



A 5 Day Course on **BIOPROCESS ENGINEERING AND BIOFACTORIES**

2 - 6 December 2018

Jasmine Room, N22, IBD UTM Johor Bahru, Johor

OBJECTIVE This course is designed an integrated structure to give broad overview on topics that govern both science and technology in bioprocess research and industries. It includes the technical and professional information required to start up, establish and grow this type of industries.

The first part of this course will focus on the process related issues such as: Biofactories used, cultivation strategies and systems, bioprocess design and control using different types of bioreactors, down-stream processing and scaling up. This will include hands-on training for design and operation of high cell density cultivation platform for recombinant protein production. The second part will give complete over view about the production facility from start of the project up to the production process and how to carry out all project steps according to the guidelines of the cGMP. The third part will be focused on the regulatory issues related to biotechnological product to ensure the production of safe product and how to protect this high-tech product(s) under the different Intellectual Properties Regulations (IPR) at different levels.

COURSE CONTENTS

- 1.0 Process
- 1.1 Biofactories in biotechnology (from Gene to bioproduct)
- 1.2 Cultivation requirements for different types of Biofactories
- 1.3 Sterile Manufacturing
- 1.4 Bioprocess Technology (Operation modes and scale)
- 1.5 Bioreactors, Type and Design
- 1.6 Bioprocess Control (on-line, off-line, in-line systems)
- 1.7 Bioprocess Platform Design
- 1.8 New Platforms in Biopharmaceutical Industries
"Case study: High cell density Platform for Bioprocess Industries"
- 1.9 Bioprocess Scaling up (Art and Science)
- 1.10 Down-stream Processing
- 1.11 Final Product Formulations

(This part of the module will include Practical training on Bioprocess platform design, Cell banking, Cultivation systems, Bioreactor operation Trouble shooting and Scaling up. Training will also include how to interpret the data collected during bioreactor cultivation.)

Case of study: High cell density cultivation Platform for recombinant production. protein

- 2.0 Facility (cGXP requirements)
- 2.1 cGMP Basic Requirements
- 2.2 cGMP Guidelines for Biopharmaceuticals
- 2.3 cGMP for Building and Utilities
- 2.4 API Manufacturing Area design and flow (personal, material, product and waste)
- 2.5 HVAC system for clean room
- 2.6 cGMP and Equipments
- 2.7 cGMP and Manufacturing Processes
- 2.8 GLP and cGMP requirements
- 2.9 Validation
- 2.10 Biosafety in Biopharmaceutical facilities
- 3.0 Regulations in Biotech. Industries.
- 3.1 Working with GMO in Biotech facility (Research and Manufacturing)
- 3.2 Risk Assessment
- 3.3 Intellectual Property Right (IPR) in Biotechnology Protecting What?, Where? and When?
- 3.4 Bioethics for Biopharmaceuticals

WHO SHOULD ATTEND

This course is designed for M.Sc. and Ph.D. students, scientists and professionals in the biotechnology, biopharmaceutical and pharmaceutical industries who need a comprehensive overview and hands-on training on bioprocess, cGMP and regulations.

Enquiry |
INSTITUTE OF BIOPRODUCT DEVELOPMENT
UNIVERSITI TEKNOLOGI MALAYSIA
81310 UTM Johor Bahru, Johor

tel **+607.553 1559**
fax **+607.553 6464**

Mrs Asmarahana |
asmahana@ibd.utm.my
IBD UTM Jalan Sultan Yahya
Petra 54100 Kuala Lumpur

tel **+603.2615 4406**
fax **+603.2693 7921**

Mrs Yatie | nikyati@ibd.utm.my

www.ibd.utm.my



Prof. Dr. rer. Nat. Hesham A. El Enshasy

Prof. Dr. rer. Nat. Hesham A. El Enshasy is currently a Professor at IBD. He holds a PhD. in Industrial Biotechnology from TU Braunschweig, Germany and holds various postdoctoral positions at Ohio State Univ. and Germany Research Centre for Biotechnology (GBF), which now has changed its name to Helmholtz Centre for Infection Research. He established different research and industrial platforms for the production of biopharmaceutically important compounds using microbial and non-microbial cells. He also organized different training courses on operation and maintenance of biotechnology equipment both for upstream and downstream applications. Dr. El Enshasy is also working as consultant for biobusiness, technology transfer and biotech. facility design/auditing for many biopharmaceutical companies in Egypt, Belgium, Greece, USA, China and Malaysia.



