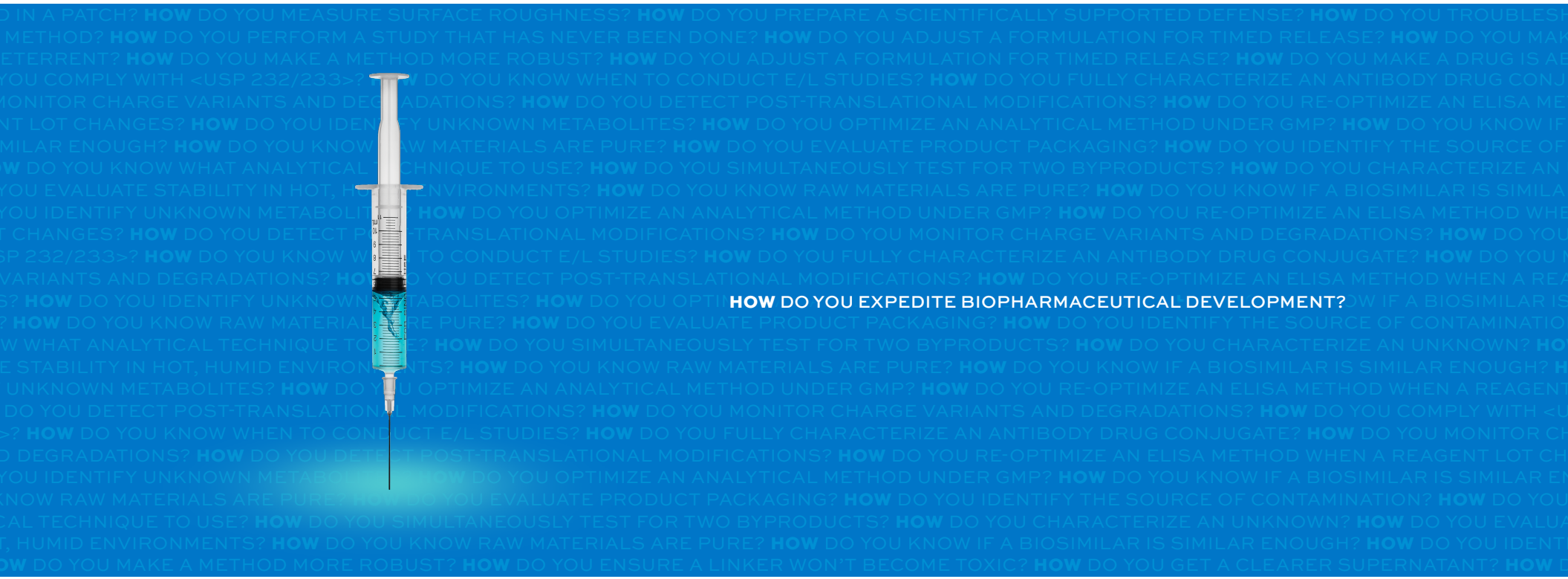

BIOPHARMACEUTICAL DEVELOPMENT: HOW WE CAN HELP

EAG Laboratories provides IND-enabling, registration and post-commercialization support for the development, quality control and lifecycle management of monoclonal antibodies, antibody-drug conjugates (ADCs), biosimilars, fusion proteins, pegylated proteins and synthetic peptides.

COMPREHENSIVE CMC ANALYTICAL SERVICES

- Analytical method development, validation & transfer
- Bioassay development
- Dose formulation compatibility studies
- Characterization of impurities/ degradants
- Stability services
- QC release testing
- Reference standard management

BIOPHARMACEUTICAL CHARACTERIZATION

- Sequencing
- Peptide Mapping
- Post-translational modifications (PTMs)
- Disulfide linkages
- Protein isoform and glycosylation profiling
- Molecular weight determination
- Charge variants and degradants
- Truncations
- Amino acid substitutions

BIOANALYTICAL ASSAY SUPPORT

- Bioanalytical assay development and validation for biological molecules
- ELISA using conventional or ECL detection
- Immunogenicity analysis (ADA)

EXTRACTABLES & LEACHABLES

- Controlled extraction studies
- Leachables method development and validation
- Toxicity evaluation for leachables
- Leachables stability programs
- E/L consulting and program design

IMPURITY, DEGRADANT AND PROCESS TESTING

- Development, validation and analysis of process and product impurities
- Forced degradation studies
- Product and process investigations
- Analysis of protein degradants including: aggregates, deamidation, oxidation and truncations
- Analysis of cell culture and downstream derived process components (antifoams, antibiotics, etc.)

INSTRUMENTATION & TECHNIQUES

EAG scientists are well-equipped with the broad array of analytical techniques and instrumentation required to fully characterize and quantify biomolecules, post-translational modifications (PTMs) and degradants.

BIOLOGICS ANALYSIS

- UPLC/UHR QTOF
- UPLC/MS/MS
- Cell Bioassay
- ELISA
- Electochemical Luminescence (ECL)
- Peptide Mapping
- Capillary Electrophoresis (SDS and iCIEF)
- UPLC (UV, PDA, FL, ELSD, CAD)
- N-Glycan Profile
- Western Blot and WES™
- SEC/MALS

SPECIALTY ANALYSES

- ICP-MS
- Thermal Analysis (TGA/DSC/DTA)
- SEM
- TEM

STABILITY

- cGMP-compliant
- All ICH conditions
- Custom conditions
- Photostability
- Fully validated Rees Scientific monitoring system
- Redundant chamber systems
- 100% backup power supply
- 38,000 cubic feet stability storage

EAG LABORATORIES | WE KNOW HOW™

ABC Laboratories is now part of EAG

EAG Laboratories is a global scientific services company serving clients across a vast array of technology-related industries. Through multi-disciplinary expertise in the materials, engineering and life sciences, EAG helps companies innovate and improve products, ensure quality and safety, strengthen supply chains, protect intellectual property and comply with evolving global regulations.

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