



Thermo Scientific Contract Manufacturing Services



Experience

Expertise

Excellence



THE RIGHT CHOICE FOR ALL OF YOUR OUTSOURCING NEEDS

Thermo Fisher Scientific offers contract manufacturing services in diagnostics, biotechnology formulation and packaging. No matter where you are in your development or production process, such as the initial research and development phase, the regulatory or compliance process, or in the final warehousing or shipping phase, we can accommodate your needs. Our focus, combined with the flexibility of our production/warehouse facilities, enables us to provide an unparalleled level of responsiveness to you – from bench to batch.

Process Capabilities

Liquid Formulation

- Aqueous product lot sizes up to 36,000 L
- Serum calibrator and control lot sizes up to 2,500 L
- Immunochemistry reagent lot sizes up to 500 L
- Chromatographic antibody purification
- Tank capacity from 9,000 – 40,000 L

Liquid filling

- 25 automated filling lines
- Aseptic processing
- Bottle sizes from 1 ml to 20 L
- Lot sizes to 200,000 bottles
- Ampuling, unit dose, and pouch filling capabilities

Organic Synthesis

- Conjugate antibodies and enzymes to latex
- Ficoll and magnetic particles

Powder Blending and Filling

- 3 automated filling lines
- Lot sizes to 150 kg
- Low humidity environment
- Lot sizes to 60,000 bottles
- Bottle sizes from 0.1 to 500 g

Lyophilization

- 13 lyophilizers
- 2,200 sq. ft. of shelving
- Vial, bulk and specialty freeze-drying capabilities

Purified Water Production

- Capacity up to 40 gal/min

Reagent Cassettes

- Fill, weld and package instrument-specific cassettes

Off-line and in-line labeling

- 2D and other bar-coding capabilities

Kit Assembly & Packaging

Final Product Testing

- Proprietary instrument testing
- Value assignment testing of controls
- Specifications tailored for each application



ISO 13485 CERTIFICATION
CLASS 100–100,000 ROOMS



Service Capabilities

Development

- Highly-qualified, experienced R&D team
- FDA-compliant, phase-based Design Control processes that permit any level of product development from on-market product transfer to full research and development

Technology Transfer

- Expertise in pilot production
- Lot-size and process scale-up
- Equipment, process and software validation
- Manufacturing site transfer
- Creation and control of FDA compliant production, testing, and MRP documentation

Packaging Development

- Resident Packaging Engineer with DOT and IATA certifications
- Primary and secondary packaging design
- Label design
- Kit design for ease-of-use and efficient assembly

Regulatory Support

- Regulatory submissions (FDA, CE, CMDR, JPAL)
- Clinical studies management
- Product development and design control
- Technical writing
- Product labeling development and review
- Expert reports

Technical Support

- Supplier identification, qualification, and surveillance
- Raw material qualification
- Troubleshooting performance and production issues
- Practical Process Improvement of products and processes

Stability Programs

- Routine and accelerated
- Analysis and technical report capability

Warehousing and Logistics Services

Inventory Management and Automatic Stock Replenishment

OEM | Contract Manufacturing Products

IVD Reagents | Calibrators | Controls

- Blood Bank Saline
- Buffers
- Clinical Chemistry
- Coagulation
- Glucose Monitoring Controls
- Hematology
- Immunoassays
- Medical Beverages
- Microbiology
- Parasitology
- Point of Care
- Reagent Grade Water
- Serology
- Standards

Production | Warehouse Facilities

- Facilities in East Providence, RI and Middletown, VA
- 300,000 square feet of facility space
- 25,000 square feet of refrigerated and freezer capacity
- 8 environmentally controlled rooms ranging from Class 100 to Class 100,000
- 27 automated and semi-automated filling lines – 25 microliters to 2,000 liters
- 13 lyophilizers with 2,200 sq. ft. of shelving
- ISO 13485, FDA-registered, cGMP-compliant, CMDS Certified



About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. (NYSE: TMO) is the world leader in serving science, enabling our customers to make the world healthier, cleaner and safer. With an annual revenue rate of more than \$9 billion, we employ 30,000 people and serve over 350,000 customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as environmental and industrial process control settings. Serving customers through two premier brands, Thermo Scientific and Fisher Scientific, we help solve analytical challenges from routine testing to complex research and discovery. Thermo Scientific offers customers a complete range of high-end analytical instruments as well as laboratory equipment, software, services, consumables and reagents to enable integrated laboratory workflow solutions. Fisher Scientific provides a complete portfolio of laboratory equipment, chemicals, supplies and services used in healthcare, scientific research, safety and education. Together, we offer the most convenient purchasing options to customers and continuously advance our technologies to accelerate the pace of scientific discovery, enhance value for customers and fuel growth for shareholders and employees alike. Visit www.thermofisher.com

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