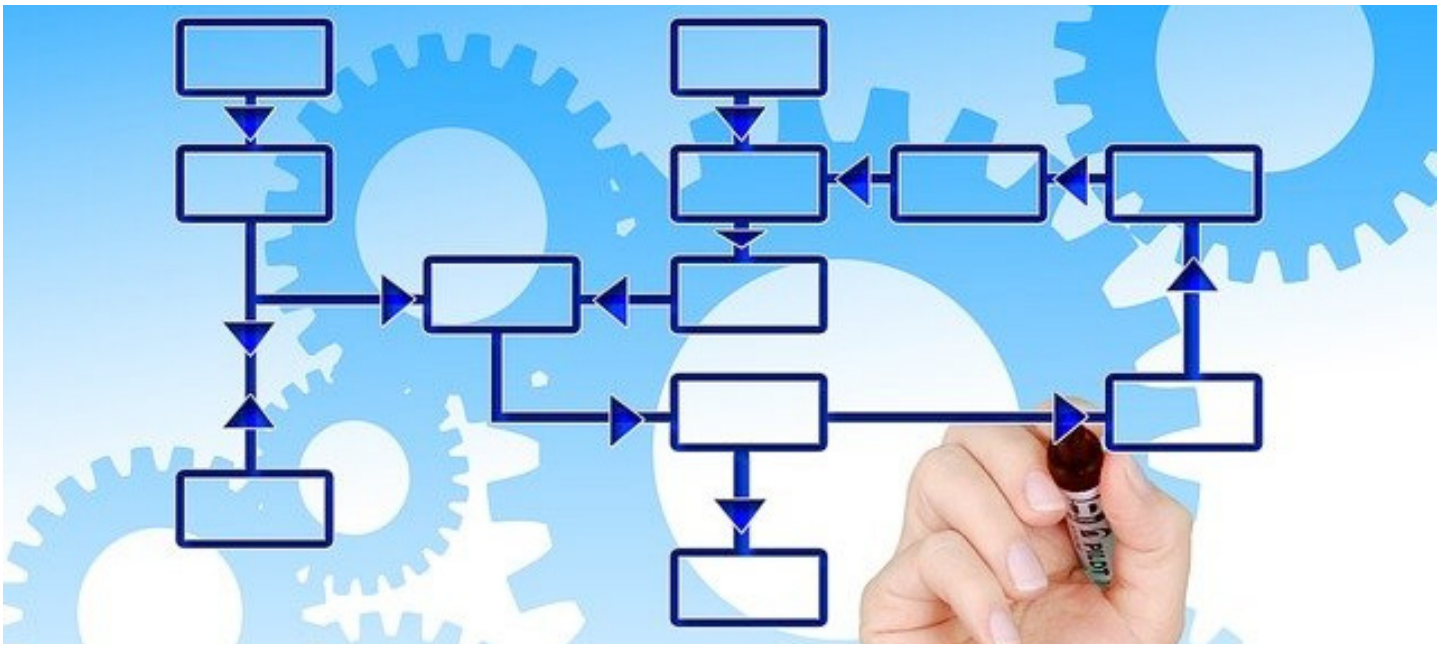
REGULATORY COMPLIANCE ASSOCIATES® INC

Wellness for Business®



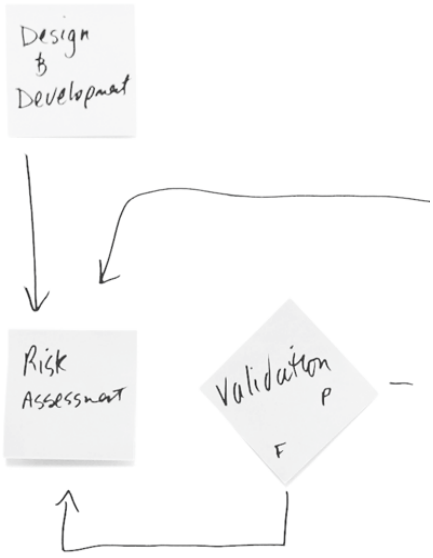
Medical Device: Audit, Assessment and Inspection Services

Regulatory Compliance Associates® Inc. (RCA) understands the pressure medical device companies face by regulators. Whether it's preparing for a successful FDA inspection or remediating operations following an inspection, RCA has a thorough understanding of the specific regulations the medical device industry must comply with to achieve and maintain quality and compliant operations. Our services include quality system audits, assessments and inspections to ensure continuous improvement, aligning with your business needs and goals.

