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Growth partnership for a self-care centric lifestyle

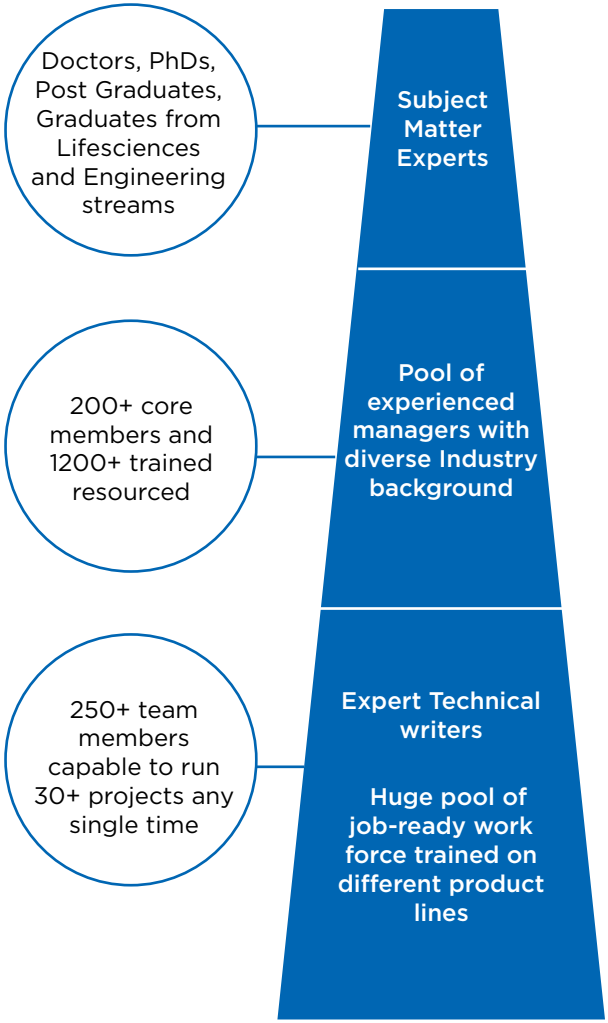
Innovation | Acceleration | Growth

Regulatory and clinical affairs capabilities

With highly experienced 350+ regulatory affairs specialists and 1200+ trained resources, established relationship with notified bodies, experience in supporting remediation of QMS dor medical devices customers, and expert physicians within the clinical team, our Regulatory and Clinical CoEs bring in right domain expertise to provide simple and efficient approach to ensure regulatory compliance and quality.

HCL REGULATORY CENTRE OF EXCELLENCE

Values delivered



8 of 10 Top Medical Device firms and 4 of 5 Top IVD Device Firms

Interacting with 40+ Sites, working in 4 Geos, Multilingual like English, German, French, Japanese

