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
Director, Xplore HealthCare Solutions
Lead Auditor, Former Joint commissioner and Drug Controller FDA Maharashtra

Ms. Rajashri Survase-Ojha
Director , Xplore HealthCare Solutions
Founder & Director, RAAJ GPRAC, Global RA-GMP, Consultant Lead Auditor

Mr. Ram Banarse
Director, Xplore HealthCare Solutions
Lead Auditor, Former Asst. Commissioner FDA Maharashtra,

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, Pharmaceutical, 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 LLP is a regulatory and development consultant, which acts as a helping hand to **Medical devices and in-vitro diagnostics (IVD)** companies to commercialize their products in India.*

We provide end-to-end product categorization services. From ideation to market entry, we design and implement efficient and effective regulatory and product development solutions which integrate science, regulations and business objectives, to overcome product commercialization challenges.

*We provide **'intelligent strategies "instead of simplified, often cost-intensive routine Device Development Programs"** to ensure the highest possible regulatory acceptance of your product. We thereby ensure effective compliance and thus help you, our customers navigate the complex, medical devices regulatory landscape and make right decisions.*

*We support clients to register your medical devices **[For all kind of Devices, IVDs, Diagnostics, PPE Kits, Masks, Coveralls, N95, NIOSH etc]** as per world-wide regulations and for all types of risk-based classes (Low, Moderate, High) as per country-specific intelligence & regulatory requirement*

OUR SERVICES

- *Sugam Portal submissions for* CDSCO/DCGI
- ***ISO 13485:2016*** *Certification*
- ***ISO 9001:2015*** *Certification*
- *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)*
- *Building Robust QMS system as per ISO 13485:2016*
- *ISO 9001:2015 for Management systems and all relevant SOPs, QM records and documentation.*
- ***USFDA filing, FEI Registration*** *and Device listing for Bouffant caps, Skull Caps.*
- *CE marks and All EU Registrations*
- *Internal and External audit in various stages of Medical devices till certifications received from Certification body* ***{BSI-UK}***
- *Labelling requirements.*
- *Conformity Assessment*

OUR SERVICES

- *Preparation of Device Master File/technical documentation/Plant Master File.*
- *Software verification and validation as per CSV, 21CFR Parts*
- *Clinical Evaluation, investigation*
- *Post marketing surveillance, PMCF, Amendments, Supplements*
- *Other ROW Country Specific Submissions*
- *Lead Audits as per ISO 13485:2016, ISO 9001-2015 GMP and Compliance*
- *Online or In House Training for Employees GMP, ISO, CAPA, 21 CFR, QMS, Risk Management*

XPLORE HEALTHCARE SOLUTIONS, LLP

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

+91 98191 25208
+91 90041 19396

directorxplore@gmail.com

https://xplore-healthcare.com/