
Satellite Session 4: Science and Business

Posters

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What you should know about generic drugs

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Generic drugs must have the same active ingredient, strength, dosage form, and route of administration as the brand name product (reference products).

Registration of generic drugs require carefully planned regulatory strategy.

A company can develop a generic drug only upon expiration of the period of data exclusivity on the reference product. This is usually 10 years from the date of the first authorization.

Each application undergoes rigorous review by authorities (EMA, FDA or local MoH).

The generic drug manufacturer must prove its drug is the same (bioequivalent) as the brand name drug. Design of the bioequivalence study, number of subjects, sampling scheme and analytical method are part of the generic drug dossier and this information is reviewed during application. All protocols and documents used in BE study must comply with Good Clinical Practice (GCP) guideline.

All sites involved in manufacturing, packaging, and testing of generic drugs must fulfill the same quality standards (GMP, GLP and GDP) as those of originator drugs.

This makes working in generic industry an exciting challenge.