



JOHARI[®]
medtech

Electronic Medical Device
Manufacturer

Overview of Company

40+ Years of Manufacturing Excellence

Johari was founded in 1979, in the city of Jodhpur in India, with the intention to serve the Healthcare industry.

Johari Digital is a **Medical Device Design & Manufacturing** company providing solutions to global MedTech giants as well as innovative start-ups. Our **end-to-end OEM services** range from **electronics** and **mechanical** design to development, prototyping, system integration, packaging and supply chain. Additionally, Johari also helps clients with **regulatory and compliance support** to quickly take their product to market.

Our **65,000 square feet**, state of the art medical device manufacturing facility in India is in compliance with **MDSAP, ISO 13485:2016 and FDA (21 CFR 820) standards and processes**. We have strong design and development teams operating from our-

- Technology Development Centre, Europe
- Product Engineering Centre, India Office
- Centre Of Excellence, IIT Jodhpur

Johari's versatile product development and manufacturing portfolio includes innovative **life science products, diagnostic devices, and therapeutic devices**. We are equipped with advanced capabilities to manufacture **complex to high-volume products**.



Certifications and Robust Processes

Johari meets the ISO standards relevant to the product, as well as cGMP requirements



Medical Device Single Audit Program (MDSAP) is QMS audit that enables our company to meet the regulatory requirement for **Australia, Canada, Brazil Japan and USA.**



This certification confirms that we follow standard processes of **medical devices design and development, production, storage and distribution, installation and servicing**



FDA 510K clearances prove that our devices meet quality standards of FDA and are **safe to known risks** and **effective for the intended use.**



CE mark signifies that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements.



100,000

Products Installed
Worldwide

500+

Active Customers
Worldwide

145+








Commercialized
Products

Our Services



Full Turnkey Medical Device Manufacturing



-  State-of-the-art manufacturing setup located in India
-  Dedicated R&D center in Europe
-  Strategically positioned to serve business partners around the globe
-  Helping customers achieve highest levels of manufacturing efficiency
-  Optimizing cost and providing support for regulatory & quality certification enabling quick Go-To-Market
-  Delivering value throughout the product life cycle
-  Ever-growing network of experts, including intellectual property

Key Service Offerings



Design & Engineering solutions to accelerate the life cycle of medical device development and optimize manufacturing costs. Our designing, prototyping, and value engineering services ensure fast-paced Go-to-Market and compliance to ISO : 13485 guidelines.



Contract Manufacturing solutions for global medical device manufacturing companies as well as innovative start-ups. Our facility is equipped with advanced capabilities to manufacture complex to high-volume products.



Strategic guidance to clients at every stage of the product development process. Our regulatory experts have extensive experience in multiple regulatory jurisdictions, including MDSAP. We minimize the client's Time to Market with streamlined & well managed process for regulatory approvals

From Product Engineering to Transfer to Manufacturing



Value Addition

We create products that offer enhanced functionality, flawless aesthetic appeal, and ease of use. Compliance with the highest standards of quality at minimal cost to deliver remarkable products is our core strength.



Upgrade Existing Product

Our Research and Development team includes highly qualified professionals with expertise in leading-edge innovation and technology to modify/customize your existing products for better aesthetics and improved performance at an optimized cost of production.



New Product Development

- Complete process of bringing new product to the market.
- Focus on reducing cost and time to market with enhanced quality
- Continuous practices and strategies to meet customer requirements with evolving industry dynamics
- Enabling client to increase their market share with the latest products

Manufacturing Capabilities



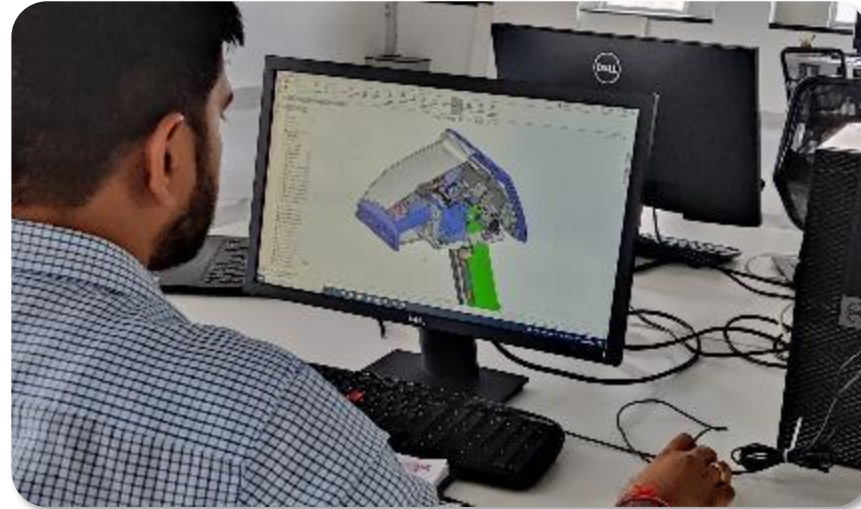
In-house Capabilities

Design and Development



R&D - (Serbia, Europe)

- World class technology development center in Europe
- Ability to quickly turn concepts into detailed product design
- 3D printing and quick prototype
- Technology research & product concepts



Industrial Design

- Brainstorming and creative sessions
- Ideas & conceptualizing
- CAD design and drafting
- Molds and tools design
- Exploring colors, materials & finishes



200+
Project
Completed !



20+
Patented
Enclosures
Designs

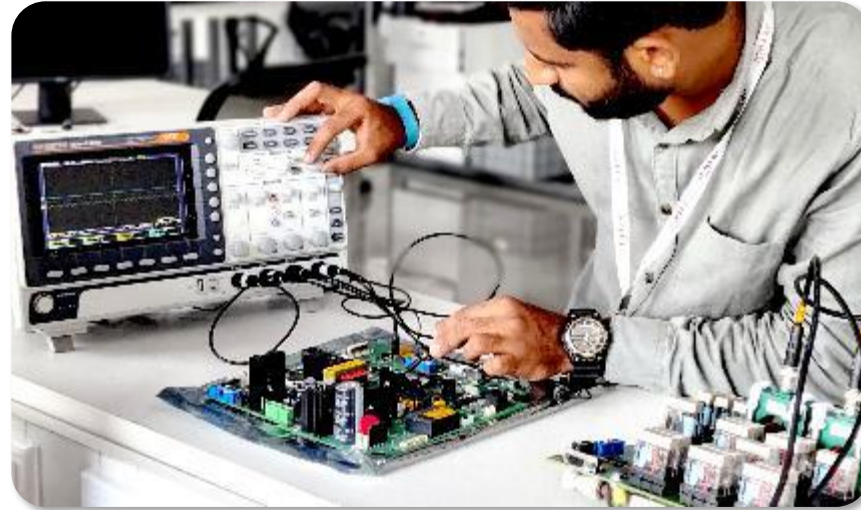
In-house Capabilities

Transfer to Manufacturing



Electronics PCB and Software Design

- Ability to quickly turn concepts into detailed product design
- Electronic and electrical circuits boards design
- Printed Circuit Boards (PCB) layout and design
- Broad prototype preparation
- Embedded software and UI design



Product Engineering (India)

- Mechanical part and tool development
- Enclosures and housing
- Cable and wire harness, clipping and stripping.
- Electrical motors, heat sink manufacturing
- EMI/RFI shielding



100%

**Focus on
Medical Device
Design and
Manufacturing**



35+

**Engineers in
Design and
Development**

In-house Capabilities

Manufacturing



PCB Manufacturing & Testing

- Capacity of 1000+ PCB production per day
- Class 100,000 clean room electronics manufacturing
- 01005 (0201) Components placing
- Mount Flip Chip, BGA, MELF, CSP
- RF Microelectronics, High Density Interconnects (HDI)
- PCB Size from Micro to 500mm x 450mm
- Flexible, Rigid, Backplanes and Multilayer PCBs
- Automated placement capacity 32000 CPH

5 Parallel Product Assembly Lines

- Multiple assembly lines for simultaneous integration of simple to complex devices.
- Full assembly from PCBA to final integration
- Box Build: Injection molding, casting, sheet metal
- Mechanical parts manufacturing
- Electrical & mechanical assembly
- Packaging assembly & hardware installation



60,000

PCB Assembly
Per Month



1 Mn

Components
Per Day

In-house Capabilities

Per Month Production Capacity

DNA/RNA Extraction
For Life Science



High Complexity
Electromechanical

High Precision
Combo Therapy



High Complexity
Embedded Systems

High Precision
Slimming Therapy



Clinical Spa & Wellness
Device

Portable Healthcare
Devices



Handheld Wireless
Health Monitor

In-house Capabilities

Pro Active Quality Control System, Error Tracing & Change Management



Quality Assurance

- Quality Control (Raw Material, Final Product)
- Validation and verification
- Product functional & performance testing
- Labeling control & device history record
- CAPA management
- Regular supplier audits & gap analysis
- Process validation

Change Management & Traceability

We Maintain **DMR** and **DHR** documents. We readily address and record changes required in the product at pre and post-market stages. Our documentation process, including ECR (Engineer Change Requirement document) and ECN (Engineer Change Note), is strictly maintained to track every big and small change at every step. The documentation process assures traceability over years.



In-house Capabilities

Regulatory and Certification Services



Go-To-Market Assistance

We offer strategic guidance to our clients at every stage of the product development process.

- Regulatory Support
- Respect for IP Protection
- Post Market Surveillance



Certification Assistance

- 510K, PMA, CE, UL, FDA, UDI applications
- Medical device risk management certifications
- RoHS, IEC 60601 certification
- ISO 13485 implementation and certification
- Technical File/Dossier File/Medical Device File



17+

**US FDA 510K
Certifications**



145+

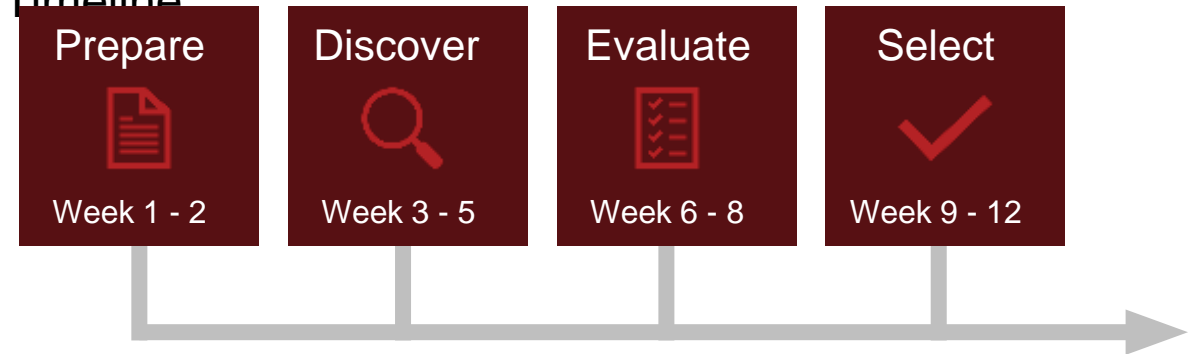
**Commercial
Products
Launched**

Supply Chain Management

Well Established Qualified Vendors



Vendor and Supplier Selection Process and Timeline



Capability to plan and execute multiple /alternate sourcing of raw materials



We have strong sourcing team managing multiple suppliers & vendors for :

- Molding and Casting
- Sheet Metal
- Multiple Job Works
- Electricals and PCB's
- Off the Shelf Supplies
- Consumable Supplies

Proven Experience

500 + molded plastic parts for Hand Held, Wearable, Desktop, Floor Models medical devices.



