



NAVIGATE COMPLEX VALIDATION REQUIREMENTS AND ACCELERATE YOUR PATH TO MARKET

Mechanical testing challenges, regulatory hurdles, and orthopedic validation complexities can derail even the most promising medical devices. When comprehensive performance testing, compliance documentation, and strategic validation support are critical to your success, you need a scientific partner who transforms these obstacles into manageable processes. Element's experts work alongside your team, delivering specialized orthopedic and cardiovascular testing services that ensure regulatory compliance while flexibly scaling with your development needs. Partner with our Cincinnati team to focus on your innovative medical devices while we provide the expert testing that validates performance, confirms reliability, supports regulatory submissions, and accelerates your path to market.

TRANSFORM PRODUCT VALIDATION FROM REGULATORY BURDEN TO STRATEGIC ADVANTAGE

PARTNER WITH ELEMENT CINCINNATI TO:

- Overcome complex testing challenges that threaten approval and delay market entry
- Benefit from end-to-end testing management, from protocol to FDA-ready reports
- Streamline submission processes
- Access comprehensive mechanical, biomechanical, and regulatory expertise
- Ensure quality with detailed validation testing for orthopedic and cardiovascular devices

COMPREHENSIVE TESTING THROUGHOUT YOUR PRODUCT DEVELOPMENT LIFECYCLE

From initial protocol development through FDA-ready reporting, we handle the entire validation process so you can focus on your core innovation. Our specialized testing services help you identify performance issues early, confirm device reliability, and compile the robust documentation needed for successful submissions. Our key services include:

- Orthopedic Device Testing
- Cardiovascular Implant Durability Testing
- Biocompatibility & Toxicology Services
- Biomechanical & Cadaveric Testing
- Failure Analysis



EARLY DEVELOPMENT

- Accelerate research with efficient prototype testing
- Make data-driven design decisions
- Establish baseline performance parameters

REGULATORY SUBMISSION

- Generate comprehensive testing submissions
- Address complex regulatory requirements
- Meet critical regulatory timelines

COMMERCIAL SUPPORT

- Ensure consistent product performance
- Support continuous product improvements
- Maintain ongoing compliance

SPECIALIZED EXPERTISE FOR YOUR MOST CHALLENGING VALIDATION NEEDS

Element Cincinnati provides specialized testing services:

BIOCOMPATIBILITY & TOXICOLOGY SERVICES

- **Expert ISO 10993-1:2018 Product Review** - Thorough 6-step biological evaluation process
- **Biological Evaluation Plans and Reports** - Comprehensive documentation for regulatory submissions
- **Toxicological Risk Assessment (TRA)** - Expert analysis by certified toxicologists for FDA and EU MDR
- **Complete Biocompatibility Testing** - Including cytotoxicity, sensitization, irritation, and systemic toxicity
- **Materials Characterization** - Identifying biological hazards of device materials and manufacturing processes
- **Biological Safety Risk Assessment** - Using approaches aligned with ISO 14971:2019
- **Efficient Test Planning** - Maximizing safety while minimizing costs and turnaround time

ORTHOPEDIC DEVICE TESTING

- **Axial Static & Fatigue Testing** - Comprehensive durability evaluation
- **Torsion Static & Fatigue Testing** - Critical rotational performance validation
- **Multi-axis Load and Displacement Testing** - Real-world simulation capabilities
- **Wear Testing** - Hip, knee, shoulder, spine, and pin-on-disk testing
- **Cadaveric Studies** - Authentic biomechanical validation
- **Pressure & Burst Testing** - Critical safety performance verification
- **Porous Coating & Additive Lattice Testing** - Advanced material validation
- **Particulate and Ion Characterization** - Comprehensive wear debris analysis

CARDIOVASCULAR IMPLANT DURABILITY TESTING

- **Accelerated Pulsatile & Axial Durability Testing** - For stents and structural components
- **400M & 600M cycle Durability Tests** - Per ASTM & ISO standards
- **Fatigue Life Determination** - For nitinol and other cardiovascular materials
- **Radial Force Testing** - Critical stent performance measurement
- **Multi-Axial Durability Testing** - Specialized SFA & BTK capability per ASTM & ISO
- **Custom Silicone Models** - Precision vessel simulations for device testing
- **Material Characterization** - Comprehensive nitinol property assessment

REGULATORY SERVICES

- **Regulatory Strategy** - Including RegNav proprietary compliance planning
- **Technical Consulting** - Expert guidance on testing requirements
- **Biomechanical Analysis and Test Design** - Optimized validation approaches
- **Predicate & Comparative Analysis** - Strategic guidance for 510(k) submissions
- **Risk Analysis** - Comprehensive hazard identification and mitigation
- **Literature Support** - Evidence-based documentation for regulatory filings
- **Submission Services and Documentation Review** - Expert quality assurance
- **Summary Reporting and Guidance** - Clear, concise regulatory documentation

DIGITAL ENGINEERING SERVICES

- **FEA Modeling** - Performance prediction for complex device designs
- **Digital Simulation** - Virtual testing for rapid design optimization
- **Multiphysics Modeling** - Complex interaction analysis
- **Performance Assessment** - Comprehensive virtual validation

READY TO STREAMLINE YOUR PATH TO REGULATORY CLEARANCE?

Discover how Element Cincinnati's specialized testing expertise can help ensure the performance and regulatory compliance of your medical devices. Our experienced team is ready to discuss your specific testing requirements and develop a customized solution.

Click or scan the QR code to learn more.

