**SHWETA SHARMA**

Mob No.- 7340304625 \* E-Mail – [shwetasharma.891115@gmail.com](mailto:shwetasharma.891115@gmail.com)

SUMMARY

Highly experienced Clinical Research professional with a versatile background spanning 10+ years in the industry. Expertise in Clinical research coordination, pharmacovigilance, and FMEA/CMC. Proven track record in managing global clinical trials, ensuring regulatory compliance, optimizing patient recruitment, fostering strong relationships with key stakeholders, and optimizing study outcomes. Skilled in Risk assessment and mitigation, driving innovation, and fostering collaborations. Dedicated to ensuring regulatory compliance and enhancing overall organizational performance.

# SKILLS

Professional skills

* Failure Mode and Effect Analysis (FMEA)
* Common Minimum Controls (CMCs)
* SIPOC
* Project Management
* Workflow Management
* Quality Management
* KPI Management
* People Management (Cross regional communication, Employee engagement)
* Onboarding Design
* Training Management
* ICH GCP, ICH Q9

Technical Skills and Tools

* UAT tester for BOT
* QC-BOT in Automation Anywhere
* UAT tester for Apex migration on HP ALM
* EDA
* ARISg Safety Database (6+ years)
* OCRDC Safety Database (3 years)
* MS suits applications (MS excel, Power point etc)

# WORK EXPERIENCE

* 1. **Cognizant Technology Solutions** From: Dec 2022 - Till date

Team lead - Operational Risk and Control

* Conduct FMEA on processes and systems to identify failure modes and assess their effects and assign appropriate severity, occurrence, and detection rankings.
* FMEA review including risk identification, failure mode acceptance threshold evaluation, impact assessment, control evaluation, treatment & closure and risk removal, risk tracking and helping projects for FMEA approval.
* Collaborate with cross-functional teams to develop and maintain a library of Common Minimum Controls (CMCs) to mitigate identified risks and ensure compliance with industry regulations and standards.
* Identify potential risks, evaluate their likelihood and potential impact, and develop risk mitigation strategies and action plans.
* Review of project SOW/MSA, training documents, quality plans, quality record, billing invoices, to identify potential gaps.
* Collaborate with senior management to establish strategic goals, drive process improvements, and optimize risk management practices.
* Follow-up with risk owners regarding extension and closure of open project risks & organizational risks (overdue risks and risks with upcoming due dates) in alignment with FMEA documentation.
  1. **IQVIA** From: Feb 2016 – Dec 2022

Operations Specialist 2 (Team Lead)

* Process Safety data according to applicable regulations, guidelines, Standard Operating procedures (SOPs) and project requirements
* Perform Pharmacovigilance activities including but not limited to, collecting and tracking incoming Adverse Events (AE), writing narratives, Literature review, Quality review, assisting with reconciliation, case closure related activities, coordinating translations, as per internal/ project timelines
* Creating, maintaining and tracking cases as applicable to the project plan
* Liaise with management for regulatory tracking requirements and electronic reporting
* Contribute knowledge and expertise and lead assigned deliverables in the field of Quality management, Workflow management and Training management
* Manage workflow of ICSRs tracking, allocation across all workflows and monitor the current status of inventory management of the project and prioritize to move them across workflows to meet regulatory timelines and DLPs as requested by client
* Perform Line Listing review for all types of cases by using user defined reports from ArisG to review significant fields, and communicating with client, tracking quality, collecting CAPA and take appropriate actions for quality improvement and analyze error trend. Perform corrections within regulatory timelines.
* Perform AESI reconciliation and track error trends
* Conduct Knowledge Check Test on top error fields which has highest contribution, repetitive errors in inline/end line quality/AESI reconciliation/Line Listing review and evaluate understanding on conventions, process guidelines, timelines, updates etc.
* Certified trainer and perform mentoring and training new hire and operations staff and take team huddle as and when required
* Keep the team updated and revised of conventions with DID YOU KNOW updates by using innovative and catchy flyers
* Created Onboarding training plan for new hires
* SME of Onboarding Training, Line Listing review, Correction process, KCT, and Quality review
* UAT tester for Life Cycle Safety Apex migration on HP ALM
* UAT tester for BOT analysis and real time quality check
* Other than project specific role, I am working as a people pillar where I am dedicatedly working towards continuous improvement in engaging and conducting various team engagement activities and cross regional leadership connects and sending out newsletters throughout the organization
  1. Worked for **MEDANTA – The Medicity** as a Research Coordinator from **Novartis Healthcare Pvt. Ltd**

Clinical Research Coordinator From: May 2015 to February 2016

* + Screen, Recruit and Enroll Qualified subjects into the trial and monitor their status and schedule their visits and schedule follow-up appointments and become their intermediary.
  + Oversee subject reimbursement.
  + Coordinates, communicate and network with other studies and technicians to ensure scheduling efficiency; communicate with any affiliated groups.
  + Collect data during subject visits; enter data from visits, procedures, lab tests, and other subject- related participation into databases like OC-RDC in a timely manner.
  + Use CENDUIT for randomization.
  + Assure studies are carried out according to the Good Clinical Practice, and Regulatory requirements.
  + SAE reporting to Regulatory Authority (DCGI), Sponsor, Head of the Institute & Ethics Committee.
  + Work on Interactive Web Response System (IWRS) and Interactive Voice Response System (IVRS).
  + Coordination with Ethics committee
  1. **Paras Hospitals**

Clinical Research Coordinator From: April 2014 to February 2015

* + Subject recruitment and enrollment into the study and perform all study related activities.
  + SAE Reporting
  + Worked on databases like RDC, IWRS, INFORM
  + Coordination and communications with Ethics Committee
  + Conduct trainings for new joiners
  + Assure studies are carried out according to the Good Clinical Practice, and Regulatory requirements.
  1. Worked for **Delhi Heart and Lungs Hospital** as Research Coordinator from **St. Jude Medical Pvt. Ltd.**

Clinical Research Coordinator From: March 2013 to April 2014

* + Subject recruitment and enrollment into the study and perform all study related activities.
  + SAE Reporting
  + Worked on OC-RDC
  + Assure studies are carried out according to the Good Clinical Practice, and Regulatory requirements.
  + Coordination and communications with Ethics Committee
  + SAE Reporting to DCGI, EC and Sponsor

# EDUCATIONAL BACKGROUND

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| --- | --- |
| 2013-2015 | **M.Sc Biotechnology** |
|  | NIMS University, Rajasthan |
| 2012-2013 | **Advance Post Graduate Diploma in Clinical Research** |
|  | CLINO-VISION INSTITUTE, DELHI |
| 2008-2011 | **B.Sc Biotechnology** |
|  | INSTITUTE OF ENGENEERING AND TECNOLOGY, ALWAR, RAJASTHAN  (Rajasthan University) |
| 2006-2007 | **12th standard** |
|  | BAL BHARTI Sr. Sec. SCHOOL, ALWAR, RAJASTHAN (Rajasthan Board) |

**CERTIFICATIONS**

* Managing Organizational Change for Managers
* Project Management Foundations Risk
* Quality Management Foundations
* PowerPoint Eight Easy Ways to Make Your Presentation Stand Out

**PERSONAL VITAE**

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| --- | --- |
| Date of Birth | 15-Nov-1989 |
| Nationality | Indian |
| Gender | Female |
| Status | Single |
| Languages known | English, Hindi |
| Address | 955, Scheme N0. 10, Vivek Vihar, Alwar Rajasthan, India |

Date:

Name: Shweta Sharma

Place: Alwar, Rajasthan