**Yogesh R. Patel (Project Quality Manager; CSV Consultant – Infosys Ltd)**

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###### **Career Objective :**

To utilize my knowledge and skills towards a challenging career in a growth oriented and leading edge organization that recognizes and values individual contribution and will provide opportunity for continuing growth and advancement.

###### **Professional Summary : { CSV\_10.0 Yr + QMS \_3.5 Yr }**

* A competent professional with about ***13.5 years*** of experience in ***Computer System Validation , GxP Validation & Quality Assurance*** in the IT Industry & Pharmaceutical Industry.
* Presently working with **Infosys Limited**, Pune, (Maharashtra) as ***Project Quality Manager, Consultant -CSV*** providing services for **Novartis NBS ISRM Group**.
* Having audit exposure of regulatory agency i.e. USFDA, MHRA, TGA, WHO, UKRAINE, etc.

###### **Qualification:**

* Successfully completed M. Pharm with first class from Annamalai University (TN) and B. Pharm with first class from North Gujarat University (NGU).

###### **Education Qualification :**

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| --- | --- | --- | --- |
| **Degree/ Subject** | **Name of the University** | **Year of Passing** | **Class / Grade** |
| M.Pharm (Q.A) | Annamalai University, TN | 06/2009 To 05/2011 | 71% |
| B. Pharm | North Gujarat University, Patan | 07/2005 To 05/2009 | 67% |
| H.S.C | G.S.H.S.E.B , Gandhi Nagar | 06/2003 To 05/2005 | 82% |
| S.S.C | G.S.EB, Gandhi Nagar | 06/2002 To 05/2003 | 84% |

###### **Professional Experience :**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Organization** | **Duration** | **Designation** | **Area** |
| Infosys Ltd, Pune | 04/2022 To Cont.. | Project Quality Manager | GxP Validation |
| Intas Pharmaceuticals Ltd, Ahmedabad | 12/2016 To 04/2022 | Manager | GxP Validation & QMS |
| Sun Pharmaceuticals Ltd, Vadodara | 01/2016 To 12/2016 | Executive | GxP Validation |
| JBCPL , Ankleshwar | 06/2015 To 01/2016 | Executive | QMS |
| Zydus Cadila Healthcare Ltd, Ahmedabad | 03/2014 To 06/2015 | Officer | GxP Validation , CQA |
| Cadila Pharmaceuticals Ltd, Dholka | 01/2010 To 03/2014 | Executive | QA- IPQA |

**CAREER HIGHLIGHTS:**

###### **Infosys Limited, Pune (Apr-2022 To Cont….)**

###### **Project Quality Manager–GxP Validation (Providing services for Novartis ISRM Group)**

* Subject matter expertise in computerised system GxP & Non GxP validation requirements for various applications as per 21 CFR Part 11, Annex 11 & GAMP Guidelines.
* Exposure about SDLC Cycle and utilizing Agile method for software development.
* Knowledge and exposure about Application life cycle management tools like; JIRA , Confluence and PROTON.
* Arrange and participate Daily stand-up meeting with Project Manager and testing team.
* Establish regular check point meetings with Business Information Security Expert (BISE) & eCompliance Manager to align the validation strategy. Also, ensure that project team is covering security and compliance with applicable laws regulations like; 21 CFR, ISRM Policy and respective SOPs
* Contribute the project related Audits, Assessment and Inspections during the project life cycle (wherever applicable)
* Performing Project Control Maturity Assessment (pCMA) for each project and providing monthly PQM Dashboard report
* Designing and reviewing of all SDLC validation deliverables like; Project documentation list , Quality plan and Report, Functional & Design specification , Test plan, Product increment plan & Report , Quality summary report .
* Expertise in computer system validation / qualification , compliance and quality management system of Various application like; QMS Software i.e. -QMS Module, DMS, Process XE -eBMR
* Preparation and review of SOPs to help the business process in line as per FDA regulations.

