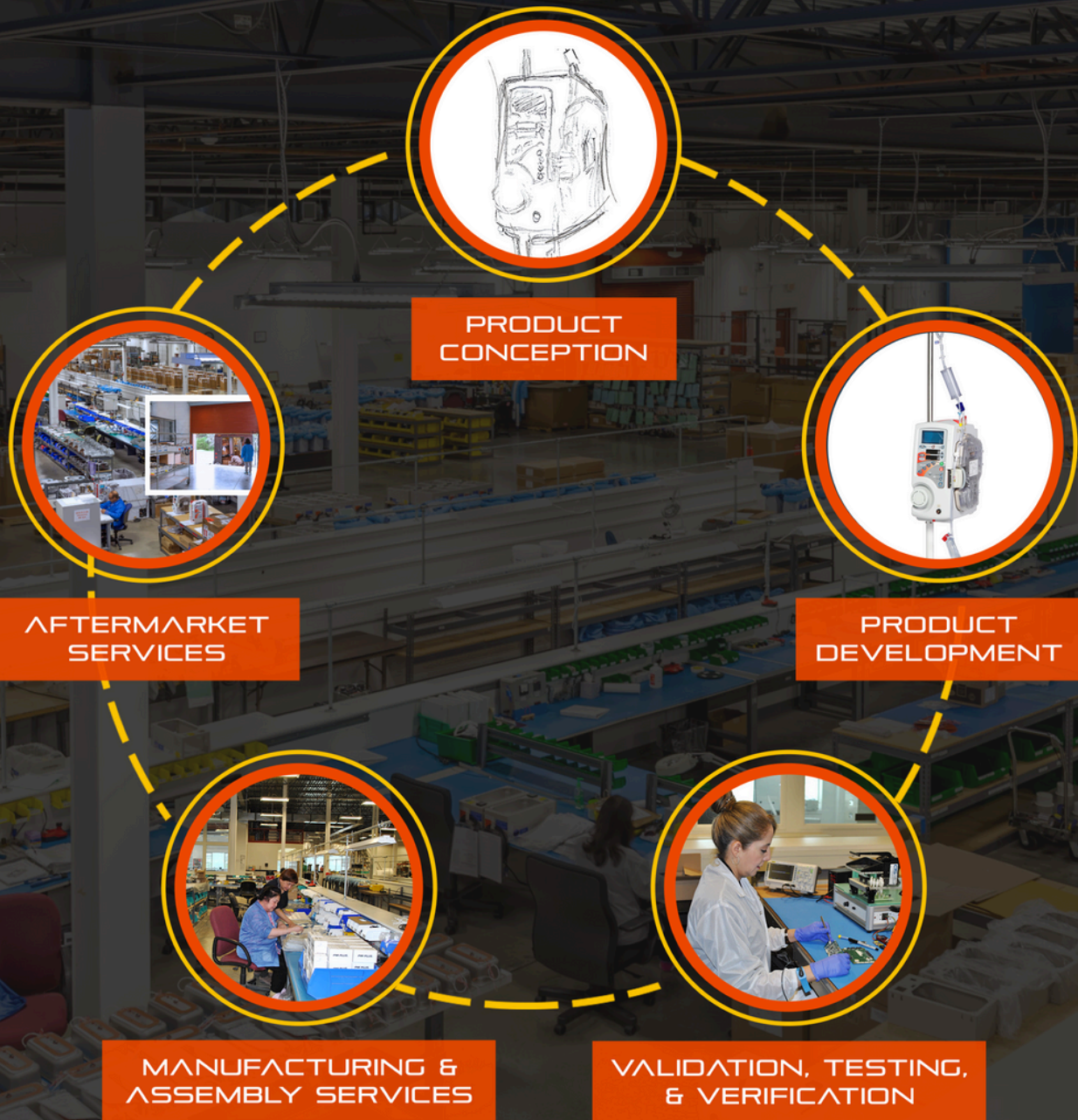


YOUR DEDICATED MEDICAL DEVICE CONTRACT MANUFACTURER



PROVIDING SUPPORT EVERY STEP OF THE WAY

EMPOWERING YOUR PRODUCT'S JOURNEY WITH QUALITY MANUFACTURING SOLUTIONS

MFG One is a global contract medical device contract manufacturer specializing in bringing innovative healthcare solutions to life. We take your vision and leverage our 5-phase development process to create a commercially viable product.

