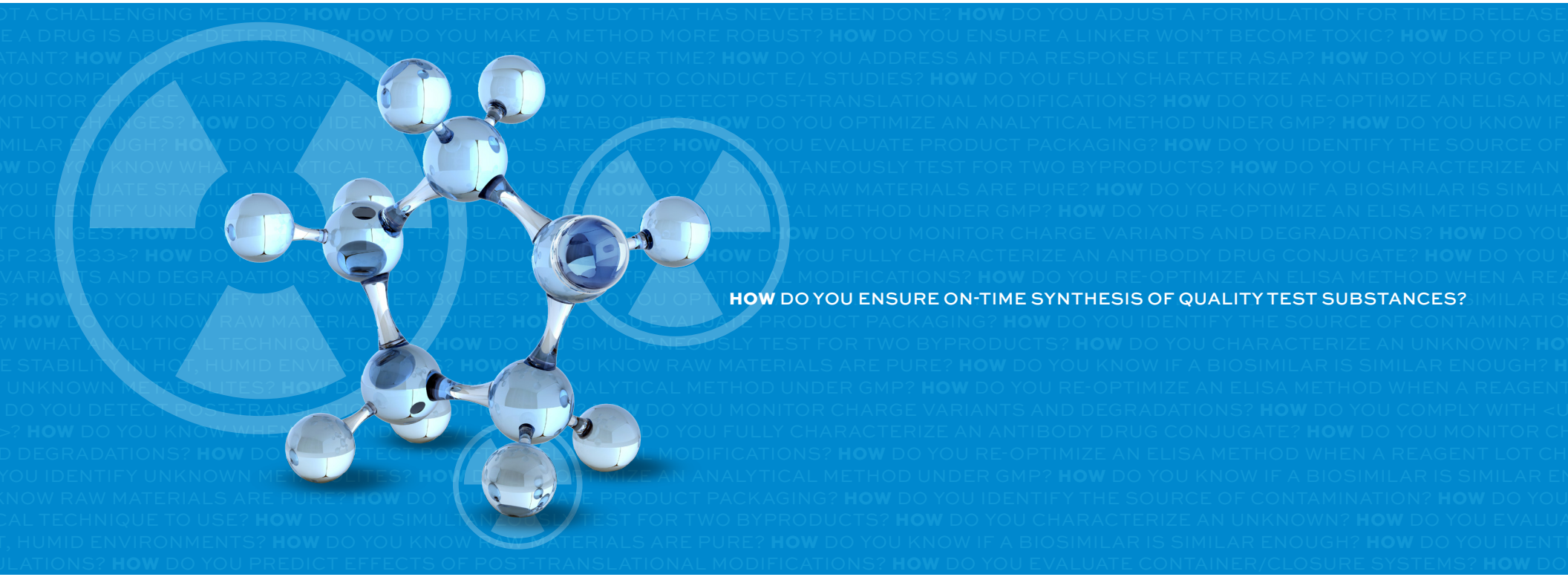

EAG LABORATORIES | WE KNOW HOW™

How do you optimize a multi-step reaction scheme? How do you know where to place an isotopic label? How do you scale a process from discovery lots to clinical supply? From active ingredients and reference standards for early research, to certified material for regulatory testing, **Ask EAG. We Know How.**

www.eag.com/custom-synthesis

CUSTOM SYNTHESIS & RADIOLABELING: WE KNOW HOW

No contract service provider has more experience synthesizing custom and proprietary materials to support product development in life science, chemical and related industries than EAG.

Whether you need radiolabeled clinical trial material synthesized under cGMP, substance for environmental fate and effects testing, stable-labeled active ingredients, or analytical standards complete with certificates of analysis, turn to EAG.

Our experienced team of PhD-level chemists, broad-scope NRC license, and dedicated analytical support make EAG the partner of choice for quantities of 100 milligrams to 100 grams and higher.

CUSTOM SYNTHESIS OF INGREDIENTS, INTERMEDIATES AND FINE CHEMICALS

Access to high-quality test substances is key to ensuring an efficient testing program and reliable laboratory results. You can depend on EAG's team of organic chemists and synthesis experts to deliver the quality custom materials you need, when and where you need them.

