

# Global GMP Senior Quality Auditor

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REQ-10073874  
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Испания

## Сводка

In this role you will lead, support and report independent GMP audits according to the Novartis Quality System and the current GMP regulations to assess compliance with applicable regulations, standards, and guidance documents. Review and approve corrective action plans in support of the audit observations. The audits performed include internal and external targets of manufacturing sites, development centers, quality systems, contract manufacturers, laboratories, warehouses, country organizations, and suppliers.

The Global GMP Senior Quality Auditor also ensures alignment with strategic direction of the company and assist in driving implementation of the applicable actions and provides consultation to Novartis business units through risk based assessments.

## About the Role

In this role you will be required to travel up to 60% of time. You can be based either in Spain (Madrid or Barcelona) or Slovenia (Ljubljana).

### Major accountabilities:

- Support the strategic development of an effective global risk-based audit strategy and program. Collect, collate, and incorporate input into the audit strategy and plan.
- Plan, lead, conduct, document, and follow-up of GMP audit according to the requirements specified in the respective Novartis Quality procedures as well as applicable regulations, standards, quality agreements, and guidance documents.
- For this role, auditors will be given more complex and higher-risk audits, such as sterile API, aseptic DP, and combination products. The ability to assess risk of these operations is critical to success. Provide technical guidance, mentoring, and training on audit activities.
- Provide regulatory guidance for timely remediation and recommendations regarding acceptability of the proposed filing.
- Prepare audit reports according to NVS requirements and timelines. Identify and report best practices and lessons learned to support development/training of GMP auditors. Mentor junior GMP staff as required. Act as GMP compliance consultant for GMP trainings, task forces, continuous improvement projects as needed.
- Ensure appropriate escalation to responsible management in case of critical findings and support immediate follow-up measures according to NVS requirements on Management Escalations and other relevant procedures. Ensure adequate definition and recording of mitigation plans when applicable.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with the stakeholder QA representative and Auditee.
- Review and advise on relevant policies and procedures. Maintain current knowledge of regulations, standards, and guidance documents.

### Essential requirements:

- 12+ years broad experience in Pharmaceutical or Medical Device Industry. 3 years auditing experience preferred, and excellent knowledge of regulatory requirements.
- **Strong knowledge of GMP regulations**, sound and practical judgement in the interpretation and application of regulations and standards.
- **Solid operational experience**, that should include QA/QC management and manufacturing, development or other relevant experience e.g. working at a regulatory health authority.
- **Strong experience in Sterile** and/or expertise in at least one of the following areas: DP Manufacturing, Laboratories activities, Medical Devices, API, Biologics, Microbiology, Computer System Validation, Quality Systems, Cell&Gene therapy, Radioligand therapy.
- Strong interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis colleagues, vendors and customers.
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Fluent English, written and spoken. Other languages are a plus.

### Desirable requirements:

- Experience and/or interaction with local Health Authority and sporadically with other Health Authorities is a plus.

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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.

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Дивизион  
Operations  
Business Unit  
Quality  
Место  
Испания  
Сайт  
Barcelona Provincial  
Company / Legal Entity  
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.  
Alternative Location 1  
Ljubljana, Словения  
Alternative Location 2  
Madrid Provincial, Испания  
Functional Area  
Quality  
Job Type  
Full time  
Employment Type  
Regular  
Shift Work  
No

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