

**MATERIOVIGILANCE SPECIALIST M/W****DEPARTMENT**

GPRM (Global Pharmacovigilance and Risk Management)

**OBJECTIVES / PURPOSE OF JOB**

Act as Deputy of the French Local Qualified Person for Materiovigilance and manage communications for French Competent Authorities (ANSM)

**KEY ACTIVITIES / RESPONSIBILITIES**

- Support for Materiovigilance activities in France.
- Serve as Local Qualified Person and manage communications for French Competent Authorities (ANSM)
- Case management of materiovigilance cases reported in France (collection, documentation of cases, translation in English, assessment, follow-up of cases with health professionals or patients, recording in corresponding data base, archiving).
- Forward cases to different partners, in English.
- Cases reconciliation with Quality department.
- Develop local materiovigilance SOPs in cooperation with global team and provide training for local employees.
- Review of local SDEAs (Safety Data Exchange Agreement) in cooperation with global team.
- Participate to audits and MV inspections.

**SUPERVISE DIRECT REPORTS**

No.

**KEY RELATIONSHIPS**

- GPRM functional group.
- Customers services, commercial team.
- GDCM ( Global Device Complaint Management)
- ANSM French competent authorities
- Global Quality
- Medical Affairs

**QUALIFICATION / TRAINING**

- MD degree strongly preferred, Pharmacist, Scientific degree.
- Knowledge of French and EU laws and guidelines related to medical devices
- Good spoken and written English knowledge, including medical terminology
- Basic computer literacy, including Excel and PowerPoint
- Analytical thinking and problem-solving skills
- Excellent interpersonal and presentation skills
- Strong customer/ patient orientation

**EXPERIENCE**

- Minimum 2-4 years of experience working in pharmaceutical/ medical device industry or competent authority
- Minimum 2-4 years of experience performing the functions of materiovigilance or pharmacovigilance, including review and reporting of adverse events, communication with Competent authorities/ notified bodies.

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