

THE GLOBAL LEADER  
IN MEDICAL DEVICE TESTING

Trust our unmatched expertise, certainty and service

# THE MEDICAL INDUSTRY'S TRUSTED TESTING PARTNER

Element is a global medical and pharmaceutical testing provider.

We work with medical OEMs and contract manufacturers to test and certify life-changing and life-saving technologies which transform the lives of patients worldwide.

Using experts who are leaders in their field and our global network of ISO 17025 accredited medical testing laboratories, we provide custom testing solutions for both large enterprises and growing start-ups.







# OUTSOURCE TO AN R&D PARTNER YOU CAN TRUST TO DELIVER

Our customers value and rely on the certainty, speed and flexibility we provide.

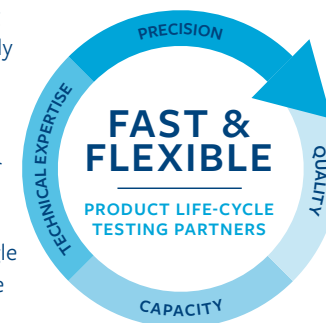
In our U.S. and European laboratories, Element delivers the largest and most effective testing capacity in the world. This enables us to deliver faster and at greater scale, and to react quickly to the dynamic and urgent needs of your organization.

Our industry-leading capacity underpins an agile approach to testing which allows us to complete projects ahead of schedule while maintaining rigorous standards. As a result, our team has a proven record in meeting the most complex logistical and technical challenges.

With Element as your comprehensive medical device testing partner, you'll also have a single source supplier you can rely on, however wide-ranging and complex your needs. You'll save time on vendor management and unlock the potential for significant cost efficiencies.

With leading experts that participate in industry standards committees, Element can serve as an extension to your R&D and production groups. Our experts bring the latest knowledge to your project, focusing on customer centricity and responsiveness to adapt to your changing project needs.

Together, our effective combination of expertise, agility and capacity allows our customers to trust Element to deliver.



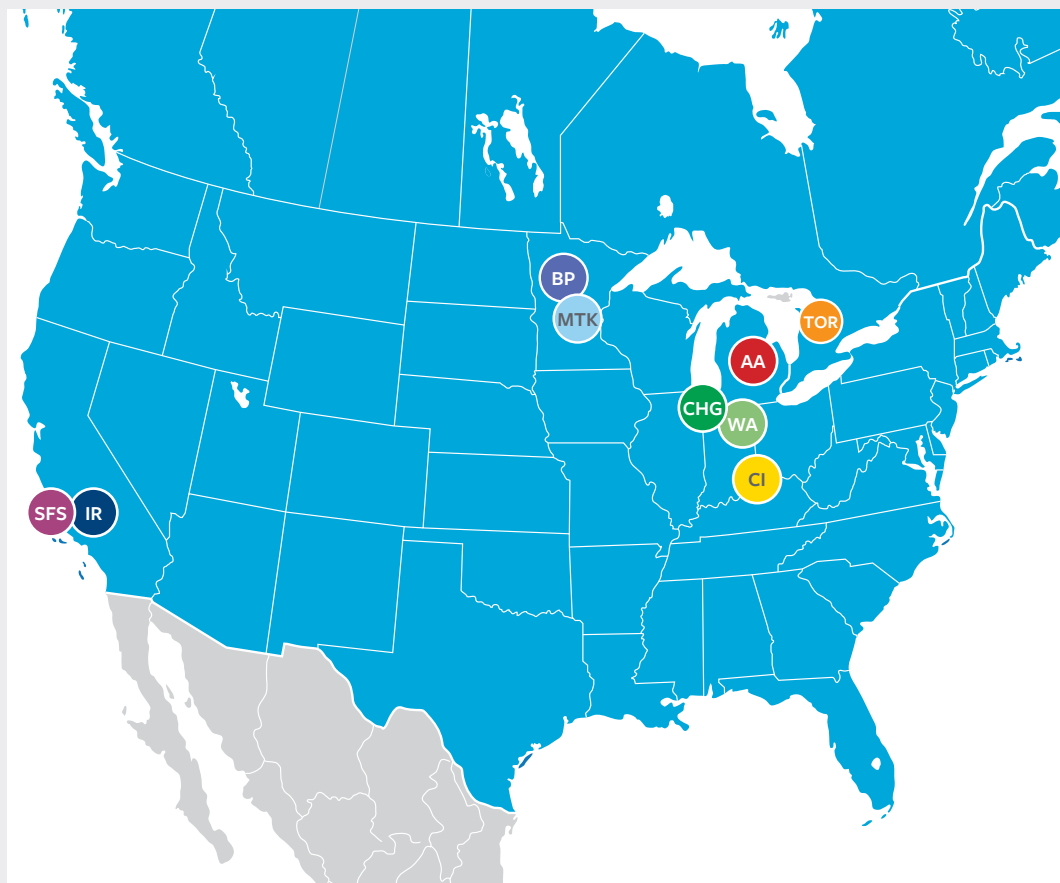
# WORLD-CLASS MEDICAL DEVICE TESTING SERVICES

