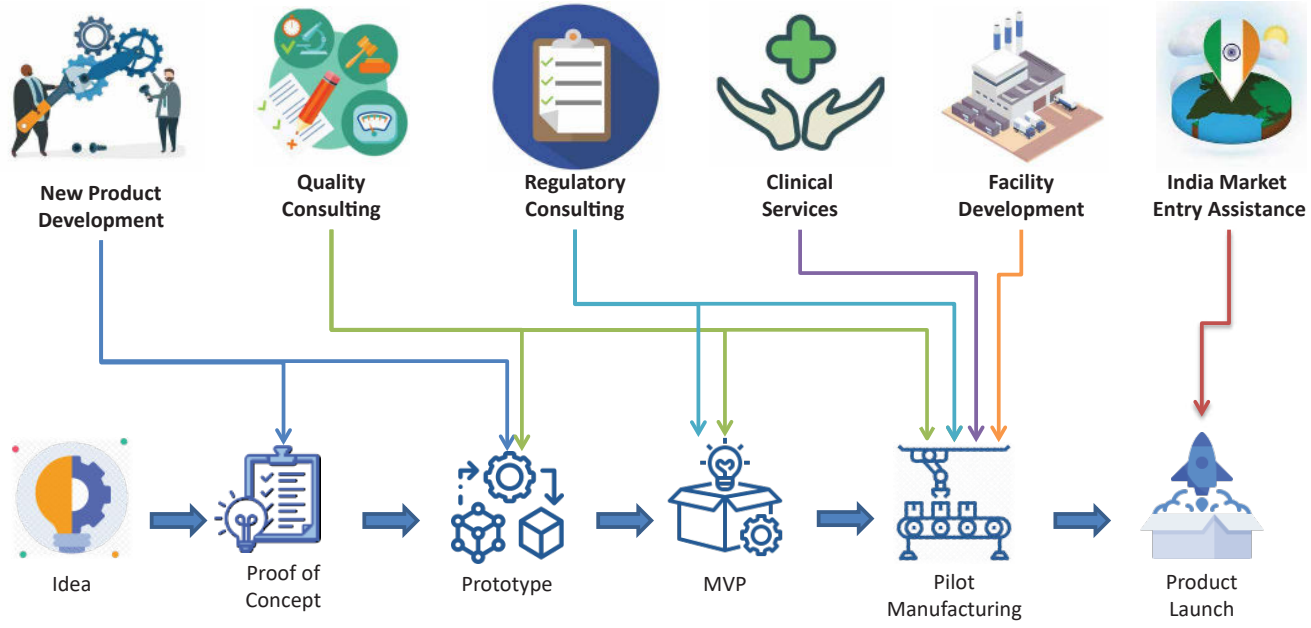
D2R Global Consulting
Solutions & Services for MedTech

NO. 1
TURNKEY MEDICAL DEVICE ADVISORY SERVICES AND SOLUTIONS



How We Operate

Our Services

New Product Development

Device Prototyping

- Architecture Creation/ Selection
- SRS & FRS Creation
- Schematic Development
- Layout Development
- End to End Design Verification
- Turnkey project solutions
- Manufacturing of Bare PCB
- Assembly line (SMD and Through Hole)
- Board Bring Up
- PoC Development

Device Testing

- Safety
- EMC/EMI testing
- RF testing
- Wireless co-existence
- BIS testing
- CB testing
- FCC
- RED/ETSI
- RoHS

Facility Development

- Site Identification
- Obtaining Statutory Approvals
- Facility Layout Design in AutoCAD
- AHU Design
- ISO Cleanroom Development
- Process Validation (Sterilization, Men-Material Movement)
- Building Management System (BMS) Integration
- Facility Validation Document Development
- Facility Parameter Validation by 3rd Party NABL lab
- Facility Acceptance Test Certificate
- Simulation Lab Setup for Medical Colleges as per NMC

