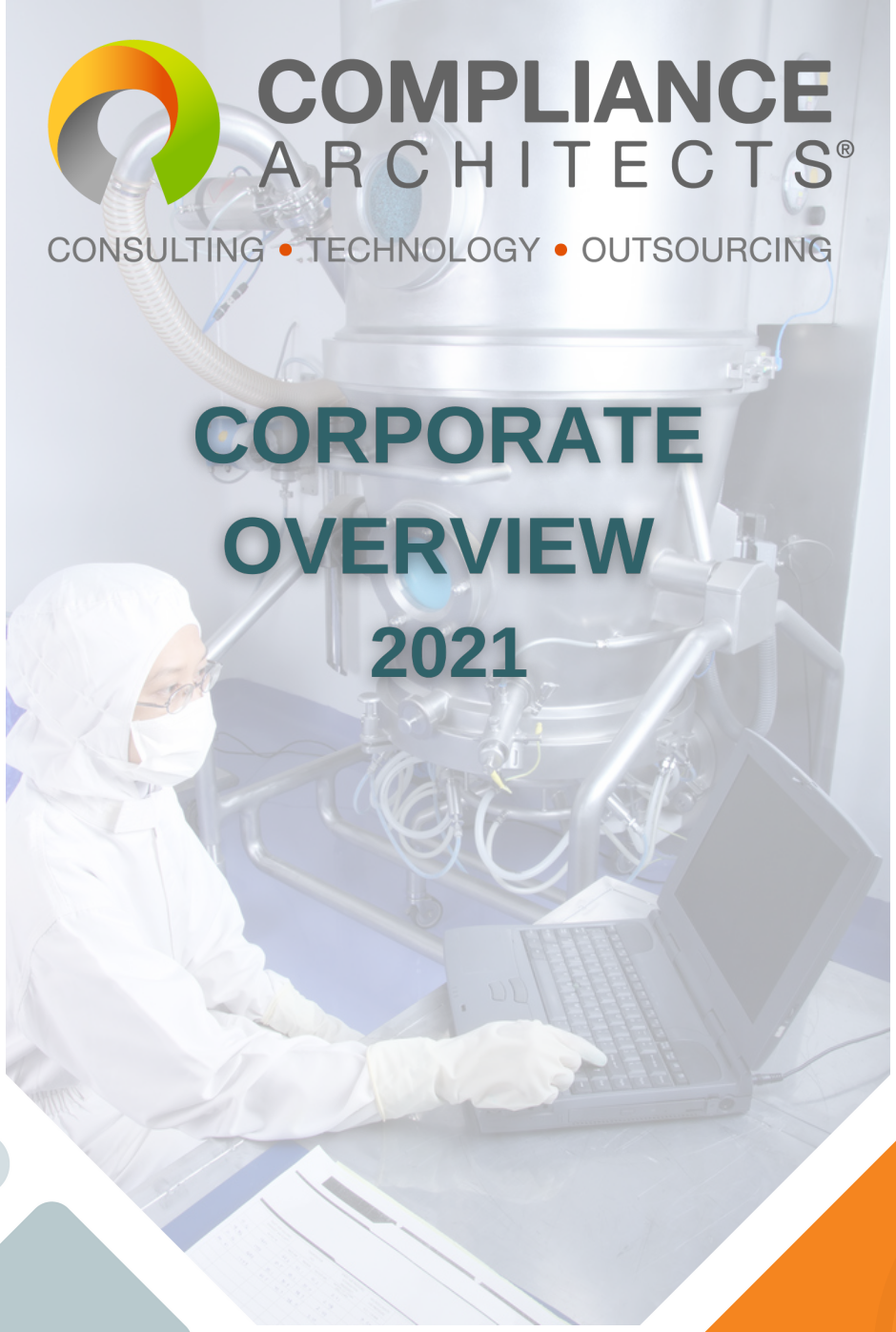
COMPLIANCE ARCHITECTS®

CONSULTING • TECHNOLOGY • OUTSOURCING



# CORPORATE OVERVIEW 2021

QUALITY PULSE™

CRPN QUALITY ROADMAP®

WRITING FOR COMPLIANCE®

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# WHO WE ARE

Compliance Architects® provides comprehensive, hands-on GMP, quality, compliance and regulatory consulting services to pharmaceutical, medical device, biopharmaceutical, 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

We serve the pharmaceutical, medical device, dietary supplement, biologics, cosmetic, and food industries – in short, any industry regulated by the US FDA. Our clients range from small, family-owned companies to the world's largest and most diversified healthcare-manufacturers. 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.

No matter where you are located, if your organization and/or products are regulated by the US FDA, we can help you manage and reduce your risk from adverse compliance enforcement outcomes, which in turn helps your business and your bottom line.

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# WHAT WE DO

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

## Remediation

- 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

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



## 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.

## Quality Assurance and 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

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# PROPRIETARY OFFERINGS

WRITING FOR COMPLIANCE®

CRPN QUALITY ROADMAP®

QUALITY PULSE™

BEST-IN-CLASS SERVICE

COMPLIANCE ARCHITECTS®

# Risk Management

CRPN QUALITY ROADMAP®

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.

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WRITING FOR COMPLIANCE®

# Quality Culture Diagnostic

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.

QUALITY PULSE™

## $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 DEVEVELOPED ONE."

### 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.

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