Shruti Prafulla **Anikhindi**

Address	Körösistraße 118/6, 8010 Graz
Mobile	+43-6608135814
Email	anikhindishruti@gmail.com
DOB	14.08.1989
Work Permit	Rot-Weiss-Rot – Karte plus
Nationality	Indian

Short Profile

I have 5 years and 6 months of experience in Pharmaceutical and Healthcare Industry mainly in IT Quality and Compliance domain. I have gained vast experience in IT Compliance/CSV (computer system validation) and Regulatory Systems. I am perceived as an energetic and committed person and have good communication and interpersonal skills.

Professional Experience

05/2016 – 05/2019 **Consultant - Quality & Compliance, Novo Nordisk Service Centre, India**

- Providing solutions to the stakeholders from compliance perspective and thereby providing the value add to the stakeholder
- On-boarding of new periodic reports services
- Perform review of the configuration management of the systems against its baseline; documentation of the configuration review report
- Review of the incidents, problems, change request, non-conformities and deviations to evaluate the overall validated status of the system
- Documentation of the Annual Compliance Reports (mainly for GxP Systems) like System Impact Assessment, IT Security Risk Assessment and Plan, System Definition Document for Affiliates
- Conducting trainings sessions and mentoring the new joiners of the team

02/2012 – 08/2014 **Associate Consultant - Quality Assurance & Compliance, Wipro Technologies, India (Client : Glaxo Smith Kline)**

- Review and approve key deliverables as defined within the Validation Plan to assess their compliance with applicable Pharmaceutical Regulatory Agency expectations and GSK QMS.
- Review of Master Configuration Item List [MCIL] and performing Configuration management audits for GxP Applications
- Conduct Internal Audits for SDLC Phases and for Regulatory Compliance adherence per customer QMS.

Education

2007 – 2011	Bachelor of Engineering in Computer Science Visvesvaraya Technological University (VTU), India

Certifications

ITIL Foundation in IT Service Management (ITIL v3)

cLEAN 1st Star Certification (related to Six Sigma and Lean)

Project Management Foundation level

German Language A1 & A2 certification from IFA-Akademie Stuttgart, Germany (Goethe Recognized)

Professional Skills

Languages	German – Basic (A1) Kannada, Hindi – Mother tongue/ Regional Language English – Professional
IT	MS Office
Knowledge	Quality Management Quality Assurance Computer System Validation (CSV) Good Manufacturing Process (GMP) Regulatory Guidelines: GxP, FDA, 21 CFR Part 11 Continuous Improvement Initiatives Stakeholder Management Ability to integrate, communicate and work in multicultural and multidisciplinary teams Conducting of Internal Audits for projects across the SDLC Phases Knowledge on the Complete Value Chain of Pharmaceutical Industry