra

**11:15** Cell and gene theory *Mathieu Streefland* 

**12:15** Lunch

**13:00** Scale-up/Scale-down *Cees Haringa* 

14:00 Metabolic modelling of vaccines

Dirk Martens

**15:00** Case study **17:00** End of the day

## WEDNESDAY 17 SEPTEMBER 2025

Theme: Downstream processing

**09:00** Intro to DSP in biopharma

Michel Eppink

**09:15** (Small) therapeutic proteins

Silvia Pirrung

**10:15** Antibodies / Antibody drug / Conjugates / New modalities

Michel Eppink

**11:00** Vaccines *Mariken Segers* 

11:45 Modelling in DSP

Marcel Ottens

12:30 Lunch

13:30 Viral Vectors

Marc Bisschops

**14:15** Gene therapy

Mariana Neves Sao Pedro

15:15 Cell therapy

Emile van den Akker

**16:00** Case study

**17:30** End of the day

### **THURSDAY 18 SEPTEMBER 2025**

Theme: Analytics and Economics

**09:00** Introduction to PAT

Marieke Klijn

**09:30** Monitoring and control

Marieke Klijn

**10:15** Mass Spectrometry (MAM)

Martin Pabst

**11:15** Analytics and specifications

Eef Dirksen

12:15 Lunch

**13:30** Operations and Plant digitalization *Valentine Tuyishime* 

**14:15** Process costs and improvements *Michel Eppink* 

15:00 Case study

18:00 Course dinner

# **FRIDAY 19 SEPTEMBER 2025**

Theme: Regulatory and case study presentation

09:00 Introduction ot regulatory landscape

Marcel Hoefnagel

**09:45** Patient Perspective (Patient engagement)

Sophie van Tomme / Evelyn van der Aa

**10:55** Protein-based products *Ingrid Overes* 

11:30 ATMPs

Pauline Meij

**12:15** Lunch

**13:00** Case study

**15:30** Presenting the case study

Van der Maasweg 9

2629 HZ Delft, The Netherlands

17:00 Evaluation and certification





### **COURSE REGISTRATION**

Please register via the website to attend the course. Deadline for application is 25 August 2025. We can host a limited number of participants. A short motivation letter can be requested after registration, before we can confirm your participation.

### **COURSE FEE**

€ 3.000 in case of registration before 7 July 2025 or € 3.250 in case of registration after this date. In the event of cancellation before 21 July 2025, a full refund will be granted. After this date, a 25% fee charge can be made.

The fee for SME companies is  $\leq$  2.250 and for SME of Biotech Campus Delft is  $\leq$  1.750.

To facilitate enrolment of young PhD-students from universities, a limited number of fellowships is available. The course fee with fellowship is € 1.750. To apply, please include a copy of your registration as a PhD-student from your university.

The fee includes course materials, lunches, the drinks on Monday and course dinner on Thursday. The fee does not cover other meals and lodging.

When the number of participants is too low to have a fruitful course, BioTech Delft will cancel the event no later than six weeks before the start of the course. The course fee will be reimbursed within three weeks after cancellation.

In case a speaker will not be able to present his/her lecture due to unforeseen circumstances, BioTech Delft will arrange an equivalent replacement.

Preparatory texts will be sent after receipt of the course fee, a month before the start of the course. The complete digital course book will be supplied at the start of the course.

**BioTech Delft** organises biotechnology education at postgraduate level. BioTech Delft closely cooperates with the department of Biotechnology of Delft University of Technology. Since its foundation, in 1987, BioTech Delft has very successfully organised various types of postdoctoral education.

Currently BioTech Delft offers Advanced
Courses given each year, covering the
multidisciplinary spectrum of biotechnology.
The courses have a long track-record dating back
to 1988.

- Microbial Physiology and Fermentation Technology (1988)
- Downstream Processing (1989)
- Biocatalysis and Protein Engineering (1999)
- Bioprocess Design (2014)
- Modelling and Computation for Microorganisms in Bioprocesses (2018)
- Integrated Multi-Omics approaches for Improvement of Industrial Microbes (2020)
- Cellular Agriculture (2024)
- EPS for Resource Recovery (2025)
- Biopharmaceutical Bioprocessing (2025)

## **FURTHER INFORMATION**

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