

# Inženir zagonov in kvalifikacij (m/ž/d) / C&Q Engineer II (m/f/d)

Job ID  
389413BR  
May 07, 2024  
Slovenia

## Summary

Inženir zagonov in kvalifikacij (m/ž/d) bo zagotavljal podporo pri načrtovanju, izvedbi, zagonih na področju investicij za področje merilnih sistemov. Vaša jedrna odgovornost bo predvsem upravljanje sistema kalibracij redne proizvodne dejavnosti v skladu z dobro proizvodnjo prakso (GxP) na opremi in sistemih. Z vašim znanjem in izkušnjami boste podpora pri določitvi kritičnosti meril/senzorjev, planiranju, koordiniranju, izvajanju kalibracij in pripravi poročil ter inženirsko/ vzdrževalni podpori na področju merilnih sistemov. Vaša temeljna odgovornost bo tudi sodelovanje/podpora internih in eksternih presojanj sistema kalibracij.

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We are seeking a C&Q Engineer II (m/f/d) who will provide support in planning, implementation, commissioning in the field of investments for the measuring systems. Your core responsibility will primarily be the management of the calibration system of regular production activities in accordance with Good Manufacturing Practice (GxP) on equipment and systems. With your knowledge and experience, you will be a support in determining the criticality of measurements/sensors, planning, coordinating, performing calibrations and preparing reports, as well as engineering/maintenance support in the field of measurement systems. Your primary responsibility will also be to participate in/support internal and external calibration system audits.

## About the Role

**Lokacija:** Mengeš #LI-Hybrid

### Vaše ključne odgovornosti:

- Vzdrževanje glavnega seznama meril (Master Instrument Inventory - MII).
- Vzpostavitev vzdrževanja za novo merilno opremo skladno z dobro proizvodnjo prakso (GxP) na opremi in sistemih (vključno s potrebnimi rezervnimi deli, naročanjem in obvladovanjem stroškov).
- Priprava metode dela za namen vzdrževanja/kalibracij na merilnih sistemih ter priprava navodil za delo.
- Upravljanje internih in zunanjih pogodbenih izvajalcev kalibracij (naročanje, nadzor in potrjevanje certifikatov).
- Upravljanje tehničnih / inženirskih sprememb (priprava, potrjevanje in zapiranje zahtevkov za spremembe).
- Sodelovanja pri investicijskih projektih in spremembah (Uporabniške zahteve, funkcijska specifikacija, izbor opreme, zagoni in testiranja/kalibriranja).
- Izvedba GMP ocen tveganja (vključno z začetnimi SRA ter revizijami ob spremembah).
- Strokovna podpora ostalim sodelavcem na področju meroslovja, kalibracij ter vzdrževanja merilnih sistemov in senzorike.

### **Vaš doprinos k delovnem mestu:**

- Visokošolska izobrazba tehnične (elektrotehnika/mehatronika) ali druge ustrezne smeri.
- Minimalno 1 leto izkušenj na področju projektov v inženiringu, zagonih obratovanja, kvalifikacijah in skladnosti v farmacevtski industriji.
- Tekoče znanje angleškega jezika in znanje lokalnega jezika.
- Poznavanje orodja Microsoft Office.
- Veselje do pridobivanja novega znanja, radovednost, dinamičnost in zavzetost.
- Dobre organizacijske sposobnosti in natančnost.

### **Zaželeno:**

- Izkušnje na področju meroslovja, kalibracij merilne opreme ter sistemov.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev**.

### **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: <http://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, 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.

**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: <http://talentnetwork.novartis.com/network>

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**Location:** Mengeš #LI-Hybrid

### **Key Responsibilities:**

- Establish Master Instrument Inventory (MII).
- Planing/coordinating/ reporting of periodic calibrations for equipment and systems.
- Execute work orders for maintenance / calibration as per method statement / procedure.
- Coordination of maintenance/calibration activities for internal and external audits (procurement, control and validation of certificates).
- Manage technical / engineering changes: originate Change Request, approve Change Request, close Change Request.
- Participation in investment projects and changes (User requirements, functional specification, equipment selection, commissioning and testing/calibration).

- Perform GMP risk assessments (incl. Sensors SRA).
- Support in resolving deviations in metrology, calibration and maintenance of measurement systems and sensors (identification, analysis, corrective and preventive actions).

**Essential Requirements:**

- Degree in electrical engineering, Mechatronics (Dipl. Ing. / M. Sc. / B. Sc.) or equivalent.
- Minimum 1 year of experience in project engineering, commissioning, qualification and/or compliance in the pharmaceutical industry.
- Fluent in English and proficient in local language.
- Knowledge of Microsoft Office.
- A desire for knowledge, curiosity, dynamism and commitment.
- Good organisational skills and accuracy.

**Desirable Requirements:**

- Experience in electrical equipment maintenance, metrology, calibration of measuring equipment and systems.

We offer **permanent employment** with **6 months** of probation period.

**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, 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 (Well-being), 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.

**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:

<http://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:

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

Division

Operations

Business Unit

Innovative Medicines

Location

Slovenia

Site

Mengeš

Company / Legal Entity

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

Functional Area

Technical Operations

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.

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

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7. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Menge/Inenir-zagonov-in-kvalifikacij--m--d---C-Q-Engineer-II--m-f-d-\\_389413BR](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Menge/Inenir-zagonov-in-kvalifikacij--m--d---C-Q-Engineer-II--m-f-d-_389413BR)
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