# Wipro's QARA Services

## (Quality Assurance & Regulatory Affairs)

**End-to-end comprehensive regulatory and compliance services for medical device and life sciences OEMs**

## Introduction

Wipro provides expertise in quality assurance and regulatory affairs for improved device safety and effectiveness and reduced risks associated with non-compliance. Our extensive working knowledge of global regulatory requirements and an in-house device testing lab facility helps balance compliance goals with market requirements.

## Key Takeaways

Support global product launch strategy in line with latest requirements such as FDA 21st Century Cures Act of 2017, EU MDR regulations of 2017 and SaMD

QMS accreditations: ISO 13485, IEC 62304, ISO 14971, IEC 60601-1, EUMDR 2017/745, FDA QSR-21CFR820

Tarang: Wipro's 24x7 independent product qualification and compliance laboratory with testing capabilities for Electromagnetic Compatibility (EMC), safety, environment, Wi-Fi, Bluetooth, shock & vibration, noise, material, calibration, medical devices, etc.

**Wipro provides expertise in QARA for improved device safety and effectiveness while reducing risks and costs of non- compliance and non-quality**

## Key Features

- **Design Quality, Design Validation and Verification**

  Design controls, DHF preparation, technical documentation, risk management, system verification, regression testing, test automation, non-functional testing, reliability testing, FMECA, and FTA

- **Product QA**

  Process validation, equipment validation, manufacturing quality, CSV, CAPA remediation, and end of line automation

- **Regulatory Services**

  Regulatory consulting, global product registration, QMS harmonization, EU MDR, IVDR, SaMD, CAPA, risk management, CER/PERs, PSURs, usability

testing, GCP, GLP audits, supplier audits, and certification support

- **Safety & Compliance Services**
  Wipro's Tarang labs - EMI/EMC, acoustics, reliability, safety test, wireless test, environmental testing, bio-compatibility, RoHS, cytotoxicity, and sterilization testing

- **Post Market Surveillance**
  Complaints management, medical and safety writing, ICSR management, regulatory submissions, device product periodic & aggregate safety reports, and literature search

- **QARA Ecosystem**
  Wipro has established strategic partnerships with some of key platforms and service providers that complement and accelerate the QARA services

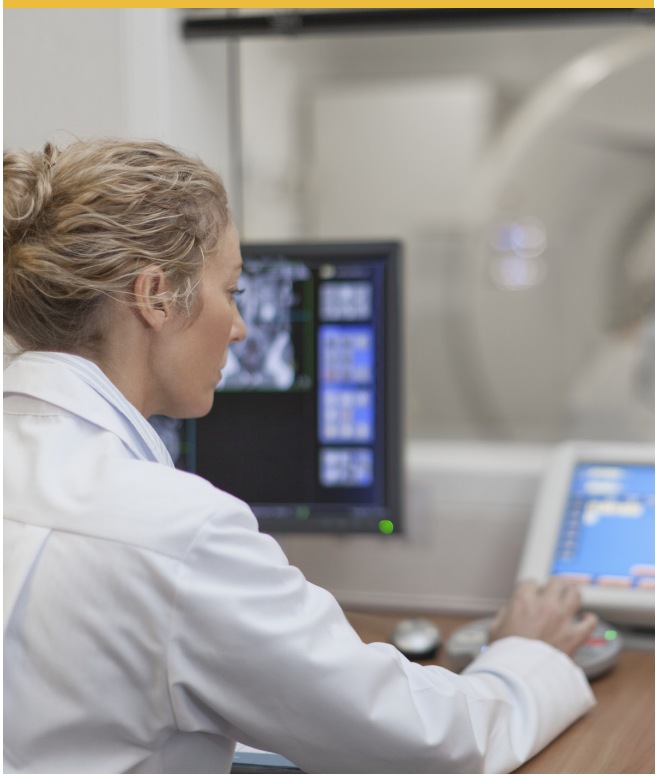
# Key Benefits

- For the NPD and sustenance products, meeting the regulatory requirements in time and helping OEMs achieve faster time-to-market

- Lab and partner lab eco-system help achieve pre-compliance and compliance tests needs and meet notified body audits

- End-to-end regulatory services combined with any shore model gives OEM the flexibility and scale for all their compliance needs

**Wipro saved more than 18,000 hours of effort for a global med-tech customer by remediation of technical files across 800 unique products and 15,000 variants resulting in savings of $2M**



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IND/TBS/MAY-DEC 2020