WE ACCOMPLISH THIS BY:

1 Guiding you from initial ideation to successful market launch.	2 Seamless integration of design, engineering, and manufacturing.	3 In-depth understanding of regulatory landscapes and compliance requirements.	4 Delivering safe, effective, and user-friendly solutions.	5 Your true stop shop for end-to-end product development and commercialization.
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OUR SERVICES



Concept Development



Engineering and Design



Product Prototyping



Manufacturing & Assembly



Testing Services



Design Validation & Verification



Global 3PL Fulfillment Solutions



Aftermarket Services




OUR CAPABILITIES

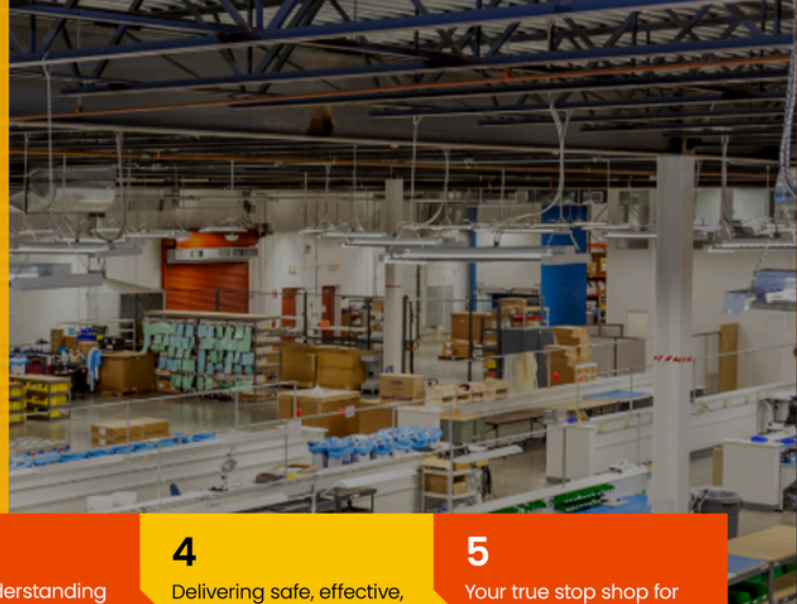
- ☑ Design & Rendering
- ☑ Mold Tooling
- ☑ Metal Stamping
- ☑ Electromechanical Product Assembly
- ☑ Plastic Injection Molding
- ☑ 3D Printing
- ☑ Electronic Wiring
- ☑ Fabrication
- ☑ Printed Circuit Board Assembly

OUR FULL-PHASE DEVELOPMENT SERVICES

PHASE 1: PRODUCT DEVICE CONCEPT DEVELOPMENT

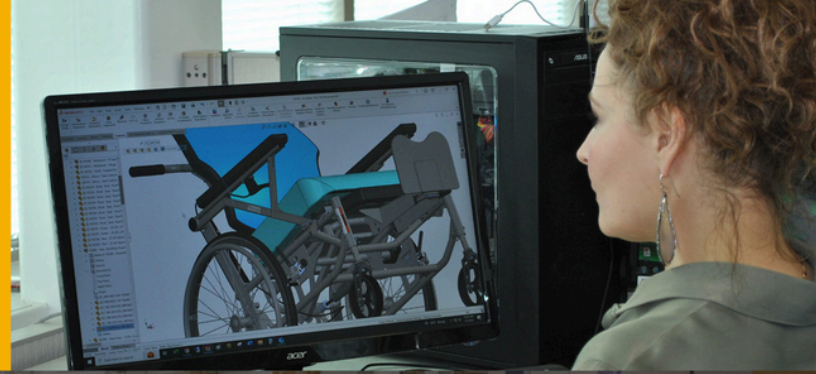
Have an idea? We can bring it to life. Our expert team can take even a simple sketch on a napkin and develop it into a fully realized product concept.

COLLABORATIVE BRAINSTORMING  We work closely with you to refine your initial concept, ensuring it addresses a clear medical need.	FEASIBILITY ANALYSIS  We identify potential road blocks by carrying out thorough feasibility studies to assess technical viability, regulatory requirements, and potential market fit.	DETAILED PRODUCT SPECIFICATIONS  We will define the key functionalities, technical parameters, and user needs of your device.
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PHASE 2: PRODUCT DESIGN AND DEVELOPMENT

As a medical contract manufacturer, we offer a full range of engineering and design services to address almost every aspect of your product development journey:



Human Factors Engineering



Electrical and Software Engineering



Biomedical Quality Engineering & Support



New Product Introduction (NPI)



Cost Analysis

PHASE 3: VALIDATION, VERIFICATION, & TESTING

As an ISO-certified and FDA-registered contract manufacturer, we ensure your product meets quality standards and regulatory requirements before entering the market.

