

SpectronRx

Theranostics, contract manufacturing and logistics specialists



End-to-end radiopharmaceutical and theranostic solutions for all phases of your drug development & commercialization

As proven experts in monoclonal antibody labeling, with a variety of isotopes, we are a logistics champion of import/export, and a top-tier expert in world procurement of isotopes.

A Proven History of Success

SpectronRx is your experienced early-stage to commercialization contract developer with a global and domestic respected outreach in theranostics. The varied and experienced SpectronRx teams bring you the excellence needed for rapid advancement towards key milestones and increased demand for early phase therapeutic and diagnostic development services.

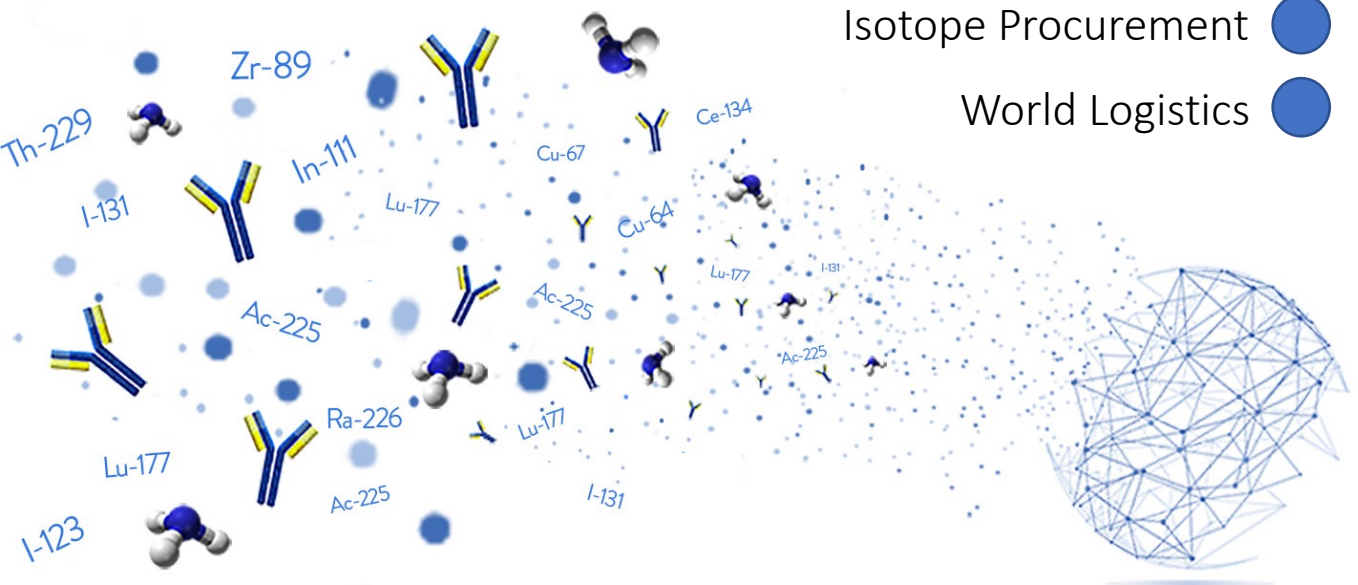
SpectronRx can be your end-to-end solution for ALL critical phases of drug development now or scalable to your budget and timeline.

Monoclonal Antibody Labeling ●

Contract Manufacturing ●

Isotope Procurement ●

World Logistics ●



White Glove Theranostics Services

Choosing a service provider for your delicate theranostic and manufacturing needs is not an easy process. Rest assured that SpectronRx excels in all steps of the drug development process.

We bring you expert end-to-end services throughout your theranostic development lifecycle, from isotope procurement through manufacturing - offering the highest quality in product, services, and staff who prioritize your patient needs.

