Course Title

Manufacture & Registration of Biological and Biosimilar medicines

Presented by PharmaConnect Africa & International Centre for Genetic Engineering and Biotechnology

Course Dates

Thursdays via Zoom 09.00 – 11.00am SAT

17 June 2021

24 June 2021

1 July 2021

8 July 2021

15 July 2021

22 July 2021

Brief Description

Biopharmaceuticals are defined as drugs produced using biotechnological processes from proteins and nucleic acids which are used for therapy or diagnosis[1]. They include insulins, vaccines and new generation advanced therapy medicinal products (ATMPs) such as monoclonal antibodies, interferons, interleukins etc[2]. The industry is relatively new with the

[1] https://www.bioprocessonline.com/doc/what-is-biopharmaceutical-0001

[2] *European Medicines Agency, "tooltip definition of advanced therapy medicinal products", Committee for Advanced Therapies (CAT)*

first commercial *advanced therapy medicinal product* (ATMP) being recombinant insulin the early 1980s[3].

With a global value of USD 302.63 billion in 2020, the biologics market is projected to grow to USD 509.23 billion by 2026, registering a CAGR of 9.06% between 2021 and 2026[4].

The biopharmaceutical industry is a highly specialized industry requiring a high level of skilled personnel to manufacture and regulate the medicines, as well as sophisticated and efficient bioprocessing infrastructure.

Biotherapeutic products are increasingly being used in medicine to deliver potent treatments which are more efficacious that chemical entities, making it imperative that African countries invest in the development of a biopharmaceutical industry.

This course aims to present the theory and practice of biological / biosimilar manufacture, quality control and regulation. Delegates will gain a working understanding of basic upstream and downstream processes involved in the industry and the regulatory aspects involved in compiling and assessing biosimilar dossiers.

Course content and presenter

Module 1 - Dr. Skoko, ICGEB: “Technologies for the production of biologics/biosimilars"
Module 2 - Dr. Guarnaccia, ICGEB: "Downstream and Quality Control of chemically modified biologics/biosimilars”
Module 3 - Dr. Terdoslavich, ICGEB: “Designing a biologics manufacturing facility, GMPs requirements and Quality Assurance Principles: ICGEB experience”
.Module 4 - Dr Henry Leng, Pharmeducon: “Regulatory assessment of biologics and biosimilars”
Module 5 – Dr Victor Moyo, Leaf Pharmaceuticals: “Commercial development and FDA registration of biosimilar – a case study”
Module 6 – Industry showcase “Benchtop to scale up production”

Learning outcomes

[3] https://www.bioprocessonline.com/doc/what-is-biopharmaceutical-0001
[4]https://www.mordorintelligence.com/industry-reports/biologics-market#:~:text=The%20biologics%20market%20was%20valued,forecast%20period%2C%202021%2D2026.

After successfully completing this course, you will have gained:

- A clear understanding of the biologics and biosimilars and how they are manufactured and regulated
- An appreciation of the quality management systems for biopharmaceutical production
- A working understanding of upstream and downstream processes involved in biopharmaceutical production;
- Familiarity with benchtop and industrial pharmacy equipment for manufacturing and analysis (this may incorporate a laboratory visit or simulated learning);
- A working understanding of regulatory guidelines (WHO, MCC, EDQM) relevant to the manufacture, registration and sale of biopharmaceuticals;

Who should enrol?

- Staff from medicine regulatory agencies and trade departments (e.g. Dept of Health, Dept of Trade etc)
- Personnel working in regulatory affairs departments of manufacturers and pharmaceutical companies
- Entrepreneurs interested in biopharmaceuticals
- Researchers, clinicians and students in medicine regulation and policy

Course fees

Early bird (ends 1 June) - R 42500.00 per delegate (VAT incl.)
Late registration (end 10 June) – R4950 per delegate (VAT incl.)

Course material and/or other materials are included in the fee.

Scholarships

Postgraduate students and regulatory staff from ICGEB member states can apply for scholarships to attend the course

Admission requirements

Prospective delegates should at least have a bachelors' degree.

Assessment

1. Online quiz

Accreditation and certification

Delegates who successfully complete a course and comply with the related assessment criteria are awarded certificates of completion by PharmaConnect Africa and CPD points for their professional skills development.

Registration and enquiries

nano@pharmaconnect.co.za

Our trainers

This is collaborative training involving experts from South Africa, US and Italy with extensive practical, commercial and regulatory experience in the sector.
All regulatory information shared is the public domain.