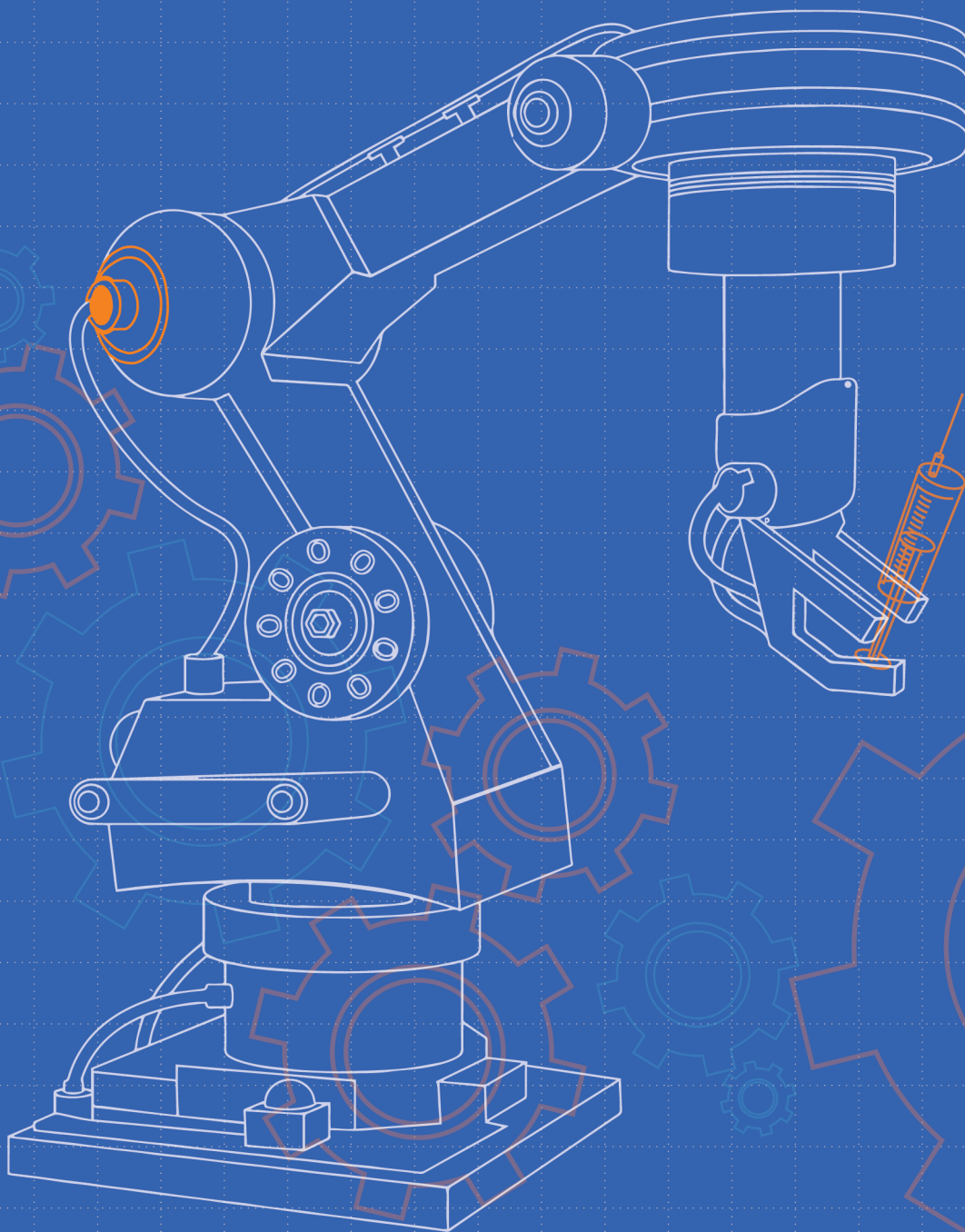




IZIEL HEALTHCARE

inspire : engineer : achieve



WHO WE ARE



IZiel is an ISO 13485 certified organization built on a foundation of technical excellence, strong management practices and a commitment to customer trust.

IZiel Healthcare provides Engineering, Software & Regulatory Services for global medical device companies from our offices in USA and India.

Our outcome-based delivery and cost-effective resource model combined with robust evaluation and monitoring systems, ensures efficient and timely deliveries for customers across the USA, Europe and Asia.

