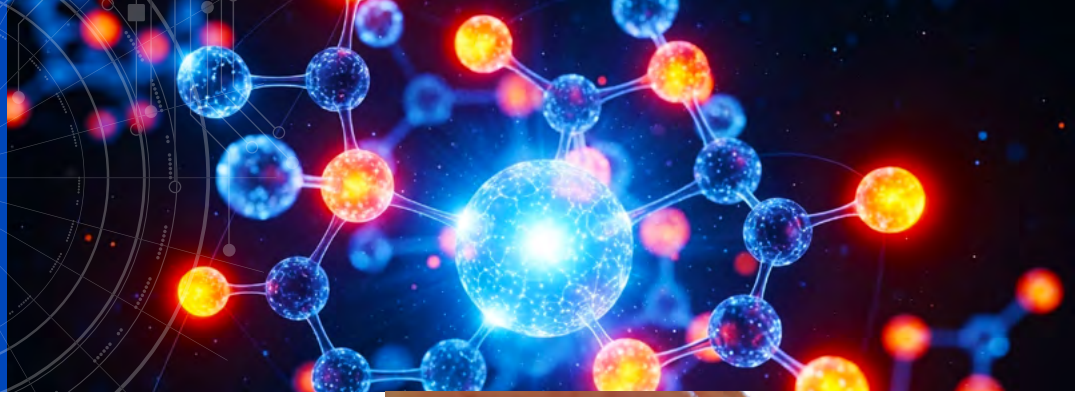




SOUTHWEST RESEARCH INSTITUTE



Clinical Supply Facility

The Southwest Research Institute® (SwRI®) Clinical Supply Facility (CSF) supports pharmaceutical development and bioengineering research. The 21,000-square-foot facility is the Institute's flagship Current Good Manufacturing Practices (CGMP) facility and provides scale-up and clinical trial support up to Phase III.

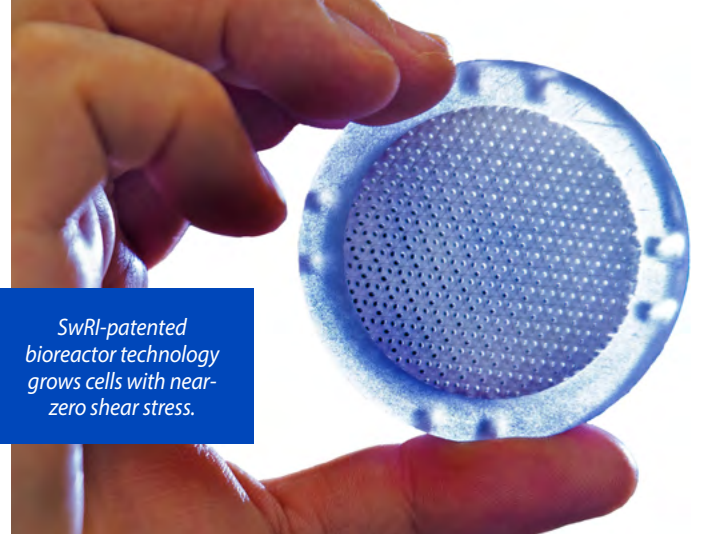
The facility provides dedicated bioengineering suites and filtered cleanrooms to develop and produce clinical supplies. The CSF can facilitate the production of active pharmaceutical ingredients, formulated products, biologics or cell-based materials, including in vitro stem cells, and vaccine components. It can streamline workflows to support everything from regenerative medicine to vaccines, small-molecule therapeutics, and rare disease treatments.

SwRI is home to FDA- and DEA-inspected laboratories and follows all Current Good Manufacturing Practices.

The SwRI Clinical Supply Facility was designed with process flow and scale-up needs of clients in mind while offering flexibility that other production facilities often cannot. From receiving, storing, sampling, testing, producing, and packaging chemical compounds — the CSF supports the entire lifespan of every CGMP project at SwRI.

Key Features

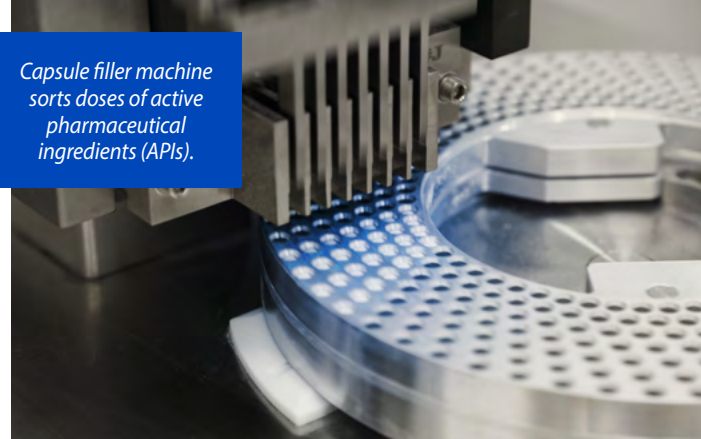
- 21,000 sq-ft facility
- 4,200 sq-ft of ISO-rated production spaces/support rooms, including three 16-ft-tall high bay production suites and four 10-ft-tall ceiling suites
- 2,700 sq-ft of analytical support lab spaces
- Controlled storage environments supporting a range of applications, including:
 - Room Temperature
 - 4°C
 - -20°C
 - -80°C
 - Cryogenic
 - Standard & Accelerated Stability
- On-Site backup Power Generator for Critical Operations & Storage Support



SwRI-patented bioreactor technology grows cells with near-zero shear stress.



Sprays drying operations coat APIs for dosage formulations.



Capsule filler machine sorts doses of active pharmaceutical ingredients (APIs).

Quality Certifications

SwRI's Chemical and Chemical Engineering activities are certified to ISO 9001:2015 Quality Management Systems, ISO 13485:2016 Medical Devices Quality Management Systems, and ISO 14001:2015, Environmental Management Systems. The Pharmaceutical and Bioengineering Department is also registered with the U.S. Food and Drug Administration (FDA) as a manufacturing facility and hold licenses issued by the Drug Enforcement Administration (DEA) for Schedule II through V controlled substances for both research and manufacturing purposes.



The 21,000-square-foot Clinical Supply Facility support government and industry clients with integrated pharmaceutical and bioengineering research and development, expanding the Institute's bioengineering laboratory footprint and adding dedicated bioengineering production suites with filtered air and low airborne particulate counts.

We welcome your inquiries. For more information, please contact:

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SOUTHWEST RESEARCH INSTITUTE

Southwest Research Institute® is a premier independent, nonprofit research and development organization. With multiple technical divisions, we offer multidisciplinary services leveraging advanced science and applied technologies. Since 1947, we have provided solutions for some of the world's most challenging scientific and engineering problems.

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