CONTACT

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EDUCATION

Executive Program in Healthcare Management
Jun 2023 - Sep 2023
ISB-Hyderabad
(Process Excellence, Strategy Mgmt)

Ex.Adv.Project Management
Sep 2023 - Present
IIM Rohtak (PMI-Approved)

PhD-Pharmaceutics Science
Aug 2010 - Dec 2012
CMJU-Shilong,India

Master in Pharmacy-QA
May 2003 - Apr 2005
Annamalai University

Bachelor in Pharmacy
Oct 1997 - Feb 2022
RIPSAT (Regional College)

Diploma in Chemical/ Instrumentation(Dist)

EXPERTISE

- QMS-Audit|Monitoring|Vendor Mgnt.
- Clinical Operational|BABE|CT P-I-IV
- Regulatory Inspection Management
- CRO Management-Project | Client
- Pharmacovigilance (REMS)|AEPC
- Bioanalytical|Pharmacokinetics
- Research and development (R&D)
- Learning & Development (eLMS)
- Digitalization|CSV|Data analysis
- Leadership & Talent Management

Dr.Debashish Kar| Ph.D| MPh-QA|ISB|PM-IIM|6σ-BB

PROFICIENT IN QUALITY & CLINICAL OPERATION | BABE | PV-QA| RA| AUDIT | MONITOR|VENDOR MGMT.|CRO MGMT.

SUMMARY

19 years Pharma/Biotech/CRO|Ex.Ranbaxy-Daiichi| Alembic| Panacea Biotec|MTR|

Diverse experience in GCP|GLP|GPV |CSV|GMP (P.Complaint |Tech.Transfer)

Succeed senior role in multi domain | VP-QA-Clinical Operation|Head-**CQA** (Audit & Monitoring), **Clinical** and **Pharmacovigilance|Inspection|** Head (Director-CT)-**CRO Management** |Manager-Quality Risk Mgmt| Sr. Research Scientist **(Bioanalytical)**

PROFESSIONAL ACHIEVEMENTS

- Prime responsible QA| >40 Inspections|>60 Sponsor audits| >40 Vendor|CDSCO, MHRA, ANSM, BfArM, ANVISA, WHO, MPA, AEMPS, NPRA| All USFDA-**Nil-483.**
- **Pharmacovigilance** Inspection of USFDA -Nil 483 | TGA- Australia (both twice).
- Promoted-Head of Operation (BA-BE/CT) from Sr. Manager (Just in 3 months)
- **Four fold raise** in CRO turnover in 2 years (2012- 2014)| Project & Client Mgnt.
- **Manage 200+** Scientific/non-Scientific staffs |All Site Head BA/BE;Trial;Head RQA.
- Successfully coordinated to design and implemented LMS|DCS|eQMS|eCRF|
- MRM with JMD & HoDs (GM//VP) at 6th year of corporate|**Observational learning**
- Project Leads **(Study Director)** multiple Clinical sites|Protocol & Report|eCTD
- **Setting CROs**|Planning to Approval-CLA|**Budgetary & financial** planning of CRO.

EXPERIENCE

VP-QA Clinical Operation | Admerus Bio.
Apr 2023 - Present

- Most responsible person of QMS for clinical operation (BE & CT)-global clients.
- Implemented sustainable quality system of global standards -healthy|patient trials.
- Key management person - Local & Global client's audit|regulatory inspections.
- Investigate and resolve customer complaints related to product quality or safety.
- Representing the company in quality related conferences, and industry forums.
- **Highlights:-**Successfully accomplished audits|onboard|Top Generics|MNC-3months

Head-CQA- Clinical |BE| Pharmacovigilance
May 2014 - Mar 2023

Alembic Pharmaceuticals Limited-Report Sr.VP-CQA

- **Domain:** -Audits|Monitoring|Vendor Management|Regulatory Inspection| Clinical| Operation|BABE|Pharmacovigilance(REMS)|Product Recall(AEPC)|eDoc & CSV.
- Most responsible to ensure QMS for clinical operation & Pharmacovigilance.
- Responsible for un or announced inspections –BE/Clinical & Pharmacovigilance.
- Perform audit- BE & Trial Site / QC & QA / Selection of Site & Sponsor-monitoring.
- Conduct project audits and process audits of different functions such as Clinical Operations, Project management, Data management, Biostatistics, PV, IT System.
- Quality Professional (Technically competent) in Clinical/Bioanalytical/PKBS/C-Trial.
- Collaborate with functional teams to resolve quality issues and implement CAPA.
- BE & CT - OSD/Complex molecules/ 505b2/ Injectable/Derma on healthy/patients.
- Provide input for the safety specification, Risk Plan & minimization for globally marketed products. Member of drug safety, signal detection and mitigation team.
- Develop & Implement e-Clinical Records /eQMS; eLab data; automated critical processes-ECG /Subject enroll/ SOPs/Trainings/ Deviation /Change Control/CAPA.
- Provide Scientific input to scientific team to develop method & design study protocol.
- Vendor Management -prequalification,finalization, oversee vendor performance.
- Training and develop the operation & quality team on industry trends and guidelines.
- Lead & manage a team of 22 professionals, providing guidance & mentorship.
- **Highlights: -**Lead QA- 40 + Regulatory Inspection | All US-FDA inspection -Nil 483 |Joint European Inspn–BfArM Germany-AEMP-Sweden|ANSM- France|ANVISA-Brazil|NPRA-Malaysia|MPA-Sweden|Ministry of Health-Turkey|WHO|DCG(I)
- Pharmacovigilance Inspection twice-USFDA (Nil 483) |TGA- Australia twice

