Clinical Affairs by ELC

Biowaiver

What is it?

A Biowaiver means that in vivo bioavailability and/or bioequivalence studies may be replaced (not considered necessary for product approval) by in vitro study. Instead of conducting expensive and time consuming in vivo studies, a dissolution test could be adopted as the surrogate basis for the decision as to whether the two pharmaceutical products are equivalent. Biowaiver may be for lower strengths or based on Biopharmaceutics Classification System (BCS).

Note: according to BSC, drug substances are classified to four classes upon their solubility and permeability.
BCS classification enables development timeframes to be shortened for Class 1 (high solubility, high permeability) and Class 3 (high solubility, low permeability) drugs.

1. Literature search

Thorough literature search to identify studies which can justify biowaiver for BCS class as per regulatory requirement.

2. Evaluation of Go/No Go decision point

Thorough review of permeability data especially the efflux ratio and literature references which helps MAH in deciding “go or no go” for potential molecule for biowaiver strategy.

3. Due-diligence of dissolution data

Thorough review of dissolution data for line extensions (biowaivers of additional strengths) and post approval changes.

4. Justification for Biowaiver

Review and write-up of justification for biowaiver to meet regulatory expectation and answering agency query.

How ELC can support in Biowaiver?

ELC can offer biowaiver support and provide justification document. We offer:

- review of permeability data
- review of dissolution data;
- thorough literature search;
- preparation of biowaiver justification.

Activities	ELC timeline
Evaluation of biowaiver strategy to boost biowaiver application success.	2-3 weeks
Preparation of Biowaiver Justification	3-4 weeks

Reference: EMA guideline – CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** dated 20 January 2010

ELC Group is a fully-fledged global regulatory partner, working with pharmaceutical stakeholders for over a decade. From the development stage through to the implementation of clinical trials, completion of product registration, and successful marketing of the product, ELC Group aligns itself as a strategic partner to help pharmaceutical companies achieve their goals.

Concept to Compliance

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