



Medical Device Development and Testing

Southwest Research Institute[®] (SwRI[®]) offers expertise in diverse areas such as biomaterials and tissue engineering, materials characterization, biological encapsulation, and medical device development. Scientists in the Materials and Bioengineering Section have more than 35 years of experience in designing, prototyping and testing medical devices for the healthcare industry. SwRI uses a proven, quality-based development process to transform product concepts into reality.

SwRI offers clients a multidisciplinary approach to problem solving and a significant resource for complete medical device design and development. In addition, SwRI engineers and scientists are experienced in developing high-quality documentation necessary for FDA 510(k), PMA, and EU submission.

- Extractable/leachable
- Spectroscopy
- Viscosity
- Biological
- Biocompatibility
- Antimicrobility

Design and Prototyping

- Material/chemical
- Electrical/computer
- Mechanical
- Optical
- Software

Testing and Evaluation

- Mechanical
- Tension and compression
- Shear/torsion/fatigue
- Wear debris
- Creep/vibration/shock
- Environmental
- Corrosion/salt/fog/UV exposure
- Temperature/humidity/pressure
- Thermal shock/stability
- Flammability
- Material/chemical
- Chemical analyses (GC, MS, HPLC, NMR, FTIR, LC, RID, X-ray diffraction, etc.)

Applications

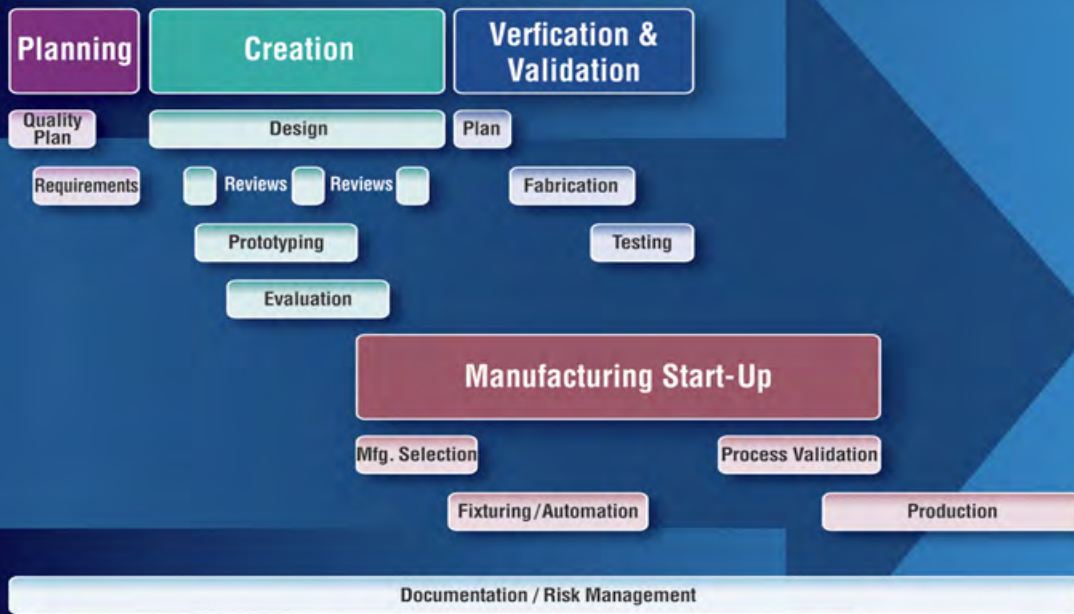
- Surface coating
- Tissue engineering product
- Perfusion system
- In vitro diagnostic device
- Drug delivery device



Blood testing



Instrument evaluation



Translational development process under ISO 13485 quality system

The Chemistry and Chemical Engineering Division at SwRI is ISO 9001:2008 certified. Staff in the Materials and Bioengineering Section also follow current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP) and Medical Device ISO 13485:2003 procedures that comply with FDA Quality System Regulation 21 CFR 820.20.

We welcome your inquiries.

For additional information, please contact:

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SOUTHWEST RESEARCH INSTITUTE

Southwest Research Institute is a premier independent, nonprofit research and development organization using multidisciplinary services to provide solutions to some of the world's most challenging scientific and engineering problems. Headquartered in San Antonio, Texas, our client-focused, client-funded organization occupies 1,200 acres, providing more than 2 million square feet of laboratories, test facilities, workshops, and offices for more than 2,700 employees who perform contract work for government and industry clients.

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