



COMPLIANCE ARCHITECTS®

CONSULTING • TECHNOLOGY • OUTSOURCING

CORPORATE OVERVIEW



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WHO WE ARE

Compliance Architects® provides comprehensive, hands-on GMP, quality, compliance and regulatory consulting services to biopharmaceutical, pharmaceutical, medical device, dietary supplement, and related life science manufacturers. Our consultants – former industry experts and professionals – possess deep subject matter expertise gained working in the world's most successful FDA-regulated companies, to help you plan, implement, and sustain business-supporting, quality, compliance and regulatory systems and practices.

From FDA risk management to business improvements, enforcement remediation, regulatory submissions, quality systems redesign, and more, **when life sciences companies need help, they call Compliance Architects®**. Whether you need to improve quality performance, reduce the number of outstanding NCs or CAPAs, implement new computer-based systems, improve quality documentation, or remediate enforcement risk, Compliance Architects® can help. We work with FDA-regulated companies to assess risk, determine strategy, build sophisticated project plans, and develop the systems, processes and procedures that help companies achieve better outcomes from their business. Our proven successes with complex assignments and demanding clients has solidified our industry reputation as the go-to firm for critical quality, compliance, GMP and regulatory consulting support.

WHO WE SERVE



Our clients range from the world's largest and most diversified healthcare manufacturers to small, family-owned companies. We operate globally, and have the flexibility and scale to support companies with a variety of different business models, from consolidated, vertically-integrated organizations to de-centralized, virtual organizations.



WRITING FOR
COMPLIANCE®

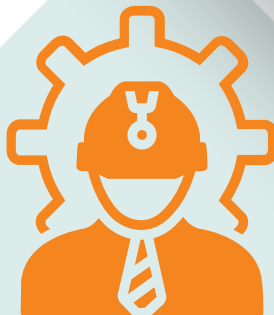
PROPRIETARY OFFERINGS



CRPN **QUALITY
ROADMAP**®



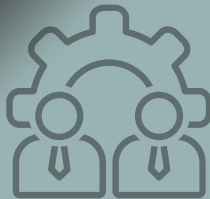
**QUALITY
PULSE**®



BEST-IN-CLASS SERVICE

WHAT WE DO

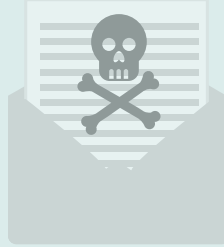
Best in class service offerings and solutions for life-sciences organizations



Interim Experts & Executives

Compliance Architects® has developed a **proprietary, best-in-class capability** to source, screen, qualify, and rapidly place the best talent available. We provide the best talent at the best possible costs to meet your organization's needs. Whether your need is short-term, project-based, longer-term, or a permanent hire, Compliance Architects® has the expertise and qualifications to get you the right people for the right roles.

- FDA-483 and Warning Letter Response Advice & Development
- Consent Decree Remediation / Prevention
- Recall Criticality Assistance, Response Advice and Plan Development
- Remediation Program Management & Execution



"Compliance Architects® helped us to **prioritize our quality and compliance** initiatives in a **risk based manner**, which enabled us to **focus on what matters most**."

Audits

- REMS
- Mock FDA Inspections
- Compliance / Quality Assessments
- Compliance / Quality Audits
- Supplier Audits and Assessments
- Quality and Compliance Staff Assessments



Quality Assurance & Engineering

- CRPN Quality Roadmap® Methodology
- Quality Pulse® Quality Culture Diagnostic
- Data Integrity
- Product Quality Consulting
- GMP Consulting Services
- Operational efficiency / Compliance Effectiveness
- Project / Program Management



CRPN **QUALITY
ROADMAP**®

Risk Management

In another breakthrough innovation, Compliance Architects® has developed a highly-structured methodology and corresponding web-based application to help regulated life-science companies assess risk and develop corresponding strategic and tactical remediation plans in a pragmatic, resource-considered approach. The **CRPN Quality Roadmap**® service offering has been embraced and utilized by some of the world's most respected companies, helping to drive effective quality planning activities, and facilitating both strategic planning and tactical remediation efforts.

94%

WOULD RECOMMEND
TO A COLLEAGUE

**Inspection-Ready
Documents**

Writing for Compliance® is FDA-regulated industry's first-and-only formal training (delivered virtually or live) devoted to improving FDA inspection outcomes through improving writing skills.

Incorporating extensive input from former FDA Investigators and feedback from prior participants, the program features more exercises, more assistance with "what does good look like" and a new, defined writing process to provide increased consistency and improved outcomes for compliance writing activities.



**WRITING FOR
COMPLIANCE**®

Quality Culture Diagnostic



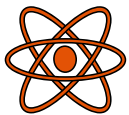
QUALITY PULSE[®]

Compliance Architects[®] has developed industry's first plant-floor and staff-focused innovative methodology, based on proven cultural survey science, to assess staff and line employee perceptions of quality culture – and its potential impact – by assessing and measuring individual and aggregate employee responses to fact-based questions scenarios simulating actual business situations.

\$350 Million

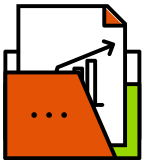
"A COMPANY WITH A HIGHLY DEVELOPED CULTURE OF QUALITY SPENDS, ON AVERAGE, \$350 MILLION LESS ANNUALLY FIXING MISTAKES THAN A COMPANY WITH A POORLY DEVELOPED ONE."

- HARVARD BUSINESS REVIEW



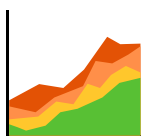
SCIENTIFIC, RESEARCH-BASED

Quality culture assessment model designed specifically for FDA-regulated and life sciences companies.



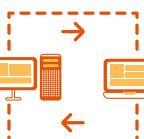
ACTIONABLE INTELLIGENCE

The methodology and outcome reporting provides actionable intelligence that helps company leadership direct and implement improvement programs that will result in better quality outcomes and improved organizational excellence.



STATE-OF-THE-ART ANALYTICS

Using state-of-the-art analytics technology and natural language processing (NLP) capabilities, the assessment scoring report incorporates both scored, fixed-answer responses and open-ended, text-based narratives.



INTERACTIVE, WEB-BASED

Unlimited ability to slice and dice data, and analyze response information by function, department, or subject matter, in both static or interactive, web-based report formats.

What our clients are saying...

"As a leader in the development of products for the biomedical research market, (we) **gained tremendous value** from Compliance Architects® assistance in restructuring our overall quality management system for pharmaceutical products.

CA started by assessing our current operations for gaps and risks, and then recommended – and built – the new systems and processes we needed..

Working with their experienced consultants, we learned things that will really help us in the future. We had the foundation, and CA **helped us fill in the details**. Compliance Architects® helped us to create a strong platform for our future **growth** and **success**."

95%

STATED THAT THE WORKSHOP
WAS RELEVANT TO
THE WORK THEY
CURRENTLY DO

**"Really enjoyed
the session!
Very much in line
with the issues I
fight daily."**

- Director of Manufacturing

"Within months following the work with Compliance Architects®, we received an **FDA inspection**, where we received **no 483 observations**.

Inspection readiness support from Compliance Architects® helped us with our approach to the inspection, **giving us the confidence to build a deeper and stronger relationship with the FDA.**"



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