We specialize in orthopedic, cardiovascular, diagnostic and therapeutic devices, and support every stage of medical device testing from test protocol development and prototype/feasibility trials to testing and consultation for 510(k), CE marking and other regulatory submissions.

Our dedicated team of experts has unparalleled experience in a wide range of testing services for Class I, II and III medical devices. We give all of our customers the certainty they demand through compliance with regulations and the knowledge that every element on your medical device product has been thoroughly evaluated and tested.

Element stands alone in providing a comprehensive suite of medical device testing and support services including:

- Mechanical & Materials Characterization
- Product regulatory testing
- Microbiological evaluation
- Chemical Characterization, Extractables & Leachables
- Reprocessing validation and instrument evaluation
- Electrical safety testing
- Wireless coexistence
- Regulatory submission services and technical consulting



AA Ann Arbor, MI

CI Cincinnati, OH

SFS Santa Fe Springs, CA

BP Brooklyn Park, MN

MTK Minnetonka, MN

TOR Toronto, ON, Canada

CHG Chicago, IL

IR Irvine, CA

WA Warsaw, IN



# GET SUPPORT THROUGHOUT THE LIFE CYCLE OF YOUR PRODUCT

Our testing services play a vital role in the credibility and market readiness of your products. To give your products the best chance of success, we provide expertise and testing advice during the R&D and production cycles, aligning to industry standards and latest regulatory trends.

We understand the importance of working in dynamic regulatory environments across Europe and the U.S. Our experts can help you navigate complex issues and protocols and provide regulatory submission support.

## Our life cycle support includes:

- Material discovery
- Feasibility characterization of prototypes
- Physiological product safety testing
- Production control and qualification
- Regulatory strategy

