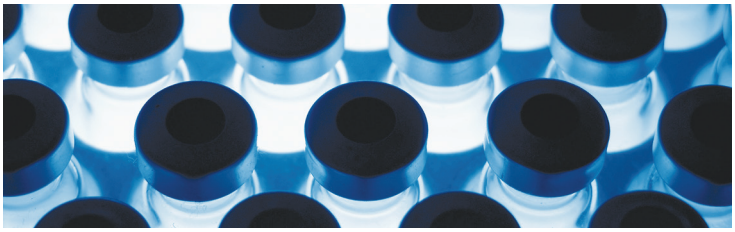
AVID BIOSERVICES TRUSTED PARTNER. QUALITY SOLUTIONS. RELIABLE RESULTS.

Your Partner from Concept to Commercial

APPLYING ANALYTICAL METHODS TO ACHIEVE SUCCESS

Our Analytical Methods Development (AMD) group offers extensive experience in transferring, developing, qualifying, and validating client assays. We tailor our methods to your particular processes and initiate development work at any stage, depending on your needs.

Our AMD team works with you to design an analytical program that will adequately characterize your product to meet regulatory guidelines.



Analytical methods development capabilities:

- Standard assays in place to support upstream and downstream development
- Physiochemical analytical methods development [SEC, IEX, CE SDS-PAGE, etc.]
- Functional assays [bioassay, antigen binding using Biacore®, etc.]
- Protein characterization [carbohydrate, peptide mapping, deamidation and oxidation analyses, etc.]
- Extensive experience and technical knowledge enable us to troubleshoot challenges throughout the development process, ultimately providing you with a robust and reproducible method

Customizable Analytical Capabilities

SUITE OF ANALYTICAL CAPABILITIES, TAILORED TO CLIENT NEEDS

PURITY ASSAYS

- Ion exchange chromatography
- Size exclusion chromatography
- Capillary electrophoresis

IMPURITY ASSAYS

- Residual ELISA's (HCP, Protein A, Insulin, etc.)
- Residual DNA by qPCR

IDENTITY ASSAYS

- Peptide map
- Capillary isoelectric focusing

POTENCY & BINDING ASSAYS

- Cell based potency (BSL1 cell lines and "Thaw and Go" format)
- Potency binding ELISA

CHARACTERIZATION ASSAYS

- Reverse-phase and hydrophilic interaction chromatography
  - Sialic acid, glycan and monosaccharide analysis
  - Deamidation and oxidation analysis
- Mass spectrophotometry analysis
  - Intact mass
  - Peptide map primary sequence verification
  - Post-translational modification profiling (oxidation, deamidation, N- and C-terminal modifications, glycosylation)
  - Disulfide mapping

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Uncompromising Quality Control

VERIFYING PROCESS AND PRODUCT EXCELLENCE—THROUGH SCIENCE AND COMPLIANCE

Full Lot Release Capabilities
- In-process, final testing, and lot release
- CoA and SoT generation

Stability
- Protocol generation, study design, and time point management
- ICH recommended conditions and Q1E trending
- Summary and final reports

Process Support
- Raw material testing and release
- In-process product testing

Analytical Methods
- Development of new methods
- Transfer of existing methods from external laboratories
- Phase appropriate assay qualification and validation

Process Validation Support
- Process characterization analysis
- Statistical analysis of all data

Process Validations

Preparation activities including:
- Complete FMEA of final process, materials, and equipment
- Critical Process Parameter (CPP), Key Process Parameter (KPP), and Operating Ranges defined

Protocols
- Master validation plan
- Validation (both upstream and downstream)
- Process scale-down
- Column lifetime
- End of production cell line characterization
- In-process hold time
- Buffer stability

Production Batch Production Records
- Reviewed and approved with client SMEs
- Complete change and version control documentation

Final reports as requested

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