EBOOK

Early and Strategic Application of Advanced Analytics Can Improve Biologic Development, Manufacturing, and Clinical Outcomes

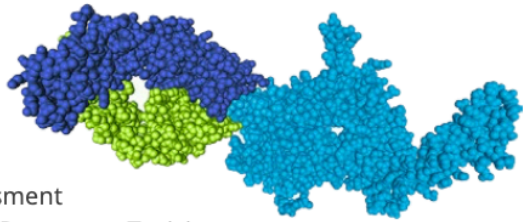
BioAnalytix
A Protagen Protein Services Company

Introduction

The strategic use of advanced analytics is an essential element in today's early-stage product selection and development. This is particularly true for more complex biologics and emerging modalities such as gene therapy, gene editing, and structurally complex conjugated and fusion biologic products.

Establishing critical attribute monitoring methods early in a biologic's development lifecycle can improve product development, manufacturing, and clinical outcomes. Advantages range from mitigating risk of manufacturing or process delays, product failures, and negative clinical outcomes to addressing the evolving expectations of the regulatory environment to include appropriate use of available and increasingly advanced analytical methodologies.

Molecular Characterization by Mass Spectrometry Supports:



- CQA Determination
- Comparability Assessment
- Attributes Impacting Potency or Toxicity
- Stability Assessment and Degradant Profile

Applications

We Apply Advanced LC-MS and Biophysical Analytics to Develop Attribute Monitoring Methods:

- ✓ CQA Monitoring Methods Applied to Process Development or Manufacturing Bridging Studies
- ✓ CMC/Product Characterization and Comparability Profiling
- ✓ Low-Level Impurity/Peak ID and Peak Characterization
- ✓ *In Vivo* Analytics Including Drug and Expression Products
- ✓ Quantitative Monitoring from Clinical PK Samples
- ✓ QC/Lot Release/Stability Methods
- ✓ OOS/OOT and Clinical Hold Resolution