Building a Sustainable Culture of Compliance

Discussion Document

Deloitte Consulting LLP
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Regulatory compliance is among the key focus areas for Life Science executives and business leaders worldwide.

Regulatory bodies governing the Life Sciences industry across the globe drive serious implications for non-compliance, including prosecution, exorbitant penalty costs or damage to reputation and brand.

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### Regulatory Bodies

**The Food & Drug Administration (FDA - US)**

**Drug Enforcement Agency (US)**

**World Health Organization (WHO)**

**World Trade Organization (WTO)**

**Korea Food & Drug Administration**

**State Food and Drug Administration (China)**

**Pharmaceuticals and Medical Devices Agency (Japan)**

**Health Canada**


**European Medicines Agency (EU)**

**MHRA – Medicines and Healthcare products Regulatory Agency (UK)**

**Centers for Disease Control and Prevention (CDC - US)**

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### Chart 1: Drug Recalls

- **2006**: 397
- **2007**: 431
- **2008**: 426
- **2009**: 1,742
- **2010**: 317

Up 309%

### Chart 2: Medical Device Recalls

- **2005**: 505
- **2006**: 545
- **2007**: 717
- **2008**: 1,183
- **2009**: 1,291
- **2010**: 717

Up 41%

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*Source: Article “Drug recalls surge”, CNNMoney.com, 2010*
Potential non-compliance consequences have a wide-ranging negative impact across the business …

- Delays in regulatory approvals
- Rejection of marketing authorizations
- Broader and more frequent inspections
- Added cost and time for product development and launch
- Adverse impact to product quality
- Risks to product safety
- Damage to public image and reputation
- Financial penalties, imprisonment

The perception of the organization’s overall ability to be compliant with government regulations and its moral obligation to patient safety has a direct link to the market’s appreciation of the organization’s performance and enterprise value.

Compliance Impacts

Revenue Growth
Operating Margin
Asset Efficiency
Expectations

Shareholder Value

SG&A
COGS
Income Taxes
PP&E
Inventory
Receivables & Payables
Company Strengths
External Factors

Strong compliance practices should be integrated into the organization’s daily operations. Compliance does impact shareholder value, but more importantly, it impacts the organization’s ability to protect patient rights and safety.

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… and may cause a negative affect in every step of the product lifecycle

Life Sciences R&D Process

Research/ Discovery Preclinical Development Clinical Development Launch & Commercialization

Lab-Scale Production Small-Scale Production Large-Scale Production Commercial Scale

4 - 5 years 1 - 2 years 5 - 10 years 1 year

- Increased cycle time
- Missed window of opportunity for new product development
- Higher costs of R&D
- May not generate enough revenue (during product launch) to recover the average development costs
- Design rework and associated costs
- Increased investor pressure
- Rise in development costs
- Rise in clinical trial costs
- Increased number of amendments
- Last minute design changes
- Higher levels of instability and volatility
- Fines and fees
- Manufacturing/outsourced production issues, e.g., cycle time, labeling, repacking, regulatory documentation
- Delayed product approval/product not approved
- Delayed time-to-market
- Higher product or drug recalls and claims
- Loss in revenue and sales
- Increased risk for consumers
- Negative public perception
- Criminal prosecution
- Fines and fees
- Loss of market share
- Plant shutdowns

Bringing a new drug to market can cost upwards of $900 million and take 10-15 years. Taking shortcuts to compliance (e.g., inadequate quality systems, misfilings) may result in delays in clinical trials that cost companies US$1 million a day for getting a drug to market.