EAG brings unparalleled expertise to custom synthesis of active ingredients, intermediates, analogs, metabolites, impurities, analytical reference standards, controlled substances and other chemical compounds. We have extensive experience with complex chemistries, such as lithiation, Grignards, nitration, heterocycles and multi-step reaction schemes.

cGMP-RADIOLABELED CLINICAL TRIAL MATERIALS (CTMs)

Clinical pharmaceutical studies conducted using ^{14}C-radiolabeled CTMs result in detailed DMPK, ADME and mass balance information, providing great insight into a drug's behavior in vivo. Few contract research laboratories maintain the radiochemistry expertise and rigorous cGMP-compliant facilities, processes and systems required to produce certified radiolabeled Active Pharmaceutical Ingredients suitable for human clinical trials.

While Chemistry, Manufacturing and Controls requirements for traditional non-labeled clinical trial materials (CTMs) are well understood, successfully incorporating radiolabeled versions of drugs into a development plan requires specialized expertise. EAG

COMPREHENSIVE CUSTOM SYNTHESIS SERVICES

- ^{14}C and ^{3}H Radiolabeling (cGMP and non-GMP)
- Stable isotopes ^{13}C, ^{2}H, ^{15}N
- Novel route design
- Process development, optimization and scale-up
- Chiral resolution, testing and re-purification
- Identification and characterization of unknowns

SMALL MOLECULES AND OLIGOMERS

- Active ingredients (AIs) & active pharmaceutical ingredients (APIs)
- Intermediates, analogs, metabolites
- Analytical standards (with CoA)
- Controlled substances (DEA Schedule I-IV, including opioids)

chemists have decades of experience developing synthetic pathways and determining the optimal position for a radiolabel in a test substance to ensure metabolic stability so that it will be conserved in degradation products in plasma, tissue, and/or excreta. We also have the deep technical expertise to evaluate radiolabeled drugs' stability and impurity profiles—information that is critical to ensure patient safety and the validity of studies.

EAG maintains four Class 10,000 cGMP synthesis suites with 22+ liter capacity each, a dedicated Quality Assurance staff and a group of analytical chemists with years of experience supporting labeled isotope studies. This unique capability complements in-house drug metabolism and impurity ID expertise, and streamlines project management.

IN-HOUSE ANALYTICAL EXPERTISE ENSURES QUICK TURNAROUND OF COAs.

When it comes to understanding the physical structure, chemical properties, composition and behavior of synthesized materials, no other scientific services company offers the breadth of experience, diversity of analytical techniques or technical ingenuity of EAG. This in-house expertise ensures quick turnarounds of purity, structural confirmation and Certificates of Analysis.

We don't just perform testing, we drive commercial success—through thoughtfully designed investigations, technically superior analyses and expert interpretation of data.

The custom synthesis and radiolabeling of chemical materials have a variety of applications: analytical testing, medicinal chemistry, process research and development—even litigation involving intellectual property!

EAG has a strong technical team that gets work done and meets timelines.

REFERENCE STANDARD MANAGEMENT

Superior quality systems and unparalleled analytical expertise

Analytical reference standards fall into the category of things that are easy to forget—until the moment you learn you don't have what you need to start a time-sensitive study. Put EAG Laboratories' superior quality systems and analytical expertise to work for you. We know how to deliver the peace of mind that comes with a centralized, professionally managed reference standard program.

In-house custom synthesis and radiolabeling expertise to efficiently replenish all types of standards, including primary API reference material, internal standards, degradants, metabolites, and impurities — including mutagenic/genotoxic impurity standards.

A validated, GXP-compliant LIMS system including barcoding, established storage and inventory tracking and reporting, shipping to external vendors, and an automated notification system for triggering retest and reorder

Unparalleled characterization and identification expertise, and an arsenal of spectroscopy and other analytical techniques for primary characterization and retest/requalification, and rapid generation of Certificates of Analysis

EAG LABORATORIES | WE KNOW HOW™

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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