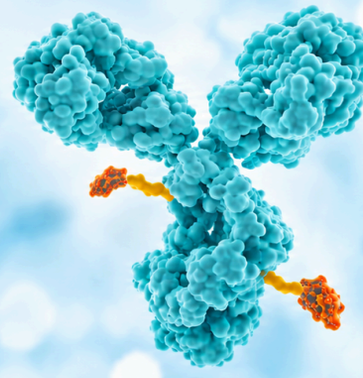
nuvalore

# mAb & ADC Development

## DoE-Driven Formulation Development & Advanced Analytical Characterization



### THE CHALLENGE

mAbs and ADCs present complex stability profiles and intricate critical quality attributes (CQAs). Traditional workflows silo formulation screening away from analytical characterization.

**This separation can slow development and make formulation-related risks harder to identify early.**

### THE NUVALORE SOLUTION

**nuvalore** integrates Statistical Design of Experiments (DoE) with advanced analytical characterization under a rigorous Quality by Design (QbD) framework.

**We connect formulation development with CQA-focused analytical characterization to guide data-driven formulation decisions and reduce development risk.**

**GMP-Certified Analytical Testing**

### INTEGRATED APPROACH

**1. FORMULATE**
Explore formulation variables using DoE.

**2. CHARACTERIZE**
Assess critical quality attributes (CQAs).

**3. UNDERSTAND**
Identify degradation pathways and risks

**4. OPTIMIZE**
Define a robust formulation design space

### EARLY FORMULATION & FORMULATION DEVELOPMENT

#### Early Formulation Assessment

- Assess key formulation risks & molecular behavior
- Evaluate pH sensitivity, aggregation, & degradation risks

#### DoE-Driven Formulation Screening

- Evaluate pH, buffers, concentration, ionic strength, excipients, & stabilizers
- Identify critical formulation variables

#### Forced Degradation & Stress Testing

- Assess physical & chemical stability under accelerated, thermal, mechanical (shear), & photolytic stress
- Identify degradation & instability pathways

#### mAb & ADC-Specific Optimization

- Control aggregation, fragmentation, & charge heterogeneity
- Preserve linker-payload integrity & prevent hydrophobic aggregation or premature release

### ORTHOGONAL ANALYTICAL CHARACTERIZATION

#### LC-MS Characterization*

- Intact, subunit, native & reduced LC-MS
- PTMs, DAR species, conjugation-site assessment, identity & structural integrity

#### DAR & Conjugation Profiling

- DAR average & distribution
- Conjugation-related heterogeneity
- HIC-HPLC, RP-HPLC, LC-MS*

#### Peptide Mapping & PTM Analysis

- Peptide mapping for identity and PTM trending
- RP-HPLC / HILIC for glycosylation profiling

#### Orthogonal CQA Characterization

- SEC-HPLC / CE-SDS — size variants & purity
- icIEF / CEX — charge variants
- HIC-HPLC / RP-HPLC — free payload & impurities
- HILIC — glycan profiling

* LC-MS capabilities are expanding. Discuss project-specific MS requirements with nuvalore.

**Bridge Formulation and Analytics.**
**Accelerate mAb & ADC development with integrated, data-driven insights.**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