



Quality Management, Inc.

Quality Standards

QMI's products are manufactured and assembled by strategic partners who maintain high standards for quality and professionalism in the industry. Components from our septum sampling devices that come in contact with your products are made from food grade contact materials. These materials comply with liquid contact components of the Food Code of Federal Regulations (CFR) for the Food and Drug Administration (FDA), Title 21, Paragraph 177.26. Our septa are manufactured with partners that are registered ISO 9001 companies and are audited on a regular basis for adherence to their management systems.

Though QMI's products are not medical devices, we maintain high standards for quality for assembling our devices. Our septum devices are assembled and sterilized in a Minnesota facility registered with the FDA since 1988. This facility incorporates a quality system that is compliant with cGMP, ISO 13485:2005, ISO/IEC 17025, and EN/ISO 17665.



Our strategic partners host frequent external audits from their customers demonstrating their ability to manufacture high quality products and related services that consistently meet customer requirements. Accreditations of our partners cover laboratory testing, assembly, packaging, validation and sterilization of customer supplied products.

Our Aseptic Septums are sterilized in compliance with ISO 11135-1: 2014 and applicable Federal and state regulations (FDA, NRC, EPA and OSHA). Our septums are sold as aseptic devices.

Our 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 and 12 port fittings. These products are manufactured under a rigorous quality system that incorporates ISO 9001 guidelines.

Our Sampling Bags are manufactured at facilities registered under ISO 13485: 2003 and conform to FDA Regulations 21 CFR Part 820. These products undergo a gamma irradiation process that is compliant with ISO 11137-1: 2006 and ISO 11137-2: 2012.

QMI Products are authorized to display the industry standard 3-A logo which includes an independent audit of our manufacturing practices (Number 63-03).

QMI takes great pride in providing educational tools on the use of QMI products. QMI provides Standard Operating Procedures/SOP's in both English and Spanish which are available on our website.