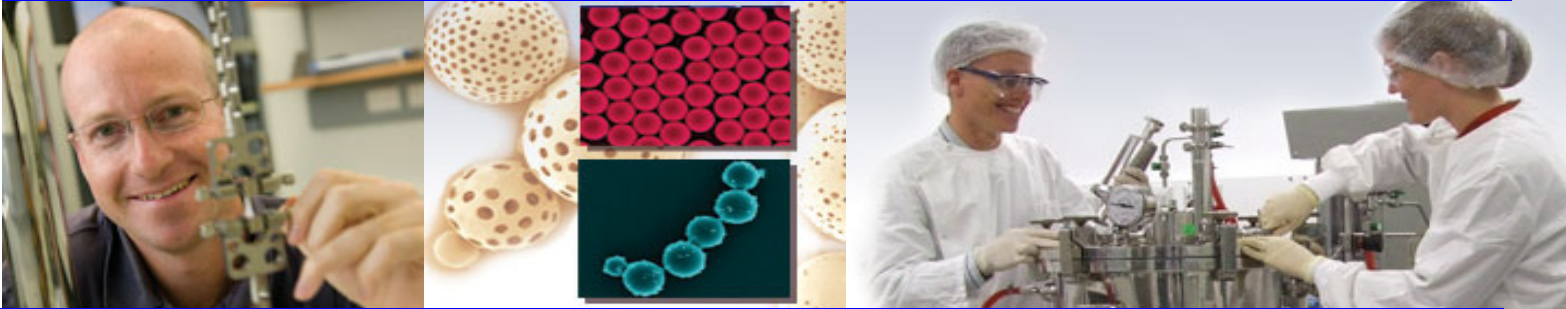


SBL Claimable
subject to PSMB Approval

Biologics

Course Program



WHO SHOULD ATTEND

Employees in pharmaceutical companies with a desire to up-skill in these more recent areas of drug development and biologics; scientists employed in Universities, hospitals, government sponsored research institutes and industry who are associated with research programs in biologics development/production. Employees involved in regulatory affairs and/or GMP/GLP within their respective institutions.



14-16 January 2009

Kompleks EUREKA, Universiti Sains Malaysia, Penang.

Presented by:

USAINS
HOLDING SDN BHD
(Wholly-owned by USM)

In collaboration with:



INTRODUCTION

The present growth in the biologics industry is due to the demand for new therapeutic entities for the treatment of a variety of diseases including diabetes, heart disease, cancer, inflammatory diseases and many other indications. This growth is occurring at a time when the rate of registration for new pharmaceutical drug entities is decreasing. Significant opportunities are arising in the biologics industry, particularly with the expiry of a number of patents for biologics, which opens the door for the production of follow on biologics or biosimilars.

Participants can expect a thorough, in-depth analysis of biologics, ranging from an initial overview of the industry, commercialisation issues, coverage of the enabling technologies, through to details of classes of biologics and production systems, process economics and the code of Good Manufacturing Processes.

OBJECTIVE

- To enhance the knowledge of participants in these areas.
- To provide refresher and up-skilling modules to enable participants to grasp the many facets of biologics and their production.

METHODOLOGY

The course will consist of a series of face-to-face presentations by Assoc. Prof. Stephen Mahler and Dr. David Chin, and will include various audiovisual aids such as videos and power point presentations. Each topic will be followed by a brief group discussion to highlight any significant issues that arise and to answer queries and questions.

FACILITATORS

ASSOC. PROF. STEPHEN MAHLER

Email: s.mahler@uq.edu.au

Stephen Mahler is an Associate Professor at the Australian Institute of Bioengineering and Nanotechnology at the University of Queensland. He has a PhD in biochemistry from the University of Queensland and is a Graduate of the Australian Institute of Company Directors (GAICD). He has been involved in the biotechnology industry in Australia for over 20 years both in industry and in academia. Between 1989-2006, he held an academic appointment in the School of Biotechnology and Biomolecular Sciences, and was co-director of the Bioengineering Centre from 2004-2006 at the University of New South Wales. His expertise is in the production of recombinant biopharmaceuticals, and has developed and managed bioprocesses for producing clinical grade therapeutic proteins. He has specific expertise in antibody engineering and humanization of antibodies, and was visiting scientist at Cambridge Antibody Technology, United Kingdom in 1992/1993, and project leader in the CRC for Biopharmaceuticals 1993-1999. He has a number of collaborations with key biotechnology companies in Australia associated with the research and development of pharmaceuticals and biopharmaceuticals. As an academic of 20 years standing he has been involved in significant educational endeavours, including teaching and managing an off-shore Master of Science in Biopharmaceuticals Program in Hong Kong.