PERSONAL SKILLS

Result Driven | Passionate & Committed | Deliver than Deserve

Quality Conscious | Process Driven | Customer Oriented

People centric | Demonstrate empathy & respect (Team Player)

Loyal and Trust worthy | Positive role model of the company/team

Excellent communicator | Inter-personal and Leadership skills

Firm decision maker | Good influencer | Problem-solving abilities

First learner - always seek to improve and adoptable to change

LANGUAGES

English

Hindi

Bengali

HOBBIES

Sports

Reading

Socializing with Friends

Travelling

PERSONAL DETAILS

Date of Birth-17 Dec 1979

Gender-Male

Marital Status-Married

Nationality-Indian

Passport Number-E 745 1527

Reference-On request

Head-Clinical Operation / Head-RA & QA — Jun 2012 - Apr 2014

Micro Therapeutics-Reported to Managing Director

- **Domain:** -Head Clinical Operations| CRO Management|Study Director| Regulatory Inspection|Client & Project Management| Budgeting CRO|Liaising with regulatory
- Most responsible to manage project|synopsis to report filing |CRO Management.
- Managing and overseeing all aspects of clinical trials and research projects.
- Coordinate with cross functional to ensure efficient & timely execution of projects.
- Responsible for BA/BE and patient based multicenter PK studies, Trials (cardio ; infectious ; cosmetology and nutraceutical), medical writing (IB,protocol,ICF,report).
- Developing and maintaining relationships with investigators, hospitals,clinical sites.
- Implement quality systems & processes across-organization & manage inspections.
- Leading regulatory activities, include preparing & submitting regulatory submissions.
- Overseeing the regulatory affairs and quality functions within the organization.
- Management's representative - manage the Local & Global client's-provide services at affordable cost, on time with quality|Manage Local & Global client's audits
- Strong organizational awareness (e.g., cross-functional; business priorities; liaison)
- Training and educating staff on regulatory guidelines and quality requirements.
- **Highlights:** Single contact - Managing Director. Head in 3 months-Sr. Manager.
- 4X raise in CRO turnover in 2years| People Management - 200+ Scientific/ nonscientific senior members Head RA; Head analytical & Head Clinical (MD).
- Setting CROs-Clinical and Pre-clinical facility- planning, budgeting to approval.
- Lead 10 + inspection USFDA, MHRA, WHO, ANSM, ANVISA, CDSCO.

Manager-Review & Monitoring (CQA-RM) — Oct 2010 - May 2012

Panacea Biotec Ltd-Report to Vice President-Generic Business

- **Domain: -**Risk Management|Site Management |Vendor qualification| Monitoring| Clinical trial|Biosimilar |Vaccines|Manufacturing |Product Profiling|R&D-QA
- Report to senior management on the status of review activities and update trends.
- Manage complete clinical phase of outsourced trials for BA/BE-Biosimilar/Drug.
- Perform site qualification/monitoring of trial site-bio similar/vaccines/drug.
- Coordinate with expert/scientific reviews of protocol & report, quarries response.
- Ensure quality harmonization across- Biosimilar/Drug-F&D/manufacturing plants.
- Evaluate & mitigated Quality Risk by using tools e.g. FMEA, FMECA, RCA and FTA.
- Identifying gaps and areas for improvement in the quality management system.
- Conduct training sessions for employees on quality standards and best practices.
- **Highlight:** Key member of quality harmonization projects of R&D and manufacturing plants| Active member of WHO plants inspection for oral polio vaccine.

Senior Research Scientist-CPP — May 2005 - Oct 2010

Ranbaxy-Daiichi Limited-Reported-Group Leader

- **Domain:** - Bioanalytical|Clinical | Pharmacokinetics|Technology Transfer.
- Method development, validation & bioanalysis of large to small molecules in compliance with regulatory guideline| SOP,MSOP & Data Review & Report writing
- Technology transfer across international in vitro labs for analysis prior to bioanalysis.
- Remain updated with the latest advancements and discoveries in the field of CPP.
- **Highlight:** Global acknowledgement at Ranbaxy for outstanding performance.

Trainee -Panacea Biotec /Dig-Medi Pharma — Jun 2004 - Apr 2005

- Panacea Biotec Limited, Lalru 2004-05 & Dig-Medi Pharma; Agartala 2002-03.

CERTIFICATION

Six Sigma–Black Belt:-AIGPE-QFD specialist — 2023-02-01

Advanced Innovation Group Pro Excellence (AIGPE™)

ISO/IEC27001,Information Management;Integrated Management - ISO 9001 & ISO 14001 & ISO 45001-Udemy — 2020-10-01

Diploma in Signal detection and assessment — 2018-12-05

Uppsala Monitoring Centre

Management for a Competitive Edge — 2017-07-01

International College of Management Sydney (ICMS)

Pharmacovigilance for Trials-PharmaSchool — 2016-10-10

Diploma in Operations Management-ALISON — 2015-01-06