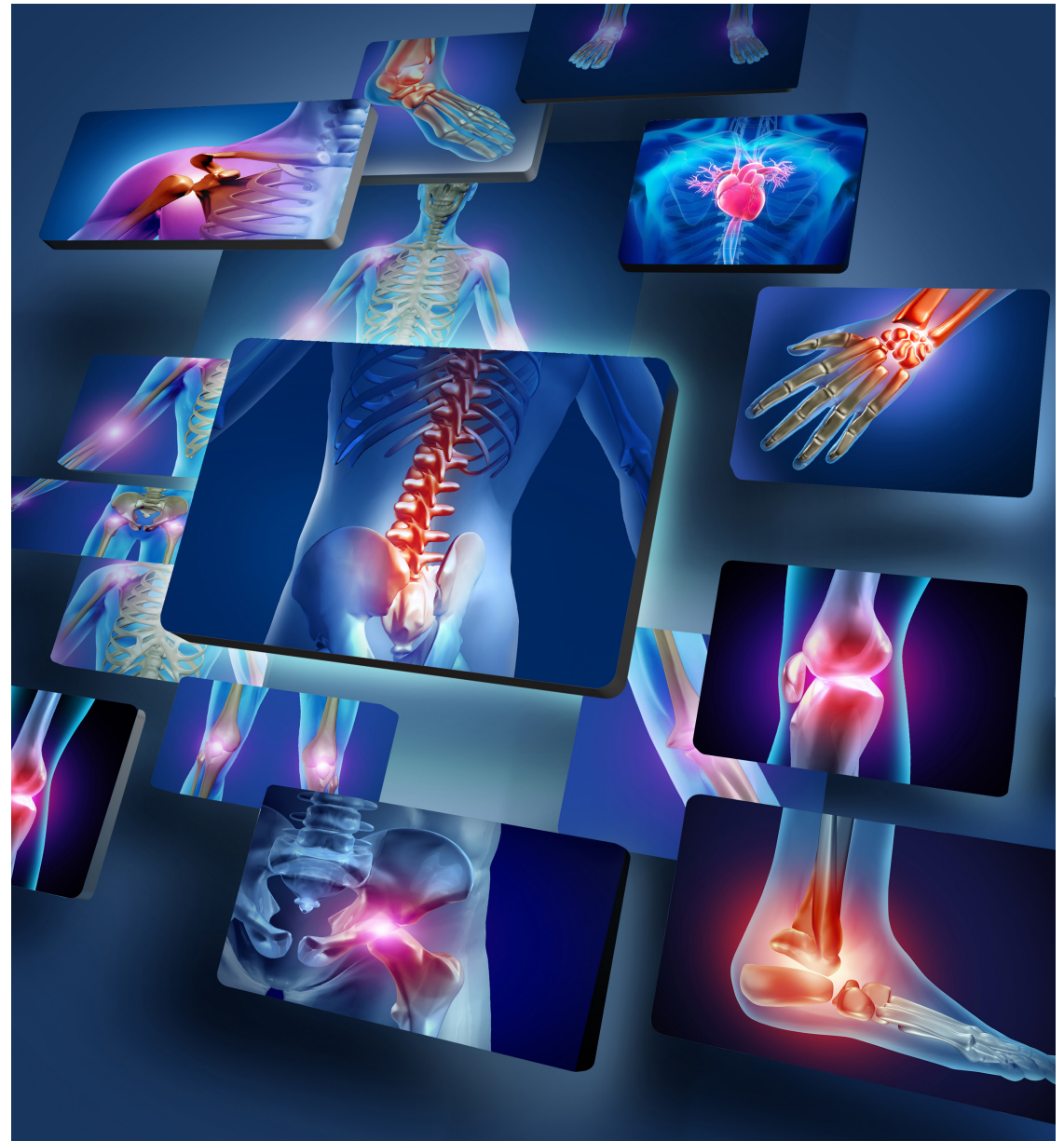


# ACCESS UNRIVALED AGILITY AND CAPABILITY

Our experts have worked with manufacturers across the world in a wide range of clinical areas, so we understand better than anyone the challenges involved in bringing a device to market.

Whether you're evaluating a cast knee replacement, forged hip stem or additively manufactured spinal implants, we recognize that dependable delivery of results is critical in mitigating your production risk. That's why our processes are designed with timely delivery at their core.

In addition, hundreds of medical devices come through our labs every year. Knowing that we see what works and what doesn't can improve your R&D and time to market, avoiding costly unmitigated risks. We work to understand your products and be a trusted extension of your research, development and production groups so we can react quickly to changing schedules and regulatory questions.





# LEVERAGE INVALUABLE PRODUCT EXPERTISE

With unrivaled product knowledge to call on, we can assist you with improved planning and decision making, to reduce delays, costs and the impact of additional regulatory queries. Coupled with the largest capacity in the medical industry, our product expertise allows you to meet unexpected regulatory deadlines and accelerate your product roadmap.



Products we test include:

## CARDIOVASCULAR

- Stents & Grafts
- Heart valves
- Occluders
- Catheters
- Stimulators
- Pacemakers

## ORTHOPEDICS

- Hips
- Knees
- Shoulders
- Spine
- Small extremities
- Dental
- Coatings
- Prosthetics
- Breast implants
- Trauma

## INSTRUMENTS

- Surgical tools
- Endoscopes
- Ultrasound probes
- CPAP components
- Light guides
- Syringes
- Autoinjectors

## DIAGNOSTIC & THERAPEUTICS

- Combination products
- Pulse oximeters
- Defibrillators
- Ultrasound
- Hearing aids
- Ventilators
- Patient Monitoring/Diagnostic devices
- Implantable pulse generators/