OUR GROWTH STORY



TOP 10
MEDICAL DEVICE
COMPANIES



500+
PROJECTS
COMPLETED



100+
GLOBAL
CUSTOMERS



FLEXIBLE
ONSHORE-OFFSHORE
MODEL



70%
REDUCED
WORKLOAD



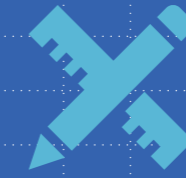
35%
COST & TIME
SAVING

CUSTOMERS (100+)

- Medtronic
- Becton Dickinson
- Harvard Biosciences
- Coloplast
- Cantel
- SLH Medical
- Heraeus
- Hiossen
- Helen of Troy
- Enraf Nonius
- Amsino
- Spacelabs
- Magic Leap
- Epicor
- Remidio Innovations
- Primus Sterilizer
- Erbe Vision
- Mediso Imaging
- Cair LGL
- Sterisys
- Air Liquide
- Medikor
- Zest Dental
- Skanray
- Nitto Denko
- USM Healthcare
- Hospitech
- Alveofit

OUR EXPERTISE

DESIGN



PROCESS



SOFTWARE & TOOL
VALIDATION



QUALITY SYSTEMS
& CAPA



REGULATORY



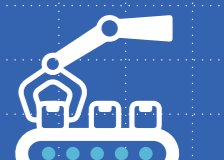
REMEDiation



ACQUISITION
INTEGRATION

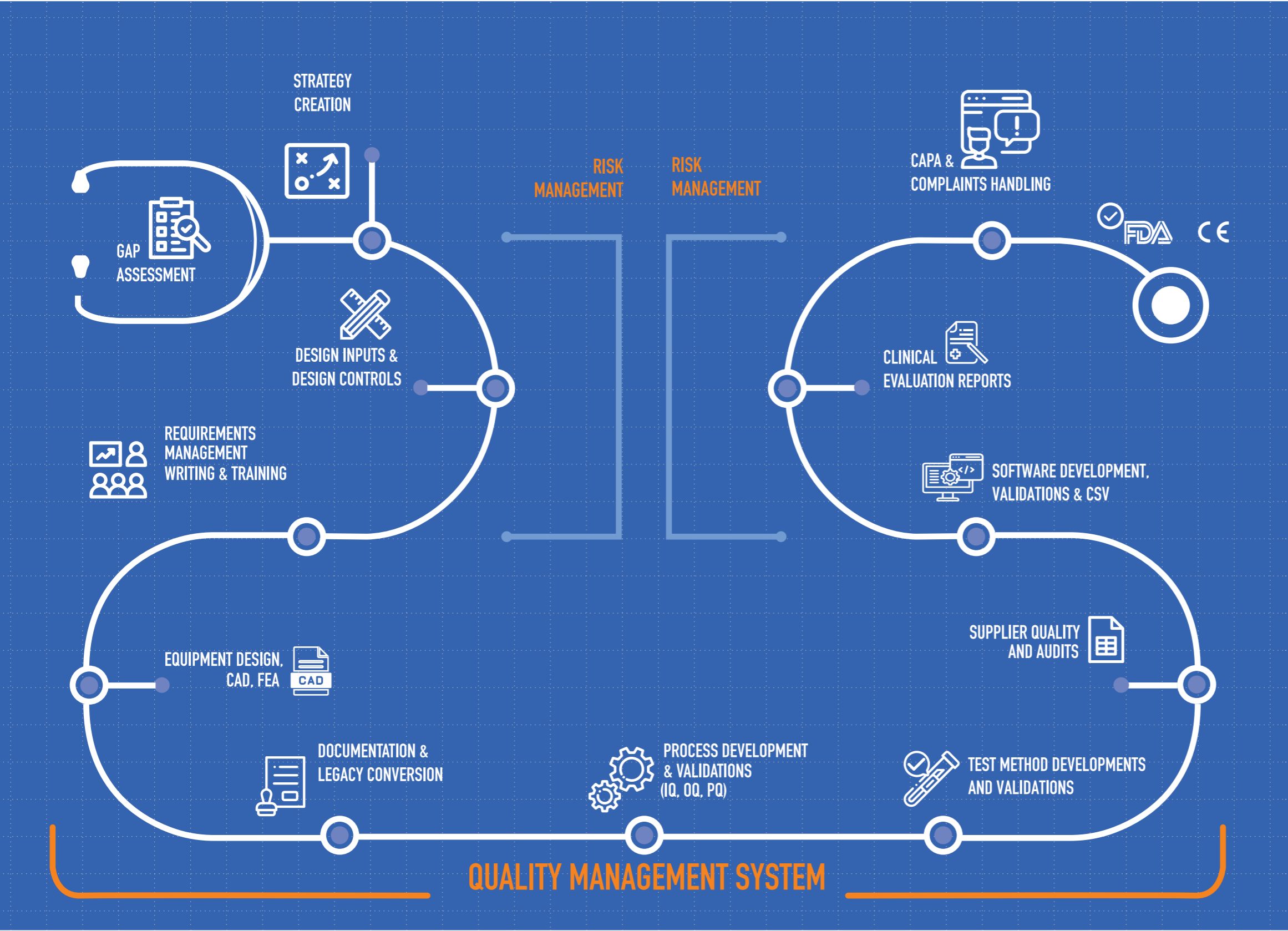


COLLABORATION



Iziel Advantage: Driving Compliance & Innovation in Healthcare Solutions

Product Development Lifecycle Management



Why IZiel Healthcare ?

- Expertise in medical device product development lifecycle
- Outcome based Delivery Approach
- Quick Scalability of Skilled Resources
- Flexible Onshore / Offshore Model
- Significant Time and Cost Advantages
- Strong Project Management
- Collaboration - GCC Global Capability Center

ACQUISITION INTEGRATION

- Successful integration for one of the largest Class III Medical Device Manufacturer
- Team led by experts with 20+ years experience with Global Medical Device companies
- Robust Post Acquisition Assessment
- Acquisition Risk Mitigation

Resources | Implementation | Regulatory | Delay



2000+

Documents Completed



350 +

DCO Approvals



30 +

TMDs & TMVs Completed



2500+

Labels Updated



15+

CAPAs



200+

PCH & RCH Completed

Engineering Support

- Design Support – CAD, Cell Layout & Tools
- MPI Updates & Process Validation
- Labels Update – ISO 15223 & EU-MDR
- Product Commercialization

CAPA, Software & CSV

- CAPA Owners for Process Validation, PVP, Internal Audit NC, Operator Certification, Bacterial Endotoxin & Software Validation
- Executed CSV for 25+ Softwares

Risk Management

- Creation of User, Design & Process FMEA
