

# Vodja upravljanja kakovosti - skladnost (m/ž/d) / Site QA Compliance Lead (m/f/d)

Job ID

REQ-10029913

nov 18, 2024

République de Slovénie

## Résumé

#LI-Hybrid

Na naši lokaciji v Ljubljani vzpostavljamo nov proizvodni obrat za aseptične izdelke, opremljen z najsodobnejšo tehnologijo. Iščemo visoko motivirano in strokovno osebo, ki bi vodila ekipo za skladnost kakovosti.

Pričakujemo komunikativne ljudi, ki so usmerjeni v timsko delo, doseganje rezultatov in reševanje problemov. V kolikor ste pripravljeni sprejeti nove izzive, mentorirati mlade talente in si prizadevati za širjenje svojega znanja, bomo veseli vaše prijave.

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We are establishing a new Aseptic Production Facility equipped with cutting-edge technology at our Ljubljana site. We are looking for highly motivated professional to lead the Quality Compliance team.

We expect communicative people who are oriented towards teamwork, achieving results and problem solving. If you are ready to take on new challenges, mentor emerging talents and strive to expand your knowledge, we would love to see your application.

## About the Role

### Vaše ključne odgovornosti:

- Zagotavljanje skladnosti proizvodnje in laboratorija z GxP standardi ter izvajanje dejavnosti v skladu z vsemi relevantnimi zakonskimi zahtevami in standardi podjetja Novartis.
- Implementacijo sistema za upravljanje kakovosti in nadzor nad skladnostjo na celotni lokaciji.
- Učinkovito obvladovanje incidentov, regulatornih pregledov, GMP revizij in izjem v skladu s standardi podjetja Novartis.
- Odgovornost za razvoj talentov, uspešnost, optimizacijo procesov ter nadzor proračuna, s ciljem podpirati ambicije oddelka ter zagotoviti razvoj in pridobivanje potrebnih veščin pri zaposlenih.
- Proaktivna vključenost v strateške dejavnosti, projekte in odločitve, ki zagotavljajo najnovejšo proizvodno in testno opremo ter postopke.
- Nudjenje podpore organizaciji za izobraževanje in zagotavljanje, da so sodelavci usposobljeni za opravljanje nalog v skladu s predpisi o dobri proizvodni praksi pred samostojnim delovanjem.

## **Vaš doprinos k delovnem mestu:**

- Izobrazba farmacevtske, kemijske ali mikrobiološke smeri.
- Minimalno 5 let delovnih izkušenj v farmacevtski industriji (aseptika), na področju kakovosti, razvoja ali proizvodnje.
- Dokazana uspešnost pri upravljanju inšpekcij.
- Prednost predstavljajo delovne izkušnje na področju medicinskih pripomočkov ter izkušnje z vodenjem.
- Aktivno znanje angleškega jezika.

Ponujamo zaposlitev za nedoločen čas s 6-mesečno poskusno dobo. Vljudno vabljeni, da oddate svojo prijavo in življenjepis v slovenskem in angleškem jeziku.

## **Kaj nudimo:**

Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, zaposlitev v podjetju s certifikatom TOP Employer, 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.

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## **Key Responsibilities:**

- Ensure production and laboratory's GxP compliance and execution of activities in accordance with all relevant legislation requirements and Novartis standards.
- Guarantee the implementation of Quality Management System and the oversight of compliance across the site.
- Ensure an effective management of incidents, regulatory inspection, GMP audits and exceptions according to the Novartis standards.
- Responsibility for talent development, performance, process optimization and budget control to ensure that team capabilities will support site ambitions and that people will develop the required skills.
- Be proactively engaged in strategic activities, projects, decision, assuring state of the art manufacturing and testing equipment and processes.
- Support the training and learning organization by ensuring associates are qualified for a Good Manufacturing Practice task prior to independent performance.

## **Essential Requirements:**

- Education in the field of pharmacy, chemistry or microbiology.
- Minimum 5 years of professional experience in a pharmaceutical industry (aseptic products) in one or more of the following areas: Quality, Production, Regulatory or MS&T.
- Proven performance in management of Health Authority inspections.
- Advantage is work experience in the field of medical device and previous experience in managing team of associates.
- Active knowledge of the English language.

We offer permanent employment, with 6 months of probation period. You are kindly invited to submit your

application and CV in English language.

**You'll receive:**

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, 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 (Wellbeing), employment at Top SI Employer, Unlimited learning and development opportunities.

**Commitment to Diversity and 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>

**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

Operations

Business Unit

Innovative Medicines

Emplacement

République de Slovénie

Site

Ljubljana

Company / Legal Entity

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

Functional Area

Qualité

Job Type

Full time

Employment Type

Regular

Shift Work

No

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**Accessibility and accommodation**

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to

[diversity.inclusion\\_slo@novartis.com](mailto:diversity.inclusion_slo@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

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