One Mission One Campus

Radiopharmaceutical CDMO/CMO Fact Sheet
Contract Development and Manufacturing Organization

NorthStar® MEDICAL RADIOISOTOPES

- Diagnostic
- Therapeutic
- CDMO
- CMO
- Radiopharma Development

NorthStar Medical Radioisotopes is a leading developer and provider of novel, domestic, and environmentally preferred technologies that produce commercial-scale radiopharmaceuticals.

We recognize the need for new technologies to advance development and production of important radiopharmaceuticals that are critical for the treatment of cancer and other serious diseases.

Our patient-focused Radiopharmaceutical Contract Development and Manufacturing Organization (CDMO/CMO) will address this important need.

NorthStar will be the first and only US company to offer co-located, commercial-scale multi-radioisotope production and radiopharmaceutical contract development/manufacturing. This integration offers cost savings to collaborator companies, as well as logistical and regulatory advantages.

*non-carrier added

NorthStar® MEDICAL RADIOISOTOPES

Providing Patients Global Access to Game-Changing Radiopharmaceuticals

www.northstarnm.com

For more updates, follow us on LinkedIn

Why NorthStar?

Our expertise in technical innovation, engineering, manufacturing, quality assurance, regulatory compliance, and logistics provides tailored solutions for each customer's specific needs.

NorthStar provides comprehensive services to support partner companies in the complex process of radiopharmaceutical development and manufacturing while adhering to stringent global therapeutic GMP standards.

NorthStar's CDMO/CMO services cover the entire spectrum of radiopharmaceutical drug development, encompassing research and development, technology transfer, scale-up, commercialization, and adherence to clinical trial and patient use standards.

Benefits of a partnership with NorthStar include the following:

- World-class facility designed and licensed specifically for diagnostic and therapeutic radioisotopes
- Working side by side throughout all phases of your drug development and clinical trial journey
- Co-location of our CDMO/CMO facility, isotope production and processing, and project teams
- Nearly 300 solutions-driven employees with proven experience
- Expert logistics teams with easy access to multiple international airports

Services

- Programs designed for radiopharmaceuticals and radioactive medical devices
- Radionuclide supply: internal production or external procurement
- Alpha, beta, and gamma flexibility and capabilities
- Batch scale-up and process automation
- Test methods, formulation, process development, and optimization
- Technology transfer and integration efficiencies
- Stability assessment and stability program management
- Packaging and labeling development (vials and syringes)
- Fully dedicated logistics team that is available 24/7

52,000 sq ft R&D/CDMO/CMO facility on NorthStar's Beloit, Wisconsin campus

Facilities and Equipment

- 55-acre campus designed with a purpose
- 52,000-sq ft, fully equipped radiopharmaceutical CDMO/CMO facility with immediate expansion opportunities
- Full-service analytical and microbiological laboratories
- Redundancy of equipment, capabilities, personnel, and power
- Research and Development (R&D), preclinical, and early phase development suites
- Phase I, II, and III clinical trial manufacturing
- Flexible current Good Manufacturing Practice (cGMP) suites fully equipped for alpha/beta/gamma
- Clinical unit dose preparation (vials and syringes)
- Type A packaging and DOT-certified shipping with cold chain capabilities
- Dedicated office space on site for sponsor access

Quality Assurance (QA)

- cGMP-compliant (Title 21 CFR Parts 210/211) Quality Management System (QMS)
- Periodic internal audits and sponsor qualifications
- Integrated quality event and complaint handling procedures, including investigation, tracking, trending, and reporting

Regulatory

- Regulatory and administrative services to support Investigational New Drug Application (IND), New Drug Application (NDA), and Drug Master File (DMF)
- Ability to author, publish, and submit sections of the Common Technical Document (CTD)
- EU/JP-capable suite

For more information, visit us at NorthStarnm.com/CDMO-CMO or email cdmo@northstarnm.com