**CURRICULAM VITAE**

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A pharmaceutical Quality Assurance professional with more than 23 years of versatile professional experience spanning across all area of Pharmaceutical Research & Development and Manufacturing QA/QC Quality Management.

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**AREAS OF EMPHASIS**

**Good Clinical Practices/ Good Laboratory Practices/ Good Pharmacovigilance Practices/ Development Quality in Drug Substance & Product Research, Analytical Research/ Good Manufacturing Practices in Investigational & Commercial Products Manufacturing.**

***Knowledge & Experience***

* More than 23 years of extensive experience of establishing overall Quality (QA) Management System in practically every facet of pharmaceutical R&D (discovery & development) area at global organization level, specifically in Clinical Research/GCP, Pre-Clinical Research/GLP, Clinical Safety & Pharmacovigilance/GPvP, Drugs Substance & Products Development Research including Biologics Research and Analytical Research.
* Partnered effectively with R&D/Business Units resulting numerous successful drug substance & product dossiers approvals (DMF, ANDA, NDA, IND, etc.), and supported through successful various national/international regulatory inspections (FDA, MHRA, HC, AFSAPS, WHO, EMA, ANVISA, IMB, OECD-GLP, NGCMA, DCG-I, etc.) of company’s Clinical & Pre/Non-Clinical Research facilities, and Pharmacovigilance operation sites and IMP manufacturing plants at global level
* Rich experience of establishing Developmental Quality/ Quality by Design/QbD system in various area of R&D operations starting from Drug Substance & product development, and technology transfer to manufacturing plants, and continuous improvement thereafter.
* Sound Knowledge of national/international (FDA, MHRA, WHO, ANVISA, TGA, EMA, ICH, DCG-I, ISO, etc.) regulatory requirements specific to GCP, GLP, GPvP and GMP.
* Extensive experience of conducting wide range of GxP audits (> 300 in nos) as Lead Auditor in GCP/global clinical trials & BA/BE studies, GLP/Pre-clinical safety & efficacy studies, and GPvP/global Pharmacovigilance operations & systems.
* Global experience for due diligence/ qualification audit & monitoring of CRO & Service Providers for Clinical, Pre-Clinical studies, and Pharmacovigilance operations including PV audits of various affiliates and business partners globally.
* Exceptionally rich experience to prepare for and host various national and international successful regulatory inspections (> 100 by US-FDA, MHRA, WHO, EMA, Health-Canada, ANVISA, TGA, AFSAPS, IMB, PMDA, MCC, OECD-GLP, NGCMA-GLP, DCG-I, etc.) at global level in overall GxP area of R&D & Manufacturing operations such as Clinical Research, Pre-clinical Research, Pharmacovigilance, Investigational Medicinal Product/IMP manufacturing.
* Established Global Policy/Standards & Quality Manuals in GCP, GLP & Pharmacovigilance Quality operations at erstwhile Ranbaxy, and gained ample experience in establishing/harmonizing Global Quality Standards in Research & Development during association with Daiichi-Sankyo being member of Global Quality core team member.
* Instrumental in leading the execution of R&D Quality organization and establishing a harmonized quality system & processes at global level while take over/integration of Ranbaxy with Daiichi-Sankyo, and Sun & Ranbaxy merger/acquisition.
* Rich experience of managing & supervising team of GxP Quality team having diverse culture & complexity based at various R&D & PV geographies across the globe.
* Got ample opportunity to work closely with various consultants such as McKinsey, PRTM, Quintiles, Boston Consulting, etc on various Quality & Productivity enhancement projects.

**PROFESSIONAL EXPERIENCE**

***Present Association***

* **Sun Pharmaceutical Industries Ltd (Erstwhile Ranbaxy Laboratory Ltd.)** Gurgaon, India

March’2015-Present

Role: Head- R&D/PV Quality Assurance (Quality operations of erstwhile Ranbaxy R&D centers at Gurgaon & Romania, and Pharmacovigilance Quality operations globally)

* **Ranbaxy Laboratories Ltd (Research & Development),** Gurgaon, India

Sept’2014 - March’2015

Role: Head- Global GCP, GLP, GPvP & CMC Quality Operations

Dec’2010 - Sept’2014

Role: Head- Global GCP, GLP, GPvP Quality Operations

Jan’2008 till Dec’2010

Role: Head- Global GCP Quality Operations

Nov’2005 till Dec’2007

Role: Group Leader- R&D and Contract Mfg. Quality Operations

## Key Responsibilities of Present Role

As Head-R&D/PV Quality Assurance at Sun Pharma R&D (erstwhile Ranbaxy Labs Ltd.), managing a team of about 40 R&D/PV QA members team and having oversight of quality outputs of more than 800 R&D scientists at two R&D centers of Sun Pharma at Gurgaon/India & Cluj/Romania involved in Drug Product and Drug Substance Development Research, Analytical Research, Clinical Research, Pre/Non-Clinical Research, and global Pharmacovigilance operations.

