MEDLARK

SUMMARY OF QUALIFICATIONS

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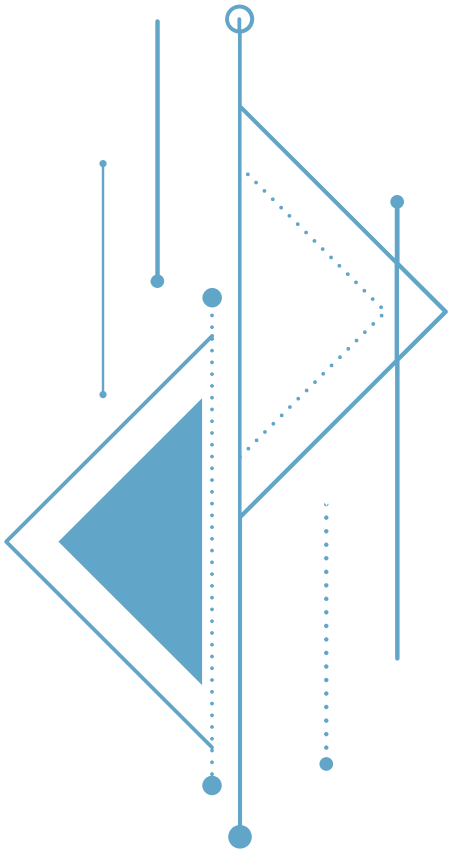

ABOUT US

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MedLark LLC is a Quality and Regulatory consulting firm dedicated to the healthcare, medical device, pharmaceutical, and biotech industries. The firm specializes in development, maintenance and remediation of quality management systems, whilst upholding regulatory compliance standards and communicating with clients in a manner that is easily understood by involved parties.

OUR GOALS

ESTABLISHING COMPLIANT PRACTICES

MedLark will help companies successfully develop new healthcare products while maintaining a compliant environment and upholding safe and effective practices for patients.

PROMOTING GROWTH

Our expertise resides in developing robust quality systems in firms that may not have prior industry experience. Our goal is to help each client establish their footing as a manufacturer with market footprint.

PURPOSEFULLY PERSONALIZED

Our services are customizable and hands-on. We pride ourselves on ensuring you get the experienced advertised. We aim to be available and dependable.

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OUR SERVICES

Our Services

THIRD PARTY AUDITS AND INSPECTION READINESS

- Quality System Audits
- Inspection Readiness Audits and QMS Gap Identification
- Due Diligence Audits
- Acquisition/Integration Preparation
- Audit Front Room / Back Room Management for Regulatory or Health Authority Audits

QUALITY SYSTEM MAINTENANCE, DEVELOPMENT, OR IMPROVEMENT

- Acquisition Integration
- Quality Planning and QMS Project Management
- SOP Development and Documentation Reviews
- Standard / Regulation Assessments
- Quality System Remediation Management
- CAPA, Nonconformance, Audit Responses

TRAINING

- Instructor-Led or Read and Comprehend Training
- Quality System Regulations
- Internal Auditing
- Inspection Readiness
- Audit Management
- Root Cause Analysis
- Audit Response

REGULATORY SUBMISSIONS

- Regulatory Strategy Development
- Technical Documentation Review
- Submission Writing / Review

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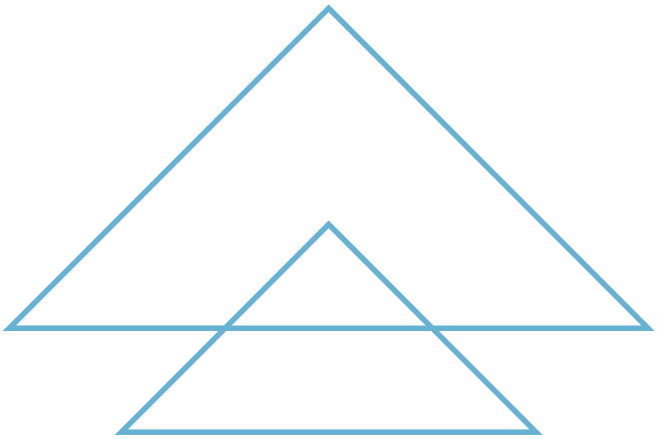
KEY PERSONNEL



CONTACT

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medlarkconsulting.com

EDUCATION

2010-2014

Master of Engineering and Bachelor of Science

Biomedical Engineering

Rensselaer Polytechnic Institute

PUBLICATIONS & CERTIFICATIONS

- K161882 CUSA Clarity Ultrasonic Surgical Aspirator System, 2016
- Foundations in Leadership, 2021-2022
- 13485 Lead Auditor Certification, BSI, 2021
- Regulatory Affairs Certification (RAC) – Medical Devices, RAPS, 2021

RESHAM RAMSAY

CEO AND FOUNDER

SUMMARY OF QUALIFICATIONS

- Highly skilled quality systems professional with nearly a decade of proven performance in leading compliance and quality system improvement.
- Certified lead auditor conducting internal audits and third-party inspections. Specialist in regulatory authority inspection readiness, audit response creation and warning letter remediation activities.
- Achieved 100% audit response acceptance rate with notified bodies. Leader in inspection readiness, resulting in 93% of external audits with 1 or fewer minor nonconformances.
- Responsible for development and implementation of ISO 13485, MDSAP and EU MDR-compliant quality systems across 15 manufacturing locations.
- Regulatory affairs certified in medical devices, with experience in 510(k) clearance.
- Managed acquisition and integration of companies into a challenging corporate environment, on time and on budget.

INDUSTRY EXPERIENCE

CEO and Founder, MedLark LLC
2023 to Present

- Providing dedicated Quality and Regulatory consulting services to the healthcare, medical device, pharmaceutical, and biotech industries.
- Project management resource for companies in the healthcare industry, guiding clients in techniques and strategies to increase project timeliness and predictability, workflow reliability, strategic relationship mapping and development and effective communication.
- Conducting third party inspections, regulatory authority inspection readiness, audit response and QMS remediation, QMS development.

Quality Compliance Roles at Integra LifeSciences
2015 to 2022

- Sole compliance representative for 6 manufacturing locations with products covering animal and human tissue, instruments, and combination products. Directed QMS maintenance, regulatory, and continuous improvement projects for each manufacturing site.
- Internal auditor for ISO 13485, MDSAP, MDD / EU MDR, 21CFR820. Backroom manager and strategy SME for notified body and regulatory audits.
- Corporate document control manager and trainer. Developed and conducted company-wide training on backroom management, ISO 13485, MDSAP, tissue regulations, root cause analysis and corrective action.
- Conducted verification and validation (V&V) testing for a tissue ablation device. Trained and supervised a shift of engineers to ensure timely completion of testing in support of FDA application.