IZIEL
HEALTHCARE

inspire : engineer : achieve
WHO WE ARE

IZiel Group is built on the foundation of technical excellence, sound management practices and winning customer trust.

IZiel Healthcare provides Engineering & Regulatory Services for global medical device companies from our offices in USA & India. IZiel has successfully completed projects in design, engineering documentation, process validation & improvement, software validation, regulatory approvals (USFDA, CE) and remediation to resolve observations (Form 483) & warning letters.

IZiel’s approach for an Outcome-Based Delivery along with the Cost-Effective Model using competent global teams in USA & India has worked very well for customers in USA, Europe and Asia. Our comprehensive evaluation and monitoring system ensure effective and timely deliveries.

OUR EXPERTISE

DESIGN

PROCESS

SOFTWARE VALIDATION

QUALITY SYSTEMS & CAPA

REGULATORY

REMEDINATION

CONSULTING & TRAINING

COLLABORATION - MANUFACTURING & MARKETING

OUR VALUES

INTEGRITY & TRUST
Build relationships within our team and with our clients.

COMPETENCE
Build competent teams to deliver value added outcomes.

WALK THE EXTRA MILE
Be an equal partner with the client to achieve their goals.
What is Remediation?
- Observations (Form 483)
- Warning Letters from USFDA
- MDD – MDR Conversion
- Resolve product design & process development issues
- Substantial number of unplanned resources & budgets
- Declined opportunity to sell

Why IZiel Healthcare?
- Conduct a Methodical & Comprehensive Gap Assessment.
- Outcome Based Delivery Approach
- Partner with Remediation/MDR Experts
- Quick Scalability of Skilled Resources
  - Design
  - Process Engineering & Validation
  - Systems Engineering
  - Software Validation & Testing
  - QMS and Regulatory.
- Assist in complete implementation
- Flexible Onshore/Offshore Model
- Significant Time and Cost Advantages
- Strong Project Management
IZIEL - OBELIS Collaboration

Together, IZiel & Obelis formed a partnership to create a "One-Stop Shop" to fully support Class I, IIa, IIb, III medical device manufacturers across USA, Europe & Asia to obtain conformity with the MDR (2017/3545) requirements and maintain their CE Marking - this, through technical support, consultancy, representation and device registration services.

Obelis is currently representing over 3000 exporters from more than 60 countries around the world.

ONE STOP COMPLETE SOLUTION

- Gap Assessment
- Technical File
- QMS Documentation
- CEP & CER
- Software Validation
- Expert Review & Recommendations
- European Authorised Representative (EC REP)
- EUDAMED
- Mock Audits & Trainings
- PPRC Services

KEY MDR CHANGES

- Conformity Assessment
- Detailed Clinical Evaluation Reports
- Labeling - UDI Implementation
- Intensive PMS & PMCF
- PPRC & Vigilance

CASE STUDIES

- Remediation of a Diagnostic Imaging Product
  - Create FDA Compliant Design, Process and Risk Management Documentation.
  - Software Validation (Software and Firmware) of an Image Acquisition, Post Processing and Systems Control Software.
  - Revamp Quality Management System & provide comprehensive training.
  - Onshore-Offshore Model implementing flexible resource allocation.

- USFDA Approval & Regulatory Strategy for Diagnostic Imaging Equipment
  - IZiel Hybrid Model bringing in cultural change to complete Design History File (DHF).
  - USFDA Approval through US-India Regulatory teams saving cost and time.

- New Acquisition Integration
  - New acquisition integration for one of the largest Fortune 100 Medical Device companies.
  - Revise and Create Work Instructions, Conduct Test Method Validations (TMV).
  - Complete Process Validation projects in accordance to the newly implemented Quality Management System.
  - Project Management using highly efficient Onshore - Offshore Model bringing in huge speed of implementation and cost saving to the entire integration effort.

- Offshore Support to US & European Clients and Partners
  - Procedure Development, Process Validation Support for FAT, SAT, IQ, OQ, PQ, TMV, & FMEA.
  - Highly Competent Team ensuring Cost & Time savings of 40% or more.

- Productivity Improvement for Disposable Products of a large German Manufacturer
  - Adopted DFSS & Lean Manufacturing Principles alongside Process Automation.
  - Productivity increased by 25% occupying only 70% of the existing space.

- Product Design & Development for Myonic Arm
  - Project Approved and Funded by BIRAC, Government of India.
  - Product Design, Modeling & Detailing for 5 gestures covering 80% of hand movement.
TEAM COMPETENCY

CARDIOVASCULAR

DIAGNOSTIC IMAGING

ORTHOPEDIC

IN VITRO DIAGNOSTICS

DIABETOLOGY

GENERAL SURGERY

HOSPITAL EQUIPMENTS

OPHTHALMOLOGY

ACHIEVEMENTS

- MedTech Outlook magazine

Empanelled with Andhra Pradesh MedTech Zone, Government of India

‘25 fastest growing MedTech companies in India, 2017’
- CEO magazine

10 Best Startups in Medical Devices in India, 2017.
- Startup City magazine

CLIENTS

Work done for medical device companies through iziel Healthcare.

- Medtronic
- Medicos
- Sterisys
- Agape Diagnostics
- Skanray Technologies
- Jana Care
- Mediso Imaging
- Primus Sterilizer
- Dispose
- Omnileks
- USM Healthcare
- Kalyani Additives
- Heartware
- Hospitech
- Amolab
- Prognosys
- Dee Dee Labs
- Epsilon
IZiel Healthcare has developed a strong global presence by developing collaborations and partnerships to help medical device companies with -

- Functional Teams in USA, Europe & India
- Quick Scalability for Faster Timelines
- Lower Budgets / Costs
- Strategy & Implementation
- Short Term Deployment with quick turnaround

**COGNITION CORPORATION (USA) —**
- Sole Reseller of QMS & Requirements Management Software in Asian Region
- Data Migration, Implementation, Training & Customization of Cognition Cockpit

**OBELIS (BELGIUM) —**
- MDD - MDR Transition for Class I, IIa, IIb & III medical devices
- EC / UK Representative alongwith expert review for documentation

**MEDICAL ENGINEERING CONSULTANTS (USA) —**
- USFDA Remediation to resolve findings, observations and warnings
- Onshore – Offshore Model for Engineering & Regulatory Services

**REGULATORY CONSULTANTS (USA) —**
- Regulatory Partners for 510(k) / PMA Submissions for USFDA Approval
- Ex-FDA Auditors with more than 3500 + reviews and approvals

**PRAGMATEK CONSULTING GROUP (USA) —**
- Process Improvement, Change Management and IT Consulting
- Product Remediation support as per USFDA requirements

**SPELLBOUND INC. (INDIA) —**
- Preparation of Clinical Evaluation Plans & Reports
- 30 + National Board Certified Physicians

IZiel Healthcare is looking to collaborate or make joint ventures with organizations abroad for distribution & manufacturing of niche products. IZiel has developed the necessary industrial infrastructure, team and technical capabilities for manufacturing & assembling in India. Industrial infrastructure includes a building of around 20,000 sq.ft. with a land of approximately 100,000 sq.ft. for future expansions.

**MARKETING**

- Set-Up Representative Office for companies manufacturing unique products.
- Develop Sales & Marketing Team, Super Distributor to appoint distributors, agents.
- Joint Venture, Collaborate for Manufacturing & Sale in Asian countries.