Xplore HealthCare Solutions, LLP

" 35+ years of Proficiency "

Offering expertise as Auditors, Consultants and trainers in:

- *Medical Devices*
- *Pharmaceutical*
- *Bio-Tech / Biosimilars*
- *Nutraceuticals / Food*
- *OTC*

Mr. Omprakash S. Sadhwani
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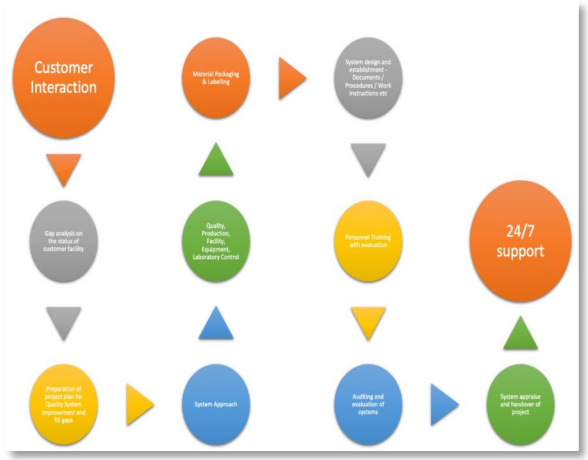
CGMP Compliance / Regulatory Approval



Vision & Mission

Mission
To provide the best consulting services and support to our customers and stakeholders.

Vision
- To help our customers achieve excellence in their fields.
- To provide hassle-free regulatory and documentation process.

ABOUT US

With 35+ years of rich experience as a CONSULTANT, AUDITORS & TRAINERS into Medical Devices,Pharma, Biotech / Biosimilars, *Nutraceuticals* / Food & OTC Industries, we aim to deliver our commitments to the clients, focusing on transparency, high quality standards on stipulated time and wish to offer services to your esteemed organization with an aim to explore an alliance between you and us that could help you to get faster approvals across the Globe along with start to end services.

We are based at ***Thane-Mumbai*** and providing services across the Globe [USA, Europe, Canada, Brazil, ASEAN, Bangladesh, MENA, GCC, ROW & PAN India]

Xplore Healthcare Solutions aims for ***precision and productivity***, drives our deep knowledge of Medical Devices, Pharma, Biotech / Biosimilars & Nutraceutical / Food, OTCs about global regulations and keeps us focused on the issues that matter to your organization. We provide tools that optimize employee productivity and free them up to focus on providing the highest quality patient care and with fastest approval from Regulatory bodies.

XPLORE HEALTHCARE SOLUTIONS, LLP

UNIT No-144, LODHA BOULEVARD COMMERCIAL PREMISES CO-OP-SOC- LTD, Nashik Highway road, Majiwada, Thane-west, Pin-400601

OUR SERVICES

Medical Devices

- Sugam Portal submissions for CDSCO/DCGI.
- Preparation of Device Master File/technical documentation/Plant Master File
- ISO 13485:2016 Certification
- ISO 9001:2015 Certification
- Lead Audits as per ISO 13485:2016, ISO 9001-2015 GMP and Compliance.
- MDD to MDR Implementation as per Indian MDR-17 & EU-MDR
- Medical Device Registration in USA, Europe, (EUDAMED), Singapore, Brazil, Canada, India and rest of the world (ROW)
- Regulatory Filing to USFDA like 510(k)

Audit

- Audits & Pre Approval Inspection as per country-specific requirements
- Regulatory Compliance Audits, and Mock Audits (PAI)

Compliances

- Regulatory Compilation of all modules CTD-M1, M2, M3, M4, M5 and Global Submissions (pCTD, eCTD, ACTD, NEES formats)
- Technical , CMC writings, GMP Validation documentation support as per USFDA, EMA, TGA, MCC, UK-MHRA, SFDA, GCC, CFDA , RoW, Russia & CIS, Indian DCGI & CDSCO and other country-specific requirements.
- GxP compliance services which includes [GMP, GLP, GCP, GDP, Due diligence, Validations, CSV, Data integrity etc

Labelling Management

- Labelling Management - Preparation of draft Labels for Primary and Secondary Packaging Materials, Patient Information Leaflet &SPC.
- Structured Product Labelling (SPL) for US
- Expertise in conversion of FDA compliant & validated SPL files (XML)
- NDC Labeller Code / Establishment Registration / GDUFA Identification
- Drug Labelling (Prescription, OTC and Compounded)
- Life-cycle management of SPL (version and set id management)
- SPL validation as per FDA compliant and specification (zero error)

OUR SERVICES

Common Technical Document

- MAA CTD for Europe Submission, South Africa-CTD, Australia-CTD, Kenya & Uganda CTD
- ACTD ie. ASEAN CTD (Malaysia, Thailand, Philippines, Singapore, Myanmar, Cambodia, Vietnam, Indonesia, Brunei, Laos)
- Preparation and submission of ANVISA GMP Inspection documents, ANVISA CTD dossiers, Validation package

Documentation

- Dossier writing from Module 1 to Module 5 for generic and new drug application [IND, NDA, ANDA, BLA].
- Quality Module 3- CMC and Scientific Writing
- Critical Review of Dossier and Preparation of GAP Analysis Report,
- Existing dossier suitability to new market (Gap analysis and solution
- US-DMF [Type II Drug Master File review and writing in ICH-M4Q format], Active Substance Master File (ASMF)-EU, KDMF (Korean), DMF Type III & Type IV [Excipients & Packaging materials].
- APIMF (WHO), MF (PMDA, Japan) and emerging markets DMF

CEP & CoS

- CEP & CoS (Certificate of Suitability to the monographs of European Pharmacopoeia) submission to EDQM

Product Management

- Product Life cycle Management i.e. Product variation / amendment application - Defining the type of variation (Type I or Type II for EU, PAS, CBE 30 or APR for USA)
- Reviewing technical data, preparation of application and submission to health authority
- Query response - Preparation of query response based on Health Authority's query and timely submission to our client / authority

Validations

- Validations Services (i.e. Analytical Method Validation, Process Validation, Computer System Validation - CSV as per EU Annex-11, GAMP-5, 21 CFR parts11)
- Validation & Qualification of Pharmaceutical Manufacturing equipment & Laboratory Instruments [DQ, IQ, OQ, PQ] with complete validation documentation.

OUR SERVICES

Training

- In House Training and Workshops into RA, QA, GMP, ICH, QbD, Clinical Research, PV, Patent, Validations and related areas, etc.. We can make TAILOR-MADE training programs as per your requirements.
- We are specialized into customized certified Skill Development Programs as per the need of the organization
- Pharmacovigilance & Medical Writing services

Clinical Trial/ Clinical Study

- Formulation Development (QbD) , Support for Clinical Trial, BE study and Toxicity Study and Technology and Site transfer etc
- Helping Hand to CRO's
- Support in Product Development and Technology Transfer, and support in BA/BE studies

OUR CLIENTS

- Accenture
- Alembic Fredun
- Apoorva International
- ATOS
- Bajaj healthcare
- BKS Textile
- Cipla
- Cognizant
- Galpha Laboratories
- ESSTEE Healthcare
- Ives Healthcare
- Kamani Oils
- Mann Pharmaceuticals
- Meha Chemicals
- Micron Pharmaceuticals
- Naturmega C.S. Teva pharma, etc.
- Novartis
- Piramal Healthcare
- REPL
- Sandoz
- Solco Healthcare
- Sonal Plasrub
- Syncom Formulations
- TCS
- Titan Labs
- Troikaa
- Venus Remedies