* Partner with R&D to set GxP (GMP, GCP, GLP & GPvP) quality goals, objectives, and strategic direction in alignment with Global Quality goals in line with Sun Pharma compliance, product quality goals and regulatory requirements.
* Responsible to assure implementation of applicable GxP ( GMP, GCP, GLP & GPvP) policies & procedures as per national & international regulatory guidelines/ requirements in R&D operations which include Clinical Trials (including BA/BE studies) Pre-clinical safety & efficacy Studies, global Pharmacovigilance, and drug substance & product development research (i.e. Chemical Research, Formulation Research, Analytical Research, IMP manufacturing) operations at erstwhile Ranbaxy R&D operations globally which include India &Romania.
* Responsible for Implementation of well-defined documented Quality Assurance programme in overall R&D GxP operations which include Clinical Research, Pre-clinical Research, Pharmacovigilance operations and Drug Substance/Product Development Research (API/Formulation/Analytical Research) at erstwhile Ranbaxy R&D location globally.
* Responsible to develop and manage a GxP QA auditing program of erstwhile Ranbaxy R&D sites associated Clinical Research, Pre-Clinical Research and Pharmacovigilance & Regulatory Affairs activities/ operations to assure adequacy of & compliance with established Quality Management Systems.
* Develop and manage a global GCP, GLP and GPvP audit program for outsourced parties (CROs, Service Providers, Vendors), Affiliates & Partners etc., associated with erstwhile Ranbaxy Clinical, Pre-Clinical and Pharmacovigilance operations.
* Assure all-time readiness at erstwhile Ranbaxy GCP, GLP & GPvP sites globally, and other R&D functions (IMP Manufacturing/packaging), for regulatory agency/partner inspections, and implementation of appropriate Corrective and Preventive Actions (CAPA).
* Building talent, skills and competencies needed within R&D Quality to support developmental R&D and ensuring that the group delivers value and gain acceptance with R&D.
* Mentoring leaders within the group for critical quality management skills, including decision-making, handling of quality exceptions, staff development, personnel and budget requirements planning, etc.

***Previous Association***

* **Zydus Research Centre (Cadila Healthcare), Ahmedabad, Gujarat, India** (April’2002-Oct’2005)

**Title: General Manager- Quality Assurance**

Role: Head- R&D Quality

**Key Contributions**

* Established well defined Quality Management Systems at Zydus Research Centre in Pre-Clinical Safety & Efficacy Research, Clinical Research (Clinical Trials/Phase-I & BA/BE studies), Investigation Medicinal Product Research, Biologics Research supporting to company discovery and development research programme.
* Received first GCP certification by DCGI & ANVISA, and GLP certification by OECD/NGCMA-India within 3-4 years of establishing R&D facilities of Clinical & Pre-clinical research programme.
* Significant contributions to assure overall accuracy & adequacy of first IND dossier/application of R&D first NCE programme.
* **Cadila Pharmaceuticals Ltd., Ahmedabad, Gujarat, India** (April’1998- March’2002)

Title: Sr. Manager

**Role: Head of Quality Assurance**

**Key Contributions**

* Being Head of QC, significant contributions towards planning and execution of overall all Validation Programme for company new DF manufacturing plant at Dholka.
* Established a fully functional QC labs consisting about 75 staff, and Quality Management Systems as per national/international GMP requirements which resulted various regulatory certifications (WHO, MHRA, MCC, TGA, Russia, etc.) within short period of plant operations.
* **SPARC, Sun Pharmaceuticals Ltd., Baroda, Gujarat, India** (Dec’1996-March’1998)

Research Scientist- Analytical Research Lab.

* **Core Healthcare Ltd, Ahmedabad, Gujarat, India** (Nov’1995- Dec’1996)

Management Trainee- QC/QA

**Academic Education**

* **Doctorate**/Ph. D. (Chemistry), Banaras Hindu University, Varanasi, India (1991-1995)
* **Master of Science**/M.Sc. (Analytical Chemistry), Banaras Hindu University, Varanasi, India (1990-1991)
* **Bachelor of Science**/B.Sc. (Chemistry Honors), Banaras Hindu University, Varanasi, India (1985-1989)

**Scientific Publications**

* Eight (08) research publications in various reputed international chemistry journals during Ph.D. course.
* Contributory chapter on “GLP in Toxicokinetics Studies” in Preclinical Development Handbook – Toxicity, edited by Cox Gad, John Willey Publications, 2008.

## Certification/Membership/Association

* Certified GCP/GLP Auditor by SQA, USA, 2010
* Member of British Association of Research Quality Assurance (BARQA).
* Life member of Indian Chemical Society.
* Member of DIA-India.

## Scholarship/Award

* “Junior Research Fellowship” qualified National Eligibility Test (NET) by CSIR-UGC, India in 1993.
* “Young Scientist Award” by Indian Chemical Society, 1994.
* Ranbaxy “APPRECIATE” Award in 2010 & 2012
* “Star Performer of the Year-2000”, Cadila Pharmaceutical Ltd

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