DR. DAVID CHIN

Email: d.chin1@uq.edu.au

Dr. David Chin has over twenty years experience in biotechnology both in academia and also in industry. His PhD thesis involved the development of new immunisation systems for the production of novel monoclonal antibodies. His more recent experience as a biotechnologist is associated with molecular biology and protein expression in relation to biologics discovery/production. Between 2003-2007, he was an Australian Research Council Fellow at the University of New South Wales. During this period he developed production strategies for biologics and managed the production of biologics for clinical trials. He is presently Operations

Manager of the National Collaborative Research Infrastructure Strategy (NCRIS) Biologics Facility at the Australian Institute for Bioengineering and Nanotechnology, University of Queensland.

FEE

Non-Academic: RM1,800.00

Academic: RM1,200.00

Student: RM600.00

(Including lunches, refreshments and course documents)

Participants are responsible for arranging their accommodation. We propose the following hotels which are located the course venue:

USM GUEST HOUSE

Universiti Sains Malaysia

11800 USM Penang.

Tel: 04-653 2030 / 04-653 2050

Fax: 04-659 7124

E-mail: guesthouse@usainsgroup.com

www.usainsgroup.com/guesthouse

B-SUITE

B Tower, Bayan Point

19 Medan Kampung Relau

11900 Bayan Lepas, Penang

Tel: 04-646 7777 Fax: 04-644 5000

www.B-suite.com.my

HOTEL VISTANA

213, Jalan Bukit Gambir

Bukit Jambul, 11950 Penang.

Tel: 04-646 8000

Fax: 04-646 8343

www.ytlhotels.com.my

THE KRYSTAL SUITES

Jalan Tun Dr. Awang

11900 Bayan Lepas, Penang.

Tel: 04-613 3333 Fax: 04-613 3332

www.thekrystalsuites.com

RECSAM INTERNATIONAL HOUSE

11700 Gelugor, Penang.

Tel: 04-659 7928 Fax: 04-658 7558

www.recsam.edu.my

ANGGERIK LODGING

351 Hilir Pemandar

11700 Gelugor, Pulau Pinang

Tel: 04-658 3760 Fax: 04-659 9052

www.anggeriklodging.com

For alternative lodging, please visit:

www.penang-hotels.com

| DAY 1: 9:00 AM – 5:00 PM (WEDNESDAY, 14 JANUARY 2009) | | |
|--|---|---------------------------------|
| Time | | Speaker Time + Questions |
| 9:00 am | Introduction to Biologics by Assoc. Prof. Stephen Mahler | 15 + 5 |
| 9:20 am | Overview of Global Biologics Industry by Assoc. Prof. Stephen Mahler | 25 + 5 |
| 9:50 am | Commercialization of Biologics by Dr. Amin Malik Shah Abdul Majid | 50 + 10 |
| 10:50 – 11:10 am | TEA BREAK | |
| | OVERVIEW OF ENABLING SCIENCE AND TECHNOLOGIES | |
| 11:10 am | DNA, RNA and Proteins by Dr. David Chin | 15 + 5 |
| 11:30 am | Recombinant DNA Technology by Dr. David Chin | 25 + 5 |
| 12:00 noon | Introductory Immunology by Assoc. Prof. Stephen Mahler | 25 + 5 |
| 12:30 – 1:30 pm | LUNCH BREAK | |
| 1:30 pm | Genomics by Assoc. Prof. Stephen Mahler | 35 + 5 |
| 2:10 pm | Proteomics by Dr. David Chin | 35 + 5 |
| 2:50 – 3:10 pm | TEA BREAK | |
| 3:10 pm | Approaches to Drug Discovery and Impact of Genomics and Proteomics on Drug Discovery by Assoc. Prof. Stephen Mahler | 35 + 5 |
| 3:50 pm | Identification of Gene Expression Patterns by Assoc. Prof. Stephen Mahler | 35 + 5 |
| 4:30 pm | General Discussion | |
| DAY 2: 9:00 AM – 5:00 PM (THURSDAY, 15 JANUARY 2009) | | |
| | CLASSES OF BIOLOGICS AND THERAPEUTIC MODALITIES | |
| 9:00 am | Classes of Biopharmaceuticals and Therapeutic Modalities by Assoc. Prof. Stephen Mahler | 35 + 5 |
| 9:40 am | Oligonucleotides by Assoc. Prof. Stephen Mahler | 25 + 5 |
| 10:10 am | Introduction to Monoclonal Antibodies by Dr. David Chin | 15 + 5 |
| 10:30 – 10:50 am | TEA BREAK | |
| | MONOCLONAL ANTIBODY TECHNOLOGY | |
| 11:50 am | Monoclonal Antibody Production by Dr. David Chin | 25 + 5 |
| 11:20 am | Antibody Engineering by Assoc. Prof. Stephen Mahler | 35 + 5 |
| 12:00 noon | Therapeutic Application of mAbs by Assoc. Prof. Stephen Mahler | 40 + 10 |
| 12:50 – 1:30 pm | LUNCH BREAK | |
| | PHARMACOLOGY OF BIOLOGICS; CLINICAL TRIALS; REGULATORY ISSUES | |
| 1:30 pm | Pharmacology of Biologics by Assoc. Prof. Stephen Mahler | 25 + 5 |
| 2:00 pm | Clinical Trial Issues with Biologics by Dr. David Chin | 25 + 5 |
| 2:30 pm | Regulatory Issues for Biopharmaceuticals by Dr. David Chin | 30 + 10 |
| 3:10 – 3:30 pm | TEA BREAK | |
| | PRODUCTION OF BIOLOGICS; INTRODUCTION | |
| 3:10 pm | Introduction to Biologics Production by Assoc. Prof. Stephen Mahler | 50 + 10 |
| 4:30 pm | General Discussion | |
| DAY 3: 9:00 AM – 6:00 PM (FRIDAY, 16 JANUARY 2009) | | |
| 9:00 am | Bacterial Expression by Dr. David Chin | 40 + 5 |
| 9:45 am | Mammalian Expression by Assoc. Prof. Stephen Mahler | 40 + 5 |
| 10:30 – 11:00 am | TEA BREAK | |
| | PRODUCTION OF BIOLOGICS: UPSTREAM | |
| 11:50 am | Fermentation; Cell Culture by Assoc. Prof. Stephen Mahler | 50 + 10 |
| 12:00 – 2:30 pm | LUNCH BREAK | |
| | PRODUCTION OF BIOLOGICS: DOWNSTREAM PROCESSING AND PROCESS ECONOMICS | |
| 2:30 pm | Downstream Processing by Dr. David Chin | 50 + 10 |
| 3:30 pm | Process Economics by Assoc. Prof. Stephen Mahler | 40 + 5 |
| 4:15 – 4:30 pm | TEA BREAK | |
| | PRODUCTION OF BIOLOGICS: GOOD MANUFACTURING PROCESSES | |
| 4:30 pm | Good Manufacturing Processes (GMP) by Dr. David Chin | 35 + 5 |
| 5:10 pm | Summary and Final Group Discussion | |

