Kartik Dutta

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A detail-oriented professional with **nearly 9 years** of experience in Pharmacovigilance domain targeting administration opportunities with an organization of high repute to leverage expertise, creativity, and capabilities to drive credible performance, growth, and success.

Summary

- Pharmaceutical expert with a successful track record in the Pharmacovigilance sector across renowned companies such as Tata Consultancy Services, Cognizant Technology Solutions, and IQVIA.
- Acknowledged for maintaining detailed and accurate medical narratives with precision and thoroughness.
- Abilities in coordinating the day-to-day office functions as per department's Standard Operating Procedure.
- An effective team player with abilities in achieving organisational objectives and adhering to industry best practices.
- Showcasing leadership and mentorship skills to uphold high-quality standards in case management.
- Excel in the fields of clinical research, drug development, and adherence to regulatory standards.
- Skilled in Serious Adverse Event (SAE) and Non-Serious Adverse Event Report Processing, ensuring adherence to regulatory guidelines and maintaining high-quality standards.
- Achieved reduction in overutilization through strategic business process improvements at IQVIA, optimizing operational efficiency and enhancing employee satisfaction.

Professional Experience

Operations Specialist
IQVIA, Bangalore
May 2021 to Present

Responsibilities:

- Implementing and optimizing operational processes to improve efficiency and productivity.
- Implementing quality control measures to ensure products or services meet established standards and customer expectations.
- Conducting regular audits and inspections to identify and resolve quality issues proactively.
- Providing training, mentoring, and guidance to team members to enhance their skills and performance.
- Collaborating with cross-functional teams, including sales, marketing, finance, and customer service, to ensure seamless coordination and communication.
- Identifying potential operational risks and developing mitigation strategies to minimize their impact on business operations.
- Ensuring compliance with regulatory requirements and industry standards to avoid legal and financial penalties.
- Participating in continuous improvement initiatives and projects to drive operational excellence and innovation.
- Identifying cost-saving opportunities and implementing cost-reduction initiatives without compromising quality or performance.

Jr. Data Analyst
Cognizant Technology Solutions, Mumbai.
July 2018 to May 2021

Responsibilities:

- Analysed operational data to identify trends, patterns, and areas for improvement.
- Generated regular reports to communicate performance metrics and key insights to management.
- Prepared and organized data for analysis by cleaning, transforming, and structuring it into a usable format.

Soft Skills

- Communicator
- Innovator
- Team Player
- Analytical
- Collaborator

Knowledge Purview

- Reporting & documentation
- Statutory coordination
- Compliances and approvals
- Liaising and coordination
- Relationship Management
- Inventory Management

Technical Skills

- MS Excel
- MS Word
- Power BI
- MedDra
- Emergency and SUSAR Unblinding request

Core Competencies

- Data Analysis
- Data Visualization
- Project Management
- Stakeholder Management
- Regulatory Compliance
- Risk Management
- Clinical Research
- Quality Assurance
- Process Management

Achievements

- Received Team Excellence Award from Boston Scientific for outstanding performance.
- Received appreciation from client for good quality case processing in TCS.
- Awarded as one-man army in rewards and recognition program in Cognizant.
- Worked for Moderna vaccines for COVID-19 during pandemic.

- Identified patterns, trends, and correlations in the data to uncover insights and opportunities for improvement.
- Generated and presented comprehensive reports summarizing data analysis results, insights, and recommendations to stakeholders, management, or clients.
- Interpreted data analysis results to derive meaningful insights, trends, and patterns that can drive business decisions and strategies.
- Managed and maintained databases, ensuring data security, integrity, and availability.
- Implemented data governance and security measures to safeguard data assets and maintain trust and credibility with stakeholders.

Drug Safety Associate
Tata Consultancy Services (TCS), Mumbai
July 2016 to July 2018

Responsibilities:
- Processed Suspected Unexpected Serious Adverse Reaction (SUSAR) cases in clinical studies, strictly compliant to 7-Day and 15-Day timelines.
- Undertook MedDRA coding and Narrative writing, processing of different cases like E2B.
- Maintained the safety database and performed coding of diseases as well as adverse events according to the project-specific coding convention ns.
- Assured medically cohesive narrative with completeness and accuracy.
- Assessed causality and expectedness of adverse events as per documents like IB, CDS (Company core data sheet).
- Engaged in Adverse event (AE) coding by MedDRA browser and drug coding by WHO-DD browser, working on ARGUS 8 safety database, coding events, indications and patient history based on MedDRA.

Project

Formulation and Development of Elastic Vesicle as Drug Carrier for Ophthalmic Drug Delivery
- The project was presented in poster form at SFEC 2015.

Personal Details

Date of Birth: 12th May 1993
Languages Known: English, Bengali, Marathi & Hindi
Address: Shop No. G – 06 Ras Al Khor Industrial No. 2, Dubai, UAE
Nationality: Indian
Marital Status: Married
No. of Dependents: 4
Passport No.: Z7170029
Visa Status: Valid till 20th April 2024
Driving License: Indian Driving License

Education

- **MBA (Operations Management)**
  2021
  Welingkar Institute of Management and Research
  78.00
- **Bachelor of Pharmacy**
  2016
  Sharad Pawar College of Pharmacy (S.P.C.P.) W Anadongari, Nagpur, RTM Nagpur University
  71.00
- **HSSC (Class XII)**
  2011
  Shivaji Science College, Congress Nagar, Nagpur
  Maharashtra State Board
  79.17
- **SSC (Class X)**
  2009
  Somalwar High School, Nikalas branch
  Maharashtra State Board
  93.07

Domain Skills

- Clinical Research & Pharmacovigilance Domain Awareness.
- Knowledge on drug development (Phase I -IV) of clinical trial.
- Processed company sponsored and investigator sponsored trials.
- Expedited case and its reporting time lines.
- Regulatory guidelines and same time following strict timelines and Knowledge of m medical terminology.
- Worked on dossier preparation and medical cohesive narrative writing for independent CEC (Clinical events committee).
- Knowledge of processing device complaints.
- Managed operations for safety management that includes site query management and EDC reconciliation.