

## Vigilance Process Expert

Job ID  
REQ-10034131

1月 08, 2025

Spain

### 摘要

You will be responsible for the End to end management of assigned pharmaco and devices vigilance processes across Novartis and leadership of PS&PV projects to ensure compliance to global regulatory requirements with maximum efficiency.

### About the Role

#### Major activities

Drive continuous process improvement by alignment of relevant stakeholders globally and locally, assessing opportunities for streamlining and automation.

Lead assigned PS&PV projects and support higher complexity/criticality projects led by (Senior) Vigilance Process Managers, including IT projects/systems, in alignment with the company and

department strategy.

Act as process owner / deputy process owner for assigned vigilance processes:

- Support active surveillance and analysis of emerging regulations, perform impact assessments, and drive process changes to ensure ongoing compliance to global regulatory requirements.
- Author and maintain the assigned processes and the associated procedural documents.
- Mentor and train new starters in PS&PV and participating in the creation and maintenance of training material and communications for Novartis and third-party associates.
- Act as Subject Matter Expert / consultant to PS&PV associates, Country Organizations and other Global Line Functions on regulatory requirements and assigned business process.
- Own and maintain relevant PSMF sections and annexes.
- Maintain the content of Business Continuity Plans for all respective processes, including IT applications for Key Business Processes.

### Role requirements

- PhD, PharmD, MSc degree or Life sciences degree or equivalent
- Minimum 2-4 years of experience in the pharmaceutical industry, particularly pharmacovigilance. Experience in medical device vigilance desirable.

### Skills

- Experience of leading working groups.
- Procedural document writing experience.
- Good analytical skills / proven ability to work with data.
- Strong presentation and communication skills, and ability to operate effectively in an international environment and across functions.
- Strong organizational skills
- Ability to mentor and coach
- Quality focus

### Languages

- Fluency in English. Knowledge of other languages desirable.

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部门

Development

Business Unit

Innovative Medicines

地点

Spain

站点

Barcelona Gran V í a

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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