

# Commissioning & Qualification Engineer

Job ID  
REQ-10030465  
Nov 29, 2024  
China

## Summary

Responsible for defining, planning, executing and reporting on Commissioning & Qualification for CAPEX projects and/or routine manufacturing operation ensuring GxP compliance of plant/facilities/equipment.

## About the Role

### Strategy & Organizational Development:

- Support internal and external audits
- Create and maintain GOPs and provide standard training
- Implement GOPs
- If needed, create regional / site SOPs & templates
- C&Q related IT system owner for Haiyan Site

### Project Engineering & Control:

- Develop Project schedule
- Perform project risk assessment
- Identify technical solutions
- Prepare project quality plan
- Develop project document management and archiving concept
- Perform project reviews (e.g. Technical Quality Review (TQR), constructability, sustainability, HSE)
- Develop project commissioning plan / strategy
- Establish project change management and manage changes
- Develop project execution plan (e.g. C&Q)
- Prepare / execute Project Health & Safety Risk Assessments (Equipment / Process)
- Expedite and manage project vendors / contractors / 3rd parties in project
- Develop test specification / plan for commissioning & qualification in projects
- Perform new equipment FAT / SAT / inspections in project
- Implement and monitor construction contractor safety and inspection plan
- Execute work orders for projects as per method statement
- Perform commissioning activities
- Manage project deficiencies and deviations
- Perform provisional and final project handover

### Maintenance & Calibration:

- Plan initial calibrations

- Coordinate maintenance / calibration activities
- Plan resources for maintenance / calibration
- Allocate work for maintenance / calibration to technicians
- Identify spare parts for maintenance and maintain pick-lists
- Establish Master Instrument Inventory (MII) and Master Equipment Inventory (MEI)
- Get permits for maintenance / calibration / projects
- Execute work orders for maintenance / calibration as per method statement / procedure
- Provide front line support for technicians
- Supervise maintenance and calibration works
- Assess quality impact and release after maintenance work
- Manage technical / engineering changes: originate Change Request, approve Change Request, close Change Request
- Execute change requests
- Investigate deviations (root cause analysis)
- Create / maintain / verify engineering documents (protocols, drawings, lists, schedules, diagrams, layouts, calculations, datasheets)

**(Re-) Qualification:**

- Develop qualification plan
- Perform GMP risk assessments (incl. Sensors SRA)
- Create DQ, IQ and OQ protocols
- Execute DQ, IQ and OQ
- Create DQ, IQ and OQ reports
- Provide technical trouble shooting during PQ and validation
- Develop periodic requalification plan
- Execute periodic requalification plan

**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

Location

China

Site

Haiyan (Zhejiang Province)

Company / Legal Entity

CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area  
Technical Operations  
Job Type  
Full time  
Employment Type  
Regular  
Shift Work  
No  
[Apply to Job](#)

## 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 [diversityandincl.china@novartis.com](mailto:diversityandincl.china@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.

Job ID  
REQ-10030465

## Commissioning & Qualification Engineer

[Apply to Job](#)

---

**Source URL:** <https://prod1.id.novartis.com/id-en/careers/career-search/job/details/req-10030465-commissioning-qualification-engineer>

### List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Haiyan-Zhejiang-Province/Commissioning---Qualification-Engineer\\_REQ-10030465](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Haiyan-Zhejiang-Province/Commissioning---Qualification-Engineer_REQ-10030465)
5. <mailto:diversityandincl.china@novartis.com>
6. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Haiyan-Zhejiang-Province/Commissioning---Qualification-Engineer\\_REQ-10030465](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Haiyan-Zhejiang-Province/Commissioning---Qualification-Engineer_REQ-10030465)