Biologics 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 physical-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 biological / biosimilar dossier received from a principal.
- Regulatory Affairs pharmacists / scientists responsible for compilation and submission of a biological / biosimilar dossier to SAHPRA.
- Regulatory Affairs pharmacists / scientists responsible for the life-cycle management of a biological / biosimilar dossier.
- Quality assurance pharmacists / scientists responsible for product release.
- Pharmacovigilance officers involved in risk management of biological medicines.

Course Content

This 2-day workshop will cover the following:

Day 1: “Understanding the scientific basis of development, manufacturing and testing of Biologics”.

1. Scientific definitions
2. Features of small chemical entities vs biologics vs biosimilars
3. Technologies
    a. Manufacturing processes
    b. Qualitative & quantitative laboratory techniques
4. Immunogenicity & allergenicity
5. Therapeutic applications

Day 2: “Regulatory pathways and approval of Biologics”.

1. Regulatory requirements for dossier submission
2. Totality of evidence
3. Risk management plan
4. 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.