Quality, Safety and Efficacy of Biosimilars

Presenter:
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Introduction:
An understanding of the differences in the nature, physico-chemical properties, development, manufacturing, purification, quality control, clinical applications and safety profiles between small chemical entities and biopharmaceuticals is crucial for submitting a successful application in support of the registration of a biopharmaceutical.

With an emphasis on biosimilars, this workshop focusses on protein structure, protein biochemistry, essential methods used in biopharmaceutical development and quality control, the differences in the technical requirements between a *small chemical entity* dossier and a biosimilar dossier and the differences in the clinical requirements between a *small chemical entity* dossier and a biosimilar dossier.

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.

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:
<u>Day 1: 30 August 2022 – (9:00 – 13:00):</u>

Understanding the scientific basis of development, manufacturing and testing of biopharmaceuticals

1. Features of small chemical entities vs biologics vs biosimilars
2. Qualitative & quantitative laboratory techniques
3. Immunogenicity & allergenicity

Day 2: 31 August 2022 – (9:00 – 13:00):

Specific regulatory requirements pertaining to biopharmaceuticals

1. Data requirements
2. Dossier compilation
3. Risk management plan

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