

# “BIOLOGICS & PROCESS TECHNOLOGY”

MASTER CLASS



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## PROGRAMME OVERVIEW

**BIOLOGICS MAKE UP MORE THAN 1,000 MEDICINES AND VACCINES THAT TARGET MORE THAN 100 DISEASES.** Unlike medicines produced by chemical reactions, most biologics are produced by biotechnology methods from a variety of natural sources – human, animal or microorganism. These products include antibodies, hormones, vaccines, blood products, DNA, cells, etc. Biologics manufacturing contributes to about 20% of our manufacturing output and creates more than 10,000 high-paying jobs. Over the past 5 years, the biologics manufacturing industry has attracted S\$2.7 billion in investment. This includes investments from companies like AbbVie, Amgen, Baxter, GlaxoSmithKline, Lonza, Novartis and Roche. The new manufacturing facilities set up by the companies will employ close to 2,000 workers. The local workforce is set to expand by 700 to 1,000 high-value jobs over the next 4 years.

**TO REGULATORY AUTHORITIES, QUALITY ISSUES ARE HIGHLY CHALLENGING BECAUSE BIOLOGICS ARE DIFFERENT FROM CHEMICAL DRUGS.** This is because: (1) use of living source materials to produce the biologic, (2) increased complexity of biologic manufacturing processes and (3) increased complexity of the biologic molecules themselves. While chemical drugs can become generics, biologics products are best viewed as “biosimilars”, and not as bio-generics. “Biologics” are highly susceptible to adventitious agent contamination – prions, viruses, mycoplasmas, and bacteria/fungi microbes. Risk control procedures – such as barriers to entry, testing to confirm absence, and inactivation/removal – are essential. Lessons can be learned from reported contaminations of biologic manufacturing processes. Compared to a chemical drugs, biologics have a more complex process-related impurity safety profile, especially due to the living system-related impurities (e.g. host cell proteins, host cell DNA).

**THE COMPLEXITY OF A BIOLOGIC REQUIRES A RANGE OF CELLULAR AND PHYSICOCHEMICAL FUNCTIONAL ACTIVITY ASSAYS TO DISCERN POTENCY.** Extensive physicochemical characterization of protein and monoclonal antibody molecular structure, employing multiple, complementary, as well as state-of-the-art analytical methods is necessary, covering primary amino acid sequence changes (e.g. truncation, deamination, oxidation), post-translational modifications (e.g. glycosylation), and higher order structural changes (e.g. secondary folding, aggregation). Because of the molecular structural complexity of a biologic, including its many possible structural variants, functional activity assays are required that can discern, which structures have what amount of potency. While bioassay functional activity assays (i.e. in vivo and in vitro) are required for measuring potency, surrogate (analytical) assays can be used if properly correlated to the bioassays. Many manufacturers underestimate the amount of resources and time needed to properly implement these functional activity assays.

**EFFECTIVE STRATEGY IN INDUSTRY AND RESEARCH FOR BIOLOGICS.** This masterclass will help the attendees to develop an effective strategy for biologics, teaching about the challenges all the way from R&D to clinical studies through commercialization and aims to introduce “Biologics and Process Technology” to individuals who strive for a career in biologics R&D and manufacturing, both fresh graduates and experienced.

## PROGRAMME HIGHLIGHTS

### Why Should You Attend?

- Learn about principles and effective strategies for biologics development
- Learn to address challenges all the way from R&D, clinical studies and commercialisation
- Gain practical knowledge and insights into the biologics R&D and manufacturing sectors



## BENEFITS

### What Will You Gain?

- Obtain an overview of the biologics industry and biologics manufacturing processes
- Gain knowledge of Good Manufacturing Practice (GMP) and understand operations within biologics manufacturing plants, including a field trip
- Understand the basics of process operations, controls and optimization
- Exposure to media and buffer preparation, sterilization, industrial fermentation, cell banking, seed culture and aseptic cell techniques
- Learn about bioreactor systems and designs, operations and scale-up, product purification including analysis and QC

## WHO SHOULD ATTEND

This programme is designed for individuals who have a background in Chemical & Life Sciences or Chemical Engineering. Open to GCE O Level, GCE A Level, NITEC, Diploma or Degree holders.

