QA CONSULTING

Medical Device Microbiology Analysis Consulting

Lean into our Microbiology Analysis Know-How

Medical device manufacturers require a range of microbiological services, depending on the type of product. With experienced microbiologists on staff, our team utilizes national and international standards to derive microbiological requirements from the concept phase throughout validation, and the regulatory approval process.

QA Consulting can serve as your liaison with a network of supporting laboratories to develop a plan that helps you achieve biological safety of your medical device.

Contamination of your medical device and/or your production facility can cause significant issues that not only impact your bottom line but can also harm users of your device. Partnering with one of our experienced professionals to develop a customized plan for the biological safety of your device will help you meet your production timelines while ensuring industry requirements are met.

We have medical device microbiology consultants ready to work with you on custom-tailored solutions for:

- Biocompatibility assessments
- Biological evaluation reports
- Cleanroom qualification and monitoring
- Sterilization efficacy and validation studies for ethylene oxide (EO), gamma, e-beam, and moist heat (steam) processes
- Cleaning and disinfectant efficacy and validation studies for reusable devices

Contact us to set up a discovery call 512-328-9404

Staff Expertise

- ASQ Certified Quality Auditor
- ASQ Certified Quality Engineer
- ASQ Certified Software Quality Engineer
- ASQ Certified Quality Inspector
- ASQ Certified Quality Technician
- ASQ Certified Manager of Quality/ Organizational Excellence
- Exemplar Global Lead Auditor
- RQAP- Good Laboratory Practices

Company Credentials

bsi. ISO 13485 Medical Device Quality Management

certified WBENC WOMEN'S BUSINESS ENTERPRISE

HUB Statewide Historically Underutilized Business Program

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