- Technical File Remediation
- Legacy Translation of Harms and Hazards
- Risk Management for transferred lines

Supplier Quality

- Identified Supplier Risk with PPK analysis of existing data
- FLQIA, PLQIA, CQD and Spec Updates
- Support SCR and SCC activities

COMPETENCY & CASE STUDIES



CARDIOVASCULAR



DIAGNOSTICS
IMAGING



AI BASED
DIAGNOSTICS



IN VITRO
DIAGNOSTICS



DIABETOLOGY



DRUG
DELIVERY



ORTHOPEDIC



DENTAL

MDD-MDR Transition

- Created MDR & FDA Compliant Design, Process, Software and Risk Management Documentation
- Developed CEP & CER for Class I & II medical devices
- Supported medical device manufacturers for Complaints Handling, PMS & Vigilance requirements

Software Validation & Computer System Validation

- Developed Technical File for Medical devices, AI based & wearables compliant to IEC 62304 & 82304
- Led Software CAPA resolutions for leading medical device companies
- Resolved FDA queries & remediate several Class II SaMD devices

Acquisition Integration

- Completed Post Acquisition Assessment, Process Validation, Risk Management, CSV, Supplier Quality and CAPA projects for one the largest Class III medical device manufacturer
- Established robust Project Management using highly efficient Onshore-Offshore Model
- Achieved Significant Cost and Time Savings with Complete Customer Satisfaction

USFDA Approval & Regulatory Strategy for Diagnostic Imaging Equipment

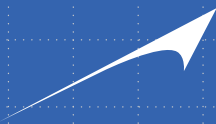
- Brought in cultural change using IZiel Hybrid Model to complete Design History File (DHF)
- Received USFDA Approval for X Ray Equipment within 1 month

Product Design & Development for Myonic Arm

- Project Approved and Funded by BIRAC, Government of India
- Executed Product Design, Modeling & Detailing for 5 gestures covering 80% of hand movement

Productivity Improvement for Disposable Products of a large German Manufacturer

- Adopted DFSS & Lean Manufacturing Principles along with Process Automation
- Increased Productivity by 25% occupying only 70% of the existing space



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Visit us



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