



Contract Manufacturing Services

Technology transfer

Method transfer/qualification/validation

Process flow determination

Raw material specification/development/testing

In-process development treatment

Formulation (aqueous and organic)

Vial filling, stoppering, and crimp capping

Vial inspection

Vial labeling

Final product release testing

ICH-compliant stability programs

Quick batch record reconciliation and review

Microtest is the problem-solving company for pharmaceutical contract manufacturing. Our unique combination of deep scientific knowledge and process flexibility provide creative solutions that reduce cost and enhance reliability while integrating seamlessly with your supply chain. With a broad portfolio of contract manufacturing services, we offer single-source production and testing capabilities plus dedicated project management. The result is immediate project startup, single technology transfer, easier regulatory submissions, and accelerated time to clinical trials.

Our Capabilities

Microtest focuses on parenteral manufacturing. Our capabilities include aseptic processing of liquid dosage forms at both clinical and commercial scales. The company's facilities are designed for multi-product operations, which include FDA-regulated biologics, drugs, and devices. Products range from Phase I clinical trial material to commercially available offerings. We've developed manufacturing solutions for vaccines, small molecules, biological proteins, oligonucleotides, and suspensions.

The Synergies of Manufacturing and Testing

Our heritage in life science testing has converged with enhanced production capabilities to create integrated, single-source manufacturing solutions. For example, we can deliver fill-finish services integrated with stability and testing services for a complete solution that lowers cost, improves quality, and compresses time to revenue. Microtest recently invested \$7.5 million in laboratories, people, and technology



to create the industry's most advanced contract manufacturing environment. We've expanded essential areas such as aseptic processing and support while doubling the size of our facilities.

Manufacturing Highlights

Dedicated aseptic processing suites

- ISO 7 glassware preparation area
- ISO 7 formulation room
- ISO 5 fill line contained in an ISO 6 fill/finish room
- Lot sizes from <500 to >25,000 vials
- Fill volumes from 0.5 ml to 20 ml

Dedicated manufacturing staff and project management

In-process and release testing of final drug product

Automated labeling

Aqueous and oil-based product handling

Approved to handle DEA Schedule III drug products

FDA and DEA registered and inspected facilities

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The Knowledge That Solves Your Problems The Flexibility That Gives You Control

Microtest offers the quality and convenience only a single-source manufacturer can provide. Our solutions are built on an innovative platform of scientific knowledge, process flexibility, and exceptional project management. Single-source production means shorter, less complex supply chains. Your products stay in-house throughout the manufacturing and testing process, never leaving our controlled environment.

Expertise

Microtest's team of manufacturing and testing experts can solve your most challenging problems. Our highly trained, degreed staff bring years of education and experience to their assignments. This knowledge gives clients the assurance their products will meet the highest standards of safety and security. It generates greater confidence that schedules and cost targets will be met. With no learning curve required, we provide immediate project startup. And our greater creativity in solving problems helps lower cost, improve reliability, and ensure repeatability.

Flexibility

Our highly flexible approach enables single-source production and assures seamless integration with your manufacturing process and philosophy. Only Microtest gives you the power of custom method development for maximum confidence and greater control. We perform all method and technology transfer activities under an engineering run in a formalized system. Our method transfer qualification and validation activities include microbiology, virology, vial integrity, biologics analytical testing, and pharmaceutical analytical testing. This process ensures we meet all government contract requirements and accelerate your time to clinical trials.

Project Management

Microtest offers dedicated project management that provides transparency to the manufacturing process. You get immediate access to information and early warning on issues before they become problems. Your project manager is a single point of contact and accountability who facilitates communications and ensures we operate as an extension of your business. That means on-time and on-budget projects, easier regulatory submissions, and seamless integration with your supply chain.

Microtest does not manufacture penicillin-containing products, cephalosporins, live bacteria, or live viral vaccines.