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Yet many organizations face challenges to make the compliance programs sustainable

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### Typical Employee Challenges with Compliance

- Lack of understanding of compliance requirements, including uncertainty of the applicability of these requirements to their jobs
- Employee behaviors are largely controlled or influenced by rules rather than empowerment and judgment, which may undermine employee’s acceptance
- Stress of balancing traditional responsibilities (e.g., manage staff, revenue generation, etc.) with ensuring and enforcing compliance
- Afraid of retaliation for reporting non-compliance
- Experienced difficulty of translating learnings from compliance training to daily responsibilities
- Unsure of how to resolve seemingly contradictory compliance requirements

### Underlying Root Causes

- Compliance programs are rarely linked directly to tangible business benefits
- Communications are often framed around abstract statements and do not address specific situations or specific behaviors that need to change
- The approach to implementation is often based on legal requirements, one-way communication and training, with little effort to engage employees to define the incremental changes in behaviors they need to make
- Rarely do organizations employ structured programs to reinforce and embed the new behaviors in the performance processes

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Compliance programs help keep patients safe and may save millions of dollars in fees annually. Creating a sustainable culture of compliance should be an integral component of daily operations and not a patch-work solution applied after an incident has occurred.

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To be successful, compliance programs need to drive consistent integration of key practices into the organization’s processes and culture.

Compliance activities require constant review and updates in order to maintain appropriate status with regulatory bodies and drive adoption of compliant practices as part of the organizational culture.

### Key Components of Compliance Success

- **Compliance Requirements and Regulations**: Integration of compliance activities into everyday processes and activities
- **Organizational Dimensions**: Alignment of organizational structures, processes and procedures to support compliance activities
- **People Dimensions**: Inclusion of compliance requirements into job activities, training, performance metrics and rewards
- **Driving a Culture of Compliance**: Consistent monitoring and adjustment of the integration through on-going metrics aligned to business outcomes, and mission-driven objectives such as patient safety

A set of Organizational and People dimensions serve as the foundation for sustainable and scalable compliance processes and programs.

#### Compliance Requirements and Regulations

<table>
<thead>
<tr>
<th>Organizational Dimensions</th>
<th>People Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision &amp; Strategy for Compliance</td>
<td>Does your vision and mission statements reflect a commitment to compliance?</td>
</tr>
<tr>
<td>Do you have internal policies, procedures, roles and responsibilities defined?</td>
<td>Is a culture of compliance woven into your firm’s business processes and decision making?</td>
</tr>
<tr>
<td>Governance of the Compliance Program</td>
<td>Do you define compliance requirements for each job and for each employees’ daily activities? Do you regularly update job descriptions?</td>
</tr>
<tr>
<td>Leadership Alignment and Accountability</td>
<td>Do you reward compliant behavior in your organization? Does your performance system measure and reward compliance behavior?</td>
</tr>
<tr>
<td>Compliance Requirements Inventory &amp; Risk Mitigation</td>
<td>Have you analyzed and assessed the current training offered to employees against the key requirements of compliance policies and procedures to identify potential gaps?</td>
</tr>
<tr>
<td>What is leadership’s involvement in ensuring and enforcing compliance? Are there defined common compliance priorities among key leaders?</td>
<td></td>
</tr>
<tr>
<td>Are compliance requirements well captured? Can you identify your control processes and risks within each of your compliance touch points?</td>
<td></td>
</tr>
<tr>
<td>Technology Enablers and Solutions</td>
<td>What is the degree in which an integrated technology platform is adopted, extendable to a variety of compliance risk areas, and optimized across the organization?</td>
</tr>
<tr>
<td>What efforts are made to ensure employee are aware of compliance requirements?</td>
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</tr>
</tbody>
</table>

**Culture of compliance is not an elusive element – it can be achieved through integration of requirements into business processes, and becomes truly sustainable as the organization consistently works on the integration process.**
The integration of the Organizational and the People dimensions drive an increased maturity of the organization’s compliance programs and overall culture of compliance.

### People Dimensions
- Communication and content reciprocity is managed in an ad-hoc manner by individual business units.
- Organization is indifferent to compliance.
- Limited compliance-related training.

### Organizational Dimensions
- No defined compliance processes or policies.
- Siloed and inconsistent practices.
- Business areas follow different paths to reconcile compliance issues.
- No systems in place to track key processes.

### Integration of Compliance Capabilities
- Compliance programs are centralised and ubiquitous, but may lack proactive efforts or coordination.
- Manual or limited compliance testing.
- Limited involvement from key stakeholders.

### Phase I - Defensive
- “We do just as much as we have to do.”
- Compliance programs are centralized and ubiquitous, but may lack proactive efforts or coordination.
- Manual or limited compliance testing.
- Limited involvement from key stakeholders.