Regulatory Services | Quality Analytics | World Logistics

Isotope Procurement

- Actinium 225
- Cerium 134
- Copper 64
- Indium 111
- Iodine 131
- Lead 103
- Lutetium 177
- Radium 226
- Zirconium 89

Theranostics Engineering

Not all products are made to order and readily available. Theranostics, and the demand changing as quickly as a decay scheme, requires special tooling and equipment for the task.

CDMO

From bench to patient, no one has more experience in the development and labeling of molecules with a variety of isotopes for the complexity of global logistics, knowing newer ideas bring newer isotopes and demands for change.

CMO

Space/equipment leasing or SpectronRx can manufacture for you. Why spend your capital on excess space and expensive instrumentation if a scalable sharing program can be developed?

End to End Capabilities

The widest array of capabilities in life sciences, we can guide you through the theranostic drug development lifecycle - assisting as much (or as little) as you need. Our experience, competencies and facilities bring you the most capable range of services available.

World Class Team

Our people and facilities are top-tier – not only producing the best theranostics products in the world, but working as a cohesive, well-synchronized team – every day of the year, with every project and customer. Our staff knows we exist to bring hope to the patients we serve.

White Glove Service

Your program receives the highest level of care. When in our hands, you can be sure that your theranostics products (and patients) are well cared for in the highest regard.





Contract Development Manufacturing & Theranostics

We have the solution to your needs. Our services cover a wide breadth and depth of theranostic and contract development manufacturing needs.

We provide end-to-end services to elevate your drug development through all stages and needs, reducing timelines and achieving maximum levels of quality. Our staff brings advanced knowledge and expertise to your program, in addition to compassion for the patients you serve.

Capabilities



Monoclonal Antibody Labeling



Shared full-service GMP Manufacturing



World Logistics



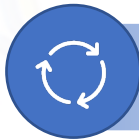
Theranostics Engineering



Isotope Procurement



End-to-End Regulatory Support



Development Services



Drug / Molecule-Specific Analytical Services



Peptides and Nano Development



Hardware Instrumentation Analysis



Quick Facts: SpectronRx Capabilities

SpectronRx Quick Facts:
Our growing facilities and logistics capabilities, led by experienced leadership, specializing in true theranostics.

Facilities

- Indianapolis, 50,000 sf with 14 ISO-7 cleanrooms (growing to 30), and 1 Pharmacy cleanroom
- South Bend, 20,000 sf, with 8 ISO-7 cleanrooms and 1 Pharmacy Cleanroom
- SpectronRx is very flexible with respect to scaling up. Our company is growing rapidly in personnel, manufacturing space, and locations so that we can grow with our clinical trials and provide CMO services for later-phase clinical trials and commercial products. Further details on growth and expansion may be available upon request.

Logistics Capabilities

- International shipments to over 21 countries
- Experience with all aspects of country-specific and DOT paperwork requirements
- 3 SpectronRx facilities within 2.5 hours of international airport (Chicago), the largest airport for Hazmat/RAM handling
- SpectronRx Lifeguard is employed for west coast deliveries counter to the door

Senior Management

- CEO, John Zehner, R.Ph., and President, Anwer Rizvi have a combined 65 years experience with medical isotopes in leadership roles as executives and founders of several leading companies.
- Chief Radiochemist, Dr David Trump, has over 20 years of experience in many roles in nuclear medicine, including research and development, radiolabeling, manufacturing, quality control, oversight and regulatory submissions.
- Beth Kraemer, VP of Quality, Regulatory and Technical Compliance, has been a licensed Nuclear Pharmacist in multiple states for over 30 years. She has broad based experience in multiple disciplines within the radiopharmaceutical industry.

Analytical Services

- SpectronRx provides full QC analytical support for therapeutic radiopharmaceuticals from development, analytical method validation (upon customer request), manufacturing process validation, and routine clinical supply. This support includes stability storage in cGMP storage at any desired temperature from -86 C to +40 C and stability testing at any desired timepoint.
- SpectronRx currently has numerous therapeutic radiopharmaceutical projects, including multiple projects using Ac-225; we have developed deep knowledge and experience with QC for these radiolabeled compounds.

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