

# Process Expert - Comecer Lines

Job ID  
REQ-10025733  
Oct 11, 2024  
USA

## About the Role

Major accountabilities:

- Responsibilities include but not are limited to:
- Support a culture of safety, quality, diversity, and inclusion.
- Provide front line support to manufacturing shifts to ensure safe, quality, and timely completion of product batches.
- Manage and maintain manufacturing documentation including Master Batch Record, applicable SOPs, risk assessments, protocols, and other documentation as needed.
- Track and trend critical process parameters and in process checks as part of ongoing process verification (OPV) and identify CAPAs to address any trends.
- Identify, assess, and own technical changes through GMP change control processes.
- Investigate deviations and determine root causes and identify CAPA.
- Act as Subject Matter Expert (SME) for process flow and support data gathering for Annual Product Review.
- Ensure processes are inspection ready at all times.
- Support continuous improvement through identification of opportunities, technologies, and owning changes to implement improvements.
- Support on going self learning and ensuring training is up to date.
- Provide support to production team through training and knowledge sharing.

Minimum Requirements:

- Bachelor's degree in Engineering, Pharmacy, Pharmaceutical Technology, Chemistry or other science related fields or equivalent experience.
- 1+ years of experience in a manufacturing environment, preferably in pharmaceutical manufacturing
- Direct experience in a GMP or aseptic/sterile environment is highly desired.
- Radio pharma experience is a plus
- Word, Excel, Powerpoint, and Teams Experience
- Ability to work in a cross functional team
- Technical writing experience preferred
- Excellent communication skills
- English fluently, verbally and in writing

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

Indianapolis

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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