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Why Choose NorthStar Medical Radioisotopes: Strategic Advantages of Outsourcing to a Differentiated Radiopharmaceutical CDMO

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NorthStar®
MEDICAL RADIOISOTOPES

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The Value of a Radiopharmaceutical CDMO

Radiopharmaceutical Contract Development and Manufacturing Organizations (CDMOs) deliver value through rapid project completion, leveraging purpose-built equipment staffed by proven personnel. This value stems from a CDMO's established infrastructure and freedom to initiate projects on demand. Partnering with a CDMO enables a sponsor to quickly and cost-effectively advance its pipeline products into the clinic by gaining immediate access to the CDMO's shared resources and assets. These include the following:

- Built-for-purpose facilities
- Management and personnel with industry/regulatory experience within the nuclear arena
- Appropriate licenses to operate
- Specialized equipment
- Established Quality Management System (QMS) for cGMP compliance
- Proven logistics channels and packaging solutions

CDMOs typically operate on a fee-for-service model, though more complex partnership arrangements can also be established. Partnering with a CDMO provides sponsors access to advanced infrastructure, facilitating seamless project collaborations. Service offerings include, but are not limited to, research and development support, facilitation of technology transfer projects, and clinical or commercial manufacturing.

Partnering with a CDMO also allows for centralized manufacturing, offering advantages such as streamlined communication and regulatory oversight through minimal or single critical touchpoints, ensuring better control over your processes.

Specific Benefits of Working With a Radiopharmaceutical CDMO

Specifically, CDMOs draw on their expertise across a broad spectrum of

1) **Targeting molecules:** These include small molecules, peptides, biologics, and more. Experienced CDMOs possess the capability to execute projects involving all of these, applying specialized knowledge to address the unique considerations of each category
2) **Isotopes:** Including alpha-emitters, beta-emitters, SPECT, PET, and others

Aligning on safety considerations, regulatory standards, and analytical techniques for such a diverse range of molecules and isotopes impacts every aspect of a CDMO's operations. This demands institutional expertise and flexible equipment and processes. Radiopharmaceutical facilities and equipment are highly specialized to meet industry requirements, featuring shielded workstations and hot cells, lead-lined fume hoods, isolators, and biosafety cabinets. Additionally, equipment such as remote telemanipulators, automated synthesizers, and semi-automated dose dispensers ensures the safe handling of radioactive materials and allows for seamless integration and scale-up of batch sizes. Advanced systems for personnel safety, access control, and air/waste management safeguard both the facility and the surrounding environment.

NorthStar Differentiators: One Mission, One Campus

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At NorthStar, our mission is to provide patients with global access to game-changing radiopharmaceuticals. Our CDMO offering encompasses all the value drivers mentioned above, plus key differentiators—most notably our unique "One Mission, One Campus" advantage. Situated on a single 55-acre site in Beloit, WI, **NorthStar offers centralized isotope production and CDMO services on the same campus.** This co-location significantly reduces the variables, risks, and costs commonly associated with transporting and managing the decay of radioisotopes between manufacturers and CDMOs, as the facilities are directly connected with no public roads separating them. On-site isotope production also allows for flexible scheduling and faster turnaround times, with on-demand access to non–carrier-added actinium-225 (n.c.a. Ac-225) and copper-67 (Cu-67) in Beloit.

Our state-of-the-art, 53,000 square-foot radiopharmaceutical CDMO/CMO facility features prebuilt capabilities for both small-scale, early-phase projects and large-scale, automated production. It offers expansive shared spaces for material storage, warehousing, analytical and microbiological testing, and waste management. Additionally, there is built-in expansion space for dedicated projects. The facility mezzanine design enables 24/7 maintenance access and houses all of the functional and operational equipment.

Likewise, NorthStar's large campus has significant room for further CDMO growth, with less than half of the usable space currently occupied. The remaining area is already zoned and approved for future development, allowing for the expansion of isotope and CDMO capabilities.

NorthStar Differentiators: High-Level Experience and Highly Qualified Personnel

NorthStar's staff brings a wealth of industry expertise, with a management team extensively experienced in radiopharmaceuticals and CDMO operations, along with key relationships that can be leveraged for added insights. Working with NorthStar provides access to our in-house experts, whose skills and industry knowledge guide programs throughout the product life cycle. From project kickoff to commercialization, assigned teams ensure continuity by preserving critical knowledge. Close collaboration and resource sharing among the isotope and CDMO teams, including technical and laboratory personnel, further boost efficiency.

Our scientific departments are led at the PhD level and staffed with exceptionally qualified industry experts. The nuclear pharmacy group includes Board Certified Nuclear Pharmacists (BCNP), Certified Nuclear Medicine Technologists (CNMT), and process chemists. The radiochemistry and analytical chemistry group consists of doctorate-level nuclear chemists/

radiochemists, analytical chemists, and other process chemists. The microbiology group features principal and product development microbiologists.

NorthStar's Radiopharmaceutical CDMO facility, located in Beloit, WI

NorthStar Differentiators: Quality and Regulatory Units

NorthStar's established Quality Management System (QMS) is purpose-built for Title 21 CFR Parts 210/211 and 21 CFR Part 11 Compliance Guidelines, ensuring data integrity and compliance. Our electronic QMS streamlines collaborations and investigations.

NorthStar personnel have extensive experience with U.S. Food and Drug Administration (FDA) and third-party audits, including GMP inspections for commercial generator products and sponsor audits for isotope supply and CDMO operations.

Our dedicated Regulatory team adheres to global regulations established by agencies such as FDA, International Council for Harmonization (ICH), and European Medicines Agency-European Union (EMA). The experienced team can provide multiple levels of services including the following:

- Preparing FDA meeting requests and requisite briefing packages
- Creation of Chemistry Manufacturing & Controls (CMC) documentation for Drug Master File (DMF), Investigational New Drug Application (IND), New Drug Application (NDA), or Abbreviated New Drug Application (ANDA) submission
- Ability to author CMC sections of the Common Technical Document (CTD) as required

NorthStar Differentiators: Research and Development Capability

While NorthStar's central campus in Beloit is home to isotope production and CDMO facilities, research and development (R&D) capabilities are distributed across multiple locations. In Beloit, our CDMO facility houses a dedicated R&D suite with production and analytical capabilities. Further north in Madison, WI, our Femrite Drive facility conducts Good Laboratory Practices (GLP) development and optimization studies. The site includes shielded workstations for radiolabeling, with teams of scientists focused on analytical method development, formulation optimization, and stability studies. The Femrite team consists of nuclear pharmacists, chemists, and project managers.

NorthStar Differentiators: Logistics

NorthStar's veteran logistics team excels at managing just-in-time deliveries. We utilize specialized containers, known as Type A packages, equipped with cold chain and GPS capabilities, that meet regulatory standards for the safe transport of hazardous materials on behalf of our customers. Our purpose-built facilities feature dedicated preparation areas and secure spaces to ensure all appropriate procedures are precisely followed. Leveraging strong relationships, we work with a network of specialized couriers providing white-glove service, ensuring that life-saving radiopharmaceuticals are transported securely from our campus to a patient's bedside.

Concluding Statement

The growing radiopharmaceutical industry relies on innovation from drug developers to provide the next generation of cancer diagnostics and therapies. Radiopharmaceutical CDMOs play a critical role in enabling supply of these game-changing treatments by assisting in further development and providing ready-to-use solutions for manufacturing and distribution of the finished product. NorthStar is committed to providing high quality, reliable, and scalable solutions to meet this growing demand. **Our mission is clear: providing patients global access to game-changing radiopharmaceuticals.**