###### **Intas Pharmaceuticals Ltd, Matoda , Ahmedabad (Dec-2016 To Cont….)**

###### **Manager–Quality Assurance; CSV & QMS**

Reporting to: Deputy General Manager- Quality Assurance -CSV

**Computer System Validation (CSV):**

* Handling, monitoring and managing a team of 10+ QA personnel associated with various quality assurance functions of CSV.
* Subject matter expertise in computerised system validation requirements for various applications as per 21 CFR Part 11, CFR Part 211, Annex 11, GAMP Assessment.
* Expertise in computer system validation / qualification , compliance and quality management system of Various application like; QMS Software i.e. -QMS Module, DMS, Process XE -eBMR
* Developing and reviewing Configuration specification, System validation plan , User Requirement Specifications (URS), GxP assessment & system classification.
* Co-ordinate with the vendors in commissioning of the upgrade version of software, implement new system or maintenance of systems and resolving technical issues.
* Project management support to global projects with computer system validation activities and deliverables, coordination with internal team and vendor for implementation of CSV projects.
* Preparation of SOPs to help the business process in line as per FDA regulations.

**Quality Management System (QMS):**

* To prepare agenda of QMS (Quality Management System) and ensure compliance of action plan.
* Preparation of Monthly Information System (MIS) /Monthly Report of QMS Department & to submit Quality review steering committee (QRSC) details to senior Management.
* Leading the QMS team, involved in investigation of Deviations / OOS / OOT. Involved in managing the changes and devising CAPAs to prevent recurrence of the non-conformances.
* Handling Regulatory / Customer audits and providing compliance to the same. Majorly involved in third party audits conducted as per schedule.
* Providing training to QA personnel as a part of Training calendar Matrix (Qualified departmental trainer).
* Involving in Self inspection/Internal audit of plant premises. (Qualified auditor)

###### **Sun Pharmaceuticals Limited, Halol, Vadodara (Jan-2016 To Dec-2016)**

###### **Executive, Investigator – CSV & QMS (Event/Incident Investigation)**

* Co-ordinate with the vendors in commissioning of the upgrade version of software, implement new system or maintenance of systems and resolving technical issues.
* Project management support to global projects with computer system validation activities and deliverables, coordination with internal team and vendor for implementation of CSV projects.
* To review of Incident report of Deviation, OOS, OOT , CAPA, Interim investigation report, Effectiveness check.
* To guide and lead the investigation team for investigation , Perform investigation as cross functional team member. To monitor the incident investigation is completed within stipulated time frame.

###### **J B Chemicals & Pharmaceuticals Ltd, Panoli, Ankleshwar (June-2015 To Jan-2016)**

###### **Executive , IPQA In-charge (Experience letter not available)**

###### **Zydus Cadila Healthcare Limited, Moraiya, Ahmedabad (Mar-2014 To June-2015)**

###### **Officer, Corporate Quality Assurance**

Reporting to: Manager – Corporate Quality Assurance

* Handling of Market Complaints , Change Controls & Deviations..
* Quality Audit of Loan license facilities & Compliance of site.
* To ensure cGMP compliance (Schedule M) during the manufacturing operations as per the requirements of dosage forms at LL sites.

###### **Cadila Pharmaceutical Ltd, Dholka , Ahmedabad (Jan-2010 To Mar-2014)**

###### **Executive , IPQA In-charge**

Reporting to: Sr. Manager - Quality Assurance

* In process quality assurance for manufacturing and packing of solid dosage form.
* Review of batch manufacturing and packing records.
* Investigation team member as well as CFT (Cross Functional Team) member
* Involving on Daily CFT meeting as a part of CFT Member & Monthly DOC (Divisional Operational Committee) meeting.
* Also, Member of EC (Executive Committee) meeting
* IPQA Training impart to Juniors & New joinee as a part of Training calendar Matrix.

###### **Computer skills and Exposure to Automated system:**

* Ms-Word, Excel, Ms-PowerPoint, Scientific data retrieval from various Internet portals like Google scholar.
* JIRA, Confluence, PROTON, SAP , Track wise, Quality Edge (Q-Edge) ,Quality management system (QMS).

###### **Personal Profile:**

Date of Birth : 03rd May, 1988

Nationality : Indian

Marital Status : Married

Language Known : Gujarati, Hindi & English

Present Address : 30, Dharti Parisar, Nr. Madhav Farm, Odhav, Ahmedabad ,Gujarat-382415.

Permanent Address : Ambica Nagar Society-2, Opp. Primary school , Jagudan , Ta & Dist-

Mahesana-382710,Gujarat.

Yogesh R. Patel