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National Institute for Bioprocessing Research and Training

# Contract Research

## CASE STUDY

## Generation of biosimilar characterisation data for use in regulatory submission

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## Challenge

A client requested the assistance of NIBRT Contract Research to provide detailed comparability testing of their biosimilar alongside its innovator product, in which, reported characterisation data would feature as part of a regulatory submission. To align with this request, it would be necessary to prepare a bespoke characterisation service package, which would cover a range of analytical testing methods, such as *N*-glycan analysis, primary structure analysis, product-related variant analysis, particle and aggregation analysis, and protein concentration determination. In accordance with client expectations, method performance would need to be assessed prior to proceeding with the analysis of biosimilar and innovator samples.

## Solution

NIBRT Contract Research prepared a comprehensive, characterisation service package, covering a wide range of analytical techniques across several platforms, including peptide mapping and *N*-glycan site occupancy by LC-MS; *N*-glycan characterisation by HILIC, WAX and LC-MS; oxidation analysis by RP-UPLC; aggregation analysis by AUC; protein concentration by SEC; and charge heterogeneity analysis by cIEF. To further expedite data reporting, analytical testing was divided into individual workflows, and each assigned to a dedicated analyst and subject matter expert. Throughout the lifespan of the project, contemporaneous updates were maintained, and weekly meetings put in place to deep dive experimental findings and discuss the possible need for any further method optimisation.

Method verification was performed by assessing the parameters; specificity, accuracy, precision, and linearity, limit of detection (LOD), limit of quantification (LOQ), range, and robustness. It was crucial that the agreed performance criteria were met for each analytical method. Verified methods were subsequently used to analyse innovator and biosimilar samples provided by the client.

## Outcome

For each analysis workflow, two comprehensive reports were provided to the client, detailing the results of method qualification (report 1) and analysis of biosimilar and innovator samples (report 2). The data provided was featured as part of the regulatory submission dossier for the biosimilar, enabling its successful launch to market.

# Project Process


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