

**COURSEWORX**



# THE **COMPLIANCE LANDSCAPE**

**The Executive Suite Playbook**

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# EFFECTIVE COMPLIANCE MANAGEMENT

Effective compliance management has deepened, particularly in the Life Sciences and Professional Services industries that serve FDA-regulated companies.

Effective compliance management goes beyond simple adherence to regulations. It's about leveraging these regulations to foster trust, ensure data protection, and achieve business growth.

Pharmaceutical and life sciences companies must consider a wide range of emerging risks as they adapt their business practices to changing regulatory compliance and market-driven pressures.

Some of these include globalization, the advancement of technology and expanding stakeholder expectations. Risks are no longer confined to discrete areas and functions within organizations.

From regulatory pressures to consumer demands for increased transparency, organizations are increasingly seeking total solutions. New information systems, strategies, and processes to manage compliance are rapidly evolving in response to these pressures.





LIFE SCIENCE VALIDATION  
AND REGULATORY COMPLIANCE

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# INDUSTRY INSIGHTS

## Expert Analysis

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There are a handful of subscription and membership communities that report on life science regulatory compliance, validation, quality management, and other GxP-related topics.

Many of these sites do a decent job of putting need-to-know industry news in front of you, but few—if any—provide the expert analysis and perspectives that help you understand what you need to do in light of, say, new guidance being issued.

It's up to you to digest the information, determine the impact on your organization, and plan accordingly. That takes time and attention and I suspect CoursWorx could be a good investment for you.

CoursWorx offers premium content that delivers life science validation and compliance news, as well as highly actionable analysis. Subscribers keep up on validation and regulatory compliance emerging trends seen through the lens of those who've worked in FDA-regulated industries.

Our content fills a gap. We curate regulatory and compliance content to analyze and distill it into actionable takeaways for Validation and Regulatory Compliance Professionals. We cover new regulatory initiatives and dig into existing guidance to pull out key themes.

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# **ABOUT COURSEWORX**

**CoursWorx is an online community for Validation and Regulatory Compliance Professionals working in FDA-regulated industries.**

**With over 12,000 LinkedIn members, CoursWorx provides expanded networking and learning opportunities no matter what your location, industry (pharma, medical device or biotech), or compliance interests may be.**

# COMPLIANCE & INNOVATION

As we navigate the ever-changing landscape of Regulatory Compliance, the nexus between innovation and regulatory compliance has deepened, particularly in the Life Sciences and Professional Services industries.

Rethinking innovation and compliance to drive strategy, and capabilities means creating forward-thinking processes and efficiencies that defend against regulatory complexities.

What if scientific discoveries were made safer and faster without the fear of an imminent audit from the U.S. Food and Drug Administration (FDA) or international health authorities?

Life sciences companies are challenged because the very core of their work is about human existence—improving and extending life itself.





# IMPROVEMENT POSSIBILITIES

Regulators have massive civic responsibilities, but government regulations can slow the advancement of life sciences and medicine.

## Improvement Opportunities for a Competitive Edge in Compliance

These opportunities are not ranked in order of importance, but understanding regulations and compliance frameworks could easily earn a top spot.

Knowing how to interpret regulations and apply best practices to your business enables a forward-looking approach. To achieve the appropriate level of compliance in your business planning and processes, you must be proactive.

# STRATEGIC AND SUSTAINABLE APPROACH TO COMPLIANCE

## Improvement Opportunities for a Competitive Edge in Compliance

Assessing risk to determine the level of compliance you need, identifying business processes that have the greatest impact on your success, and determining training requirements for the roles your employees perform.

Other opportunities to improve your compliance maturity include:

Helping your people work smarter. Automation is a good example of working smarter. Reduce human error, increase productivity, and create greater job satisfaction with automated processes.

Building a quality culture. Quality is everyone's responsibility. Nurture a quality culture by aligning efforts with your business goals and building quality into your product.

Embracing cloud technologies. A cloud strategy helps your organization stay relevant, scalable, and secure. Advance your progress with an IT roadmap and vendor qualification.

Putting your data to work. Data is one of your most valuable assets. Create a data-driven culture that uses artificial intelligence (AI) to analyze data and drive innovation.





# COMMON GOALS

A [recent study](#) identified and detailed five levels of maturity for compliance integration within [Life Science](#) organizations: reactive, or defensive compliance; passive, or superficial compliance; operational, or transactional compliance; strategic, or embedded compliance; and holistic, or fully integrated compliance.

These five stages of compliance maturity illustrate the considerable gap between organizations that recognize compliance at the forefront of business decisions and those that fail to consider compliance as an integral part of their product development process.

