

Conducting Compliance Assessments and Building Internal Controls In Pharmaceutical R&D

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- **Introduction to Compliance**
- **Traditional Compliance Assessments**
- **Enterprise Wide Risk Management (EWRM) in R&D**
- **Risk Assessment Approach**
- **Pharmaceutical Case Study**
- **Questions & Answers**

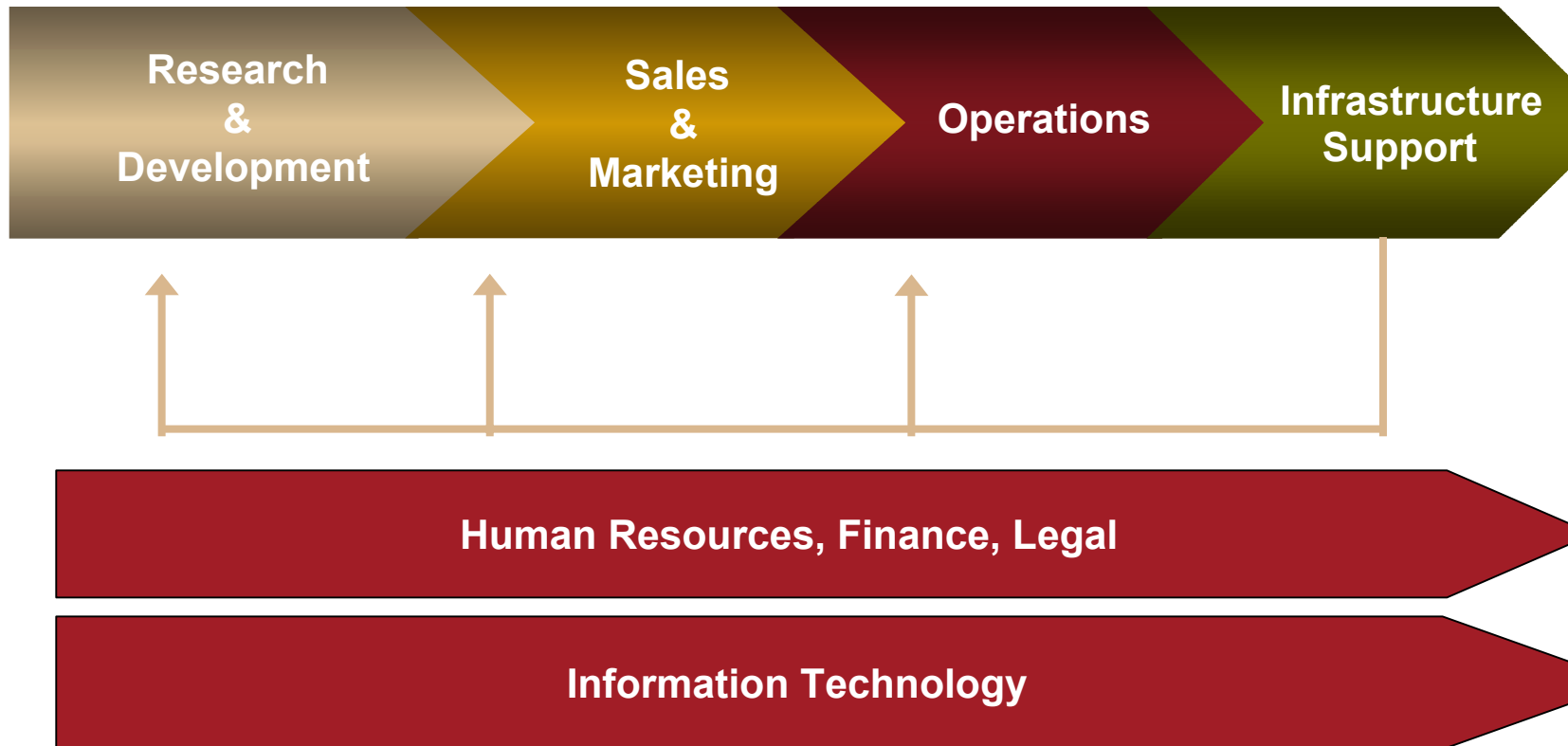
A compliance program is a management process comprised of formal reporting structures and risk mitigation systems designed to motivate, measure, and monitor an organization's legal and ethical performance around complex business practices.

