



Job Description
Drug Safety Associate I, MICC

Preferred Education: Bachelor in Health Discipline

Preferred Experience: 0 – 2 years industry drug safety or clinical research experience.

Special knowledge needed: MICC Requirements and Medical terminology

Skills Required:

- Expert on accent neutralization and should have handled calls with customers in US and UK
- Experience in managing calls from customers in US and UK would be an advantage.
- Basic competence with medical and therapeutic terminology.
- Capable to work independently but guided by documented procedure, with appropriate support
- Ability to work effectively as part of a team
- Understanding of patient safety regulatory obligations.
- Familiarize with regulatory and Pharmacovigilance guidelines and its terminology
- Deliverable in assigning the work and tasks within established timelines
- Manage to handle urgent calls

Responsibilities:

- Attend calls from people requiring medical care/who have taken sponsor's medication in a trial/post-marketing exposure to the drug and provide information as needed.
- Provide call handling training to the newly hired resources
- Training on SOPs and Workflow instructions to the newly hired resources
- Understand the requirements of the callers and provide precise information
- Provide QC support for the MICC
- Thorough understanding on use of FAQs
- Complete case entry including case narrative writing, coding from the MedDRA dictionary and WHO drug dictionary as per applicable SOPs and Client requirements.
- Manage product-specific inquiries/medical inquiries, product complaints, AEs/SAEs calls, legal complaints, call processing per SPG, SOPs and other related guidelines.
- Respond to web-based and written inquiries from Health Care Professional members and consumers concerning the safety and effective use of all products marketed in a timely manner.
- To identify and retrieve relevant data and information appropriate to answer the information requested
- Identify clinically relevant information and preparation of follow up request as needed.
- Receive, review and process Drug Safety information based on regulations and conventions
- Manage workload under the direction of Team Lead



**Job Description
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- Act as a Subject Matter Expert
- Perform/Assist in documenting RCA and CAPA
- Comply with the processes and policies laid out for information security and responsible for using the organization's information assets in accordance with the Acceptable Use Policy in ISMS
- Notify the supervisor or Information Security officer of any security breaches/incidents.
- Any other responsibilities including cross-functional assignments delegated by the organization to fulfill business needs

Name:	Manager:
Signature:	Signature:
Date:	Date: