NISSHA
MEDICAL TECHNOLOGIES

OUR **PROCESS**

YOUR **ONE PARTNER** IN **MEDICAL DEVICE**

Design & Manufacturing

NISSHA
MEDICAL TECHNOLOGIES

CONCEPT & PLANNING

We have developed a streamlined process to prove out your concept allowing you to anticipate and prepare for unexpected changes with agility.

- User Needs Assessment
- Market Analysis
- Concept Development

DESIGN & DEVELOPMENT

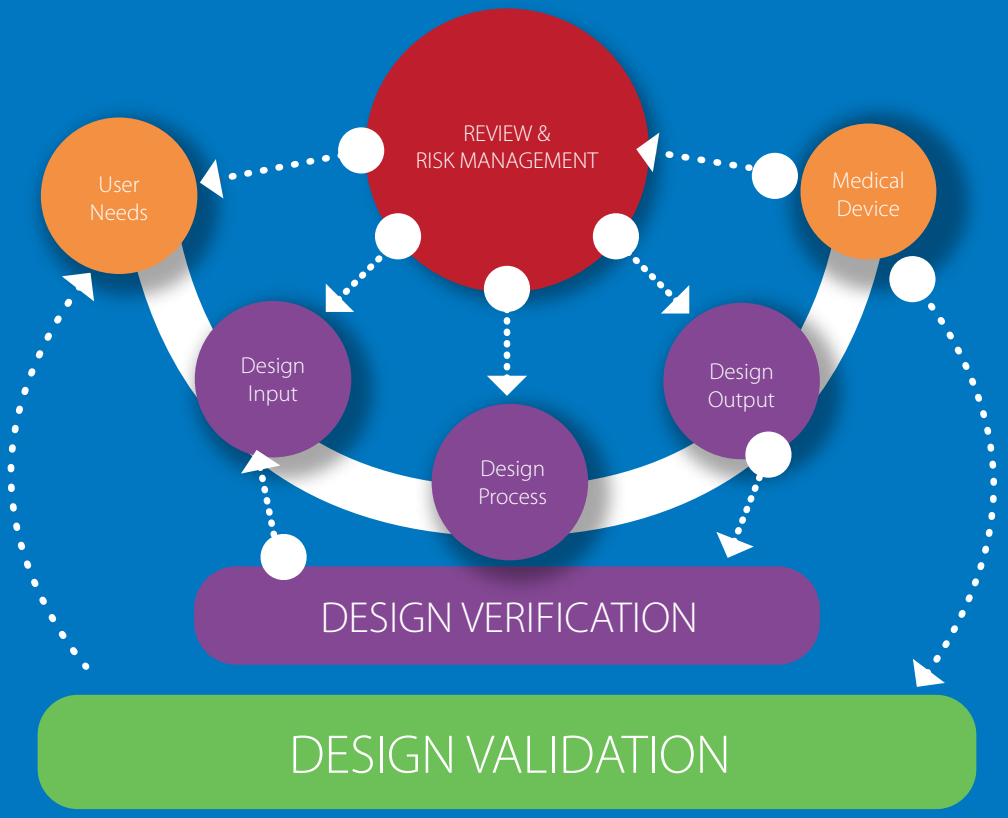
We will take the time to ensure that the user's needs are well understood and met. Our experienced team is equipped with state of the art technology and global resources.

DESIGN

- Project Plan
- Product Requirements
- IP Analysis
- Risk Management File

DEVELOPMENT

- Mechanical Design
- Human Factors
- Software Development
- Electronics Design
- Engineering Analysis
- Packaging / Labeling
- Process Development
- Tooling & Equipment



1.800.893.6361 | DM.NisshaMedical.com

Global Headquarters: 400 Exchange St. Buffalo, NY 14204

NISSHA
MEDICAL TECHNOLOGIES

Total Solution

Nissha Medical Technologies performs as the trusted partner in Design & Manufacturing of single-use medical technologies. From early concept stage to design transfer, our team collaborates closely with customers and physicians to assure that user's needs are well understood and met.

We deliver high-quality results with **Innovative Technologies** to bring our customer products from concept — to prototype and design through verification and pilot — to commercial market.

CAPABILITIES

- Idea Generation and Product Layout
- 3D Design
- Rapid Prototyping
- Design Proofing and Enhancements
- Design for Excellence (DFX)
- Dedicated Program Management
- Stage Gate Review Process
- Access to Global SME's

CONCEPT & FEASIBILITY

We can help you minimize product risk during development by collecting information and testing during the concept and feasibility stage. Taking this time early on can save costly delays and product redesign.

- Concept Development
- Human Factors / Usability Analysis
- Proof of Principle Prototype(s)
- Prototype Performance Test Report
- Stage Design Review

VERIFICATION & VALIDATION

We aim for quality that meets customer's expectations and pursue zero defects in our products that conform to relevant legislation and regulation.

- Design Verification
- Product & Process Validations
- Packaging Verification
- Biological Evaluation
- Sterility
- Compliance Testing
- Regulatory Compliance
- Process Control
- Design Validation & Usability
- Production Documentation

PILOT MANUFACTURING & RAMP UP

Specialized manufacturing support during the development stage of the product lifecycle, from concept prototypes to full product builds for pre-clinical and clinical requirements; optimizing your production line for FDA approval and scaling.

- Dedicated Pilot Line Manufacturing & Assembly Area
- Extensive Equipment Available for use without Capital Expenditure
- Process FMEA / FMECA
- Validation / Verification Pre-clinical Builds
- Design for Assembly (DFA) & Design for Manufacturability (DFM) Assistance

NISSHA
MEDICAL TECHNOLOGIES

YOUR **ONE PARTNER** IN **MEDICAL DEVICE**

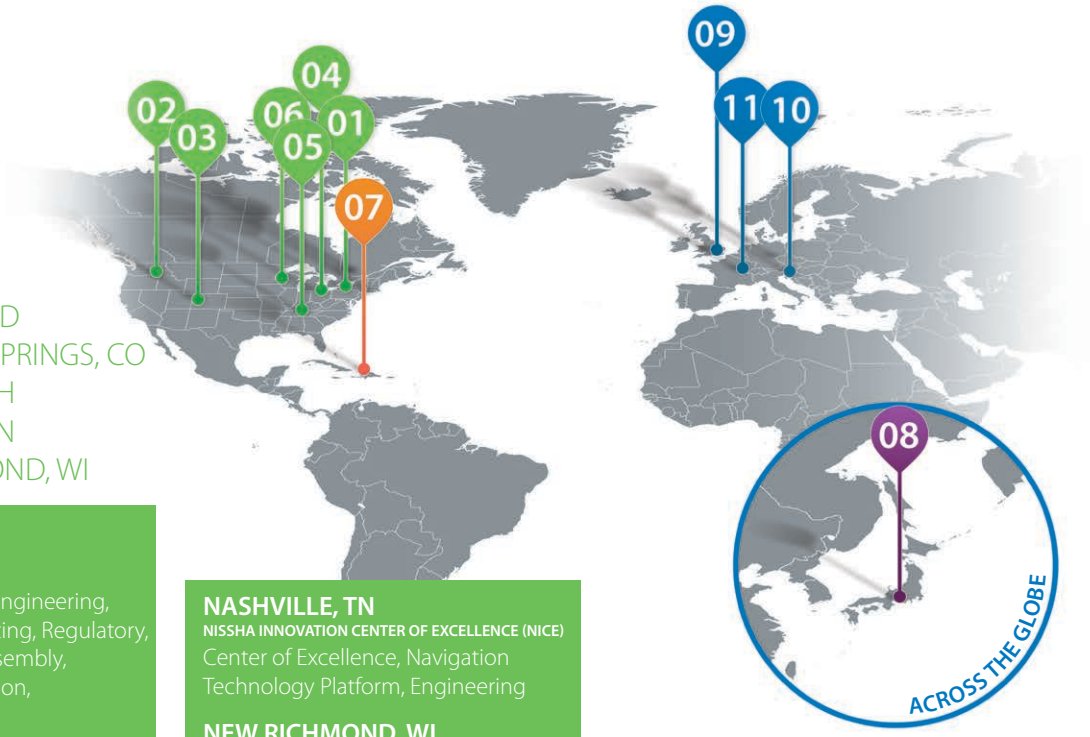
COMMERICAL MANUFACTURING

One partner manufacturing from prototype to commercialization. Let us use our total capabilities, ultimate components and our unique global footprint to bring your vision to life. Product line transfers from low volume production to high volume production in the Dominican Republic.

- Low Cost Manufacturing
- Production Facilities 105,000 sqft & Additional Lease Options
- Cleanroom & Whitespace Manufacturing Areas
- Customer dedicated manufacturing & Assembly Lines
- FDA Registered & ISO 13485 Certified
- Manual, Semi-automated & Automated Assembly
- Expertise in Adopting Specialty Process
- Complex Sub-assemblies & Finished Devices
- Extremely Low Turnover Rate < 3%
- Value Improvement Engineering

NISSHA
MEDICAL TECHNOLOGIES

OUR LOCATIONS



USA

01 BUFFALO, NY
02 SANDPOINT, ID
03 COLORADO SPRINGS, CO
04 NORWALK, OH
05 NASHVILLE, TN
06 NEW RICHMOND, WI

BUFFALO, NY
GLOBAL HEADQUARTERS
Clean Room, Coating, Engineering, Injection Molding, Printing, Regulatory, Converting, Manual Assembly, Warehousing/Distribution, Laminating, Sales

SANDPOINT, ID
WEARABLES & AUTOMATION CENTER
White room, Manual Assembly, Product Design & Dev, Converting, Semi Automation, Innovation - Process Engineering, Laminating, Full Automation, Sales, Coating, Engineering, Warehousing/ Distribution

COLORADO SPRINGS, CO
PROCESS ENGINEERING CENTER
Clean Room, Manual Assembly, Sales, White Room, Semi Automation, Regulatory, Injection Molding, Engineering, Warehousing/ Distribution, Extrusion, Product Design & Dev

NORWALK, OH
METAL PROCESSING CENTER
Cleanroom, Manual Assembly, Engineering, Product Design & Dev, Innovation – Process Engineering, Injection Molding, Machining, Prototyping

NASHVILLE, TN
NISSHA INNOVATION CENTER OF EXCELLENCE (NICE)
Center of Excellence, Navigation Technology Platform, Engineering

NEW RICHMOND, WI
MICRO MOLDING CENTER OF EXCELLENCE
Clean Room, Micro Injection Molding, Micro Automated Assembly, Regulatory, Sales, Tooling, Engineering, CT Scanning

CARIBBEAN

07 SAN PEDRO, DR

SAN PEDRO, DR
ASSEMBLY CENTER
Clean Room, White Room, Injection Molding, Manual Assembly, Warehousing/ Distribution

ASIA

08 KYOTO, JP

KYOTO, JP
NISSHA INNOVATION CENTER KYOTO (NICK)
Clean Room, White Room, Manual Assembly, Semi Automation, Engineering, Product Design & Dev, Innovation - Process Engineering, Sales, Regulatory, Warehousing/Distribution

EUROPE

09 TORBAY, UK
10 INNSBRUCK, AT
11 CERGY, FR

TORBAY, UK
CONVERTING CENTER
Converting, Laminating, Printing, Manual Assembly, Sales, Regulatory, Warehousing/ Distribution

INNSBRUCK, AT
REGULATORY CENTER
Engineering, Product Design & Dev, Innovation - Process Engineering, Sales, Regulatory

CERGY, FR
EUROPEAN HEADQUARTERS - CABLING CENTER
Clean Room, White Room, Injection Molding, Converting, Laminating, Manual Assembly, Semi Automation, Engineering, Product Design & Dev, Innovation - Process Engineering, Sales, Warehousing/Distribution

DoP: January 2026