

Modernizing Compliance

Enabling and moving with the speed of business



As the world's number one Risk Advisory Firm, Deloitte understands the imperatives of helping companies to enable and move at the speed of business while remaining compliant.

The new imperative in Life Sciences

The pressures are mounting for life sciences companies from both regulators and patients: increasing regulatory mandates, intense pressure on pricing and non-stop technological advancements. To thrive and take the lead, business leaders must address the new imperative head-on.

For too long, many compliance professionals have been focused on point solutions and analyzing tactical, transactional data in search of what went wrong. It is time for the compliance function to change its focus from hindsight to foresight and

driving insight—teaming with the business to enable business growth. This will require modernization of the compliance function and approaches to compliance.

Compliance and Regulatory functions have an opportunity to better align with business strategy and respond to external opportunities/pressure in a drive toward efficiency/effectiveness. Modern compliance organizations are risk intelligent, efficient, and deliver through business partnership and enablement.

Outcomes of a Modernized Compliance Program



Transformative change

Re-engineer core processes and automate the function to be more proactive and predictive; modern enterprises need top-of-the-house strategies and reliance models.



Flexibility

Rapidly scale up or down depending on the nature of the compliance and/or business issue



Increase to capacity

Re-engineer traditional resource model and allocation methods and use deployment of technology, analytics, managed services, and offshore resources to achieve highest and best use of resources.



New competencies

Compliance professionals are elevated to true business partners and advisors.



Potential cost reduction

Cost reduction opportunities exist by creating efficiencies and seeking ways to be more effective with increased capacity across the organization through use of tools, technology and resource allocation.



Enterprise-wide view of risk and compliance

From predicting to sensing to acting and monitoring, the lines between these formerly separate realms are disappearing quickly.

Drivers for Modernizing Compliance

Pressure for change is coming from many directions.

Internal challenges

- Lack of executive leadership buy-in
- Fragmented regulatory/ compliance change management
- Lack of compliance strategic vision
- Lack of clarity and engagement with first line of defence groups
- Resource/staffing challenges with significant manual processing
- Weak governance and oversight
- Ineffective coordination across multiple jurisdictions
- Disparate risk methodologies
- Ineffective interaction/ leverage of technology



Emerging technologies

- Regulatory Technology (RegTech)
 - Cognitive compliance
 - Risk sensing
 - Automation/ Robotics-integrated governance, risk, and compliance (GRC)
- Big data and analytics
 - Increased use of unstructured, high volume data to drive risk identification and process enhancement

Regulatory pressures

- Heightened standards and expectations given size and complexity of operations/services
- Increased regulatory examination and inspections
- Increased enforcement actions and/or fines and penalties
- New regulatory requirements
- Multiple regulator oversight
- Multiple jurisdictions with complex or conflicting laws/ regulations

Plan of action

Following a staged approach brings method to the modernization.



Determine

Determine the desired “modernized” state for the Compliance Risk Management Program.



Assess

Perform an assessment of the existing Compliance Program against the desired “modernized” state.



Prioritize

Prioritize areas that need to be addressed based on the results of the assessment, level of risk, and expected change to the organization.



Refine

Develop and update the overall vision/mission for compliance to align with the desired “modernized” state.



Develop

Develop and update the Compliance strategy; ensure it aligns to the organization’s overall strategy; and determine appropriate measures for success.



What does it look like?

Client success stories

Strengthening pharma culture

Deloitte Risk and Financial Advisory supported a leading global pharmaceutical company in an effort to modernize its approach to business engagement through policies, training and operational support. The outcome of this engagement was a stronger, value-based culture with efficient and meaningful processes and standards for responding to the ever evolving business, go-to-market strategy, and regulatory environment.

Strategy redesign

- Implementing process consultation and optimization
- Simplifying and streamlining policies, procedures, and work instructions
- Crystalizing the “how” to provide clarity and drive consistency and institutionalization
- Optimizing training to promote competency while allowing the business to make decisions effectively that align with compliance standards
- Being a strategic partner to the business
- Driving a values-based culture

Strategy redesign

An effective modernization draws from many disciplines working together.



Transforming pharma IT

For a top-five global pharmaceutical company, focusing on IT quality was crucial to meeting stringent requirements meant prioritizing on specific controls and processes throughout the software development life cycle with a defined system requirements and rules. But this became a major hurdle when the firm was faced with rapid deployment cycles, dynamic volumes, new platforms and systems, limited resources with the right skills and experience.

Why Deloitte

The company outsourced its IT quality process, but the traditional staff augmentation model did not satisfy its end-to-end IT quality needs. Faced with gradual degradation in service levels, inefficient processes, and lack of technical expertise, the firm looked to Deloitte’s Managed Risk Services.

Together—let’s move at the speed of business.

Making critical connections with Deloitte Managed Risk Services

Working with Deloitte empowered the firm to move at the speed of business with confidence and take the lead. Leveraging Deloitte’s team of specialized experts, Deloitte and this organization modernized its IT Quality and Compliance function through a transformational journey, which ultimately resulted in a distinctive output-based model and an effective solution design with standardized processes, robust workflow technology and delivery protocols, the firm can now enhance cost efficiencies and its competitive position. This holistic alignment of people, process, and technology created value additions to the systems integrity process, making it more responsive, and improved the integration of the function with the wider institution.

Other ways Deloitte is helping companies modernize (sample):

Strategy

How the organization allocates resources to Compliance and integrates compliance activities:

- Employee Engagement and Awareness
- Compliance Vision and Strategy Redesign
- Resource Allocation Methodologies
- Compliance ROI and KPI Frameworks
- Compliance Risk Appetite Frameworks

Operational

How Compliance is organized and interacts with functions across:

- Risk Management Framework
- Compliance Reporting Structure Design and Organizational Design
- Managed Services for Compliance Operations

Taxonomy

Consistent way for assessing, measuring and reporting compliance:

- Governance models
- Values based Policies and Training
- Risk Assessment Design
- Monitoring and Testing Design
- Data Measurement and Reporting
- Escalation and Investigation Design

Technology

Use of technology and data to enable and automate the compliance function:

- Robotics
- Risk Sensing
- Natural Language Processing
- Behavioral Analytics

Let's talk

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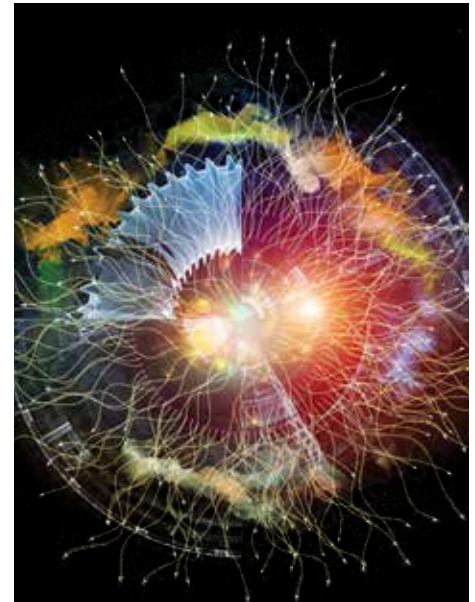
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Attributes of a Modernized Compliance Program

- Proactive instead of reactive oversight and execution
- Aligned/embed Compliance Risk Management strategy to business strategy
- Partner with the businesses to drive organization growth while remaining compliant
- Improved integration and rationalization across the three lines of defense (LOD)
- Enhanced regulatory change management coverage and process
- Alternative delivery models and deployment of technology/ analytics