Laxman J. Kumar, Ph.D
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About

An accomplished Senior Clinical and Regulatory professional in Biopharma and Medical devices with overall 21 years of progressive experience in Clinical trials, Pharmacovigilance, QA/QC, Regulatory, Medical devices and process excellence.
Having extensive experience in establishing Quality Management systems as per the ISO9001, ISO27001, ISO20000, ISO14155 and applicable national and international standards. I have conducted 300+ GxP audits which include both global and local. I had contributed in facilitating various Regulatory inspections and Global audits (USFDA,WHO, DCGI and EMA).

FUNCTIONAL EXPERIENCE & SKILLS:

Regulatory:
• Preparation and review of Product registration dossiers
• Preparation and review of T-License, import/export dossiers,
• Preparation and review of product registration and life cycle management dossiers, review of responses to regulatory authorities or review of deficiency responses.
• Preparation and review of Drug Master File (DMF)
• Preparation and review of CEP
• Preparation and review of Variations
• Review of DMF-Annual Reports
• Review of eCTDs for IND/CTA, NDA/MAA, ANDA

IDMP
• Identification of IDMP data points from CMC and SPC documents as per the following ISO guidelines: ISO IDMP, ISO:11615, ISO:11616, ISO:11238, ISO:11239,ISO:11240.
• Identified the IDMP data points present in the SmPC
• Identified the IDMP data points present in CMC documents
• Actively contributed in developing SmPxtract and CMC xtract tools for extraction IDMP datapoints from the SPC and CMC documents. Specialist in developing business rules for the

extraction of CMC and SPC datapoints
Labeling
• Specialist in CCDS and Labelling which includes SmPC, USPI, conversion of non-PLR labeling to PLR converstion, PLLR preparations
• Preparation and updation of Local product document LPD
• Specialist in preparing business rules for local labels creation from CCDS/SPS/USPI documents
• Specialist in SPL submissions, drug listing, establishment registrations
Medical Devices & MDR:
• Specislist in 14155 (medical device clinical investigations)
• Preparation and review of CER (Clinical evaluation Report)
• Preparation and submission of 510(k) submissions
• Preparation and submission of PMA submissions
• Specialist in review of Device master files and plant master filesas per 13485/QSR regulations
• Supported regulatory compliance activities for post market vigilance reporting (MDR), and product recalls.