Regulatory audits and compliance gap assessments are essential in identifying product, process and system compliance deficiencies, assessing risk and determining inspection readiness. RCA can assist your company with identifying deficiencies, providing options to correct, prioritizing activities using a risk based approach to help you select the best solutions for your company. A well plannned and executed audit is instrumental in determining FDA, ISO Registrar and/or client inspection readiness.

RCA enlists over 500 top industry experts, blending FDA veterans and seasoned quality and regulatory leaders. We have ASQ-CQA or RAB-QSA certified auditors ready to support your project for the following:

- Supplier Audits
- cGMP Compliance Audits: manufacturing, pilot plant, laboratory facilities
- Regulatory Gap Assessment
- Risk Assessment
- Pre-Approval Audits
- 21 CFR Part 11 Gap Assessment
- Development of Inspection Checklists



Internal Audits

Conducting periodic internal audits is one way that companies satisfy the requirements of the ISO standards, cGMP's as well as international regulations. RCA has extensive experience with performing short targeted audits of specific processes or more extensive audits that cover the entirety of the quality management system. Whether you are augmenting your current audit team or looking for a fresh perspective, RCA has the resources available to meet your objectives.

Quality Sytem Audits

- ISO 9001
- ISO 13485
- 21 CFR Part 820 - Quality System Regulations (QSR)
- Canadian Medical Device Regulations (CMDR)
- Canadian Medical Devices Conformity Assessment System (CMDCAS)

Assessments & Inspections

Complying with the ever changing standards and regulations can be challenging for both small and large organizations. By performing an assessment, RCA can help you understand and identify any areas or weaknesses in your existing business processes. Upon completion of the assessment, RCA will provide a detailed report outlining any deficiencies as well as recommendations for improvement.

Assessments

- Gap Assessment
- Readiness Assessment
- Risk Assessment
- Supplier Assessment

Inspections

- Mock FDA Audit
- Proof Books
- Response Letters
- Inspection Readiness Assistance

Due Diligence

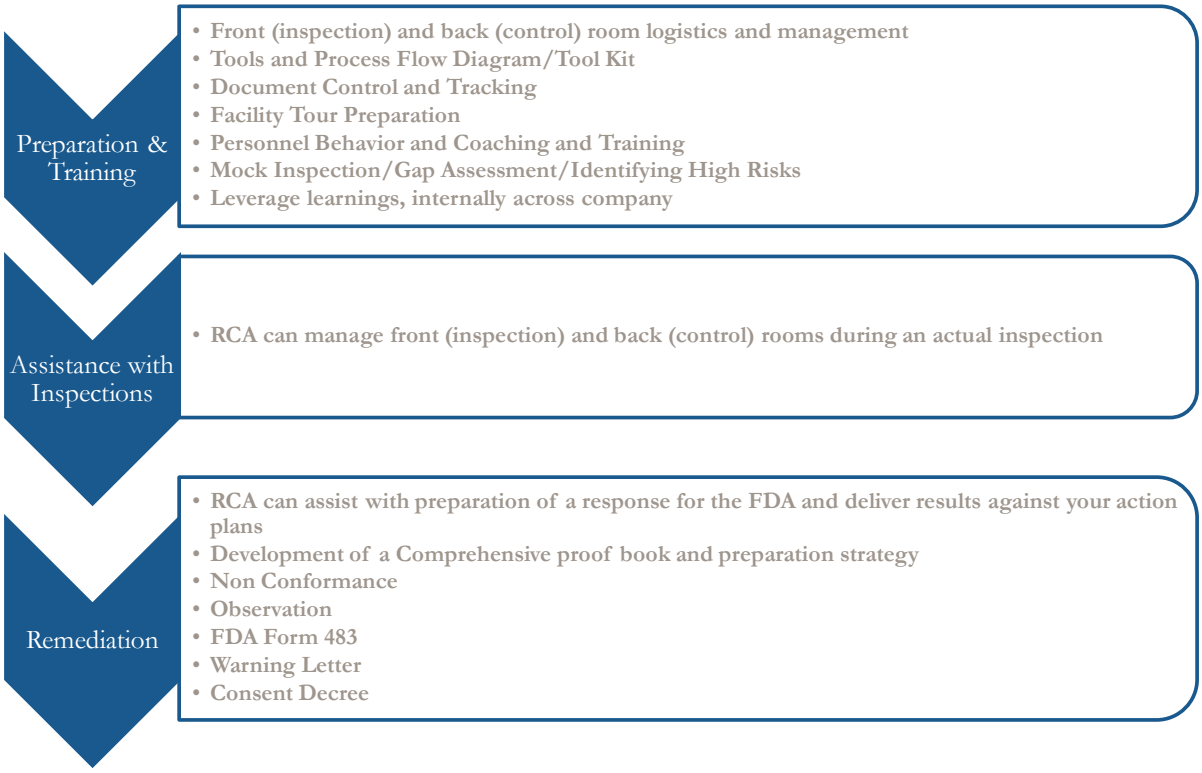
In the business press, discussions of mergers and acquisitions (M&A) invariably include percentages of deals that did not realize their expected value creation. Failure numbers, ranging from 60-80 percent, are surprisingly high. Clearly, many companies move forward on medical device deals without a clear picture of their risks. A due diligence process that's too high-level or superficial is often to blame. When a deal does not deliver value, the real causes are often strategic, cultural, or technical. RCA can assist by performing an assessment of the proposed acquisition to ensure that all risks are identified and prioritized with an action plan for mitigation prior to the final sale.