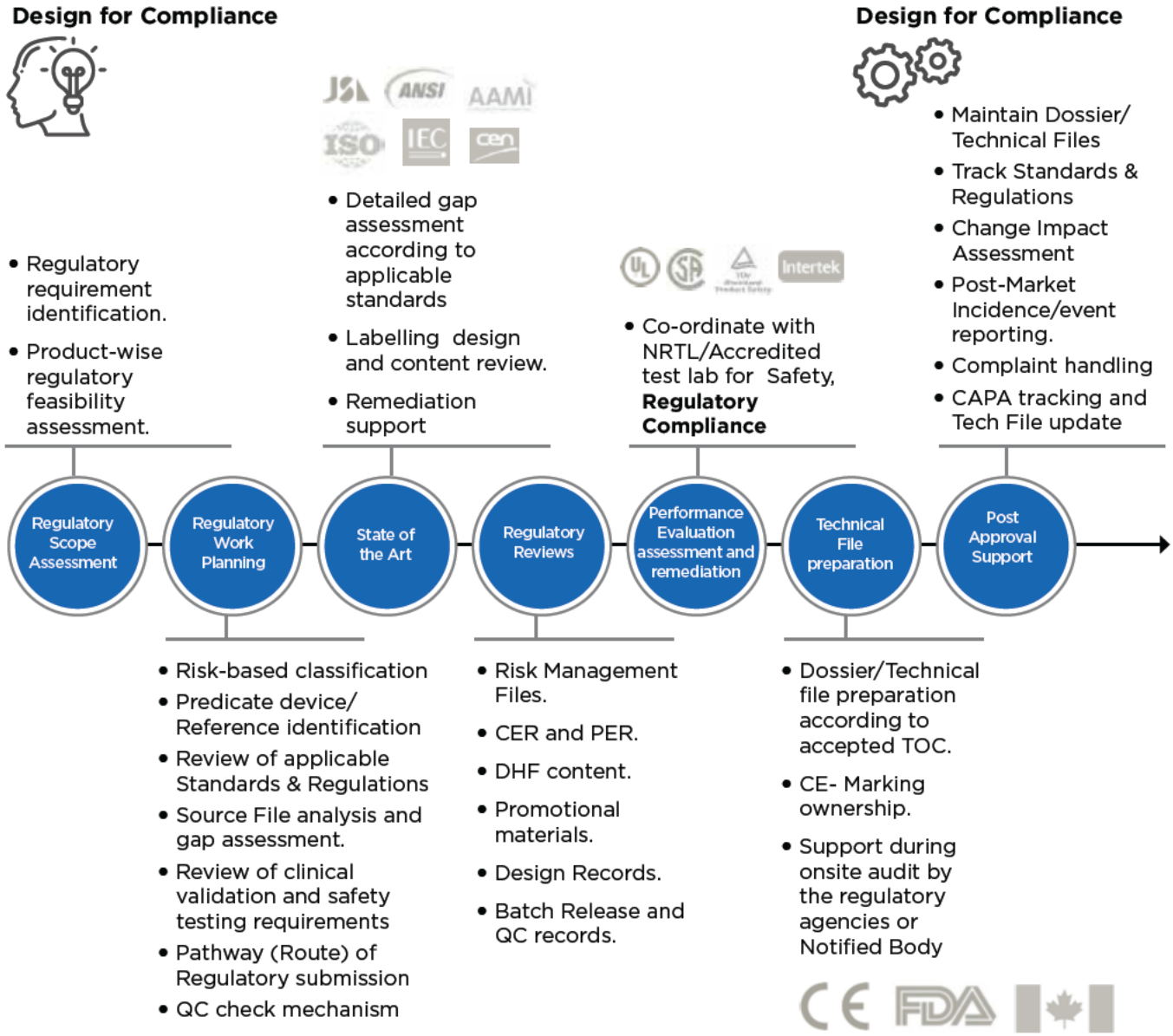
7,000+ Tech Files supported for assessment and remediation

20+ QMS Assessment - Effectiveness Analysis and Remediation of procedures and templates

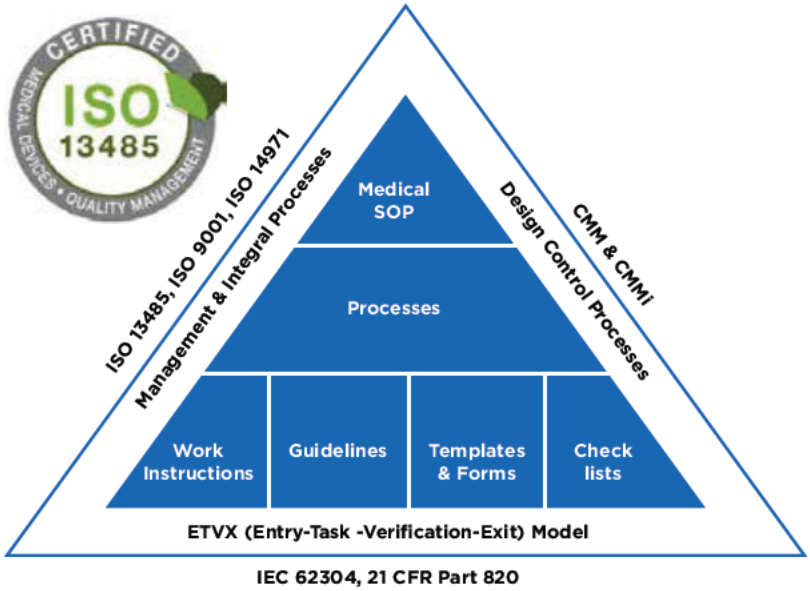
Process Maturity:
CMMI Level 5 | ISO:13485 | BS 7799 | ISO:27001

