

# Biopharmaceuticals Workshop

**Presenter:**

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**Introduction:**

The biopharmaceutical landscape and particularly the biosimilar landscape is rapidly evolving, with several products already approved for human or animal use across the United States and Europe.

In South Africa the biosimilar market is evolving at a slower pace, but with the next wave of biologics' patents expiring, a significant increase in the number of biosimilar dossiers currently being prepared by Regulatory teams within Industry and being evaluated within the walls of SAHPRA should be expected.

To understand the physico-chemical differences between small chemical entities and biopharmaceuticals, the differences in their development, manufacturing, purification, quality control, clinical applications and safety profiles is crucial for submitting a successful application for registration of a biopharmaceutical.

This workshop will attempt to equip you with the necessary knowledge to understand the content of your dossier and to know your product.

**Who should take this course?**

Regulatory Affairs pharmacists / scientists responsible for performing the due diligence on a biosimilar dossier received from a principal.

Regulatory Affairs pharmacists / scientists responsible for compilation and submission of a biosimilar dossier to SAHPRA.

Regulatory Affairs pharmacists / scientists responsible for the life-cycle management of a biosimilar dossier.

Quality assurance pharmacists / scientist responsible for product release.

Pharmacovigilance officers involved in risk management of biosimilars.

**Note:** While this course does not focus on vaccines, some of the content on the scientific basis of development, manufacturing and testing of biopharmaceuticals, may be applicable to vaccines.

**Course Format:**

Online on Microsoft Teams

**Course Content:**

Day 1 – 24 August 2020 (9:00 – 11:00): “Understanding the scientific basis of development, manufacturing and testing of biopharmaceuticals”.

1. Scientific definitions
2. Features of small chemical entities vs biologics vs biosimilars

Day 2 – 25 August 2020 (9:00 – 13:00): “Understanding the scientific basis of development, manufacturing and testing of biopharmaceuticals” continue.

1. Technologies
2. Manufacturing processes
3. Qualitative & quantitative laboratory techniques

Day 3 – 26 August 2020 (9:00 – 13:00): “Understanding the scientific basis of development, manufacturing and testing of biopharmaceuticals” continue.

1. Immunogenicity & allergenicity
2. Therapeutic applications

Day 4 – 27 August 2020 (9:00 – 13:00): “Regulatory pathways and approval of Biosimilars”.

1. Regulatory requirements for dossier submission
2. Totality of evidence

Day 5 – 28 August 2020 (9:00 – 12:00): “Regulatory pathways and approval of Biosimilars” continue.

1. Risk management plan
2. Substitution

**Course Outcomes:**

At the end of this course the attendee will have a clear understanding of:

1. The characteristics of biopharmaceuticals.
2. Technologies used in the development and manufacturing of biopharmaceuticals.
3. The complexities associated with the development, establishment of structure-function relationships, manufacturing, purification and quality control of biopharmaceuticals.
4. The requirements for showing comparability and similarity of a biosimilar against a reference product and the concept of “totality of evidence” used towards registration of a biosimilar.
5. The requirements for non-clinical and clinical data in support of the registration of biopharmaceuticals.
6. The necessity for development of a risk management plan in support of monitoring the post-marketing safety of a biopharmaceutical.