### Phase II - Passive
- “It’s just a part of doing business.”
- Compliance programs are active and documented.
- Informal compliance roles exist but responsibilities are not well defined or assigned.
- Perceived inconsistency between the organization’s statements and execution of compliance.

### Phase III - Operational
- Compliance requirements are applied without regard to position.
-Continuous monitoring.
-Metrics are established at each of the levels (i.e., enterprise, division, group and individual) but not aligned.

### Phase IV - Strategic
- Discipline is consistently applied without regard to position.
- Awareness transitioned to training, including testing of knowledge and employee certification.
- Compliance requirements are embedded in competencies and performance processes.

### Phase V - Fully Integrated
- Compliance programs are managed in unison.
- Programs offer complete visibility of requirements across the enterprise.
- Programs are regularly audited for compliance.
- Technology is an integral part of all business processes.

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We have worked with a variety of organizations to improve their compliance capabilities.

<table>
<thead>
<tr>
<th>Global Pharmaceutical Company</th>
<th>Global Pharmaceutical Company</th>
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</thead>
<tbody>
<tr>
<td><strong>Growing compliance capabilities by restructuring Regulatory Affairs group</strong></td>
<td><strong>Enhancing existing compliance capabilities by reinforcing leadership support and learning</strong></td>
</tr>
<tr>
<td>- Improvement of compliance capabilities to better respond to US and other regulatory mandates</td>
<td>- Preserving need for cultural changes to enhance compliance capabilities and to meet FDA commitments</td>
</tr>
<tr>
<td>- Transformation of the Regulatory Affairs group, focused at restructuring the function, hiring new employees, and creating better documentation of operating procedures</td>
<td>- Target change drivers included strategic change management, project management, stakeholder alignment, training and communications</td>
</tr>
<tr>
<td>- Creation of a training program on the new operating procedures</td>
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**Activities to improve Compliance Capabilities**

- **Organization Alignment**: Assessed existing structure, processes and technology and developed recommendations for new structure and operational improvements.
- **Operations and Accountability**: Streamlined regulatory operations and roles.
- **Job Design and Competencies**: Developed job descriptions with key skills needed for the future.
- **Compliance Policies and Procedures**: Created standardized procedures that can be expanded across the global regulatory organization.
- **Training**: Certified that all employees received SOP training and were in compliance with FDA regulations. Client plans to design and build a similar training program for European SOPs.

**Outcome**

- Employees demonstrated improved understanding of responsibilities and standard operating procedures resulting in decreased incidences of non-compliance.
- Reinforced compliance infrastructure by targeted learning events on compliance and quality in clinical trials (for 350 global executives), followed by trainings for 10,000 global employees.

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Our rapid assessment approach engages the organization to identify the highest impact activities to improve and enhance its compliance activities

<table>
<thead>
<tr>
<th>ASSESS Compliance Maturity Level</th>
<th>ANALYZE Organization &amp; People Dimensions</th>
<th>DEFINE Maturity Improvement Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage key stakeholders to collect data on compliance strategy, vision, existing compliance issues and potential causes</td>
<td>Analyze the findings to determine components (i.e., processes, roles, etc.) that reduce the effectiveness of compliance activities and programs</td>
<td>Conduct a review session with key stakeholders to select priority areas for improvements based on the findings and the desired maturity level</td>
</tr>
<tr>
<td>Collect diverse perspectives (using interviews, focus groups and/or a survey) on current and desired compliance effectiveness (e.g., alignment with business priorities, consistency of compliance practices and processes, alignment with people processes, degree of compliance mindset across the organization)</td>
<td>Review results with key stakeholders to determine the current maturity levels</td>
<td>Develop actionable recommendations for the selected priority areas</td>
</tr>
<tr>
<td>Use external benchmarks to determine relevant leading practices aligned to the identified compliance focus areas and appropriate organization &amp; people dimensions</td>
<td>Prepare a gap analysis against key organizational and people dimensions aligned to current and desired compliance maturity levels</td>
<td>Detail key measurement to track implementation results against the maturity model</td>
</tr>
<tr>
<td>Indicate areas that have the highest potential to create the desired outcomes and support overall compliance maturity improvement and culture of compliance</td>
<td>Compare findings to the selected benchmarks to confirm the gaps against industry practices</td>
<td>Prepare implementation roadmap with quick wins</td>
</tr>
</tbody>
</table>

