

## **Sr Process Chemist -Manufacturing, Science & Technology (MS&T)**

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Job ID  
322131BR  
Jun 25, 2021  
USA

### **Job Description**

769 million. That's how many lives are touched by Novartis products globally.

The Sr. Process Chemist owns the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving. Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s).

Your responsibilities include, but are not limited to:

- Maintain the oversight and knowledge for entire manufacturing process performed on site throughout the entire commercial lifecycle, act as SPOC.
- Responsible for ensuring the continued state of validation (process, cleaning, ongoing verification etc.). Create Process Validation protocols and generate reports.
- Monitor critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Lead/support root cause investigation of process failures, initiate and lead product improvement projects, involving cross-functional teams.
- Assess impact of technical changes, assess their technical feasibility and determine scope / design of technical batches, challenge technical risk and business benefit of technical changes proposed.
- Operation of the MS&T Laboratory.
- Ensure an appropriate process control strategy based on CQA and where necessary on CPP, CMA is in place, support improving the control strategy where applicable.
- Provide SME expertise to perform process characterization of pharmaceutical processes to increase robustness and sustainability.

<https://www.youtube.com/watch?v=IhJ9KXNWhEI>

### **Diversity & Inclusion / EEO**

*The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash*

*their full potential.*

## **Minimum Requirements**

What you'll bring to the role:

- BSc. in Radiochemistry, Chemistry, Pharmaceutical Technology, or equivalent scientific degree. MSc., or PhD a plus.
- Experience in Radioactive Parenteral Products manufacturing
- 8 years' experience in process support, e.g. Process Expert role on the shop floor of pharmaceutical manufacturing and/or QA/QC
- Proven process understanding (Pharma, GMP, Validation and Regulatory aspects)
- Strong understanding of risk assessment and risk management fundamentals/tools
- Excellent problem solving and decision-making skills
- Sound experience of data handling and applied statistics and strong in defining and implementing productivity improvement measures

You'll receive:

Competitive salary, annual bonus, long term incentive (LTI) for select levels, health insurance, paid vacation/holidays, potential flexible working arrangements and employee recognition scheme.

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Division

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Business Unit

ADVANCED ACCELERATOR APPLICATIONS

Location

USA

Site

Indianapolis, IN

Company / Legal Entity

AAA USA Inc.

Functional Area

Technical Operations

Job Type

Full Time

Employment Type

Regular

Shift Work

No

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