

	Document ID	Revision #	Effective Date
	4C-FRM033	00	03 Aug 2020
Document Title	Job Description		

Title: Safety Associate/Senior Associate/Leads

Summary: Perform Review, evaluation, classification, reportability criteria and follow up activities on medical devices product complaints. Summarize investigation results based on technical analysis

Preferred Education: Bachelor's in Life Sciences Discipline (BSC, MSC, B. Pharm, M. Pharm, Pharm D, BDS OR Engineering (BE, ME, Biomedical engineering).

Preferred Experience: 1-5 years industry drug safety or clinical research experience or Medical Device.

- Prior knowledge of medical devices or Pharmacovigilance, Regulatory Affairs
- Complaint handling or medical device vigilance

Responsibilities:

1. Receive complaint information, evaluate and database it.
2. Perform Failure coding, Event coding, Hazard coding activities.
3. Follow up to gather more information, product returns etc.
4. Assess Reportability criteria.
5. Perform trend analysis.
6. Write investigation summaries based on technical product analysis data.
7. Work with other teams such as Investigation and QA teams.
8. Complaint Closure.