WHY CHOOSE US

ONE STOP SHOP
The concept of a one-stop shop for “regulated services” greatly enhances the value for our clients. This is why we built our specialized capabilities; to provide our clients with comprehensive turnkey solutions.

CUSTOMER SERVICE
Our success as a business is dependent upon the development of solid and enduring relationships with our clients. Such relationships are the direct result of our ability to continuously meet and exceed our client’s expectations.

PART OF YOUR TEAM
We act as an external extension of your company by providing the specific services necessary to meet your unique needs. Your staff is welcome and encouraged to participate directly in all aspects of your project.

CLIENT FEEDBACK

LSO has been a great partner to work with over the last few years. They have been very detailed and organized on all orders. LSO has helped us through various validation projects all of which have been successful. We have found them to also be competitively priced which has been helpful to our small start-up company dynamic! We look forward to working with the LSO team on future projects!

Melissa
R&D Engineering Manager
Industry: Orthopedic
Divisions Worked with: Medical Package Testing, Sterilization Validation Services

Kevin
Director of Supply Chain
Industry: Orthopedic
Divisions Worked with: Medical Package Testing, Sterilization Validation Services, Medical Device Manufacturing

In the 9 months we’ve been doing business with LSO, our relationship has developed very quickly along with our confidence in their abilities. They are super responsive to our needs and have kept us out of back order several times. We enjoy working with the team at LSO and honestly feel they are an extension of our company.
<table>
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<th>LIST OF SERVICES AT A GLANCE</th>
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**MEDICAL DEVICE MANUFACTURING**
- Turn Key Contract Manufacturing
- ISO Class 5, 6 & 7 Clean Rooms
- ISO/GMP Compliance
- ISO 13485 Certified
- Facility Utilization Option
- Device Assembly
- Device History Records
- Quality Management System Development

**MEDICAL PACKAGE TESTING**
- ISTA Certified Package Test Lab
- ISO 11607-1 Compliant Validations
- Sterile Barrier Design (Pouch / Tray)
- Package Design (Shelf Box / Shipper)
- ISO 11607-2 Compliant Sealer Validation
- OQ/PQ Protocols & Validation

**STERILIZATION VALIDATION SERVICES**
- Medical & Dental Cleaning Validations
- Sterilization Validation
- Gamma, EO, and E-Beam
- Onsite Contract Steam Sterilization
- Microbiological Testing

**CLEANING & DECONTAMINATION SERVICES**
- Orthopedic Surgical Trays
- Dental Kits
- Device Field Returns

**QUALITY INCUBATOR SERVICES**
- Regulatory Address at LSO
- Quality System Documentation
- Device Master Records

**FULFILLMENT & DISTRIBUTION SERVICES**
- Order and Fulfillment
- Supply Chain Management
- Warehouse Inventory Management
- Packaging and Kitting
- Distribution

**Engineering Life**
Life Science Outsourcing, Inc.
830 Challenger Street
Brea, CA 92821
(714) 672-1090 Office • (714) 672-1093 Fax • info@lso-inc.com
The Medical Device Manufacturing Division of LSO specializes in working with Start up and Early Stage Medical Device Companies. During LSO’s nineteen years in business, we have worked with over 850 startups, resulting in approximately twenty seven companies being acquired by Multinational Organizations. The collective purchase price of these companies exceeds 4 Billion dollars. LSO has an excellent reputation in the industry for reducing time to market and assisting companies with critical tasks such as the development of Manufacturing Procedures and Process Development enhancements that result in the manufacture of well made and high quality products. Please review a partial list of services and capabilities below.

**ENGINEERING SERVICES**
- Process Validation
- Manufacturing Procedures
- Packaging Development
- Complete Documentation Packages

**ORTHOPEDIC SOLUTIONS**
- Biopharm Manufacturing
- Invitro Diagnostics
- Incubator Services
- Facility Utilization

**CATHETER ASSEMBLY**
- Radiofrequency Catheters
- Diagnostic Catheters
- Balloon Catheters
- Drug Delivery Systems
- Electrophysiology Catheters

**PROCESS VALIDATION**
- Creation of Manufacturing Procedures
- IQ, OQ, & PQ
- FMEA
- Design Verification Testing
- Complete Product Validation