Quality Consulting

- ISO 9001:2015 - QMS Certification
- ISO 13485:2016 –Medical Devices & Diagnostics
- Quality Management System Regulation (QMSR)
- Medical Device Single Audit Program (MDSAP)
- FDA 21 CFR 820 Implementation
- GLP – Good Laboratory Practices
- GCP – Good Clinical Practices
- GMP – Good Manufacturing Practices
- ISO 27001:2022 – Information Security
- ISO 15189:2022 – Medical Laboratories
- ISO 17025:2017 – Biological Testing of Laboratories
- NABH Accreditation for Hospitals
- CAP (College of American Pathologists) for Diagnostic Lab
- AABB (American Association of Blood Banks)
- DUNS (Data Universal Numbering System) Registration
- DSIR (Department of Scientific & Industrial Research)Registration

Clinial Study

- Protocol Development
- Bio-Statistics Analysis
- Site Identification
- IEC Approval
- CTRI Registration
- CRA and Physician Training
- Subject Enrolment
- Data Collection
- Data Analysis
- Clinical Evaluation Report (CER)
- Post Market Study (PMS)

Regulatory Consulting

- Test License from CDSCO/DCGI
- Wholesale License (Form MD42) from CDSCO/DCGI
- Manufacturing License from CDSCO/DCGI
- Loan License from CDSCO/DCGI
- Import License from CDSCO/DCGI
- Authorized Representative (AR) Services
- CE Certificate for European Union
- US FDA (510k, PMA, IDE, Q-Sub & Pre-sub meetings)
- International CLIA
- KPME Registration
- EPR Registration from CPCB (NOC from MoEFCC)
- PC-PNDT Registration
- AERB License (e-Licensing of Radiation Applications)
- Legal Metrology License
- NPPA/DPCO Communication and Resolution
- Biodiversity Act Compliance Registration
- Government e-Marketplace (GeM) Registration
- IVD - Performance Evaluation Testing in NIB
- COFEPRIS (Mexico) Registration
- Health Canada Registration
- UKCA (UK) Registration
- Singapore & Malaysia Registration
- Indonesia & Sri Lanka Registration
- WPC - Equipment Type Approval (ETA)
- Telecommunication and Engineering Center (TEC) Approval
- Refurbished Medical Device Statutory Guidance
- STP/Non-STP Unit registration with STPI (Software Technology Parks of India) for IT/ITES companies
- EOU (Export Oriented Units) Registration

Digital Health and Information Security

Digital Technologies

- Software as a Medical Device (SaMD)
- Internet of Medical Things (IoMT)
- Wearables
- Healthcare Web Application
- Remote Patient Monitoring
- Electronic Data Capturing (EDC)
- Clinical Decision Support (CDS) Software
- Interoperability
- AI/ML based Application

Integration

- Telemedicine/Telehealth
- Ayushman Bharat Digital Mission (ABDM) Sandbox
- HL7 and Picture Archiving and Communication System (PACS)
- Electronic Health Records (EHR)
- Hospital Information System (HIS) and Laboratory Information Management Systems (LIMS) Integration
- HFR & HPR Integration

Compliance Support

- Quality Management System Regulation (QMSR)
- ISO 27001:2022 implementation
- HIPAA, GDPR and DPDPA
- Data Processor Certificate
- SOC 1 & SOC 2 Implementation
- HiTrust Implementation
- Computer System Validation (CSV)
- Cybersecurity Testing
- Threat Modeling
- WASA and VAPT Testing

India Market Entry Assistance

- Market Analysis
- Demand & Supply Gap
- Strategy Formulation
- Entity Formation
- Construction of Manufacturing Unit
- Connecting Reliable Sales Channels
- Ongoing Support in Regulatory approvals, Quality and Operational setup
- Mergers and Acquisitions

ABOUT D2R GLOBAL

Established in 2018 (Previously Elite QARA Consulting), D2R is a turnkey medical device consulting firm with access to global markets. Our team of 30 cross-functional domain experts specializes in **Devices, Diagnostics, and Digital Health,** enabling the business success of medical device manufacturers.

We offer customized services in new product development, quality consulting, clinical studies, regulatory consulting, facility development, digital health & information security, and India market entry assistance.

We help innovators and startups to take their idea to market with quick turnaround.

In 6 years, we have served over **75 clients** and successfully delivered more than **100 projects globally**.

We understand the cross functional subject matters better than the conventional consulting.

Happy Customers

Scan the QR code to ask Questions

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