Successful support in implementation of process and product quality standards (e.g. ISO 13485, ISO 4971, ISO 60601x, ISO 10993, IEC 61010x, 61326x IEC 62304, IEC 62366x and UDI)

At every step of your regulatory affairs journey



MQMS, our principle and approach



Deployment Tools

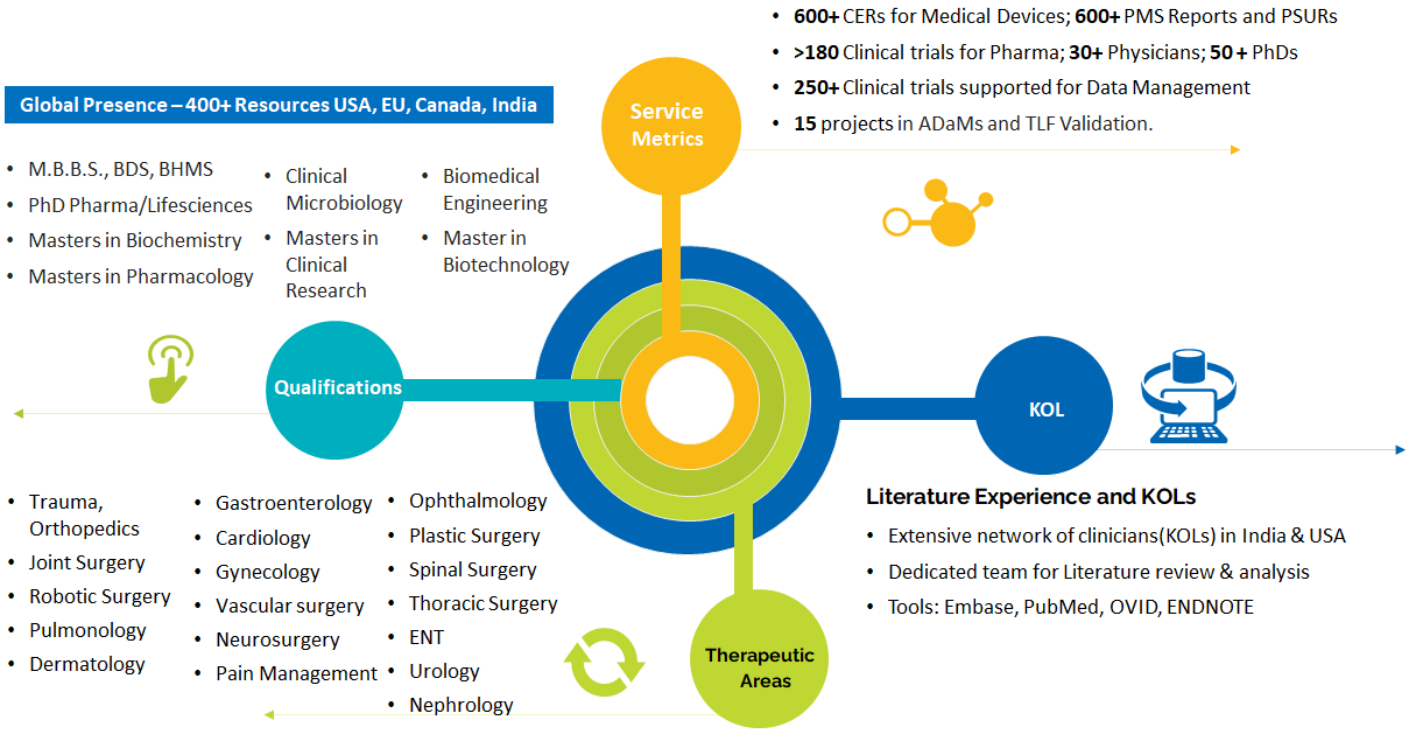
- Intranet based system
- Process database
  - Risk / Reusable components
  - Best Practices
  - Learning's

