HOW DO YOU MAKE BETTER DEVELOPMENT DECISIONS FASTER?

EAG LABORATORIES | WE KNOW HOW™

How do you know a cGMP method validation is “phase appropriate”? How do you decide when to conduct E/L studies? How do you quickly identify the source of contamination? For companies looking for a true development CRO, EAG offers deep experience in analytical method development, program design and complex study execution—with the technical and regulatory know-how to help overcome R&D roadblocks, avoid regulatory setbacks and uncover sources of problematic manufacturing issues.

www.eag.com/pharmaceutical

PHARMACEUTICAL DEVELOPMENT: HOW WE CAN HELP

COMPREHENSIVE CMC ANALYTICAL SUPPORT

- Analytical method development and validation
- Stability (developmental and commercial)
  - All common ICH and custom conditions in 38,000 ft^3 of cGMP storage, including photostability
  - Fully-compliant LIMS inventory and environmental monitoring systems
- Elemental impurities by ICP-MS for ICH Q3D and USP <232>/<233>
- QC release testing
- Reference standard qualification and program management
- Vendor qualification

EXTRACTABLES & LEACHABLES

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

COMPOSITION & SURFACE ANALYSIS

- Layer structure and chemical composition
- Particle size and composition
- Chemical imaging of drug and drug product
- Quantitation and distribution of active ingredients, excipients and coatings at the sub-micron scale

INVESTIGATIVE PROBLEM SOLVING, CONSULTING & LITIGATION SUPPORT

- Contaminant investigations
- Isolation, elucidation, identification and characterization of known and unknown materials
- Failure analysis of product, packaging and manufacturing processes
- Evaluation of supply chain inputs
- Litigation support, including expert testimony for intellectual property and product liability challenges

RADIOLABELING & CUSTOM SYNTHESIS

- cGMP, GLP-certified and R&D materials
- Stable-label active ingredients and metabolites: ^{2}H and ^{13}C
- Radiolabeled active ingredient and metabolites: ^{3}H, ^{14}C and other labels
- Custom small-scale synthesis of compounds and reference standards
- Dedicated analytical support for qualification and generation of certificates of analysis

ENVIRONMENTAL RISK ASSESSMENT FOR PHARMACEUTICALS

- Product chemistry
- Aquatic and terrestrial toxicology
- Metabolism
- Environmental fate

INSTRUMENTATION & TECHNIQUES

EAG Laboratories uses state-of-the-art instrumentation in the areas of spectroscopy, chromatography and microscopy. We offer a secure, DEA-licensed stability suite that covers all ICH conditions.

CHROMATOGRAPHY/ SEPARATIONS

- HPLC, UPLC
- Semi-prep HPLC
- GC-MS
- LC-MS
- GPC
- GC
- SEC & IC

DISSOLUTION

- Type I, II, III
- IR, ER, MR
- Bath & bathless
- Inline UV

DETECTION

- HPLC (UV, PDA, FL, RI, ELSD)
- High-Resolution MS
- MS
- MS/MS
- MS-IT
- MS-TOF
- CAD
- Conductivity

ELEMENTAL/PURITY ANALYSIS

- ICP-MS
- ICP-OES
- GDMS
- XRF
- IC
- AA
- Microwave digestion

STABILITY

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

COMPOSITION/IDENTITY

- FTIR
- Raman
- XPS/ESCA
- TOF-SIMS
- XRD
- Thermal Analysis (TGA/DSC/DTA)
- NMR
- Auger

MICROSCOPY/IMAGING

- SEM
- Optical Profilometry
- Optical Microscopy
- AFM
- TEM

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.

+1 800.538.5227 • EAG.COM