**SPECIAL PROCESSES**
- Tube Bonding & Welding
- Balloon Bonding
- Tip Forming
- Skiving
- UV Bonding
- Micro Soldering and Bonding

**COMBINATION PRODUCTS**
- Aseptic Transfer- Vials & Syringes
- Compound Blending
- Stability & Biocompatibility Testing
- QC Testing
- Packaging, Sealing & Validation
MPT is a division of Life Science Outsourcing, Inc. and is an ISTA certified packaging test lab (ID Number ST-2339). MPT is devoted to the validation, testing and design of sterile packaging for medical device manufacturers. Our testing and validation services are based on ISO 11607-1 and are designed to assure compliance with FDA, ISO, EN and CE Mark requirements.

**STABILITY & PERFORMACE TESTING**

- Accelerated Aging (ASTM F1980)
- Real-time Aging (Controlled Temp.)
- Conditioning (ASTM D4332)
- ASTM D4169
- ISTA 1A, 1G, 2A, 3A
- ICH (Stability Testing of Drug Substances)

**STERILE BARRIER TESTING**

- Visual Inspection (ASTM F1886)
- Peel Strength (ASTM F88 / EN 868-5)
- Burst (ASTM F1140)
- Dye Penetration (ASTM F1929 / F3039)
- Bubble Leak (ASTM F2096)
- Altitude Simulation (ASTM D6653)

**TURNKEY MEDICAL DEVICE PACKAGE DESIGN AND SEALER VALIDATION**

(ISO 11607-2)

- Primary Package (Pouch, Tray)
- Secondary Package (Shelf Caron, Shipping Box)
- Pouch / Tray Sealer Validation
  - OQ/PQ Protocol
  - OQ/PQ Testing
  - OQ/PQ Final Report

**TURNKEY MEDICAL DEVICE PACKAGING AND SHELF LIFE VALIDATION**

(ISO 11607-1)

- Stability and Performance Testing
  - Protocol
  - Distribution Simulation
  - Accelerated Aging
  - Real-time Aging
  - Final Report

**CHECK OUT OUR PRICE GUARANTEE!**

At Medical Package Testing we are so confident about our prices that we guarantee them! If you find a quoted price for your project which is less than our quoted price, we guarantee to meet the lower price by 5%.
At SVS we pride ourselves on our client service orientation and our ability to Develop Studies to meet client’s specific requirements. We exist to provide you with the optimal solution for your sterilization needs and guide you through the library of regulations and requirements involved.

We offer all commercial sterilization modalities such as Steam, Gamma, E-beam, and EO methods. We are also equipped to handle all future annual re-validations or quarterly dose audits.

**CLEANING VALIDATIONS MEDICAL & DENTAL**
- Medical Instrument Trays
- Hand Pieces
- Individual Components
- Cleaning Method Development

**TURKEY VALIDATION AND EXPEDITED SERVICES**
- Steam Processing - ISO 17664/17665-1/17665-2
- Ethylene Oxide Processing - ISO 11135
- Gamma Radiation Processing - ISO11137
- E-Beam Radiation Processing - ISO11137

**STEAM PROCESSING**
ISO 17664 / 17665-1 / 17665-2
- Turnkey Validations
- R&D Cycles
- Cycle Development
- Recurring Processing
- Expedited Services
- Durability testing

**RADIATION PROCESSING**
ISO 11137
- Gamma and E-Beam
- Turnkey Validations
- R&D Cycles
- Material Testing
- Dose Mapping
- Recurring Processing
- Expedited Services

**EtO PROCESSING**
ISO 11135
- Turnkey Validations
- R&D Cycles
- Material Test Exposures
- Cycle Development
- Recurring Processing
- Expedited Services
- DNA Disruption Cycles

**LABORATORY TESTING**
- Biocompatibility Testing
- Bioburden
- EO Residuals
- Particle Testing
- Expedited Services
- LAL Test Method Validation

**DECONTAMINATION SERVICES**
- Field Returns
- Explanted Devices
- Recurring Medical Instrument
- Tray Processing
- Expedited Services

**STERILIZATION VALIDATIONS**
- Instrument Trays
- Hand Piece Instruments
- Individual Components
- Cycle Development
- Expedited Services