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Wirtschaft Kultur Politik

Business Ethics in the Pharmaceutical Industry.

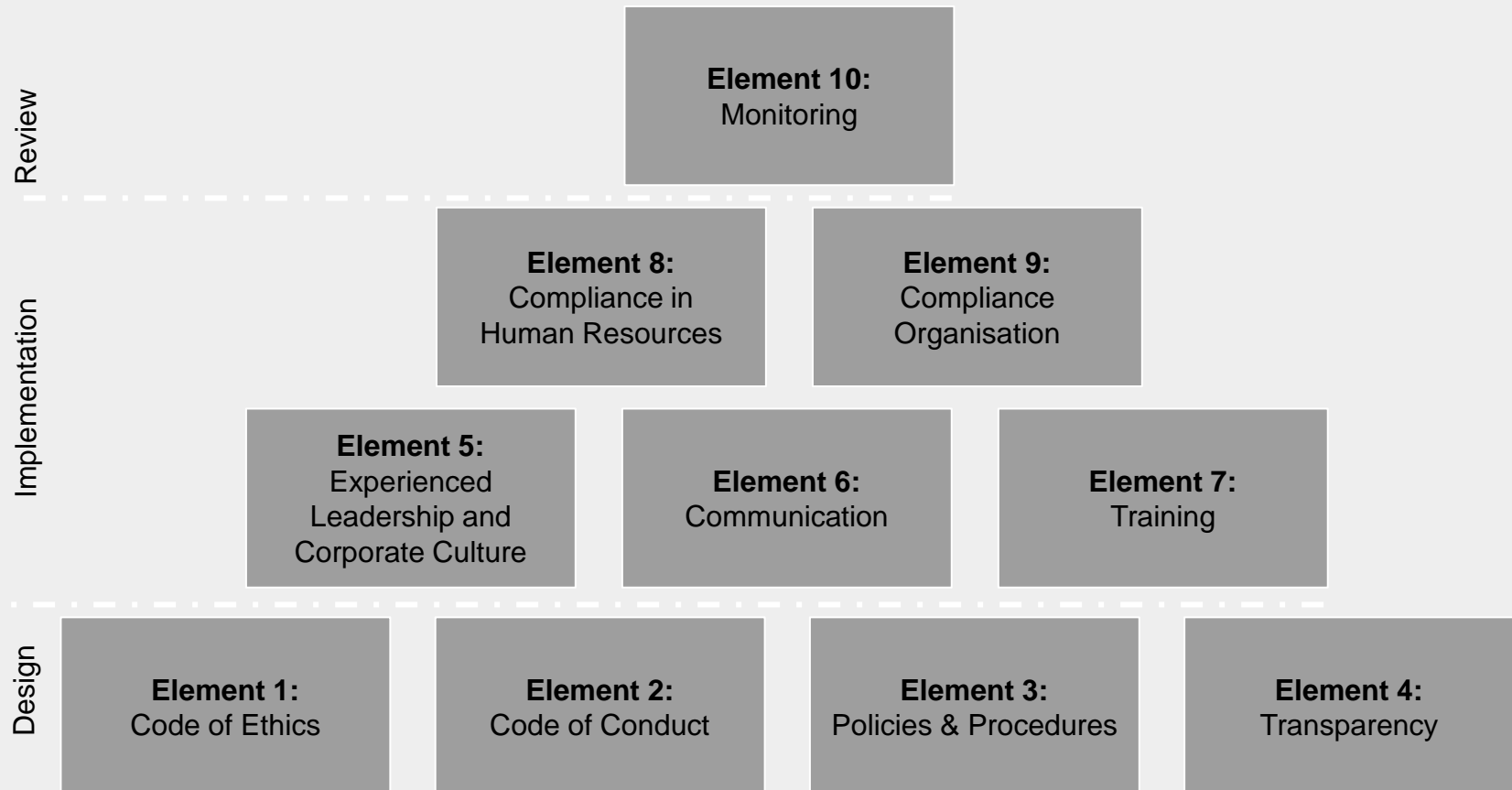
International Society of Healthcare Ethics and Compliance
Professionals

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Introduction


Building Blocks of a Compliance Management System



Introduction

Goods, Services & Morals

Goods / Service Type	Test Process	Test Criterium	Example
Inspection goods	Inspection	Quality (price)	Clothes, tools
Experience goods	Usage	Quality (price)	Grocery, cars
Trust goods	Reputation	Integrity	Financial products, insurance
Moral goods	Legitimacy	Acceptance	Medicine / medical treatment