Seven Elements of a Compliance Program

- **Standards & Procedures**
- **Oversight Responsibility**
- **Education & Training**
- **Lines of Communication**
- **Monitoring & Auditing**
- **Enforcement & Discipline**
- **Response & Prevention**

Compliance Programs Address All Components of the Value Chain

Pharmaceutical & Medical Products Value Chain



Transitioning from Traditional Compliance Programs

- **Standards & Procedures**
- **Oversight Responsibility**
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- **Enforcement & Discipline**
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QAU
Internal Audit
EWRM

Enterprise Wide Risk Management

- Best in class organizations are embedding their compliance programs into an expanded view of enterprise wide risk management (EWRM)
- Compliance transitions from a reactive, process intensive activity to a dynamic program enabling the organization to manage a broad range of changes that can impact its performance
- EWRM defines risks as events or activities that can affect the achievement of an organization's goals
- EWRM addresses all organizational goals, objectives and relationships with key stakeholders including R&D
- EWRM is an anticipatory, proactive process that becomes a key part of strategy and planning. EWRM helps mitigate surprises and ensures all organizations are aligned with key objectives

Enterprise Wide Risk Management

Building in an Enterprise Wide Risk Management program: Current best practice

- Enterprise Wide Risk Management Program
- Enterprise Risk Assessment
- Control Self Assessment
- Strategy Building
- Risk & Compliance External Reporting

- Complying with known laws and regulations
- Seeking to meet industry compliance requirements
- Managing crisis

Reactive

**Most
Organization's
Today?**

Proactive

Strategic

Pulling together the disciplines that address both sides of risk – minimizing uncertainty and maximizing opportunities – the concept pushes an organization to address risks and their management explicitly – as part of everyday business

Risk Assessments

- **Potential Impact of Risk**
- **Probability**
- **Primary Exposure**
- **Control Mechanisms**
- **Accountability**

Rating the Potential Impact of Risk

- The **Impact** on financial, operational and/or legal implications can be considered as well as the ability to achieve the stated objective in the face of that risk.
 - Low - if the impact of the risk would have some financial, operational and/or legal implications and require attention, but is no greater than an irritant to the organization
 - Medium - if the impact of the risk would have significant financial, operational and/or legal implications, and/or would significantly delay the ability to achieve the objectives or otherwise affect it
 - High - if the impact of the risk would have major financial, operational and/or legal implications and/or it is so significant one would need to abandon the objectives

Rating the Probability of Occurrence

- For rating the **Probability** of risks, the frequency of historical events can be considered as well as current outlook.
 - Low - occurrence is unlikely
 - Medium – occurrence is somewhat likely
 - High - occurrence is very likely

Identifying the Primary Exposures

- Identify the **Primary Exposure** to indicate the direct exposure facing an organization using categories such as:
 - Government Enforcement
 - Regulatory Violation
 - Financial Loss
 - Reputational Damage
 - Failure to comply with internal policy
 - Inefficiencies and/or excessive costs
 - Inappropriate financial reporting or disclosure
 - Legal Risk

Control Mechanisms

- For all risks with a high composite rating for impact and probability, existing **Control Mechanisms** should be considered. An organization's management should apply a rating corresponding to the level of control, such as the following:
 - Policies and procedures exist and are tested as part of external or internal audits, and/or monitoring controls are in place
 - Policies and procedures exist
 - Policies and procedures are in the early stages of development
 - Policies and procedures do not exist

Accountability

Pharmaceutical Case Study

Functional Areas	# of Risks Identified	# of “High” Risks Identified	# of “High” Risks Identified w/Limited Controls in Place
Sales & Marketing	22	14	8
R&D	44	12	3
Manufacturing	45	5	1
Regulatory Affairs	26	6	1
Financial Reporting	15	8	0
HR	42	12	2
IT	8	6	2
International	16	8	2

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Questions & Answers

