NOVARTIS

# Process Expert (MS&T)

Job ID
REQ-10050270
Απρ 30, 2025
USA

## Περίληψη

At Advanced Accelerator Applications, a Novartis company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy to cancer patients. We are looking for experienced Manufacturing professionals to help us reach our ambitious goals.

The Process Expert will provide front line technical and scientific expert support for all process-specific issues to ensure execution of processes on-time (business continuity), in compliance to cGMPs, SOPs and applicable guidelines and functional standards (e.g, HSE) and to allow continuously improving in quality, productivity efficiency.

## About the Role

**Major accountabilities:**

**Operational Activities:**

· Provide front line expert support for all process-specific issues to production

· Act as Subject Matter Expert (SME) for the product and process

· Support manufacturing to ensure the completion of all production operations on time, in accordance with the documentation and in compliance with GMP, SSE and 5S rules

· Ensure real time shop floor support as an expert on technical problems and ensuring that appropriate immediate corrective/remediation actions are implemented.

· Perform real time batches follow-up and batch records technical review

· Ensure that all production documents are systematically up to date and that the production documents necessary for the validation / revalidation of processes are available

· Execute validations when/where needed

· Manage the preparation and execution of changeover activities between campaigns by ensuring availability of equipment, consumables, raw materials, documentation and providing Change Over training to technicians

· Transfer of information and increase awareness of production teams following problems or modifications having a technical, quality or HSE impact

· Develop technical and scientific knowledge of shop floor technicians

· Conduct training to ensure process knowledge for operators

· Support the T&L organization in defining and maintaining appropriate qualification criteria for in-scope areas of expertise

· Support the T&L organization in defining and maintaining training to support associates achieving qualifications

· Deliver instructor-led training for areas of in-scope expertise

· Promote Quality and HSE culture on the shop floor

**Compliance Activities:**

· Ensure timely treatment of deviations, complaints, OOE, OOS, and the implementation of effective CAPs within the agreed timelines.

· Lead thorough Root Cause Investigation process using investigation tools and methodology.

· Support Validation Experts and Product Stewart with process deviations

· Ensure that all process changes in assigned products are managed through appropriate change control procedure

· Support Validation Experts and Product Stewart regarding the definition of the validation strategy

· Prepare, support and follow-up of Health authority and internal inspections

· Support Regulatory Compliance QA for dossier submissions, revisions...

· Ensure the management of all validation, revalidation / qualification / Annual Monitoring Batch (AMB) respecting deadlines and current regulations

· Support Product Stewart in setting up and monitoring trends within the framework of the CPV (Continued Process Verification) and corresponding actions

· Provide input to APQR and OPV for analysis and for driving process technology Innovations

· Ensure implementation and maintenance of the quality systems with the site in accordance with corporate and regulatory guidelines

· Ensure consistent interpretation and implementation of QMs and GOPs on local site level

· Provide compliance oversight for GMP on site

· Monitor quality systems, provide trend reports for customer and management use

· Responsible for the GMP documentation of the manufacturing unit

· Responsible for creating and maintaining the master manufacturing documents of assigned products

· Ensure timely and routinely reporting of trending and evaluation reports

· Provide, support and oversight of all site activities related to 3rd parties, keep oversight of contractors, suppliers and service providers

· Act as point of contact for platform and NTO compliance, support global initiatives as assigned, represent site at global

· Ensure quality oversight of all qualification and validation activities (i.e. instrument and equipment qualification, CSV and local e-compliance)

· Provide risk / gap assessments, determine effectiveness of related remediation actions

· Drive the site collection, monitoring, evaluation and reporting of the site Quality KPIs

**Operational Excellence & Continuous Improvement Activities:**

· Lead continuous improvements projects in collaboration with Product Stewart and in compliance with cGMPs, SOPs, applicable guidelines

· Participate in continuous improvement and productivity projects

· Provide support to teams for the implementation of improvements, actions 5S, the exploitation of production data and the implementation of controls charts

· Actively participate in the development of production staff in the continuous improvement process

· Provide operational support to teams during technology transfers

· Ensure the management of the various projects: coordinate the stages defined in the projects and ensure timely completion and compliance with cGMPs and HSE

· Conduct risk analysis, ensure the drafting of documents production and validation on time, ensuring the management of activities related to any modification of existing facilities in collaboration with stakeholders, in the case of transfer of a new process or major modifications to existing processes

· Define the technical needs to achieve the strategic objectives of the production and prepare, in cooperation with engineering, the feasibility study as well as the corresponding budget

· Author technical documents defined in the projects

· Support Engineering in URS for new equipment/investments in general

· Actively participate in the definition and writing of technical specifications

**Quality & HSE Activities:**

· Promote and improve the Quality culture in collaboration with Quality Assurance.

· Collaborate with Quality Assurance in the improvement of Quality by initiating, organizing and checking the practical application on the shop floor

· Ensure overall inspection readiness for area of responsibility

· Be responsible for the compliance to the principles and practices described in the "Novartis Manufacturing Manual" and their implementation on the site for his area

· By delegation of the Manufacturing Unit Head may be required to take decisions and take the necessary actions, in particular within the framework of the on-call management system

· Participate to, in collaboration with the HSE Lead, the upgrade and improvement of the HSE by checking the practical application in his team

· Promote and improve the HSE culture, by implementing the necessary systems and actions in line with the evolution of the site

The pay range for this position at commencement of employment is expected to be between $77,000 to $143,000/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

**Minimum Requirements:**

· BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology.

· 2+ years of relevant experience in GMP environment.

· Previous pharmaceutical experience.

· Thorough understanding of manufacturing processes and related process equipment.

· Experience in writing technical documents.

· Experience in executing validation documents.

· Radiopharmacy experience is preferred.

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