MS. ROSLINDA ABD MALEK (Senior Research Officer)

She is a graduate from Universiti Teknologi Malaysia in Bachelor of Science (Biology Industry), Malaysia. She received her Master of Science (Biotechnology) in year 2009 and working in IBD for 10 years as Research Officer in Bioprocessing, Fermentation Technology, Microbiology, Microbiology analysis and Biotechnology area. She has an interest in upstream part include scale up study bioreactor from 16L to 1500L, medium optimization, isolation several types of bacteria and basic microbiology fermentation and technology. Furthermore she successfully developed several industrial platforms for bacteria, yeast and mushroom cell cultivation for different industries. She has involved with many contract research and production of microbe from local and international company at IBD



DR DANIEL JOE DAILIN

Dr. Daniel is currently a senior lecturer for Bioprocess and Polymer Engineering, Faculty of Chemical and Energy Engineering, Universiti Teknologi Malaysia. Before joining UTM, he works as a principal scientist in the RND department for Biocon Sdn Bhd, Asia's largest integrated insulins manufacturing facility at the Biotech Park in Johor, Malaysia. He also previously worked as a research scientist under the Centre for Biofuel and Biochemical Research (CBBR), Universiti Teknologi PETRONAS in Perak, Malaysia. He received his Ph.D. in Bioprocess Engineering from Universiti Teknologi Malaysia. Dr. Daniel has more than 8 years of experience working in the operation and process scale up for bioprocess fermentation of bacteria and yeast platform; perform technology transfer activities; planning, carrying out and supervising process trials in laboratories, pilot plants and manufacturing plant.



MR. SOLLEH BIN RAMLI (Research Officer)

Mr Solleh is a research officer in Institute of Bioproduct Development (IBD) at Universiti Teknologi Malaysia (UTM). He graduated from Universiti Putra Malaysia (UPM) in Bachelor of Science (Biotechnology) in 2004. After that he takes an industry skill enhancement program of herbal plantation & processing technology course at AdvancedTM Manufacturing Institute (AMI). His research interests are in Fermentation and Bioprocessing Technology. He is person in charge to operate and handling Bioreactor 16L, 150L and 1500L for research and production of microorganisms in IBD since 2006. He specializes in scaling up process for bioreactor and downstream processing. He has involved with many contract research and production of microbe from local and international company at IBD.

- Staff from more than 450 companies have attended our life-long learning programmes.
- IBD has assisted more than 65 herbal companies in their process and product development.

COURSE FEE

Fee is inclusive of lunch, refreshments and course materials. Accommodation is not included)

NORMAL PARTICIPANTS

RM 3000 per participant

STUDENT PARTICIPANTS

RM 2000 per participant

Method of Payment

Please kindly complete and return the reply form 3 weeks before the commencement date together with :

BENDAHARI UTM (CIMB Bank Berhad)

Akaun No : **8006053536**

Cancellation & Substitutions

A full refund will be promptly made for all written cancellations 2 weeks before the meeting. 50% refund will be made for written cancellations received 7 days before the meeting. A substitute may be made at any time.

Note

a)The organiser has the right to make any amendments that they deem to be in the best interest of the course and to cancel the course if insufficient registrations are received a week before course commencements date.

b) **CERTIFICATE OF ATTENDANCE** will be awarded at the end of the course.

REGISTRATION FORM

Bioprocess Engineering and Biofactories

2 - 6 Dec 2018

Jasmine Room,
N22 UTM Johor
Bahru, Johor

YES ! I would like to register the following participants

Name 1 _____

Job Title _____

Email _____

Name 2 _____

Job Title _____

Email _____

COMPANY INFORMATION

Company _____

Address _____

Town _____

State _____

Tel _____

Email _____

AUTHORISED Signatory (*This registration is invalid without signature from an authorised officer)

Name _____

Job Title _____

Tel _____

Email _____