

# REDUCED COMPLIANCE RISK: IMPROVED BUSINESS OUTCOMES

Innovative Solutions for Today's  
*Complex* Compliance Challenges



# THE ETERNAL STRUGGLE:

Getting It Done **VS.** Getting It Done **RIGHT**

**FDA-regulated companies have one painful truth in common — radically competing business objectives. Speed versus quality. Efficiency versus compliance. Risk versus reward.**

Poor outcomes with the U.S. FDA can result in costly business impacts. And without the right systems, processes and procedures in place, costs can multiply: remediation costs due to enforcement responses, sub-standard organizational performance, loss of product market share, and costs due to diminished reputation.

In our CAPA-focused enforcement climate, the emphasis is too often on correction, and not prevention. In fact, over the last three decades, our industry's approach to compliance has remained largely the same — using a checklist approach to find and fix discrete problems rather than anticipating issues and taking steps to ensure they never reach the “dangerous and expensive” stage.

You can never out-think the FDA. But you can reduce your compliance risk by leaving behind the same old thinking and taking a fresh approach.



A checklist approach to compliance does not, and cannot, result in sustainable compliance outcomes for FDA-regulated companies.

# We Are **Advisors & Consultants** to FDA-Regulated Industry



**REDUCE** FDA  
Inspection Risk

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**IMPROVE** FDA Enforcement  
Responses & Action Plans

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**REMEDiate** Deficient Quality  
& Compliance Documentation

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**RESOLVE** Product  
Quality Deficiencies

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**MODERNIZE** GMP  
Manufacturing Control

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**EXPAND** Control Of  
Supplier Quality Activities

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**ELEVATE** Quality & Compliance  
Department Performance

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**SUSTAIN** Quality &  
Compliance Improvements



# WHOM DO WE HELP?

Compliance Architects® works with pharmaceutical, medical device, dietary supplement, biologic, cosmetic and food companies — in short, any organization directly regulated by the FDA. Our clients range from small family-owned companies to the world's largest and most diversified manufacturers. Our global operations provide the flexibility and scale to support companies from consolidated, vertically integrated organizations to de-centralized virtual operations.



*“Managing regulatory risk exposure, especially in the face of uncertain regulations... tends to be financially beneficial to organizations.”*

*- Industry Week, March, 2011*

With service capabilities ranging from quality systems implementation to audits, outsourced compliance services, inspection readiness and complex enforcement remediation, Compliance Architects® has the experience, expertise and capacity to deliver significantly improved FDA compliance outcomes for any size organization.



# WHY COMPLIANCE ARCHITECTS®?

## REAL-LIFE EXPERIENCE

Because we've been in your shoes at top FDA-regulated companies, we understand the issues facing Vice Presidents of Quality, General Counsel, Chief Compliance Officers and Chief Operating Officers. We also get the complexities associated with today's revenue-challenged business environments.

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## BUILDERS, NOT AUDITORS

Unlike many consultants, we haven't simply audited operations and reported on the results. We've built complex, functional and successful operational systems that withstand regulatory scrutiny. We've also lived with these systems, and know how difficult it can be to maintain optimal compliance in a world driven by cost and resource constraints.

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## EXPANSIVE CAPABILITY TO GET YOU WHERE YOU NEED TO GO

Compliance Architects® can operate at a strategic or tactical level. It's great to identify deficits in a company's quality systems, but then what? You're eventually going to have to write policies, procedures, validation protocols, batch records and other supportive documents. With the right framework, the next steps are easier to take and provide greater value to your organization.

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## FDA EXPERIENCE & INSIGHT

By working closely with many FDA personnel, we understand how the Agency approaches regulated operations and what they're looking for. However, no matter how close your relationship with an Investigator, the best way to achieve great compliance outcomes is to build great compliance architectures.



Compliance Architects® was founded on the belief that a different approach to compliance is essential — one that focuses on designing and building (or often, remediating) the core, structural elements essential to sustainable compliance.

Our job as *compliance experts* revolves around your unique business model. We help FDA-regulated companies define how to successfully overlay and integrate the requirements and expectations of the FDA — without sacrificing your efficiency or growth trajectory.

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