DESIGN VALIDATION SERVICES INCLUDE:

- Verification/Validation of Final Unit
- Verification/Validation of Software
- Packaging Design/Validation
- Risk Assessment
- Design Failure Mode and Effects Analysis (DFMEA)

OUR PROCESS VALIDATION CAPABILITIES INCLUDE:

- Medical Device New Product Development
- Mechanical Prototype Design
- Electrical & Software Engineering
- Prototype Development
- FDA 21 CFR 820 Compliance
- Design for Testing (DFT)
- ROHS (Restriction of Hazardous Substances)

MFG-ONE ENGINEERING SERVICES:

- 2D-3D Conversion
- Design and Development
- Electrical Engineering
- Electro-Mechanical Engineering
- Failure Analysis & Reliability
- FEA (Finite Element Analysis)
- Injection Mold Design
- Mechanical Design Services
- NPI Engineering
- Packaging Engineering
- Plastics Engineering
- Product Development
- Prototype Engineering
- Reverse Engineering
- Simulation and Testing
- Software Development Services
- Solidworks
- Sustaining Engineering
- Technical Documentation
- Test Development
- Value Engineering



TYPE OF CHANGE SPECIFIED	NAME	DATE	Med
CHANGES ARE IN INCHES		3/15/2013	TITLE: Assembly
TOLERANCES AND DIMS: 1/16" (THREE PLACE DECIMAL) #0.003	END APPROVAL		SIZE DW 7
MATERIAL	MANAGER APPE		No To Sc
Project	Project	PD112002	

PHASE 4: MANUFACTURING & ASSEMBLY SERVICES

We offer a comprehensive suite of manufacturing and assembly services designed to support your entire product lifecycle, from design and manufacturing to distribution and beyond.



MFG ONE'S IN-LINE ASSEMBLY PROCESSES

Our in-line assembly services ensure seamless integration and rigorous quality control at every stage. This translates to reliable, high-performing products delivered right to your doorstep.

01
Box Build | Turnkey Center

02
Sub-Assemblies & Full Unit Build

03
Electric-Mechanical Assemblies

04
Injection Molded Plastics Assemblies

05
Printed Circuit Board Assemblies

PHASE 5: AFTER MARKET SERVICES

Offering a range of aftermarket services to maximize your product's potential and deliver value to you and your customers.

OUR AFTERMARKET SERVICES INCLUDE:

- ✓ Management of Product Lifecycle
- ✓ Aftermarket and Remanufacturing Services for OEMs
- ✓ Return Management
- ✓ Inventory Management
- ✓ Warranty
- ✓ Screening and Triage
- ✓ 3PL (Third-Party Logistics) Services
- ✓ Repair Services
- ✓ Failure Analysis
- ✓ Refurbishment & Remanufacturing



3PL SERVICES

Global 3PL fulfillment services for your logistics needs.

- ✓ Assembly
- ✓ Distribution Services
- ✓ Transportation Services
- ✓ Regulatory Services
- ✓ Inventory Management
- ✓ Returns Management

PHARMACEUTICAL 3PL DISTRIBUTION SERVICES

Licensed as a manufacturer, distributor and warehouse of prescription medical devices. Leverage our FDA-registered and CGMP-compliant, fully validated healthcare warehouse space.

- ✓ Tailored for Pharmaceutical & Medical Industry needs
- ✓ Expert 3PL and Warehousing & Distribution Services
- ✓ Humidity Monitored Space
- ✓ Kitting, Relabeling, Returns, & other value-add services
- ✓ Expert Supply Chain Solutions
- ✓ Automated Labeling Capabilities

QUALIFICATIONS:



FDA REGISTRATION
CERTIFICATION



ISO 13485
CERTIFICATION



LOUISIANA BOARD OF DRUG
AND DEVICE DISTRIBUTORS
CERTIFICATION




VIRGINIA BOARD
PHARMACY PERMIT

GET IN TOUCH

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 MFG One, LLC™