Laser Printing
Cutting

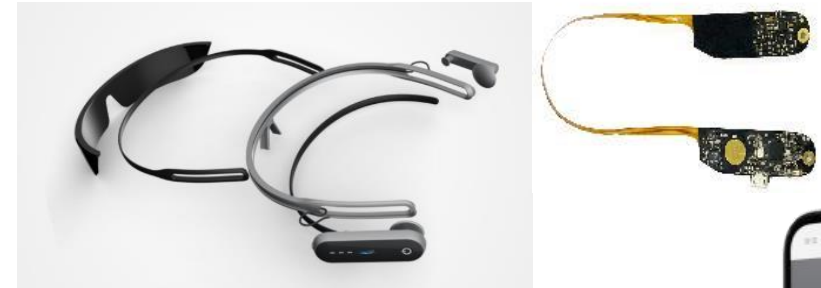


ABS Molded Complex
Plastic Parts, Poly
Carbonate Parts Table Top
Medical Devices



Large Plastic and
Sheet Metal Parts for
Floor Models

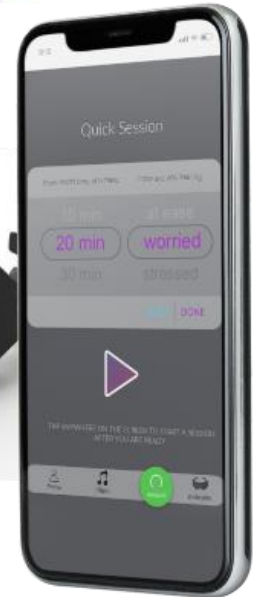
Smart wearable device with complex and micro electronics



01005 Components

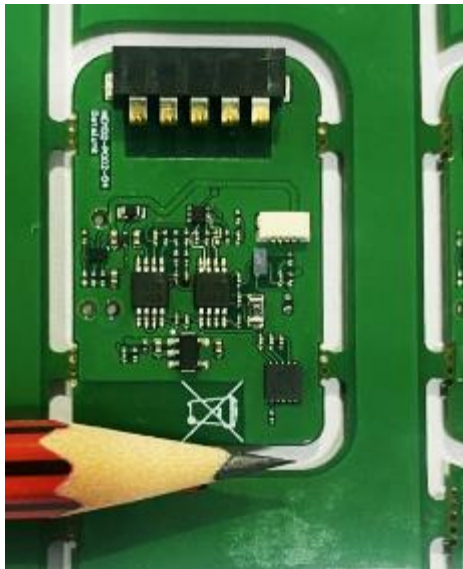


Bluetooth
Connectivity



Proven Experience

Microelectronic Components



Microelectronic PCB



Technology Landscape



Technology Offerings

With 100,000+ product installations worldwide, Our expertise in medical device manufacturing cuts across industries.



Life
Science



Medical Diagnostic



Hospital Equipment



Home Healthcare



Physiotherapy



Medical Aesthetics



Wellness



Personal Care

Our Technology Landscape | Product Folio



HOMOGENIZATION
- Life Science



COLORIMETRY
- Bio Science



SPECTROPHOTOMETRY
- Life Science



ELECTROCHEMISTRY
- Diagnostic



MUSCLE STIMULATION
- Sport Medicine

Our Technology Landscape | Product Folio



MICRO-CURRENT
- Beauty & Skin Care



COLORIMETRY
- Bio Science



**MICROWAVE
STERILIZER**
- Hospital Equipment



ELECTROTHERAPY
- Physical Medicine &
Rehabilitation



**CRANIAL ELECTRICAL
STIMULATION**
- Stress Relief

IP Protection

Having a long history of handling our partner's IP we understand the value of sensitive data. Along those lines, we pro-actively establish, monitor, and enforce security protocols to protect client's data



