



“ 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.  
Commisioner, FDA Maharashtra

## Vision & Mission

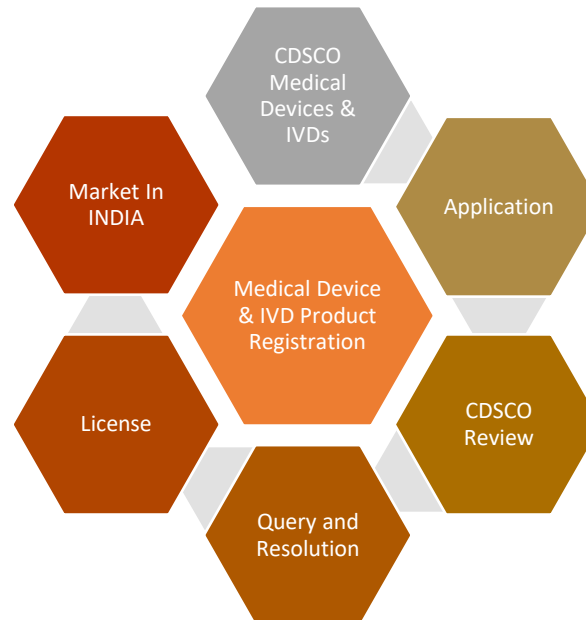
### Mission

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.

## Medical Device & IVD Product Registration



## 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]

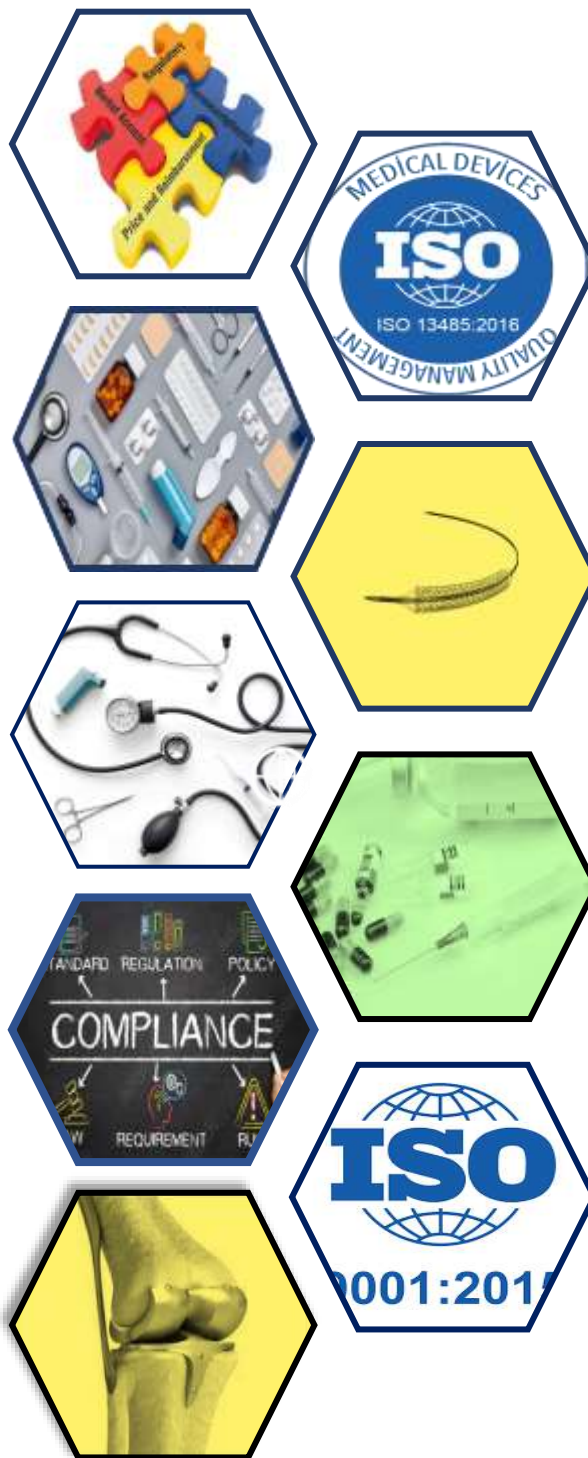
Xplore healthcare solutions LLP is a regulatory and development consultant, which acts as a helping hand to **Medical devices and in-vitro diagnostics (IVD)** companies to commercialize their products in India.

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.
- 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)
- US agent and e-filing Support
- CE marks and All EU Registrations
- Conformity Assessment
- Software verification and validation as per CSV, 21CFR Parts
- Clinical Evaluation, investigation
- Post marketing surveillance, PMCF, Amendments, Supplements
- Other ROW Country Specific Submissions
- Online or In House Training for Employees GMP, ISO, CAPA, 21 CFR, QMS, Risk Management.



## OUR CLIENTS

- Accenture
- Alembic Fredun
- Apoorva International
- ATOS
- Bajaj healthcare
- BKS Textiles
- Cipla
- Cognizant
- ESSTEE Healthcare
- Galpha Laboratories
- Ives Healthcare
- Mann Pharmaceuticals
- Meha Chemicals
- Micron Pharmaceuticals
- Naturmega
- Novartis
- Piramal Healthcare
- REPL
- Sandoz
- Solco Healthcare
- Sonal Plasrub
- Syncom Formulations
- Teva Pharmaceutical Industries Ltd.
- Titan Labs
- Troikaa
- Venus Remedies And Many Other Leading Industry GIANTS.

## XPLORE HEALTHCARE SOLUTIONS, LLP

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