



## OnPoint<sup>SM</sup> GMP Radiosynthesis Custom Services

To assure compliance and to help meet aggressive deadlines, PerkinElmer's laboratories offer GMP\* radiosynthesis and analysis appropriate for Phase 1 studies and have participated in the evolution of this important service for the pharmaceutical industry.

When customers develop drugs for human use, the FDA requires that the following ADME studies be conducted as Phase 1 investigations prior to more extensive clinical trials:

- Absorption
- Distribution
- Metabolism
- Excretion

These ADME materials must be manufactured in compliance with escalating Good Manufacturing Practice requirements including:

- Well defined documented procedures

- Adequately controlled equipment
- Accurate and consistently recorded data from production and testing.

Consistent with the stage of clinical development, the intent of these requirements also applies to the radiosynthesis of radioactive drug substances. This has compelled the creative integration of escalating GMP with the many challenges already inherent in radiosynthesis and analysis. Also, because of the time sensitive nature of these expensive human studies, a further demand facing organizations conducting in Phase 1 is the adherence to strict and absolute deadlines.

\* Consistent ICH Q7A, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, August, 2001, Section 19, API's for Use in Clinical Trials. PerkinElmer Life and Analytical Sciences has established a custom radiosynthesis process which provides acceptable GMP compliance and the assurance of quality for early drug studies.

## We are a proven resource for OnPoint GMP custom services including:

### GMP custom services including:

- Protocol Creation (synthetic protocol write-up)
- Custom Synthesis of the radioactive product
- Radiochemical Stability Testing\*
- Special Packaging
- Analytical Services
  - Radiochemical, chemical and chiral purity by HPLC
  - NMR
  - Mass Spectrometry
  - UV-Vis Spectrometry
  - Melting point
  - Thin-layer chromatography
  - Gas Chromatography
  - Radio assays

\* The purpose of radiochemical stability testing is to provide an indication of how the purity of the radiochemical varies with time under the influence of various temperatures during the short period from time of synthesis to investigational use. The study is not intended to establish an expiration date nor does it replace a formal stability study for the drug product.

### Why choose GMP Custom Services from PerkinElmer?

- **Dedicated GMP Custom Synthesis Labs.** Our GMP laboratory suite provides dedicated custom radiochemical synthesis for your unique project in compliance with international GMP guidelines for clinical trial materials. Your synthesis is conducted by GMP trained chemists.

- **Complete documentation.** The synthesis process used for your custom radiochemical is completely documented. You receive a Certificate of Analysis with your product, documenting the methods of analysis and the results vs. your specifications, certified by our Custom Synthesis and Quality Assurance Managers.
- **Project team environment.** We consider our customers part of the project team. You are welcome to visit our site to examine our laboratories, take our virtual tour, or audit the custom synthesis process or review our manufacturing records for your project.
- **Experience and expertise.** PerkinElmer has over 50 years of experience in custom radiosynthesis and radiolabeling. Our scientific expertise is second to none and our custom synthetic chemists are known and recognized by scientists in pharmaceutical companies around the world.
- **Manufacturing excellence.** Quality is built into our culture and everything we do.
- **Guaranteed confidentiality.** We understand the confidential nature of your work. You can be assured our complete confidentiality, with or without a nondisclosure agreement.

Choose PerkinElmer as your partner. You'll benefit from proven experience and expertise. An interaction that reflects an understanding of your unique needs and confidence that the confidentiality, quality, timeliness and GMP compliance you require are absolutely certain for your mission-critical project.

Visit [www.perkinelmer.com/customsynthesis](http://www.perkinelmer.com/customsynthesis) to take a tour of our GMP Suite or to request a quote.

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