There are no shortcuts when it comes to quality and regulatory compliance.

So, let's start by assuming that mutual respect between manufacturers and regulators is a prerequisite to your product's success. With the common goals of ensuring patient protection, improving patient outcomes, and reducing healthcare costs, regulators are not there to limit your time to market, or profitability.

In fact, they're there to ensure that your product fulfills its purpose to the highest possible standard.

# STRATEGIC ISSUES

## Organizational Strategic Issues to Consider Regarding Regulatory Compliance

As regulations have increased in recent decades, organizations are increasingly hiring executives to fill specific compliance roles.

Here are three of the most common positions:

- Corporate compliance officer
- Chief compliance officer
- Regulatory compliance officer

Companies that are subject to significant regulation need to consider how to structure their companies and processes to ensure they can operate well while also complying with regulations.

Company leaders need to think about the following factors:

- How to predict the potential impact of regulations on the company's strategic direction, its business goals, and its regulatory compliance processes
- How to balance the duties of compliance among legal, auditing, and other business functions
- How to encourage common compliance across different teams and company locations
- How to create internal systems that monitor and report on compliance
- How to measure the value of compliance, including in employee performance evaluations



## STEPS YOU CAN TAKE TO HANDLE REGULATORY COMPLIANCE

Companies within highly regulated industries need to hire employees – sometimes dozens or even hundreds of employees – whose primary focus is the company’s regulatory compliance.

Alternatively, smaller private companies may not even have one employee solely responsible for compliance. They may have a company lawyer or an outside lawyer handle compliance.

Or, a top company executive may be responsible. When it comes to smaller companies, “it’s helpful to have a point person” who’s responsible for regulatory compliance.

Beyond staffing, companies can use software or undergo internal assessments to help with regulatory compliance. These options include the following:

- **Acquiring Compliance Management Software:** This helps organizations track the wide range of regulations that apply to all companies as well as those within specific industries.
- **Developing a Business Continuity Plan:** This involves determining how a company can continue to operate during and after a disaster, including a natural disaster, crash, virus, or other catastrophic event affecting a business’s information technology systems.
- **Assessing Auditing Systems:** This is an internal assessment that is crucial to maintaining regulatory compliance.
- **Assessing and Improving the Security and Privacy of Information Technology Systems:** This is also an internal assessment that is central to maintaining regulatory compliance

# PRE-BUILT REPORTS

## Regulatory Compliance Report

**REGULATORY COMPLIANCE REPORT TEMPLATE**

ORGANIZATION NAME

TIME PERIOD COVERED BY REPORT

START DATE	END DATE	DATE OF REPORT

DEPARTMENT / PROJECT COVERED

REPORT PREPARED BY

NAME & TITLE	DEPARTMENT / COMPANY	DATE

NOTES BY

NAME & TITLE	DEPARTMENT / COMPANY	DATE

**EXECUTIVE SUMMARY**  
Summary of findings for the reporting period

## Summary of Major Findings

**SUMMARY OF MAJOR FINDINGS**

REQUIREMENT OR COMMITMENT	COMPLIANCE STATUS, SUMMARY OF ACTIONS RECENTLY TAKEN	RECOMMENDATIONS / OBJECTIVES REPORT NEXT REPORT

## Results and Analysis

**RESULTS AND ANALYSIS**

**COMPLIANCE MONITORING** Elaboration on compliance issues, and explanations for non-compliance or unmet objectives.

REQUIREMENT OR COMMITMENT	COMPLIANT? YES OR NO	IF NON-COMPLIANT, DISCUSS REASONS	REMARKS, IMMEDIATE ACTIONS TO MAKE / MAINTAIN COMPLIANCE

## Overall Impact

**OVERALL IMPACT**  
Include information about current and earlier monitoring results, showing trends, issues, etc.

**CONCLUSIONS AND RECOMMENDATIONS**  
Present overall conclusions on recent performance and monitoring of regulatory compliance, and recommendations for improvements.

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A photograph of two women sitting at a wooden table in a meeting. The woman in the foreground is wearing a mustard-colored top and is looking at a tablet computer that displays various charts and graphs. The woman in the background is wearing a blue patterned top and is also looking at the tablet. On the table, there is a notebook, a pen, a pair of glasses, and a small white spherical object. The background is slightly blurred, showing a computer monitor and other office equipment.

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**Understand Where to Find Regulatory Information and How To Track Changes:  
A wide range of third-party services and software are available to help  
companies understand regulations.**

**There's also a large amount of free information from CoursWorx.**

**It's important to view compliance as an ongoing process that you need to  
evaluate and tweak — based on business needs and a shifting legal landscape.**

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professional — no matter where you are in your career.**