BUILDING AMERICA'S MEDICAL CAPABILITIES

OUR DIFFERENTIATED APPROACH

Re:Build Manufacturing offers a unique combination of regulatory expertise, precision manufacturing, and quality systems that addresses the most critical challenges facing medical device programs.

END-TO-END MEDICAL SOLUTIONS

- One partner from concept creation through full-rate production
- Integrated capabilities: design, engineering, regulatory support, manufacturing, quality assurance
- Eliminates multi-vendor coordination delays and quality risks

FACILITIES AND QUALIFICATIONS

- ISO 13485 certified quality management systems
- FDA registered facilities (21 CFR 820)
- Certified BSL-2A Biosafety Lab and ISO Class 7 Cleanrooms
- Deep experience in medical devices, diagnostics, and bioprocessing equipment

REGULATORY-READY DEVELOPMENT

- Design controls and design history file (DHF) documentation
- Manufacturability for Design™ (MFD) with regulatory compliance
- Biocompatibility and sterilization planning
- FDA, ISO, and MDR compliance support

MULTI-SECTOR MEDICAL EXPERTISE

- Medical devices (surgical, monitoring, diagnostic, therapeutic)
- Life sciences (lab & process equipment, genomics, microfluidics, incubators)
- Imaging systems
- Wearable medical technology
- Pharmaceutical delivery systems

EARLY-STAGE CONCEPT DEVELOPMENT WITH REGULATORY STRATEGY

PROGRAM DEVELOPMENT & REGULATORY PLANNING

TECHNOLOGY ROADMAPPING & FEASIBILITY

- Product and technology roadmapping
- Medical device concept and feasibility assessment
- Risk management and clinical needs analysis
- Technical and clinical feasibility assessment
- Regulatory pathway determination (510(k), PMA, De Novo)
- Technology gap identification
- Competitive landscape analysis

PROOF-OF-CONCEPT DEVELOPMENT

- Rapid prototyping for validation
- Proof-of-concept prototype builds
- Trade study analysis execution
- Requirements validation workshops
- Functional demonstrations and bench-top testing
- Early regulatory feedback integration

SYSTEM ARCHITECTURE DESIGN

- Systems engineering and architecture development
- Requirements analysis and specification
- Medical device architecture design
- Biocompatibility and sterilization planning
- Quality management system development
- Interface control documents

REGULATORY PLANNING

- Regulatory strategy and pathway selection
- Risk management planning (ISO 14971)
- Clinical evaluation planning
- Design control planning (21 CFR 820.30)
- Preliminary design reviews
- Standards identification (IEC 60601-1, ISO 13485, etc.)

USER-CENTERED DESIGN FOR CLINICAL APPLICATIONS

MEDICAL DEVICE DESIGN & HUMAN FACTORS

HUMAN FACTORS

- Regulatory & standards compliance
- User capability & contextual research
- Inclusive & accessible design
- Task analysis
- Cognitive load & information design
- Physical ergonomic assessment
- Use-related risk assessment
- Formative usability testing
- Human factors validation testing

INDUSTRIAL DESIGN

- Innovation workshops
- Ideation & visualization
- Human factors & ergonomics
- Early prototyping & mockups
- Surface CAD
- Photorealistic renderings
- Product portfolio planning
- Journey mapping
- Visual brand language (VBL)

USER EXPERIENCE (UX) DESIGN

- User research & analysis
- Information architecture
- Wireframing & prototyping
- Web app design
- Mobile app design
- UI design

DETAILED DESIGN ENGINEERING

- Technology selection
- Electromechanical design
- Testing, analysis & optimization
- Requirements definition
- Multi-level prototyping
- DFM/DFA expertise
- System architecture development
- Cost analysis

MICROFLUIDICS & CARTRIDGE ENGINEERING

- Microfluidic channel design
- Capillary flow modeling
- Sample preparation systems
- Reagent delivery mechanisms
- Cartridge sealing and assembly design
- Point-of-care diagnostic platforms

MEDICAL-GRADE ELECTRONICS & DIGITAL HEALTH SOLUTIONS

ELECTRONICS, SOFTWARE & CONNECTED HEALTH

CIRCUIT BOARD DESIGN & ELECTRONICS

- Electronic and software design
- Medical-grade PCB design (IEC 60601-1 compliant)
- Low-power circuit design for portable devices
- Sensor interface electronics
- Battery management for medical devices
- Electromagnetic compatibility (EMC) design
- Patient isolation and safety circuits

EMBEDDED SOFTWARE & FIRMWARE

- Software and firmware integration
- IEC 62304 compliant software development
- Real-time embedded systems
- Device control algorithms
- Software verification testing
- Software documentation (SRS, SDD, STP)
- Cybersecurity for medical devices (UL 2900-2-1)

CONNECTED HEALTH & DIGITAL SYSTEMS

- Connectivity and data management enablement
- Wireless communication (Bluetooth, Wi-Fi, cellular)
- Cloud connectivity and data analytics
- Mobile app development (iOS, Android)
- User interface system integration
- Electronic health record (EHR) integration
- FDA guidance for wireless medical devices

DIAGNOSTIC & MONITORING SYSTEMS

- Diagnostic system integration
- Optical and sensor integration
- Real-time signal processing
- Data acquisition and analysis
- Physiological parameter monitoring
- Alarm and alert systems

MEDICAL-GRADE MATERIALS & COMPLIANCE

ADVANCED MATERIALS & BIOCOMPATIBILITY

BIOCOMPATIBLE MATERIALS SELECTION

- Biocompatibility testing planning (ISO 10993)
- Medical-grade polymer selection
- Implantable material evaluation
- Skin contact material assessment
- Material compatibility with sterilization
- Chemical resistance evaluation

