EBOOK

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

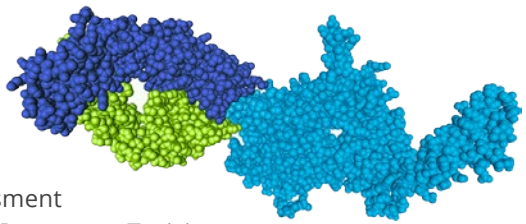
BioAnalytix
A Protagen Protein Services Company

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

Early and Strategic Application of Advanced Analytics

Increased knowledge of a product's structure, purity, stability, and/or activity is essential to inform the decisions on which a development program is built. Traditionally advanced analytics had been reserved for later-stage clinical regulatory packages, but with today's increased availability and access to many types of advanced analytical technologies, the application of these approaches is becoming increasingly used and expected earlier in development because of the valuable insights they provide.

Advantages of Earlier Use of Analytics

Insights to Guide Process Development & Manufacturing Decisions
- Biologic/DS Characterization
- MAM MS
- HCP & Impurity Profiles

Assess Clinical Impact of Attributes
- *In Vivo* Profiling & Correlations
- Transgene Expression & Editing

Improved Understanding of CQAs
- Enhanced Formulation Development
- Understanding of Degradation Pathways and Impurity ID
- Lead Engineering to Remove Degradation Hot Spots

Preclinical | IND | Phase I | Phase II | Phase III | BLA

Establish Quality Control
- DP Characterization & Comparability Assessments
- Characterization of Isoforms
- Stability-Indicating Assay Development

Assess Clinical Risk
- *In Vivo* Transgene Expression & Persistence
- PK Correlations
- Implications/Risk Analysis of Degradants Pertaining to Immunogenicity

Now more than ever, regulators are expecting extensive characterization performed strategically by applying advanced analytical approaches to generate solid and convincing data packages. High-resolution analytical tools have become more accessible and have contributed to resolving difficult issues regarding adverse clinical events. As regulators have become aware of their advantages, they are also expecting to see more complete data packages earlier. The advanced analytics that are used to characterize the molecule can now also be configured and validated for use as established analytics, such as for clinical monitoring/support methods, BLA-supporting low-level degradant and/or impurity characterization methods, or applied to PAT platforms.

As early as product engineering or lead selection, it is imperative to understand a molecule's quality attributes. The application of technologies such as mass spectrometry, advanced binding assays such as HDX, and *In Vitro* or *In Vivo* attribute monitoring for quality, stability, or expression is advantageous to the development program. They aid in the selection of an optimal lead candidate, optimization of a manufacturing process, resulting in higher yields and a process that is more robust against the generation of degradants, optimization for reduction of HCPs, and/or assurance of greater product consistency.

BioAnalytix – Your Strategic Development Partner

Throughout the product development process, production and clinical timelines can be at risk due to inadequate or insufficient analytics. Without a deep structural knowledge base of the molecule, it is very difficult to know what to control, how to optimize a process, or where to mitigate risk. We collaborate with leading groups to help develop correlations between molecular attributes identified by LC-MS and efficacy, potency/activity, and safety. BioAnalytix provides industry-leading approaches and specialized expertise to help answer key questions early to ensure efficient biologic development processes.

ADVANCE. DE-RISK. ACCELERATE.

Schedule a call today with our experts to discuss how we can help advance and accelerate your biologic development programs.

Contact Us

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