MONOCLONAL ANTIBODIES HAVE MANY CMC ANALYTICAL CHALLENGES THROUGHOUT THE PRODUCT LIFECYCLE. COVANCE HAS THE SOLUTIONS.

**PRECLINICAL**

**KEY ANALYTICAL CHALLENGES**
- Regulatory compliant analytical strategies for cell bank, drug substance and drug product
- Analytical and stability assay development
- Assay progression to GMP expectations
- Proof of protein structure, including characterization of process and analytical anomalies
- Management of reference standards and antibody reagents

**COVANCE SOLUTIONS**
- Consultation to align your Analytical Control Strategy and Plan with product CQAs
- Broad range of fit-for-purpose analytical capabilities and stability testing in cGMP stability chambers
- Qualification and testing to global cGMP quality standards
- Expertise, experience and equipment to understand protein structure and structural anomalies
- Robust characterization and control of reference standards and antibodies

**SPECIALTY EXPERTISE**
- Biopharmaceutical development
- Biosafety testing, including Next Generation Sequencing
- Platform and custom assays, most biochem and cell-based assay platforms (including CDC, ADCC)
- High-resolution MS, Edman sequence analysis, AAA, CD
- Antibody reagent manufacturing

**CLINICAL DEVELOPMENT**

**KEY ANALYTICAL CHALLENGES**
- Establishment of product specifications that demonstrate control of product
- Demonstration of process control
- Assay validation
- Manufacturing lot comparability
- Expiration dating

**COVANCE SOLUTIONS**
- Refinement of the Analytical Control Strategy by determining the list of assays to address QQAs and defining acceptance criteria
- Process validation testing and linkage to product CQAs
- Validation to ICH requirements and cGMP standards
- Expertise, experience and equipment to establish lot-to-lot comparability
- Accelerated and long-term stability testing to cGMP and ICH standards

**SPECIALTY EXPERTISE**
- In-process analytical support
- Viral clearance
- cGMP change control
- Global quality standards
- Protein structure elucidation: high resolution MS

**COMMERCIALIZATION**

**KEY ANALYTICAL CHALLENGES**
- Routine, global lot release and stability testing under commercial GMP conditions
- Monitoring and identification of data trends

**COVANCE SOLUTIONS**
- GMP testing labs located in North America and Europe
- Lead Scientist oversight of molecule data to trigger OOT/OOS alerts

**SPECIALTY EXPERTISE**
- Global project management
- Global GMP quality systems
- Control charting and review of all analytical data
MONOCLONAL ANTIBODIES
CMC ANALYTICAL SOLUTIONS

PRODUCT LIFECYCLE

Increasingly, regulatory agencies encourage management of the product lifecycle as an element of the new Quality Paradigm outlined in the ICH Q8/Q9/Q10/Q11 Harmonized Guidelines. Whether you employ the minimalist approach or an enhanced Quality by Design (QBD) approach, Covance can help you make better choices of how you manage and what you spend to support the product lifecycle. Your path to achieving this is the Covance Central CMC Analytical Solution.

CENTRAL CMC ANALYTICAL SOLUTION

By choosing Covance as a single, centralized CMC analytical laboratory, you can obtain higher quality analytical data more efficiently and at lower cost/fewer resources than by working with multiple providers/CMOs. This analytical data is the key to knowledge and quality risk management throughout the product lifecycle.

MONOCLONAL ANTIBODIES CMC ANALYTICAL SOLUTIONS

FACTS AND FIGURES

- Antibodies CMC analytical experience: More than 60 total supported in the last three years, including antibody fragments, antibody-like fusion proteins & ADCs
- Audited by FDA, EMA and other Boards of Health
- More than six subject matter experts in biopharmaceutical product development and regulatory CMC
- Structural characterization using OrbiTrap® and QToF MS, c-IEF, UHPLC and many other techniques
- cGMP stability chambers in accordance with ICH conditions
- Dedicated global project management
- Global GMP quality systems

Avoid the inherent assay variability and analytical bias created when multiple testing laboratories/CMOs test process, drug substance and drug product

Reduce the number of analytical quality agreements that you manage

Eliminate the need for increased resources required to manage technical transfer involving multiple CMOs and filling providers

Avoid the cost of staffing and maintaining internal capabilities to support development, GMP testing, validation, in-process testing and structural characterization

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