Deployment Mechanism

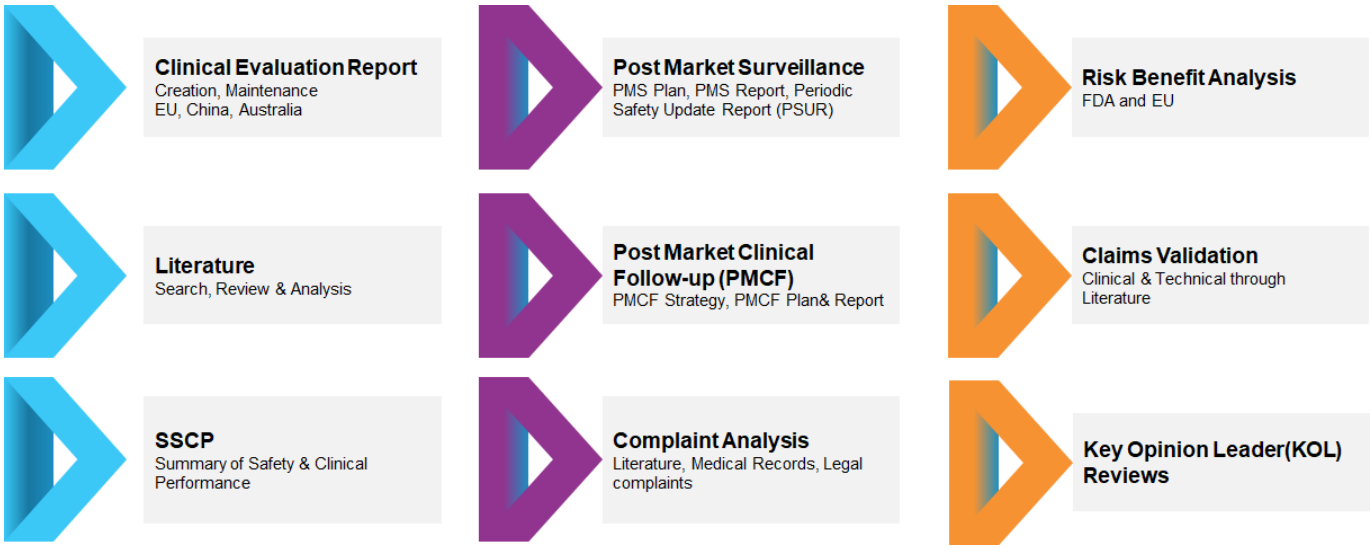
- Induction Training
- Calendar Based Trainings
  - MQMS Training
  - ISO 13485, ISO 14971, IEC 62304 & QSR awareness Trainings
- Role based Training – PQA, CC
- Process update Training

- **ISO 13485** Medical Devices–QMS–Regulatory Requirement
- **21 CFR Part 820** US FDA Quality System Regulations (QSR)
- **21 CFR Part 11** Electronic Records; Electronic Signature
- **ISO 14971** Risk Management for Medical Devices
- **ISO/IEC 62304** Medical Device – SDLC Process
- **IEC 62366 MD** - Application of Usability Engineering
- **AAMI TIR45** Guidance on the use of AGILE practices in the development of medical device software
- **USFDA** Guidance Documents
- **GAMP 5** (Good Automated Manufacturing Practice, by ISPE)
- **GDP** Good Documentation Practice
- **ISO 9001 QMS** – General Requirement
- **MHLW** Ministerial Ordinance No.169: Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents
- **CMMI** Capability Maturity Model integration (Ver 1.3) Level 5
- **ISO/IEC 27001** Information Security Management System (ISMS)

CASE STUDY:
Clinical/Medical Affairs COE



CASE STUDY:
Medical Device Clinical Evaluation - Offerings



Case Studies Snippets

30% - Reduction in Cost for a Large Medical Device Leader by setting up a Centralized Clinical Support

Completed Gap Assessments for 250+ Tech Files - For a large US based Diagnostic Provider

60,000 + Complaints reviewed for large Med Device Customer

FOR MORE INFORMATION, PLEASE CONTACT

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