NOVARTIS

# Senior Technical Manager Drug Substance

Job ID
REQ-10074092
мар 27, 2026
Польша

### Сводка

As a product technology expert, responsible within the External Supplier Relation-ship team for the management of products throughout their lifecycle, oversight of processes by data trending and statistical analysis of critical parameters, and for ensuring product robustness, proper validation status, and continuous process improvement.

### About the Role

#LI – Hybrid

Location: Poland

**Major accountabilities:**

- Maintains oversight of processes for the assigned product in a specific contract manufacturing organization (e.g. from raw materials to packaging) and maintains the knowledge and the history of the products throughout the commercial lifecycle, since transfer from development to the present moment.
- Liaises with the global/X-CMO product steward at the global level, acting as a representative of MS&T within the relevant supplier relationship teams. Closely cooperates with ESO functions (Quality Assurance, Site Change Coordinator, SCM, etc.), and establishes relations with CMOs with special focus to ensure and improve product process capability, to keep up to date the knowledge of the process and to maintain the product in a constant state of validation.
- Controls and ensures the maintenance of technical documentation, e.g. process transfer protocols/reports, comparability protocol/reports. Authoring/reviewing relative source documents for dossier, HA query and other RA tasks. Participate in deviation investigation, lead complex investigations.
- Ensure that product and process-related issues identified in the OPV / APQR process with CAPA assigned are remediated with clear interfaces with Quality, AS&T, Operations, Engineering and Technical Development (as needed). Science and risk-based approaches, to ensure that product quality can be sustainably reproduced once transferred into the CMO site. Decision to transfer to CMO based on technical evaluation at transferring and receiving organization and aligned with strategy. Monitoring routine manufacturing performance following transfer to CMO
- Participation in the CRB and in escalation meeting to represent the technical evaluations of the proposed changes and deviations. Tracking the parameters for continuous process verification received from CMOs. Monitors all critical variables and key variables as required for the assigned products (critical process parameters, in-process control parameters, quality attributes, characteristics of raw materials, etc.) by means of statistical analysis and by performing regular data trending for specific products.
- Understanding and management of data trending and statistical analysis for the following purposes: Deepening and broadening process understanding and knowledge. Detecting issues related to process capability, e.g. systematic quality defects. Identifying trends of process deviations (e.g. deviation with a common root cause). Issuing/approving quarterly/annual data trending reports. Ensures data and trend sharing within the Supplier Relationship teams, and coordination of resolutions with CMOs. Through appropriate documentation and support to the product receiving/transferring site, provides the necessary data for the technical activities involved in the product transfer, while focusing on the existing knowledge. Initiates investigations and improvement projects (quality, efficacy) based on data analysis, engaging cross-functional teams.
- Actively participates in and represents their products in the relevant committee (e.g. Product Stewardship Committee) when improvements of non-conformable products are planned, priorities are set, and improvements are monitored. Ensures that technical batches provide sufficient process knowledge by thoroughly testing critical variables; uses the data obtained to verify critical process parameters. Provides all the information needed for validation documentation.
- Supports the validation lead and experts in assessing the need and planning validations / re-validations / verifications / annual batch monitoring, consulting, approving and reviewing the process validation master plan in cooperation with the above. Approves validation protocols and reports. Ensures harmonization of (regulatory) timelines for technical changes (e.g. for drug substances), transfers or launches, major deviations. Reviews the PQR data and ensures proper discussion about it. Provides the necessary support in internal and external audits.

**Minimum Requirements:**

- Bachelor’s degree in science or pharma or equivalent
- Minimum 15+ years of experience in biotechnology industry preferably in large molecule, C&GT domain
- Strong experience in process/product expertise and good understanding of regulated systems, concurrent validations and guidelines, technically astute and can communicate business needs to stakeholders
- Demonstrated skills in trouble shooting of systems, with working knowledge of incident and problem management processes
- Strong team player in global matrix team organization with an ability to confidently manage both pharma and non-pharma professionals
- Ability to work independently under time and pressure constraints, demonstrated ability to be proactive and flexible
- Strong communication and interpersonal skills and acute attention to detail
- Excellent English language

**Desirable Requirements:**

- Quick learner with the ability to develop an in-depth knowledge of healthcare provider regulation requirements
- Ability to manage change effectively always mindful of business processes, and system implications

**Rewards**

At Novartis, we’re committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role:

· Poland: 195 700,00 zł - 363 400,00 zł

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

You may be eligible for a company vehicle or a car allowance in accordance with the applicable local Novartis policies and guidelines.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics. Read our brochure to learn more about our global total rewards offering: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Note: Benefits and compensation may vary by country and are subject to local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process.

**Commitment to Diversity and Inclusion / EEO paragraph:**

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

**Benefits and Rewards:** Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Primary location salary range
zł195,700.00 - zł363,400.00
Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Польша
Сайт
Warsaw
Company / Legal Entity
PL03 (FCRS = PL003) Novartis Poland Sp. z o.o.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No

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