Job Title: **Production Systems Engineer / Senior Production Systems Engineer – Radioisotope Processing**

SUMMARY

NorthStar's mission is to transform the medical radioisotopes industry by becoming a global leader of innovative diagnostic & therapeutic medical radioisotopes. In fulfillment of this mission, NorthStar continues to develop groundbreaking isotope processing methods.

The Production Systems Engineer II is a leader in the development, implementation, qualification, and commissioning of a novel radioisotope processing system within the Particle Accelerator Engineering Team. This position will be responsible for leading the design, planning, and execution throughout the product life cycle of novel radioisotope processing systems that will allow radiologic material created within a particle accelerator to be transported to the NorthStar's manufacturing facilities. This includes gathering, defining, and prioritizing customer requirements/specifications related to the operation, qualification, and maintenance of systems which can be efficiently transitioned into manufacturing. The successful candidate will possess a demonstrated ability to both design and integrate mechanical, electrical, pneumatic, and automated systems and must be familiar with systems engineering and manufacturing processes within a medical device/pharmaceutical industry.

This person is also responsible for working with cross functional teams, including RA/QA, Chemical Engineering, and Production to apply efficient cGMP processes which preserve data integrity and the quality of the drug product, including the safety of all production and non-production personnel. The Production Systems Engineer II is critical to the company's continued success and growth by providing technical leadership with regards to radioisotope system design, with increasing levels of productivity and safety.

This position will include a strong focus on system design involving radioactive material shielding, in accordance with all Health Physics requirements.

The Production Systems Engineer II is also responsible for assisting with the development and implementation of NorthStar Medical Radioisotopes quality system processes which meet the requirements of applicable FDA regulations. All projects and duties will be completed in compliance with the applicable cGMP, FDA, and all other regulatory agencies standards.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following, other duties may be assigned:

11. Develop, plan, implement, and support radioisotope processing based projects and solutions in collaboration with cross-functional teams, including determination and delivery on cost, time, and quality to ensure the sustained production with an overall focus on productivity and safety. The projects may be within new facilities and/or retrofit of existing.
12. Create and modify complex product assemblies based on product manufacturing needs & test and production tooling factors.
13. Work with a variety of vendors to develop high quality and cost effective product designs.
14. Lead the Design, Revision, and Commissioning of radioisotope processing systems.
15. Assist with mechanical systems design including "best practice" radioactive material shielding techniques.
16. Lead the development, prioritization, and documentation of comprehensive user requirement specifications.
17. Collaborate with internal and external stakeholders and suppliers to design, purchase, and build equipment and processes that meet associated user, design, production, and safety requirements.
18. Specify new equipment, implement solutions based on requirements, and assist with the creation of fixtures to support production processes, in accordance to cGMP regulations.

19. Assist with the development and optimization of system workflows as related to manual and electronic data collection and production flows.
20. Assist with the development of processes and associated documentation related to system calibration, preventive maintenance, and repair of production systems.
21. Assist with the development and execution of product and system verification and validation strategies.
22. Assist with the development of Risk Management Plans and executing the Risk Management activities defined by the plan which would include Use/Misuse FMEA's, DFMEA's, PFMEA, and other risk management tools.
23. Predict, analyze, and implement system improvements based on production demands, as related to product quality, identity, strength, purity, takt times, and overall system throughput requirements.
24. Anticipate and mitigate risk points. Make tradeoffs between design complexity, time and effort, schedule, cost, and quality while meeting safety and regulatory requirements.
25. Interpret detailed engineering CAD, PID, and system schematic drawings.
26. Continuously adapt to an ever-changing regulatory environment such that the Company is in compliance with current regulations. Make adjustments to work plans accordingly.
27. Effectively communicate safety and quality issues raised by customers or staff in a timely fashion.
28. Support NorthStar's Quality System and Health and Safety Programs by following procedures and implementing the respective rigor into production based system design and implementation.

Ability and willingness to travel, both domestically and internationally, up to 10% of the time.

QUALIFICATIONS
To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION and/or EXPERIENCE
The level of this position will be set commensurate with experience.

Minimum Qualifications

25) Bachelor's degree in Engineering and relevant technical experience in a medical or pharmaceutical manufacturing environment; or an equivalent combination of education and experience.

26) Experience within a production engineering environment in the specification, development and qualification of analytical and production based systems and equipment.
27) Experience in requirements gathering and definition processes and tools.
28) Experience with system requirements decomposition/system architecture design.
29) Knowledge of 3D modeling techniques of complex assemblies
30) Knowledge and skill in relation to the operation of scientific equipment.
31) Knowledge of Product Development Life Cycle ranging from product specification and concept development to product release.
32) Understanding of the relation between production systems and the environment, in relation to the use of limited resources, production capabilities and sustainability.
33) Must possess knowledge of engineering disciplines and solid knowledge of related disciplines, Electro/Mechanical, Systems, Fluid Mechanics, Software and Materials Science.
34) Ability and willingness to travel domestically occasionally, including possible visits to Argonne and Los Alamos labs. Minor international travel will be required. During install, commissioning, and qualification, daily presence in Beloit will be required.
35) Demonstrated ability to work within a multidisciplinary team.

Preferable qualifications

1) Experience in the development and execution of verification and validation strategies in a regulated environment.
2) Understanding of medical device risk management processes and tools including risk management planning, Use Misuse FMEA, DFMEA, PFMEA.
3) Experience with liquid/solution distribution/filling, automation, and conveyance systems.

4) Experience with medical/pharmaceutical design and development and/or FDA/cGMP compliance.
5) Experience with radioactive material processing.

COMPUTER SKILLS

Proficient knowledge of office software programs including project planning, Outlook, Word, Excel, and Visio.

OTHER QUALIFICATIONS

- Excellent communication skills, verbal and written
- Analytical thinker with interpersonal skills
- Ability to lead and function within project teams
- Ability to handle multiple projects simultaneously
- Ability to work in a fast-paced environment
- Adaptable to change in the work environment
- Ability to work in a team environment, as well as independently