Biologics Course Program

REGISTRATION FORM

| | | | |
|----------------------|--|-----|--|
| Dr/Mr/Mrs | | | |
| Designation | | | |
| Name of Organisation | | | |
| Mailing Address | | | |
| | | | |
| | | | |
| Tel | | Fax | |
| Mobile | | | |
| E-mail | | | |

REGISTRATION INFORMATION

Course Fee

RM1,800.00 (Non-Academic)

RM1,200.00 (Academic)

RM600.00 (Student)

(Including lunches, refreshments and course documents)

Date / Time

14-16 January 2009 / 9 :00 am – 5 :00 pm

Venue

Auditorium 2, Kompleks CUREKA
Universiti Sains Malaysia, Penang

Certificate of Accomplishment

In recognition of successful program completion, you will be presented with a Certificate of Attendance. This will reflect on your commitment towards your continued personal and professional development.

For more information, kindly contact:

Dr. Amin Malik Shah Abdul Majid

Tel: 04-653 4582 / 012-423 0842

E-mail: aminmalikshah@usm.my

Miss Norshirin Idris

Tel: 04-653 2182 / 019-461 6623

E-mail: norshirin_idris@hotmail.com

Mr. Khairol Anuar Hazir Mohammed

Tel: 04-653 4372 / 012-286 9048

E-mail: khairol@usainsgroup.com

Deadline for registration is 7 January 2009

Mode of Payment

The fee must be paid in advance of the event.

1. Telegraphic Transfer. Please note the following:

Payee Name: Usains Holding Sdn. Bhd.

Details: Biologics Course Program

Name of Bank: CIMB Bank Berhad

Universiti Sains Malaysia

11800 USM Penang

Account Number: 0709-0006708-05-7

Swift Code: CIBBMYKL

Please fax your Bank-in Slip (write your name & contact number on the slip) to 04-657 2210 (Att: En. Khairol)

2. Banker's Cheque/Bank Draft/Money Order. Please make draft payable to "USAINS HOLDING SDN. BHD."

| | |
|--------------------------------------|--|
| Cheque / Bankdraft / Money Order No. | |
| Bank | |
| Amaun | |

3. A Local Order (LO) or Purchase Order (PO) must be presented before the event.

The Organiser reserves the right to stop a registered delegate from taking part in the event if no proof of payment can be presented. This only applies to registered delegates who have NOT paid the registration fee PRIOR to the event date.

Substitution / Cancellation

Cancellation must be made in writing through fax, e-mail or post at least 5 days before the course. No refund will be made after this period. However, substitute participants are welcomed at no extra charge provided written notice of at **least 5 days** before the event is given to the Organiser.

Please complete the registration form and submit to:

USAINS HOLDING SDN BHD (473883-H)

(Wholly owned by USM)

Kompleks CUREKA, Universiti Sains Malaysia

11800 USM Penang

Tel: 04-658 3655 / 04-653 4372

Fax: 04-657 2210

www.usainsgroup.com