Biography – Manish Singh Yadav

Manish is serving Ethixinn CRS as CEO and, Lead Trainer to WHO, JJM & LSSSDC and has over 23 years of Contract Research Organization (CRO) experience in Regulated Bioanalysis for pre-clinical and clinical development including BA/BE. He has trained 200+ GCP Inspectors of various Regulatory Agencies *(China, Thailand, Malaysia, Indonesia, Singapore, Philippines, Qatar)* through WHO PQT Workshops; and over 1000 Clinical Research professionals (over 500 Bioanalytical, 400 Clinical, 100 Quality Professionals of CRO, Pharma R&D and international regulatory agencies.

Recently, he has been appointed as Authorised Trainer - NABL, GLP & QMS to CSE-JJM and trained over 500 chief chemists / chemist hailing from government water testing labs. Also, as Independent Auditor, successfully concluded & concluded over 500 audits and monitoring *(WHO, EMA & USFDA)*. AS CEO, Manish leads techno-commercial operations of Ethixinn CRS and leads a team of 50 seasoned consultants / auditors *(Clinical/GCP & Bioanalytical/GCLP experts)* dedicated to execute routine Risk based monitoring and for-cause audits, hand-holding of sponsors to face GCP-GLP based regulatory audits, basic & advanced trainings and also execute green field projects.

Prior to joining Ethixinn CRS, his professional career was spent mainly within the bioanalytical and BA/BE group at Alkem Laboratories[2014] as Head-CRO, Cadila Pharma CRO[2012] as Head-CRO, Veeda CR as Head-Global Lab Operations[2010], GVKBIO[2004] as In-charge-Bioanalytical, Aurobindo Pharma R&D[2003] as Scientist, Torrent Pharma R&D[2002] as Scientist-II and Lambda Therapeutic Research[2001] as Group Leader and, handled 500+ Research Molecules, 1000+ BA/BE/DDI studies, a few CTs and Phase I studies. **Successfully, faced 31+ international regulatory inspections *(USFDA-10, WHO-5, ANVISA-5, MHRA-5, DCGI-7)* and 500+ Clients.** He was key player in setting up and running 2 CROs *(Veeda CR and GVKBIO)*, 3 Bioequivalence centers *(Aurobindo; Cadila Pharma & Alkem Labs)* and 9 Bioanalytical Laboratories *(Torrent, Aurobindo, GVKBIO, Veeda CR - 2 Labs, Cadila, Alkem – 2 Labs and Scimagma Labs)*. Also, **executed the first LC-MS/MS experiment of bioanalytical lab of Aurobindo, GVKBIO & Veeda CR**. During his studies toward his master's degree, he accomplished the research projects on Water treatment & analysis and Pharmaceutical finished product analysis at National Fertilizers Limited *(Guna, M.P.)* and Sarabhai Pharmaceuticals *(Baroda)* respectively.

In addition to his role as a chief executive officer, he actively trains, coaches and mentors the scientists and regulators from cross-functional teams throughout Ethixinn CRS and international regulatory agencies including effective delivery of consultancy services for green filed projects *(GCP-GLP CRO & GCLP-NABL-ISO regulated laboratories)* audits, monitoring, efficiency enhancement, responses to regulatory bio-deficiencies, CAPA & standard/need based trainings. Manish received his BSc and MS degrees from Jiwaji University, M.P. along with a PhD from Gujarat University. Dr Manish Singh Yadav has authored or co-authored over 40 peer-reviewed research publications (a few posters as well) and as reviewer, reviewed over 50 research manuscripts.

Manish is dynamically contributing to various international organizations like BSAT-APA, CVG-Canada, CPhI, Omics, Biotrains, Compliance Trainings, Glostem, Global Bioanalysis Consortium *(GBC HT member - A1, A6 & A9),* Jal Jeevan Mission *(JJM)*, Centre for Science & Environment *(CSE)*; various reputed vendors (Waters, Applied Biosystems, Thermo) and various universities *(Jiwaji Univ., Poona College of Pharmacy, Gujarat Univ., Annamalai Univ., S.P. Univ., Nirma Univ.)* as Organizer/Speaker/Panel or Board member, and he has delivered over 50 invited talks to various international conferences/seminars in the bioanalytical, bioequivalence and regulated labs domain with a focus on bringing innovative workflows and quality management system *(QMS)* into the framework of regulated bioanalysis and PK-PD studies and, drinking water treatment, supply and quality management.

Worked with REGULATORY AGENCIES: USFDA, EMA, WHO, MHRA, ANVISA, CANADA, AGES, ANSM, ISO, NABL & DCGI.

Worked with COUNTRIES: US, UK, Canada, Japan, Algeria, Greece, China, Thailand, Malaysia, Indonesia, Singapore, Philippines, Dubai, Qatar and India.

LIFE PHILOSOPHY

"If you have an apple & I have an apple & we exchange apples then you and I will still each have one apple, but if you have an idea and I have an idea & we exchange ideas, then each of us will have two ideas" - George Bernard Shaw