Key Lessons Learned: Sustainable changes are most successful in the context of well aligned compliance programs and processes across the organization

- **Build and communicate a compelling business case for the culture change.** Use data, facts and anecdotes to illustrate impact of non-compliance from an individual and company perspective
- **Define the culture change in behavioral terms.** Use behavioral descriptors (e.g., increased accountability) to describe the new culture so that employees can better understand what change is actually required
- **Leaders must demonstrate the commitment and act as role models.** Executive management and the board of directors play an active role in establishing and monitoring compliance strategy and the culture of compliance
- **Sustain the culture change effort by embedding it in daily activities.** One-time marketing campaign and training events do not drive sustainable behavioral change; it needs to be embedded in how people do that work. Further reinforce by putting in place measurement and reporting as well as ongoing communications
- **Increase employee awareness of compliance requirements.** Provide and maintain clear and comprehensive compliance guidance for business units and for the ways they interface with each other and with leadership
- **Address barriers to the organization’s capacity to change culture.** Identify and mitigate the organizational elements (e.g., competing initiatives or lack of key skill sets) that will impact individual / team ability to demonstrate the desired behaviors
- **Enable compliance program success using technology.** Compliance management is efficiently supported by centrally managed technology tools including databases, processing, monitoring, analytics and reporting
- **Employees are rewarded for compliant behaviors.** Adherence to compliance requirements is integral to the organization’s performance and reward structures. Performance measures, rewards and policies should be adjusted to drive the right behaviors. A program for compliance consequence is important to driving desired behaviors
- **Implement a targeted communication and training approach.** A one-size-fits-all communication and compliance training approach does not achieve tangible results. Training and communication should be customized for the various global locations and roles so that employees understand how compliance is relevant to their specific roles and the impact on individual accountability. Provide a variety of safe channels for raising issues around compliance
It is fundamental that organizations address the recurring obligation of compliance and shift their focus from a “once and done” mentality to one of “sustained”. In order to achieve sustainable compliance, companies should build an efficient and effective compliance infrastructure that enables repeatable, reliable actions of employees.

Ways to Keep a Compliance Program Vibrant

The challenge in developing a health care compliance program is to effectively implement a program that is vibrant and one that is able to change to meet the objectives of the organization. Having a program that only complies with the regulations is just the first of many steps. Creating a robust program that enables an organization to operate effectively, ethically, and is able to grow and change as an organization evolves are the fundamental pillars towards achieving success.

Putting people first: The driving force for sustained transformation

We believe that people are the most important force that drives sustained transformation. An effective culture is one that creates sustainable business value, so it is important to focus on what really matters and reinforce it. Creating the right culture requires a deliberate program, driven by everything from hiring practices, performance measures and leadership style to systems, work processes and organizational structures.

Critical Moments. Improve strategy execution by focusing on employee behavior during key events

Employee behavior is the lead indicator of strategy execution. Through this highly focused approach, Behavior Led Strategy Execution can help an organization achieve measurable performance improvement in a short period of time, while triggering a chain reaction that can fundamentally transform an organization and its culture.

Culture Eats Strategy for Breakfast: Executing Your Strategy More Successfully

Without the right culture, even the best strategy is doomed. As with strategy execution, a key to effective culture transformation is to focus on employee behavior around a small number of Business Critical Events, which typically revolve around small groups of workers whose behaviors have a disproportionately large impact on company performance and organizational culture.

On Best Behavior: Sound Advice on Executing Strategy. It’s in the Hands of Your People

Culture is a major influence on the behavior of a corporation’s employees. It is also one of the company’s few sustainable sources of competitive advantage. The key to executing a strategy effectively lies in the behaviors of employees – the strategy must become part of an employee’s everyday actions and decisions.
# Key Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Firm</th>
<th>Phone</th>
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