charles river

Biosimilar Program – Anti-CD20 Antibodies (e.g., Rituximab)

Charles River has a range of services to support our clients' biosimilar development programs from GMP facilities for performing characterization and lot release testing, through in vivo *preclinical studies and support assays for both preclinical and clinical sample analysis. Combining the experience across the company, we have developed a comprehensive program that can be used to support the development of anti-CD20 monoclonal antibodies.*

Benefits

Charles River is a global company with expansive scientific expertise that can be used to guide clients from discovery to approval. The primary benefits of choosing Charles River for your biosimilar package are our wide range of services, unrivaled experience conducting biosimilar programs and the continuity we can provide for your entire program.

Regulatory Aspects

There are a number of guidelines that are aimed specifically at the development of biosimilars, in addition to regulatory publications from other bodies. The advice contained in this document is based on the class of drug, scientific experience and published guidance documents.

Project Package

- Structure
- Function – Biological Activity Assays
- Lot Release and Stability Testing
- Biosimilar Preclinical *In Vivo* Package
- Biosimilar Preclinical/Clinical Laboratory Support Package

Biosimilar Characterization Package

- Structure
  - Protein quantity and purity
  - Amnio acid sequence
  - Glycosylation analysis
  - Physicochemical properties
  - Aggregation analysis
- Function – Biological Activity Assays
  - Antibody-dependent cell-mediated cytotoxicity (ADCC) assay
  - Complement-dependent cytotoxicity (CDC) assay
  - Apoptosis assay
  - Flow cytometry binding assay
  - Fc receptor assays
- Lot Release and Stability Testing
  - Pilot study
  - Validation
  - Routine testing
  - Stability testing
- *In Vitro* Biocomparability with Mode of Action Assays
- Biosimilar Preclinical *In Vivo* Package
  - Pharmacology/pharmacodynamic PK/PD study
  - 4-week comparative toxicity study
  - Tissue cross-reactivity
- Biosimilar Preclinical/Clinical Laboratory Support Package
  - Bioanalysis and pharmacokinetic (PK) analysis
  - Immunogenicity
  - Pharmacodynamic (PD) endpoints, e.g., immunophenotyping
  - Neutralizing antibody assays

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