



MediZap

Advanced Sterilization

MediZap's NEW contract research organization partner Eagle Analytical brings compounding expertise and vertical integration for all USP and ISO testing services

The partnership integrates sterile compounding testing into MediZap's Four Pillar Service to meet the ever-tightening USP <797>, and cGMP guidelines for sterile compounding assurance.

SAN DIEGO, CA - MediZap, North America's leading turn-key service provider of E-Beam | X-Ray terminal sterilization for compounded pharmaceuticals announces an exciting partnership with Eagle Analytical to offer sterile compounding testing services: including ISO microbiology sterilization validations, analytical chemistry, and environmental monitoring.

The partnership adds another layer of value to the MediZap Program by expanding its services to include USP <797>, USP <800>, and cGMP FDA compliance expertise and testing solutions for compounded pharmaceuticals.

Eagle Analytical helps the compounded pharmaceutical industry:

- Ensures patient safety by validating and testing pharmaceutical products.
- Supports quality management systems that safeguard the health of their patients.
- Implements and complies with government regulatory.

The partnership is a direct integration with MediZap's Four Pillar Service, with Eagle Analytical offering services in the areas of research and development testing, safety and compliance testing, stability testing, container closure testing, quality assurance testing, and consulting services.



MediZap clients can expect these primary benefits, and more, from this partnership with Eagle Analytical:

- Peel-Off Sample Submission - Samples are taken from the terminal sterilization run for compendial quality control testing. Samples are pulled post-sterilization and immediately sent to the Eagle Analytical microbiology lab for testing, saving the client significant time and money.
- Q-Alerts - When a client has a quality event that potentially affects drug stability, or safety the joint team effort between MediZap, Eagle Analytical, and the client immediately launches a quality investigation and quickly and effectively identifies the single root cause in a unified manner.
- Advanced Technology for Testing Services – Eagle Analytical sterile compounding testing services include ScanRDI® Sterility Test, BacT/Alert Sterility Test, and USP <1207> Container Closure Integrity Test: Pressure Decay to ensure the drug safety and timeliness of results.

Eagle Analytical is a specialty contract lab, comprising FDA- and EPA-focused laboratories across the United States. It is a cGMP compliant, FDA registered, DEA registered, A2LA ISO 17025 and ISO | IEC 17025:2017 accredited company dedicated to pharmaceutical testing solutions.

“The partnership with Eagle Analytical further supports MediZap’s commitment to helping innovative 503A and 503B compounding pharmacies, small pharmaceutical companies meet the ever-tightening USP <797> guidelines for sterile compounding assurance regulated by the State Boards of Pharmacy, and FDA cGMP. It allows us to offer clients a full spectrum of microbiology and analytical chemistry testing, and sterilization services to overcome historic sterilization validation methodologies and keep their projects on track and get their products to market faster. We are excited to integrate Eagle Analytical’s services into our own Four Pillar Service that has made MediZap a leader in the terminal sterilization industry,” said Jonathan Bergstrom, CEO of MediZap.

Sterile drug manufacturing now starts with terminal sterilization, such as MediZap’s exclusive E-Beam | X-Ray Terminal Sterilization technology, providing customers with the highest standard of sterilization. Terminal sterilization provides an FDA | ISO-validated sterilization process, creates a benchmark for sterilization across the industry, standardizes third-party accountability for testing, and saves money in terms of in-house equipment, staff, and documentation.

MediZap offers the best product on the market with our new vertical integration with Eagle Analytical as the USP and ISO leader.