Strong IT and
Access Control



Strong Non-Disclosure
Agreements



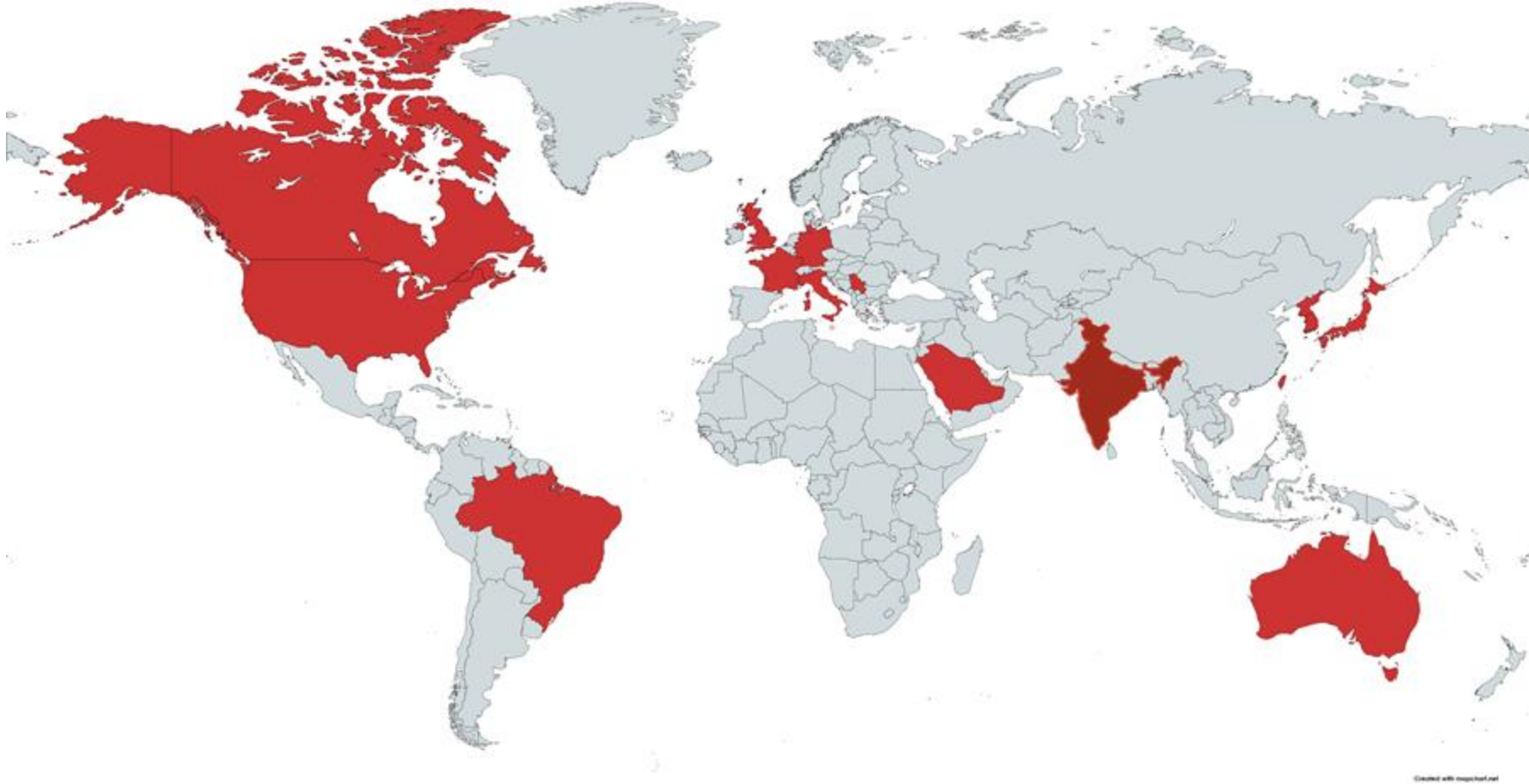
Enforced Data
Security Policies



In-House IP Experts &
Legal Consultants



Global Presence



USA | Canada | Brazil | Australia | Japan | India | UK | France | Germany | Serbia | Italy | Korea | Thailand | Malaysia | Taiwan | Saudi



Thank You