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Professional Summary

A Drug Safety Professional with 11 years of remarkable Pharmacovigilance (PV) operations experience. I have played various roles and grown through ranks by demonstrating exemplary skill set in a short span. During my tenure, I have demonstrated and gained expertise in Strategic Planning and Delivery in PV operations.

Achievements

- Expertise in handling Internal and External Audits.
- Multiple appreciations on efficient workflow management.
- Resource Planning.
- Holiday planning and volume management.
- Handled Ramp-up and Ramp down process.
- Handled critical adhoc requests and gained multiple appreciations from client on the same.
- Recognized as subject matter expert.
- Quality Management process including CAPA and associated trainings management.

Work Experience

Team Manager – Cognizant (Apr-2023 - till date)

- Interacts with Client/customer to manage and resolve customer requests and escalations through effective communication skills, negotiation skills and prioritization.
- Provides project updates and maintains performance metrics.
- Create/collate periodic reports for client report meetings.
- Reviews internal reports, needs to see customization as per client and corporate demands, ensure integrity and quality of data presented to client.
- Identifies avenues of improvement in the team, emphasizes utilization and productivity, engages and motivates the team for better retention and learning.
- Hands on experience on Veeva Vault RIM.
- Regular coaching and mentoring of team members.
- Gives more Analytical Thinking to the work done and work in progress, keeps Quality benchmarks and shares expectations.
- Ensure process deliverables are met.
- Acts as an SME for the team to Identify & resolve issues and document all process changes.
- Handle first level escalations from client.
- Identify and assess service improvement opportunities.
- Contribute to process improvement initiatives.
- Perform quality checks/audits to ensure data integrity, error free processing & identification of risks. Update Process documentation /user manuals as appropriate for the process.
- Participate in knowledge transfer.
- Manages attrition and absenteeism.
- Ensure Accurate Tracking and collating of Quality and KPI metric data.

Drug Safety Operations Manager – Qinecsa (Formerly Bioclinica) (Aug-2021 – Apr-2023)

- Ensure the recruitment, development and retention of high caliber PV staff.
- Provide ongoing team management.

- Communicate challenging objectives set for the PV Team in line with the Operations priorities and vision
- Ensure the sharing of PV expertise within the PV function, company-wide and with clients.
- Accountable for maintaining a headcount level within the PV team in line to meet the forecasted deliverables.
- Effective Management of project Ramp-up, without impact on project deliverables.
- Preparation of volume forecast for the forthcoming months.
- Manage the utilization and billability of the PV team.
- Develop and maintain a co-operative working relationship with project team members.
- Provide input into the development and update of processes including the development of SOPs and other procedural documentation.
- Preparing Managers daily reports to ensure compliance.
- Prepared client focused process related training document.
- Effective management of adhoc client request, without any escalation.

Senior Safety Science Specialist – Labcorp (formerly Covance) (Oct-2018 - Aug-2021)

- Assisted team in triage related activities while maintaining Sponsor requirements while sending Client notification.
- Reconciliation activities for project billing.
- Rave reconciliation and Query escalation to site.
- Clinical trial management system tool management to re-verify site related information.
- Point of contact for Query management regarding case related discrepancy and event related information to the site.
- Handled site related queries regarding discrepancies.
- Maintain a strong understanding of safety database or client specific database conventions, as appropriate.
- Reconciliation with data management or client on reconciliation of safety databases.
- Support/ train less experienced safety staff in all aspects of case handling, adverse event reporting.
- Maintain a comprehensive understanding of Safety's Standard Operating Procedures (SOP), Work Instructions (WI), guidance documents and directives associated with safety management, reporting and pharmacovigilance.
- Build and maintain good PV&DSS relationship across functional units.
- Participate in project teams and client meetings as appropriate.

Team Lead (Accenture) Sep-2017 to Oct-2018:

Managed a team size of 10+ associates, who dealt with hundreds of AE reports a week in global clinical safety & post marketing projects. I was responsible for managing daily work load of team and prioritization of cases to maintain regulatory compliance. I also assured timely movement of project work through process steps in accordance with regulations, control documents and service level agreements (SLA). Also worked with Pharmacovigilance management to ensure department realization and utilization targets are met. Monitored and ensured, project processes meet expected quality, financial and productivity targets. Involved in Planning, assigning, and directing work; performance appraisal and professional development guidance; rewarding and disciplining employees; addressing employee relations issues and resolving problems. Monitored and motivated staff to achieve and maintain acceptable levels of performance and to identify training and development needs of staff.

Medical Safety Analyst (Accenture) May-2015 to Sep-2017:

During this period I gained in-depth knowledge about case processing. Initially involved in case processing activities and then grew to be a subject matter expert and assisted team in preparation of training related documents. Actively involved in mentoring new joiners regarding the process and providing guidance to peers in resolving queries.

Associate Operation Specialist (Quintiles) (Jul-2012-Nov-2014):

During this period, initially was involved in case intake and triage related activities. Grew to be a non-serious case processor and then progressed to serious case processor, by demonstrating skill sets and expertise in standard operating procedures. Had been involved in performing weekly and monthly labeling, reporter and preferred term reconciliations. In this shorter time frame, grew to be a subject matter expert in management of individual case safety reports.

Education

Degree	University
BDS	Rajiv Gandhi university of health sciences
12th	PU Board
10th	Karnataka state board

Short-Term Courses

- Management of Medical Emergencies (CPR).
- Advanced Diploma course in Clinical Research.
- ISO 9001:2015 Quality management system auditor.
- The Project management course: Beginner.
- AI grand Prix-Gen AI Awareness Program.
- SIX Sigma: certified Lean Six Sigma - Green Belt.
- ServiceNow ITSM Processes.

Personal Details

Father's Name : Syed Abdul Basith
Sex : Female
Languages : English, Hindi & Kannada
Nationality : Indian

Declaration:

I hereby declare that that the information mentioned above is true to my knowledge.

(Dr.Shehla Tanveer)