

# EXPERTS. SOLUTIONS. RESULTS.

WE SPECIALIZE IN DELIVERING COMPREHENSIVE, PERSONALIZED CONSULTING SERVICES FOR TODAY'S MEDICAL DEVICE INDUSTRY.

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Whether you need expert consultant advice or to completely outsource your quality and/or regulatory department, QA Consulting will tailor a plan to accommodate your strategic goals.



Over the last 15 years, I have carefully cultivated a team of experts for QA Consulting who share integrity and enthusiasm for our work. I have handpicked each member of our staff for his or her diverse experience within our industry, as well as attention to detail. I can say with certainty that our consultants collectively provide unparalleled customer service as well as unique and creative solutions to all of our clients, regardless of the scope of their project or budget.

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ANNE HOLLAND CEO + Founder

## STAFF EXPERTISE

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

## COMPANY CREDENTIALS

- + ISO 13485:2016 Certified
- + National Women's Business Enterprise Certification (NWBE)
- + State of Texas Historically Underutilized Business (HUB)



# QUALITY SYSTEM ENGINEERING

MKT-003 REV.04

OUR EXTENSIVE EXPERIENCE IN QUALITY ENGINEERING AND PROCESS IMPROVEMENT INCLUDES:

- \* Design Controls
- \* Product and Process Validations
- \* Risk Management
- \* Corrective and Preventive Actions
- \* Quality Management System Implementation, Remediation, and Training
- \* Virtual Document Control

## REGULATORY SERVICES

WE PROVIDE REGULATORY SUPPORT THROUGH THE ENTIRE PRODUCT LIFECYCLE, SUCH AS:

- \* Regulatory Strategy Development
- \* FDA Presubmissions
- \* 513(g) Request for Information
- \* 510(k) Premarket Notification
- \* 483 and Warning Letter Remediation
- \* Technical Files and Design Dossiers for CE Marking
- \* Complaints, Medical Device Reports (MDR), and Health Hazard Analysis
- \* Recall Determination and Facilitation

## MICROBIOLOGY SERVICES

QA CONSULTING OFFERS A COMPREHENSIVE RANGE OF MICROBIOLOGICAL SERVICES:

- \* Biocompatibility Assessments
- \* Cleanroom Qualification and Monitoring
- \* Sterilization Efficacy and Validation Studies for Ethylene Oxide, Gamma, E-Beam, and Moist Heat (Steam) Processes
- \* Cleaning and Disinfectant Efficacy and Validation Studies for Reusable Devices

## AUDITS + GAP ANALYSES

WE PROVIDE THE REQUIRED INDEPENDENT AND OBJECTIVE PARTY FOR COMPLIANCE GAP ASSESSMENTS AND INTERNAL AND SUPPLIER AUDITS, INCLUDING:

QMS	STERILIZATION	MICROBIOLOGY	REGULATORY
21 CFR PART 820	ISO 11135	ISO 11737	MDD
ISO 14971	ISO 11137	ISO 10993	CMDR
ISO 13485	ISO 17665	ISO 14644	Technical File
21 CFR PART 11	ISO 14160	ISO 14698	Design Dossier

## ADDITIONAL SERVICES

- \* Expert Witness and Litigation Support
- \* Outsourced GLP QA Unit