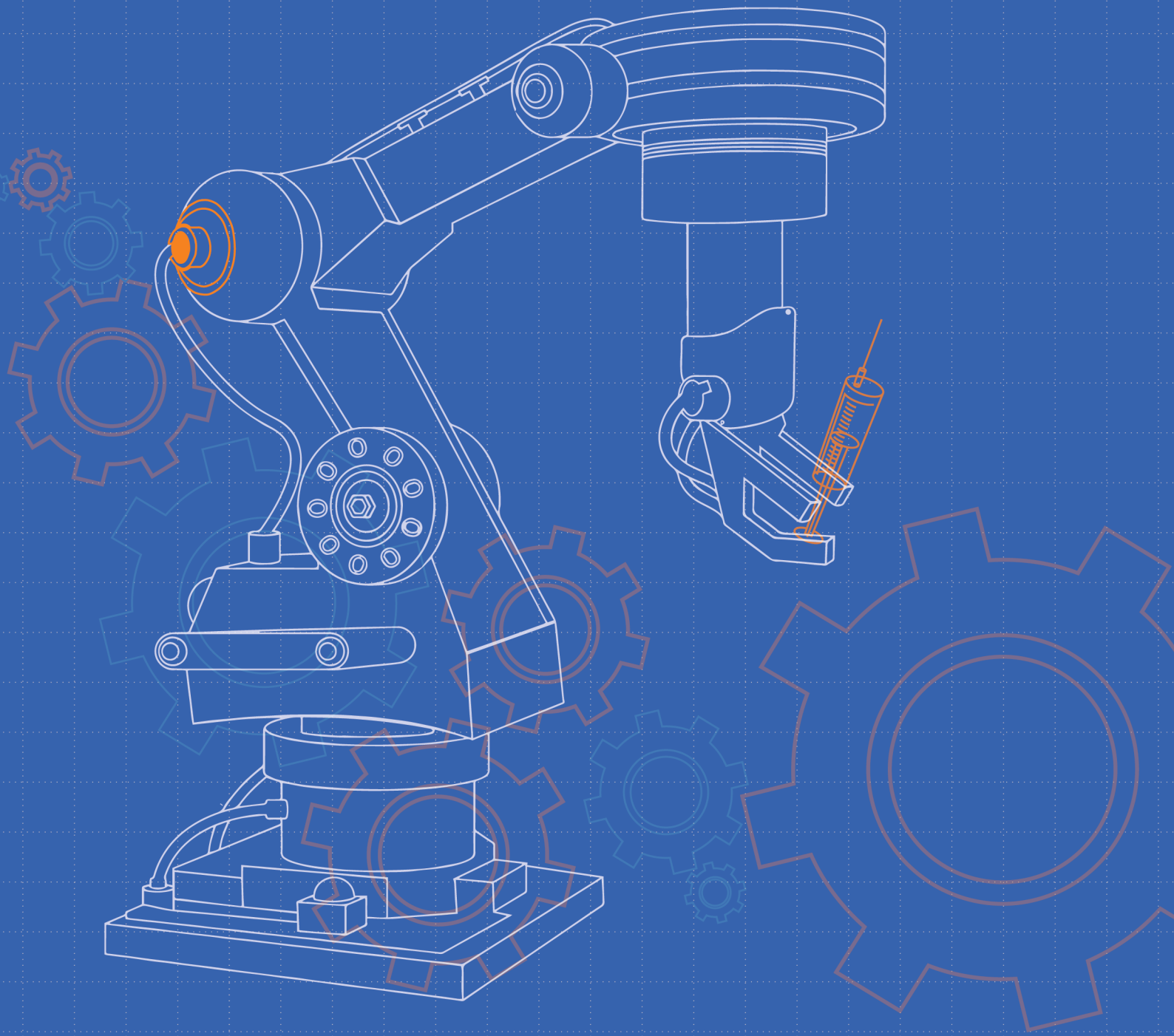
IZIEL HEALTHCARE

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

OUR EXPERTISE

DESIGN

PROCESS

SOFTWARE DESIGN, DEVELOPMENT, VALIDATIONS & CSV

QUALITY SYSTEMS & CAPA

REGULATORY

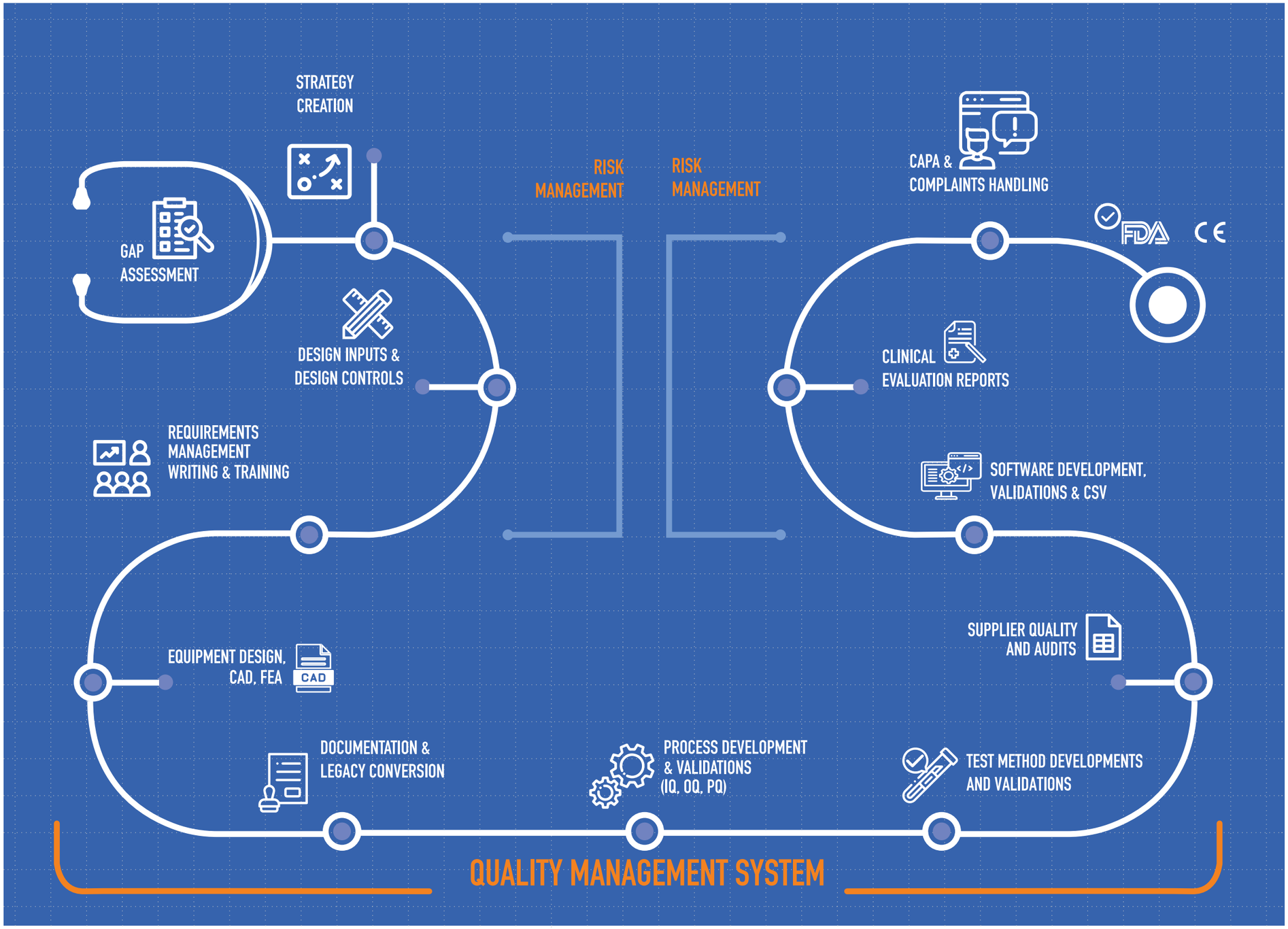
REMEDIATION

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

IMPLANTABLE DEVICES | 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 & III medical devices
  - Support medical device manufacturers for Complaints Handling, PMS & Vigilance requirements
- **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
- **Software / Firmware Development**
  - Designed and Developed medical device Software and Embedded Firmware
  - Created Technical Files in adherence to regulatory requirements
  - Engineered and Implemented application software for PC, mobile app, and web app, with integration to the cloud, including AI
  - Participated in several Digital Transformation projects
- **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 & Remediated several Class II SaMD devices
  - Performed CSV validation of software used in Design, Development and Manufacturing
- **Cybersecurity Assessment**
  - Identified threats using Threat Model through TPLC
  - Analysed security risks and its impact on medical device safety using CVSS scoring

IZIEL HEALTHCARE

inspire : engineer : achieve

ISO 13485

ISO 9001:2015

Visit us

USA : 121 Washington Avenue North, Suite 306 Minneapolis, MN-55401. Tel No. (+1) 612 445 8764

INDIA:

Pune: Pentagon P1, Office No. 601 & 604, Magarpatta City, Hadapsar, Pune-411028. Tel No. (+91) 727 621 2555

Bangalore: iSprouts Ground floor, Office Number B6, Shilpita Tech Park, Bellandur, Bengaluru-560103