- Stimulators (IPGs)
- Active Implants
- Medication/Supply management & Storage solutions
- Drug delivery systems
- Surgical navigation systems
- Connected/IoT devices

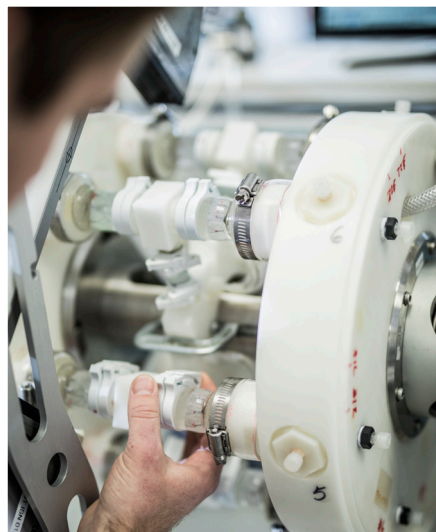
# HARNESS THE KNOWLEDGE OF ENGAGED EXPERTS

In partnership with our customers, we tackle the industry's unique market needs, testing challenges and regulatory mandates.

Many of our customers rely on Element for turnkey testing services for their regulatory submissions. Others trust us to design and deliver custom integrated testing solutions that require dedicated capacity, staffing and on-site partnerships.

We are proud to work with an extensive group of highly trained engineers and scientists who participate in AAMI, ASTM, ISO and other technical committees. Thanks to their specialist expertise, Element is trusted to take the lead on technology and industry trends.

Element also has a long record of success in Aerospace, Transportation, Connected Technologies and other industry segments. By drawing on collective insights, best practices and expertise, we deliver additional value and a unique experience for our customers.





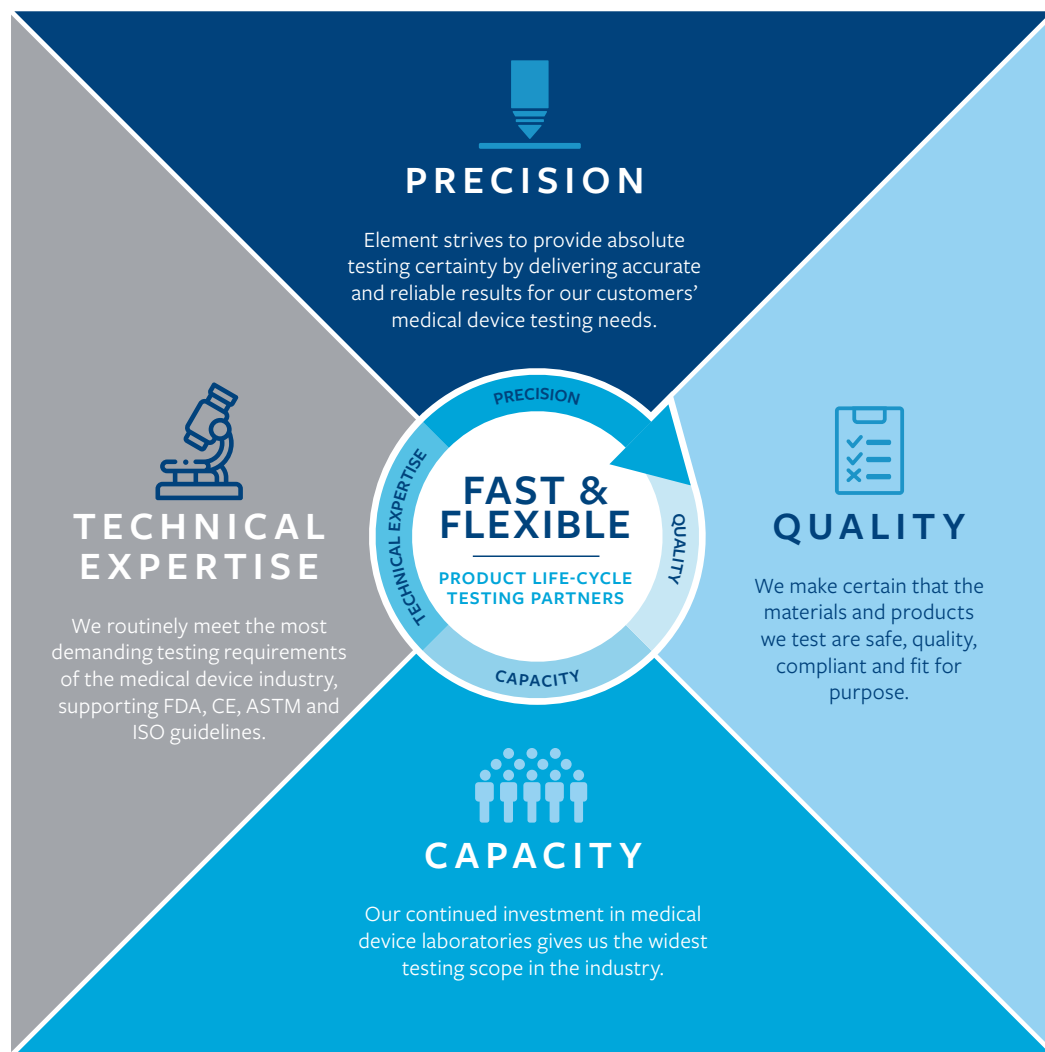
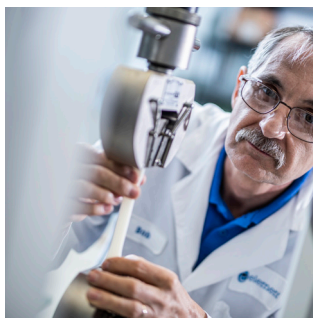
# WE DELIVER CERTAINTY, ON YOUR TIMELINE

