



BIOTECH INDUSTRY UTILIZES THE QMI SYSTEM

EPITOPIX

A biotech company that uses the QMI Safe-Septum is Epitopix in Willmar, Minnesota. Epitopix discovers, develops and sells original veterinary vaccines that improve animal health and human food safety. Its continuing discoveries bring novel vaccine products to additional markets including livestock, poultry, and companion animals.

Epitopix uses the QMI Safe-Septum for aseptic sampling of its vaccine production equipment. Mitch Schueler, Director of Manufacturing states: "The QMI Safe-Septum became the answer to two of our most perplexing aseptic sampling questions during critical stages of our process. Its application has been critical to process improvements that have drastically cut plant losses over the last few years."

www.epitopix.com



QMI 12 Port Tri-Clamp End Cap



QMI Tri-Clamp Elbow with Syringe

The Biotech industry uses the QMI Safe-Septum® as a method of inoculating bioreactors and aseptically sampling liquids in processing equipment. See also: QMI Newsletter, Fall, 2012. The QMI Safe-Septum® was validated at the University of Minnesota's Biotechnology Institute in studies published in *Genetic Engineering News* (Feb 2000) and *Pharmaceutical Process* magazine (Jan 2000).

The QMI Safe-Septum® is used worldwide in biotech facilities.

For more information including validation studies, visit: www.qmisystems.com

BREWING INDUSTRY USES THE QMI SYSTEM TO ACHIEVE ACCURATE MICROBIOLOGICAL TESTING OF TREATED WATER

COLD SPRING BREWERY

Production of high quality products is the number one objective at Cold Spring Brewery in Cold Spring, MN. “We have confidence in the accuracy of our microbiological testing because we sample treated water with the QMI Aseptic Sampling System,” said Andy Juelich, Lead Process Control Technician at Cold Spring Brewery.

Cold Spring Brewery uses reverse osmosis (RO) and ultra violet light treatment systems for quality water. A critical part of the quality control procedures requires microbiological monitoring of the water using an accurate sampling system.

Cold Spring Brewery uses the QMI Aseptic Sampling System with pre-sterilized sampling septums that are FDA approved for food contact surfaces and are validated by university laboratories. The system is easy to design into new RO water systems or retrofit into existing systems.



Sampling at Cold Spring Brewery Using the QMI Aseptic Sampling System

QMI's QUALITY STANDARDS

QMI septums (PN 7027, 7027S, 7027P, 8080 & 8080S) are manufactured under rigorous quality standards. QMI's products are not medical devices, but are manufactured with a quality and supply contract by Biotest Laboratories, Minnesota, a manufacturing and testing laboratory for the medical products industry. Biotest Laboratories is registered under FDA GMP, ISO 13485:2005 and ISO/IEC 17025. An organization registered to these ISO standards must demonstrate its ability to manufacture medical devices and related services that consistently meet customer requirements. This accreditation covers laboratory testing, assembly, packaging, validation and sterilization of customer-supplied products. Liquid contact components of QMI septums comply with the Food Code of Federal Regulations (CFR) for the Food and Drug Administration (FDA), Title 21, Paragraph 177.26. The Aseptic Samplers are sterilized in compliance with ISO 11135-1:2007 and applicable federal and state regulations (FDA, NRC, EPA and OSHA). The samplers are sold for aseptic use.

QMI Sampling Assemblies (PN 2388, 2392, 2392P, 2394) are manufactured at facilities registered under ISO standard 13485: 2003 and conform to FDA Regulation 21 CFR Part 820. These products undergo a validated and verified irradiation sterilization process.

QMI stainless steel products are manufactured at metal fabrication facilities with extensive experience in the machining processes needed to meet QMI's standards for both 7- & 12-port fittings and is a 3-A authorized facility. These products are manufactured under a rigorous quality system that incorporates ISO guidelines.

QMI products are authorized to display the industry standard 3-A logo (www.3-A.org), which includes an independent audit of our manufacturing practices.

QMI continually educates users of QMI products with Standard Operating Procedures (SOP's) in both English and Spanish in written format, on our web site at www.qmisystems.com and video format at www.YouTube.com/qmisystems.



Biotest Laboratories, Brooklyn Park, MN

www.biotestlabs.com

UPCOMING EVENTS



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Craft Brewers Conference—Booth # 4109

March 26-29, 2013

Washington Convention Center, Washington D.C.



American Society for Microbiology Meeting—Booth # 640

May 18-21, 2013

Denver, CO



AABP—Booth # 319

September 19-21, 2013

Milwaukee, WI



World Dairy Expo—Booth # 133

October 1-5, 2013

Madison, WI



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