



D2R GLOBAL CONSULTING
MedTech | BioTech | HealthTech

**Your Trusted Partner In
Regulatory Compliance**

Key stages where we partner with companies



**Specialised in Medical Device, IVD & Software
as a Medical Device (SaMD)**

Our Impact

125
Approvals

200+
Customers

350
Projects

30
Experts

“

“

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

”

Registered Office:

S8, No: 40&41, 3rd Cross, Vijaylaxmi
Layout, Babusapalya, Bengaluru,
Karnataka, India - 560043

Scan to book a
free consultation



info@d2rgc.com



+91- 63602 99044



<http://www.d2rgc.com>

Our Services

Regulatory Consulting

- CDSCO Licenses (Manufacturing, Import, Test, Wholesale)
- USFDA approvals (510k, IDE, Denovo)
- CE Certification (EU MDR & IVDR)
- Regulatory Strategy & Gap analysis
- Predicate analysis/Substantial Equivalence
- Technical Documentation (DMF, PMF, CER, Risk Management etc.)

Startup Support

- Quality & Regulatory Staff augmentation
- QMS Audit assistance
- Bench testing guidance (stability, sterility, packaging etc.)
- Manufacturing facility design
- Grant application assistance (BIRAC, PRIP, ELEVATE, SAMRIDH etc.)
- Investors connect

Quality Consulting

- ISO 13485, 27001, 9001
- ISO 15189 & 17025
- MDSAP & QMSR
- DSIR Certification
- BIS Certification
- NABH, NABL & CAP Accreditation

Pilot Clinical Study

- Protocol Development
- IEC approval & CTRI registration
- Feasibility Study for Device, IVD and SaMD
- Health Technology Assessment
- IBSC & GEAC approvals
- IVD kit's PQ evaluation

Licenses & Registrations

- GeM Registration
- SOFTEx Registration
- EPR Registration with CPCB (e-waste, battery and plastic)
- Legal Metrology License
- WPC ETA (Wireless Equipment Type Approval)
- Factory License

Prototyping

- Wearable & IoMT (Internet of Medical Things)
- Point of care (POC) & Remote patient monitoring
- Digital diagnostics & Digital therapeutics
- Pre & full compliance testing services (EMI/EMC) assistance
- Cybersecurity testing
- ESDM (Electronics System Design & Manufacturing)

**Fast-track your innovation in Medical Devices,
Diagnostics & Digital Health**

**Expertise Across
Global Compliance
Frameworks**