We recognize that time to market can be critical to your success.

To meet your deadlines, we offer a range of services including protocol support, custom fixturing design and equipment builds, silicone vessel development and regulatory support.

If you're facing regulatory deadlines with no room for error, our exceptional teams and capacity allow us to meet demanding turnaround times.

Through flexibility and agile processes such as rapid development of equipment for custom testing, we can support your strategic vision, gain first mover advantage and secure market share.



# OUR CUSTOMER-FIRST APPROACH

Thousands of customers across the world,  
trust Element experts every single day.

Everything we do is designed to help our customers develop better products, get them to market on time, save time and money, and to minimize the risk to their business.

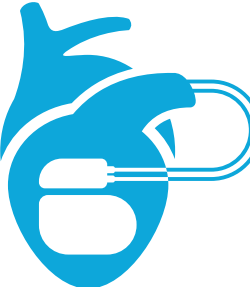
- “ Your lead on this project has been outstanding. He has been highly adaptable, flexible, and patient while our company makes changes to the project strategy, which impacts the testing. He is a great collaborator and contributes expert advice while we figure out how to do a novel test. ”
- “ Thanks for getting back to us quickly and updating the report. We were able to answer the FDA quickly as a result. Much appreciated! ”
- “ Thank you again for all of your flexibility and quick work – it’s REALLY appreciated! ”
- “ Communication with Element staff is always professional, timely and knowledgeable. The quick turnaround time is also very beneficial for both production and R&D needs. ”
- “ Whenever we have a sudden change in schedule and need an unexpected pickup, Element is always good about communicating and helping us out. We’ve worked with other labs and they can’t match you guys! ”
- “ The Element team have been and continue to be fantastic partners for this testing for us. Thank you again for the attentiveness and collaboration. ”





# SPEAK TO OUR SPECIALISTS

Engage with one of our experts today:



CARDIOVASCULAR



ORTHOPEDICS



INSTRUMENTS



DIAGNOSTIC & THERAPEUTICS



REPROCESSING VALIDATION

### General Inquiries

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# WE ARE ELEMENT

Element Materials Technology is one of the world's leading global providers of testing, inspection and certification services for a diverse range of materials, products and technologies in advanced industrial supply chains where failure is not an option.

Headquartered in London, UK, Element's team of more than 6,000 expert scientists, engineers and technicians operate from 200 locations across five continents, delivering an extensive range of solutions to customers in critical industries including Aerospace, Connected Technologies, Construction, Defense, Energy, Environmental, Life Sciences and Transportation.

## CONTACT US

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