PRECISION COMPONENTS & MATERIALS

- High-performance biocompatible materials
- Medical-grade thermoplastics
- Stainless steel (316L, 17-4 PH)
- Titanium alloys for implants
- Silicone and elastomer materials
- Optical materials and coatings

STERILIZATION & PACKAGING

- Sterilization method selection (EtO, gamma, autoclave, e-beam)
- Sterilization validation support
- Packaging design for sterile barrier
- Shelf-life testing planning
- Aging and stability studies
- Package integrity testing

SURFACE TREATMENTS & COATINGS

- Antimicrobial coatings
- Hydrophilic/hydrophobic treatments
- Biocompatible surface finishes
- Wear-resistant coatings
- Lubricious coatings for catheters
- Passivation for stainless steel

MEDICAL-GRADE PRODUCTION CAPABILITIES

PRECISION MANUFACTURING & ASSEMBLY

PROCESS DEVELOPMENT

- Manufacturing process flow development
- Assembly and fabrication procedures
- Custom equipment and tooling processes
- Sterilization and cleaning procedures
- Testing and inspection protocols
- Critical process parameter definition
- Process capability and validation studies
- Quality control plan development

CLEANROOM & CONTROLLED ENVIRONMENT MANUFACTURING

- ISO Class 7 and Class 8 cleanroom assembly
- Controlled environment setup
- Environmental monitoring and control
- Cleanroom protocol training
- Particle count monitoring
- Bioburden control

PRECISION MACHINING & MICROFABRICATION

- CNC precision machining (5-axis)
- Micro-machining capabilities
- Swiss-type turning for small components
- Wire EDM for intricate geometries
- Laser cutting and marking
- Tight tolerance machining (±0.0001”)

INJECTION MOLDING & PLASTICS

- Medical-grade injection molding
- Micro-molding for small components
- Insert molding and overmolding
- Cleanroom molding capabilities
- Tool design and manufacturing
- Process validation and IQ/OQ/PQ

ASSEMBLY & INTEGRATION

- Medical device assembly integration
- Electronic and sensor integration
- Manual and semi-automated assembly
- Adhesive bonding (medical-grade)
- Ultrasonic welding
- Heat staking and thermal bonding
- System functional testing

PRODUCTION INFRASTRUCTURE

- Custom tooling, fixtures, and equipment design
- Manufacturing line layout and material flow
- Production equipment procurement and qualification
- Operator training and work instructions
- Facility layout and infrastructure planning

COMPREHENSIVE VERIFICATION & VALIDATION

TESTING, VALIDATION & COMPLIANCE

DESIGN VERIFICATION TESTING

- Engineering prototype builds
- Performance analysis and optimization
- Bench testing and validation
- Software verification testing
- Biocompatibility and materials testing
- Functional and performance testing
- Safety and reliability testing
- Documentation and design verification reporting

DESIGN VALIDATION TESTING

- Clinical evaluation and usability testing
- Performance validation in simulated use conditions
- System reliability and shelf-life testing
- Accelerated aging studies
- Package integrity testing
- Transportation and distribution testing

REGULATORY COMPLIANCE TESTING

- Safety and regulatory compliance verification
- Electrical safety testing (IEC 60601-1, 61010)
- Electromagnetic compatibility (EMC) testing
- Biocompatibility testing coordination
- Sterilization validation
- Software validation
- Wireless performance testing (FCC, CE)

ENVIRONMENTAL & DURABILITY TESTING

- Temperature and humidity testing
- Shock and vibration testing
- Drop testing and mechanical durability
- Ingress protection (IP rating) testing
- Chemical resistance testing
- UV and light exposure testing

QUALITY ASSURANCE VALIDATION

- Process validation (IQ/OQ/PQ)
- Equipment and tooling qualification
- In-process and final quality testing
- First-article inspection data
- Manufacturing readiness demonstration

ISO 13485 & FDA COMPLIANCE EXCELLENCE

QUALITY SYSTEMS & REGULATORY SUPPORT

FULL-RATE PRODUCTION

- Target production volume execution
- ISO 13485 and FDA QSR compliance maintenance
- Customer delivery schedules
- Supply chain coordination and vendor management
- Quality control and statistical process monitoring
- Preventive maintenance and calibration programs

CONTINUOUS IMPROVEMENT & SURVEILLANCE

- Real-time performance and quality monitoring
- Data-driven process analytics and trending
- Corrective and preventive action (CAPA) implementation
- Process optimization and validation updates
- Manufacturing efficiency initiatives
- Best practice and lessons learned implementation
- Customer support and post-market surveillance

REGULATORY DOCUMENTATION SUPPORT

- Design history file (DHF) management
- Device master record (DMR) creation
- Technical file preparation (EU MDR)
- 510(k) submission support
- Design verification and validation reports
- Risk management documentation (ISO 14971)
- Clinical evaluation reports

PRODUCTION SCALING WITH COMPLIANCE

- Incremental production scaling
- Workforce training and certification expansion
- Process cycle time optimization
- Quality yield stabilization and improvement
- Automated inspection implementation
- Lean manufacturing and Six Sigma tools
- Target production rate achievement

QUALITY MANAGEMENT SYSTEMS

- ISO 13485 certified operations
- FDA 21 CFR 820 (QSR) compliance
- Quality management system implementation
- Design controls (21 CFR 820.30)
- Document and record control
- CAPA system implementation
- Management review processes

PRODUCTION QUALITY CONTROL

- Standard operating procedures and batch records
- Operator training and certification
- Statistical process control (SPC)
- In-process inspection
- Final inspection and release
- Device history record (DHR) maintenance
- Lot traceability