## PROGRAMME AT A GLANCE

### Application

To register for the programme, visit [www.tum-asia.edu.sg/biologics-run3](http://www.tum-asia.edu.sg/biologics-run3)

### Programme Dates

18 - 19 July 2016

### Location

SIT@SP Building, Level 5  
510 Dover Road, Singapore 139660

### Programme Fees\*

Standard Course Fee: **SGD 1,016.50**

e2i Funded Course Fee: **SGD 541.50**

(e2i funding is only applicable for employed Singapore Citizens or Singapore Permanent Residents)

\*All fees quoted above are inclusive of 7% GST, course materials and light refreshments

### Deadline

Applications close on **11 July 2016**



# TRAINER PROFILE



## Dr. Siew Hwa Ong

Director & Chief Scientist, Acumen Research Laboratories  
Assistant Professor (Adjunct), Yong Loo Lin School of  
Medicine, National University of Singapore  
Deputy Chair, BioSingapore

Trained as a cell & molecular biologist with focus on cancer, Dr. Siew Hwa Ong is an expert on signal transduction mechanisms that control cancer cell growth, death, motility, architecture, metabolism & cell transformation due to genomic changes or genetic mutations. Dr. Ong has conducted independent research in Singapore, US & Canada from 1995 - 2007; and then joined the pharmaceutical industry in cancer drug development. Dr. Ong is highly specialized in drug target identification, validation & testing, as well as in biomarker discovery.

In 2010, Dr. Ong founded the medical technology Acumen Research Labs, which is developing pioneering Sepsis diagnostic tests.

Since 2004, Dr. Ong has been an adjunct faculty member at the National University of Singapore & conducts lectures on Tumour Biology & Bio-entrepreneurship. From working in the academic and biomedical industry for 20 years now, Dr. Ong has an in-depth understanding on how to enhance technology valorisation and translation of basic research into innovative products and services.

Dr. Ong is also the Deputy Chairman of BioSingapore & Council member of the Singapore Manufacturing Federation. She has also set up community programs to promote science education in children from families below socio-economic norm (Science Explorers' Camp) and biotechnology entrepreneurship in youth (Asian Youth Biotechnology Network).



## PARTICIPANT TESTIMONIALS



**“This course is very useful for someone who is new to the biopharmaceutical industry.”**

- Quality Control Chemist, Baxalta Manufacturing SARL Singapore Branch



**“The pace of the class was good. The lecturers were knowledgeable and explained the concepts well. Most of the content was new materials for me and I learnt a lot from it.”**

- Lab Supervisor, Parkway Health

# PROGRAMME SCHEDULE

Day 1, 18<sup>th</sup> July 2016 (9AM - 5PM)

- Overview of the Biologics Industry in Singapore: R&D and Manufacturing
- Key Applications of Biologics: Therapies, Agriculture
- Basic Concepts: Organization of the Cell, Genetic Engineering, Gene Expression and Regulation
- Types & Modes of Action: Recombinant Proteins, Antibodies, Vaccines and Blood Components
- Cell therapy
- Gene Therapy
- Biologics Process Technologies: Cell Culture Process, Cell Line Development
- Upstream Processes And Scale-up
- Good Manufacturing Practice (GMP)
- Quality Assurance (QA)
- Quality Control (QC)

Day 2, 19<sup>th</sup> July 2016 (9AM - 5PM)

- Clinical Trial Design & Management
- Regulatory Affairs: Approval processes, Evaluations and Challenges
- Group Case Study: Herceptin
- Field Trip: TBC
- Dialogue Session on Careers in Biologics Sector

## INSTITUTION PROFILE

Founded in 1868, Technische Universität München (TUM) has produced 13 Nobel Laureates and has been ranked as Germany's #1 University for 3 consecutive years in the 2011, 2012 & 2013 Shanghai Rankings (ARWU). Known in the 2013 Shanghai Rankings (ARWU) to be among the "Top 50 Universities" in the world, TUM has earned itself a reputation of being an institute that grooms world-changers. In line with TUM's entrepreneurial spirit, TUM Asia was set up in 2002 to bring German academic excellence to Asia. Today, TUM Asia offers standalone/joint Bachelor & Master programmes in Singapore together with premier partner universities.



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