

# **Associate Director, Clinical Manufacturing Operations (f/m/d)** **/ Vodja operacij klinične proizvodnje (ž/m/d)**

Job ID  
REQ-10018918  
Oct 04, 2024  
Slovenia

## **Summary**

~Dies ist eine universelle Stellenbeschreibung, die einige der primären Aufgaben dieser Rolle erfassen soll, die in allen Funktionen oder Abteilungen üblich sind. Es ist nicht beabsichtigt, alle spezifischen Verantwortlichkeiten der Position abzubilden~Management Track

Leitung und Management des Teams für Engineering-, Logistik- und Sicherheitsexperten in das lokale Versorgungszentrum, um die Lieferung von Zwischenprodukten und Arzneimittelsubstanz, die Einhaltung interner und externer

Regulierungs- und Qualitätsstandards (GMP und HSE) und Budgetziele.

Verantwortlich für Instandhaltungs- und Investitionsbudgets und langfristige Investitionsplan für DSS.

TRD-Beauftragter für Ingenieurwissenschaften für das Rheintal.~Wissenschaftlicher / technischer Track

Hat die operative End-to-End-Verantwortung für zugewiesene Versorgungsaktivitäten. Leitet und managt komplexe und anspruchsvolle Projekte und globale Netzwerkaktivitäten und beteiligt sich an funktionsübergreifenden Teams. Verantwortlich für Initiativen zur Leistungsverbesserung.~Produziert, verpackt und produziert Medikamente, die in klinischen Studien verwendet werden. Verantwortlich für den Vertrieb, die Lagerung, den Transport, die Verpackung, die Randomisierung, die Verblindung und die Kennzeichnung von Material für klinische Studien in Übereinstimmung mit den Richtlinien der Internationalen Konferenz zur Harmonisierung der technischen Anforderungen für die Registrierung von Humanarzneimitteln (ICH), der Guten Klinischen Praxis (GCP) und der Guten Herstellungspraxis (GMP).~Überwachung der klinischen Versorgung auf der Ebene ganzheitlicher globaler Studien, proaktive Verhandlung und Kommunikation der klinischen Versorgung Plan/Timeline für interne und externe Kunden und Partner.

## **About the Role**

### **Responsibilities:**

- Responsible for setting and fulfilling the department's objectives, in close collaboration with Drug Substance (DS) and Drug Product (DP) Clinical Manufacturing Units
- Leadership and control of manufacturing operations activities to ensure their quality, timeliness and compliance with the production plans
- Management of the aligned ancillary production support processes and support of process technology for Drug Substance and Drug Product manufacturing
- Support on the introduction of new technologies and techniques, and process optimization
- Coordination of work within the department, setting priorities, and ensuring fulfillment of the department's objectives including the management of resources, responsibility for human resource development, and provision of expertise
- Takes a holistic view, recognizing the interdependencies and interactions between different operational areas and departments from GMP and Development

### **Requirements:**

- University degree in Biotechnology, Pharmacy or related science (advanced degree in scientific or relevant discipline or equivalent preferred).
- 5+ years relevant production experience in the pharmaceutical industry (Aseptic GMP and/or Technical Development), with at least 2 years of managing teams.
- Detailed knowledge of GMP requirements and its applications, industry HSE processes and procedures and a good understanding of risk management and the use of it.
- Good understanding of Development processes of NBEs and MCEs and the relevant interfaces for transfer to Clinical

Manufacturing.

- Applications of Lean Manufacturing principles.
- Very good understanding of production equipment and infrastructure; ability to evaluate business opportunities and/or remediate risks jointly with relevant teams.
- Knowledge of (micro-)biology and biotechnology principles.
- Good understanding of material and sample management systems (e.g. SAP, LIMS).
- Knowledge of facility design (e.g. HVAC, cleanliness zoning), cleanroom gowning, personnel and material flows, clean utilities, product change-over (cleaning validation) and EM sampling.
- Excellent project management skills, good communication skills, and a problem-solving mindset with a proactive approach to finding solutions.
- Fluent in written and oral English.

### Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

### You'll receive:

Competitive salary, Annual bonus, Flexible working schedule, possibility to work from home, Pension scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical, mental and social well-being, Unlimited learning and development opportunities.

### Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

### Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

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### Vodja operacij klinične proizvodnje (m/ž/d)

Kot **Vodja operacij klinične proizvodnje (m/ž/d)** se boste pridružili našemu operativnemu oddelku Klinične proizvodnje v Biokampu. Odgovorni boste za vodenje in nadzor, da proizvodni procesi ustrezajo zahtevam. Delovali boste kot podpora proizvodnji, postali boste del HSE, T&L itd. Del vaših nalog bo tudi razvoj in vzpostavljanje operacij in procesov v oddelku s tesnim prilagajanjem skladnosti klinične proizvodnje.

### Vaše ključne odgovornosti:

- Odgovorni boste za vzpostavljanje in izpolnjevanje ciljev oddelka, z tesnim sodelovanjem z drugimi oddelki (Drug Product in Drug Substance).
- Vodenje in nadzor operacij proizvodnje, da bi zagotovili kakovostno, pravočasno in skladno delovanje s cilji proizvodnje.
- Vodenje in usklajevanje sorodnih proizvodenj, ki med seboj sodelujejo, za podporo procesom proizvodnje v oddelkih Drug Product in Drug Substance.
- Podpora in pomoč pri uvajanju novih tehnologij in tehnik, odgovorni boste za optimizacijo procesov.
- Koordinacija dela znotraj oddelka, postavljanje prioritet, zagotavljanje doseganja zastavljenih ciljev, vodenje resursov in zagotavljanje razvoja človeških virov.
- Vaša naloga bo tudi zagotavljanje, da imate celoten in celosten pogled na delo, da prepoznate nuje in potrebe svojega oddelka in med različnimi operativnimi področji.

### Vaš doprinos k delovnem mestu:

- Visokošolska stopnja izobrazbe iz smeri Biotehnologije, Farmacije ali podobne ustrezne smeri.
- Minimalno 5 let izkušenj na področju proizvodnih procesov v farmacevtski industriji in vsaj 2 leti na vodilnih položajih.
- Odlično poznavanje GMP regulativ, HSE in razumevanje procesov s področja upravljanja tveganj.
- Dobro poznavanje razvojnih procesov in infrastructure, sposobnost prepoznavanja poslovnih priložnosti in prepoznati tveganja.
- Poznavanje sistemov za vodenje materialov in vzorcev (SAP, LIMS).

- Odlično poznavanje procesov načrtovanja objektov (HVAC), poznavanje pravil za oblačenje v proizvodnji, vodenje osebja in materialov.
- Odlične sposobnosti vodenja projektov, dobre komunikacijske veščine in motiviranost za reševanje težav.
- Aktivno znanje angleškega jezika.

Prijave z življenjepisom v angleškem in slovenskem jeziku lahko oddate preko spletne povezave.

### **Zakaj Novartis?**

Naš namen je soustvarjati medicino za izboljšanje in podaljševanje življenja ljudi, naša vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dosežemo? S pomočjo naših ljudi. Prav naši sodelavci nas vsak dan spodbujajo, da dosežemo svoje ambicije. Postanite del te misije in se nam pridružite! Več na spodnji povezavi:

<https://www.novartis.com/about/strategy/people-and-culture>

### **Kaj nudimo:**

Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, pokojninsko shemo, shemo nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in družbenega počutja (Polni življenja) ter dogodke, neomejene priložnosti za učenje in razvoj.

### **Predani smo raznolikosti in vključenosti**

Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

**Pridružite se naši mreži Novartis:** V kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpišete na spodnji povezavi v Novartisovo bazo talentov saj lahko tako vašo vlogo upoštevamo za podobne pozicije v prihodnosti:

<https://talentnetwork.novartis.com/network>

**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>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally:

<https://www.novartis.com/careers/benefits-rewards>

Division

Development

Business Unit

Innovative Medicines

Location

Slovenia

Site

Ljubljana

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Alternative Location 1

Mengeš, Slovenia

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regulär

Shift Work

No

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