Pharma
Industry

Introduction

New Areas of Normative Management in a Globalized World

Field of application	Leadership tasks	Standards
Integrity & Compliance Management	<ul style="list-style-type: none"> Fraud Corruption Transparency Integrity Compliance 	<ul style="list-style-type: none"> FCPA US Sentencing Guidelines UK Bribery Act OECD Guidelines – Corruption DCGK World Bank Group Integrity Compliance Guidelines
Sustainability Management	<ul style="list-style-type: none"> Ecology (Energy, water, littering) Urbanisation Economy (operating costs) 	<ul style="list-style-type: none"> Rain Forest Alliance Responsible Care
CSR Management	<ul style="list-style-type: none"> Social standards Environment Human rights 	<ul style="list-style-type: none"> UN Global Compact ISO 26.000 SR SA 8000, GRI, WMS^{ZfW} EU-Communication 2011 OECD Guidelines on CSR UN Guiding Principles on Business & Human Rights

CSR and Compliance

New Definition of CSR of the European Commission 2011

Key issues:

- | „responsibility of enterprises for their impacts on society”
- | „maximising the creation of shared value”
- | „identifying, preventing and mitigating their possible adverse impacts”
- | „long-term, strategic approach to CSR”
- | „risk-based due diligence”
- | „smart mix of voluntary policy measures”
- | „complementary regulation”
- | „transparency” ...

Source: European Commission COM(2011) 681 final

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0681:FIN:EN:PDF>

Compliance and Integrity

From Legal Compliance to Integrity Management

Evolving from a purely „Legal Compliance“ to a culture of integrity based on moral standards and values oriented.

- | Adequate procedures of the UK Bribery Act
- | U.S. Sentencing Guidelines
- | Sanctions procedures of the World Bank ...

Compliance and Integrity

UK Bribery Act 2010: 6 Principles

1. *Proportionate procedure*: Bribery prevention procedures should be proportional to the bribery risks.
2. *Top-level commitment*: Those at the top of an organisation are in the best position to foster a culture of integrity where bribery is unacceptable. (P.23)
3. *Risk assessment*: Periodic, informed and documented assessment of external and internal risks of bribery
4. *Due diligence*: Application of due diligence procedures to mitigate identified bribery risks
5. *Communication*: Bribery prevention policies and procedures understood throughout the organisation through internal and external communication, including training.
6. *Monitoring and review*: Monitoring and review of procedures designed to prevent bribery and improvements made where necessary

Compliance and Integrity

US Sentencing Guidelines

“§8B2.1. Effective Compliance and Ethics Program

- (a) To have an effective compliance and ethics program [...] an organization shall
- (1) exercise due diligence to prevent and detect criminal conduct; and
 - (2) promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.” (p. 496)

Source : US Sentencing Guidelines § 8 Sentencing of Organizations:
http://www.ussc.gov/Guidelines/2012_Guidelines/Manual_PDF/Chapter_8.pdf

Compliance and Integrity

World Bank Group Integrity Compliance Guidelines

“2. Responsibility: Create and maintain a trust-based, inclusive organizational culture that encourages ethical conduct, a commitment to compliance with the law and a culture in which Misconduct is not tolerated.

2.1. Leadership: Strong, explicit, visible, and active support and commitment from senior management, and the party’s Board of Directors or similar bodies, for the party’s Integrity Compliance Program (Program) and its implementation, in letter and spirit.

2.2. Individual Responsibility: Compliance with the Program is mandatory and is the duty of all individuals at all levels of the party. [...]” (p. 1)

Source : Summary of World Bank Group Integrity Compliance Guidelines:
http://siteresources.worldbank.org/INTDOII/Resources/Integrity_Compliance_Guidelines.pdf

CSR, Compliance and Integrity

Integrity and Integrity-Management

Definition of Integrity Management of the Working Group „Values & Integrity“, Forum Compliance & Integrity (FCI):

„Integrity and Integrity-Management denote the capability of an organisation and especially its leadership, to breathe life into its corporate values through leadership style and by setting an example in everyday practice. Integrity Management is an integral part of corporate governance and goes beyond Legal Compliance.“

➔ Integrity = Leadership Excellence

Leadership Excellence

Core Values of Global Standards

1. Integrity: Leaders should breathe life into corporate values in everyday practice , beyond legal compliance
2. Shared Value: Align your actions across the supply chain with all the stakeholders of the corporation
3. Inclusion: Integrate the interests of all the relevant and involved stakeholders in your decision making
4. Due diligence: Identify the economic, technical, political, cultural and moral risks in your business transations and examine them thoroughly.
5. Impact: Identify the consequences of your actions and try to mitigate the negative effects and strengthen the positive ones.
6. Effectivity: Corporate engagement must be effective!
7. Transparency: Act in such a way that your decisions and actions are comprehensible and are documented.
8. Monitoring: (Self-) critical analysis of suitability and effectivity of the leadership performance
9. Reporting: Report comprehensibly about your economic, social and environmental performance

Leadership Excellence

Dimensions of Leadership Integrity