"You won't find a more talented team, a more personable group, or one more dedicated to your success than Regulatory Compliance Associates."

—Senior Manager of Corporate Reliability Engineering, Mid-size company

FDA Inspection Readiness Services

Hope is not a strategy for passing your next inspection. Be prepared with inspection readiness training and support. RCA helps your team prepare for and manage inspections as well as remediate adverse findings.



RCA's Mock Inspection Services

Mock Inspections are an important part of inspection readiness. It allows companies to take the next step and practice the inspection room, the control room and appropriate behaviors while working with inspectors. A mock inspection can be used to probe further on issues uncovered during internal audits. RCA mock inspections provide:

- Compliance assessment performed by objective third party subject matter experts
- Prioritized set of recommendations for improvement right-sized to your business
- Expert counseling by RCA to help your staff prepare by understanding their roles in the inspection process, as well as provide behavior training and coaching for key personnel, and how to best interface with inspectors

"RCA not only remediated our warning letter, but they also helped prepare our teams for an upcoming audit . . . We received no observations during our next FDA inspection."

—VP Quality, Fortune 500 company

RCA's Audit Services Advantage

Some medical device manufacturers dutifully perform internal audits and even mock inspections, only to be surprised when Agency inspections uncover unknown compliance gaps.

RCA helps even the most prepared organizations to improve their audit preparedness.

- RCA staff are seasoned audit experts, many with decades of experience with FDA inspections. We bring these FDA insights to your team.
- Audits at many companies generate a deluge of reports and gaps. Companies then struggle with the resulting chaos to manage the corrective action process. At RCA, auditing is part of our culture, and we have the systems and processes to drive closure smoothly.
- With all the data, gaps and CAPA activity, some organizations become overly focused on the details. RCA brings seasoned oversight to monitor not only the small problems but also the big picture to ensure compliance of your overall quality system.

Quick Facts about RCA:

- Founded in 2000
- Headquartered in Southeastern Wisconsin, with offices in West Central Florida and Central Eastern Europe
- Expertise backed by over 500 industry and ex-FDA subject matter experts
- Regulatory Submissions in 196 different countries / dependencies
- Engagements on four continents

Why Choose RCA?

- RCA is widely recognized within the medical device industry and global regulatory agencies for its ability to help companies successfully resolve complex regulatory challenges
- By staying abreast of changing regulations, RCA continuously evaluates FDA's current thinking and leverages thought leadership networks to advocate for our clients
- We know a quality or compliance crisis can significantly impact your business. We have the experience to manage them.
- We have the know-how and proven approach to navigate warning letters, consent decrees and other situations
- We know how to partner with your executive, legal and communication teams
- We support management to assist with the growing and changing concerns
- We help navigate the storm and manage the impact to your business

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