ANAND CHAVAN

LABELING ENGINEER – R&D Sustaining

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Focused professional with more than 8 years of experience targeting challenging assignments in Product Labeling, NPD/LCM, Regulatory, Technical R&D, Project Management, Vendor Management, Supply Chain, Clinical Supply and Operations in Medical Devices & Pharma organizations of repute.

SKILLS & CORE COMPETENCIES

- **Medical Devices/Pharma Labelling/Artwork Management**
- **UDI Barcode Verification**
- **New Product Development/ Life Cycle Management / Line Extensions**
- **Project Management**
- **Vendor Management**
- **Material Selection and Qualification**
- **Regulatory Submission**
- **Quality Management System (ISO13485)**
- **Non-conformance/Corrective and Preventive Action**

PROFILE SUMMARY

- **Achievement-oriented professional with more than 8 years of expertise in Labelling/Artwork Management of Medical Devices & Pharma Products, New Product Introduction/Life Cycle Management Projects, Design Change Projects, Project Management, Vendor Management, Regulatory Compliance & Clinical Supplies.**
- **Working as Subject Matter Expert & Project Lead in Labeling/Artwork Management Projects.**
- **Experience in leading complex Labeling/Artwork Management Projects involving Commercial as well as Clinical Trial Products for Medical Devices & Pharma Industries.**
- **Successfully applied various Licenses for Ethicon Johnson & Johnson under MDR 2017 (CDSCO Portal) & having hands on experience working on CDSCO portal launched by Govt. of India for Medical Devices Licensing.**
- **Working on Technical Files such as Design Dossier, Device Master File & Design History Files for Ethicon Johnson & Johnson India.**
- **Responsible for generation of label for IMP, medication list/randomization list/randomization schedules and ensures agreed milestones, quality and costs are met for Novartis Pharma.**
- **Hands-on experience working filing regulatory submission applications.**
- **Manages all applicable finance activities, including grants, purchase orders (PO) and invoice approval for IMP labels, as applicable.**
- **Initiating, Planning & Executing Design Change projects.**
- **Skilled in Project Management & Packaging/Labelling.**
- **Working with cross-functional teams to get projects completed under timelines.**
- **Successfully completed NC/CAPA's assigned ahead of timeline.**
- **Experience of working on development of Packaging & Labeling for New Product Launches.**
- **Excellent communication and people management skills for leading personnel towards accomplishment of common goals.**

PROFESSIONAL EXPERIENCE

August 2022 – Present

<u>Labeling Engineer – R&D Sustaining at BOSTON SCIENTIFIC (On Payroll of Persolkelly India Pvt. Ltd.)</u>

- **Creates, reviews, and reproduces product text for medical products labeling and Instructions for use (IFU), patient or promotional printed components, and/or capital equipment manuals.**
- **Ensures all product text for product labeling, DFU's, and equipment manuals meet all required legal, regulatory, clinical, marketing, packaging engineering, manufacturing (both inter and outer company) and R&D requirements through the use of corporate labeling guidelines and SOP's.**
- **Establishes parameters to introduce new products into the corporate master brand (MB).**
- **Works with packaging engineer to establish sub-team for MB introduction on qualifying new product releases.**
- **Work cross-functionally with project management, quality, R&D, manufacturing, regulatory, operations, and marketing to ensure project success.**

January 2021 – August 2022

<u>Associate Clinical Label Manager – Global Clinical Supply at NOVARTIS Healthcare Pvt. Ltd.</u>

- **Leading Labeling/Artwork Development and Revisions Projects for products under Clinical Trial.**
- **Responsible for generation of label for IMP, medication list/randomization list/randomization schedules and ensures agreed milestones, quality and costs are met.**
- **Single Point of Contact for all the stakeholders involving in Labeling/Artwork Projects.**
- **Closely working with all the country regulatory persons so that regulatory submission for new IMP happens on time and closely monitor their requirements.**
- **Co-ordinate with Clinical Trial Supply Chain Team, Supply Chain Team and External Vendors for end-to-end implementation of labels.**
- **Working as SPoC for Vendor Management.**
- **Responsible for ensuring cost & quality are met for labels.**
- **Manages all applicable finance activities, including grants, purchase orders (PO) and invoice approval for Labeling Projects.**
- **Play active role in improving labeling process and supporting CAPA's involving labeling inputs.**
- **Currently working on Clinical Trials for new 38 Investigational Medicinal Product Projects.**

