AURIGENE
PHARMACEUTICAL SERVICES

Analytical & Bioanalytical Services



25
Years in Biologics

ICH
Q14 / Q2(R2) Methods

6
Biologics Commercialised

3
R&D Centers

900+
Scientists

21 CFR
Part 11 Digital QMS

Four Service Pillars

Routine & Release Testing

- HPLC / UPLC – RP, SEC, IEX, Protein-A (PA)
- Capillary Electrophoresis – CE-SDS (R & nR), iCIEF / cIEF (Maurice)
- Solo VPE for concentration
- ELISA process residuals – HCP, HCDNA, Protein-A leachables (rProA)
- Identity, Assay, Charge & Size variants, Excipients

Product Characterization

- Amino-acid sequence confirmation by LC-MS & MS/MS (multi-protease strategy)
- Multi-Attribute Monitoring (MAM) – one LC-MS run, multiple CQAs
- N/O-linked glycans, MALDI-TOF, RP-LCMS, HILIC-MS; antennary profile, sialic acid, monosaccharide ID
- CD & fluorescence for HOS
- SEC-MALS / AUC – aggregation & higher-order structure

Bioassay & Functional Activity

- Cell-based bioassays for MOA / lot release
- Proliferation, cytotoxicity, T-cell activation, reporter-gene
- FC effector function – ADCC, ADCP, CDC
- Binding – Fab, FcRn, Fcγ I/II/III; SPR (Biacore) & ELISA / flow-based
- Relative potency vs. reference standard (label-claim support)

Stability & Immunogenicity

- ICH forced degradation, real-time, accelerated, freeze-thaw, in-use (POU)
- Adaptive immunogenicity – ADA & NAb assays
- Impurity-induced – RAW-Blue / HEK-Blue TLR panels (IIRMIs)
- Point-of-Use study development for early-stage biologics

Specialised & Differentiated Capabilities

SPR-Based Assays (Biacore)

- Label-free, real-time detection
- High sensitivity & quantitative performance
- Wide dynamic range; low sample consumption
- Effector-function potency & MOA support

IIRMIs – Impurity Immunogenicity Ranking

- Sensitive, specific, quantitative ranking of impurity-driven innate immunogenicity risk
- Supports Quality-by-Design & risk-based control strategy
- Relative binding strength / functional activity vs. standard

MAM Platform - Accelerated CQA Insight

- Intelligent LC-MS workflow
- Simultaneous assessment & semi-quantitation of multiple CQAs in a single campaign
- Compresses timelines while maximising insight

Process-Related Impurities

- Host Cell Proteins – ELISA & LC-MS/MS
- Host Cell DNA (HCD) by qPCR
- Protein-A Leachables (PALs) by ELISA
- Endotoxin / NEP – LAL / MAT

End-to-end Support

01 Method Development/ Familiarisation

02 Qualification/ Validation (ICH Q14/ Q2R2)

03 Sample Analysis (in-process, DS & DP)

04 Method Transfer to QC & Regulatory Support

Why Aurigene

Depth of Platform

- Chromatography, CE, spectroscopy, mass-spec & bioassay under one roof
- Specialised CEX-MS, HILIC-MS, MALDI, SEC-MALS / AUC
- Custom, MOA-driven bioassay development

Regulatory-Grade Quality

- Fully digital QMS (DocHub, SAP Fiori, eLN, LIMS) – 21 CFR Part 11
- 6 commercial biologics released through this QMS
- Routine USFDA, EMA, MHRA, ANVISA, MFDS inspections

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For more information

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