Clinical Research Substrates

cGMP Production Capabilities

With increasing requirements from institutional review boards (IRBs) and governmental agencies, partnering with Cambridge Isotope Laboratories, Inc. (CIL) for your next stable isotope cGMP project can help ensure your regulatory compliance. With the world's largest ^{13}C and ^{18}O isotope-separation plants, CIL is able to provide the raw materials necessary for your project. Your compound of interest most likely already appears in CIL's extensive list of research compounds – if not, CIL's team of PhD chemists can determine the best method of synthesis for incorporating ^{13}C, ^{15}N, deuterium, ^{17}O, and/or ^{18}O into your compound.

CIL has manufactured bulk active pharmaceutical ingredients (APIs) since 1994. It recently added a 15,000-square-foot, state-of-the-art cGMP facility to complement its existing cGMP facilities. An additional team of experts – specializing in synthetic chemistry, customer support, quality control, and quality assurance – serves to provide technical guidance from beginning to end of your project.

Partner with CIL to help you meet your increasing regulatory compliance requirements.

"As the leading developer of stable isotope-based biomarkers, it is essential that we have reliable partners providing us with high-quality clinical and cGMP-grade materials. For over 10 years CIL has consistently provided us with high-quality clinical and research-grade stable isotope tracers for the development of our novel kinetic-based tests."

– Scott Turner, PhD
EVP Research and Development, KineMed, Inc.

Manufacturing Capabilities

- Dedicated development facility
- Five production and two isolation suites
- Dedicated packaging room
- Production scale from milligrams to multikilograms
- Clinical trials to bulk API
- Customizable projects to meet your needs

Analytical Services

- Fully equipped analytical facility
- Method development and validation
- Raw material and final product testing
- Wet chemistry and compendial methods
- Stability studies and chambers
- Dedicated cGMP instruments and facility
- Analytical instrumentation:
  - High-field NMR (^{1}H, D, ^{13}C, ^{15}N, multinuclear)
  - HPLC with UV, RI, ELSD, DA, Pickering, and MS detection
  - GC with FID, ECD, and MS detection
  - KF
  - FT-IR
  - Polarimetery
  - TOC

Quality and Compliance

- Drug master files
- FDA-audited facility
- QA release of API product
- Follows FDA and ICH guidances
- CMC sections for NDA or IND

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Products of Interest

- Cholesterol (3,4-$^{13}C_2$)
- Deuterium oxide, 70 atom % D
- D-Glucose ($^{13}C_6$)
- D-Glucose (1-^{13}C)
- D-Glucose (6,6-D_2)
- Glycerol (1,1,2,3,3-D_5)
- L-Leucine ($^{13}C_6$)
- L-Leucine (5,5,5-D_3)
- L-Phenylalanine (1-^{13}C)
- Sodium acetate (1-^{13}C)
- Sodium acetate (1,2-$^{13}C_2$)
- Uracil (2-^{13}C)
- Urea (^{13}C)

Please contact CIL at 1.800.322.1174 or cilsales@isotope.com to inquire about a product not mentioned here, more cGMP services, or to discuss your next project.

One of CIL's state-of-the-art cGMP laboratories.

"We concluded that CIL is the best-positioned company in the world to meet our future expected demands in terms of both material quantity and material quality. As we expand the use of our SILK™-based biomarkers beyond research services and into clinical diagnostic applications, CIL will be an instrumental partner to help us qualify our test kits to produce L-leucine under GMP scaled-up conditions."

– Dr. Joel B. Braunstein, CEO
C2N Diagnostics