June 2015 – January 2021

<u>Project Design Engineer - NPI/LCM Projects at ETHICON Johnson & Johnson (On Payroll of Randstad India Pvt. Ltd.)</u>

- **Leading New Product Line Extensions/Design Change Projects for both sites (Ethicon – Aurangabad & Baddi) for sutures & Kits. *(Requiring working with multiple stakeholders – Regulatory, WW NPI Council, R&D, Manufacturing, Engineering, Quality, Planning, Sourcing etc.)***
- **Solely Responsible for entire Product Graphics Lifecycle Management complying with Medical Devices Rule 2017 and Legal Metrology Act. *(Direct Reports – 2)***
- **Lead end to end Design Control Process for:**
  - **Project OMEGA: New Line Extensions for existing product families**
  - **Project RED DRAGON: Artwork revision as per China Regulatory Guidelines**
  - **Project ILEC: Artwork Labelling change as per India Legal Entity change**
  - **Project SBF to Dry Codes: Design change for changing the packaging of codes**

- **Project PUMA & JAGUAR: New Line Extensions involving importing new RM**
- **Project BUMBLEBEE: Replacing Domestic Material with New Imported Material**

- **Lead WW artwork labelling change project for review & revising IFU for products.**
- **Working on Technical Files such as Design Dossier, Device master File & Design History File for Ethicon Johnson & Johnson India.**
- **Single handedly streamlined entire process for supplying tender requirement on time.**
- **Site representative in WW Meeting involving Labeling Discussions.**
- **Successfully applied various Licenses for Ethicon Johnson & Johnson under MDR 2017 (CDSCO, Sugam Portal) & having hands on experience working on SUGAM portal (CDSCO) launched by Govt. of India.**
- **Raising purchase request for requirements of NPI/LCM Projects Department in SAP.**
- **Exhibit leadership in areas of the Quality System, including but not limited to CAPA, Risk Management, Complaints, Nonconforming Materials, etc.**
- **Responsible for Change Control & Audits (Internal & External), maintenance of products/processes throughout product lifecycle.**
- **Seamlessly leading and completing various labeling change projects involving multiple stakeholders.**
- **Lead complex CAPA for site for product issues and contributed actively for FI for NC's.**

OUTSTANDING ACHIEVEMENTS

- **Outstanding Achievement Recognitions for below activities & projects at *ETHICON Johnson & Johnson***
  - **Launching New FG codes before time.**
  - **Leading End-to-End artwork management for MDR and LMA project.**
  - **Reducing lead-time for availability of Packaging Material for Govt. Tenders.**
  - **Application of Manufacturing License for Ethicon Johnson & Johnson under MDR.**
  - **Successfully completing Tech Files Remediation Project.**
  - **Successfully completing PUMA, JAGUAR & BUMBLEBEE Projects Labeling change.**
  - **Assisting in successfully completing EPID CAPA by revising labeling.**
- **Outstanding Achievement Recognitions for below activities & projects at *Novartis***
  - **Successfully completed Internalization of Single Panel Label Project, which affected in huge saving related to labeling vendors within 7 months of joining which was on hold for 2 years.**
  - **Completed successful transition of two IMP's to commercial R&D team.**
  - **Working on developing new ways to submit regulatory labeling documents with HRA so that there is simplification of process.**

ACADEMIC CREDENTIALS

Degree/Certificate	Institute/University	Year of Passing	Marks Obtained
B.E (Mechanical)	Dr. BAM University, Aurangabad	2014	68%
12th (State Board)	Deogiri College Science, Aurangabad	2010	66%
10th (State Board)	MPS, Aurangabad	2008	85%