

**C L I F F O R D**  
**C H A N C E**



**FROM CODE TO CULTURE**

**DR. PETER DIENERS**

MEDTECH EUROPE FORUM, BARCELONA  
05 MAY 2022

# STRATEGIC CHALLENGE

Compliance functions in medtech companies have been facing multiple challenges and expectations over the last decades in order to continuously improve compliance efficiency

## From pillars 1 & 2

---

- General guidance by statutory law re. the "dos and don'ts"
- Detailed guidance by industry codes, i.a. MedTech Europe Code of Ethical Business Practice, Kodex Medizinprodukte

## over pillar 3

---

- Improvement of organisation and system, i.a. BVMed Compliance Standard
- Widening of strict legal compliance understanding to include reputation and tone from the top aspects

## to pillar 4?

---

- Proactive improvement of compliance culture

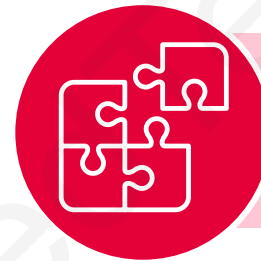
**WHAT IS LEFT TO FURTHER IMPROVE COMPLIANCE?**



# STRUCTURE AND CONCEPT FOR THE BVMED COMPLIANCE STANDARD

## MODULAR STRUCTURE

1. Compliance understanding and value basis
2. Setting up compliance positions
3. Compliance risk analysis
4. Whistleblowing system and assistance in compliance matters
5. Rules and processes
6. Training courses
7. Compliance audits and self-reviews
8. Corrective actions and continuous improvement
9. Internal investigations and sanctions
10. Documentation of the compliance organisation and its modules



## MODULAR STRUCTURE

The BVMED Compliance Standard has a modular structure allowing for each of the key elements to be dealt with clearly and concisely as part of a single module.

The modules focus on both the requirements for the individual elements and applying these to any subsequent audit.

# THE INTERNAL COMPLIANCE SYSTEM AUDIT

## PROCEDURE AND BENEFITS



**Systematic review of the compliance organisation using benchmarks and industry practice**

### **B. Self-audit of the compliance organisation**

1. Subject of the self-review
2. Procedure of the System Audit
3. Benchmarks for the System Audit
4. Audit report



A body/department within the company as far removed as possible from a compliance role conducts a formal review and produces a report based on the methodology of the BVMed Compliance Standard.



The internal self-review is intended to give the company the opportunity to confirm whether the documentation in its possession demonstrates that it implemented the organisational measures set out in the BVMed Compliance Standard.

# WHY DOES COMPLIANCE CULTURE MATTER?

Attention to culture improves compliance effectiveness and broadens its strategic reach



A sound culture is central to the effective control of the risk of regulatory breaches.



Culture complements formal compliance systems, controlling for grey-area decision making where rules alone are insufficient.



The long-term effects of regulatory breaches in the pharmaceutical sector may undermine:

- Profitability
- Societal license to operate
- Investor confidence.

## \$50bn

*Amount paid out by leading pharmaceutical companies in conduct related fines, settlements and costs (2008-2018)<sup>1</sup>*

<sup>1</sup>BMO Global Asset Management (2018). Breaking bad: Business ethics in the pharmaceutical sector

# HOLISTIC COMPLIANCE

Compliance functions are moving beyond formal rules and systems to embrace a broader understanding of how to guide organisational behaviour



## “HARDWARE”

- Rules & guardrails
- Policy & process
- Systemic enhancements

## “SOFTWARE”

- Risk culture, including:
- Awareness & deliberation
- Incentives & motivation

# THE STRATEGIC CHALLENGE – IDENTIFY AND MEASURE COMPLIANCE CULTURE

## 1. PRE-CONDITION FOR IDENTIFYING COMPLIANCE CULTURE: UNDERSTAND WHAT IT MEANS



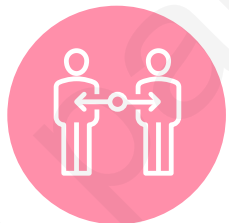
Common understanding of the norms, values, ethics and ESG-elements to be pursued and shared by the organization and its members.

The members of the organization accept, share and support its norms values, ethics and ESG-elements.



The members of the organization consider compliance a high priority and have the shared values and ethics guide their actions and decisions.

**The values and ethics are "baked" into the corporate culture and governance such that the members of the organization implicitly, or naturally, take decision or actions on their ground.**



**C L I F F O R D**  
**C H A N C E**



**DR. PETER DIENERS**  
Rechtsanwalt, Partner

**Königsallee 59**  
**D 40215 Düsseldorf**

[peter.dieners@cliffordchance.com](mailto:peter.dieners@cliffordchance.com)

Clifford Chance, Königsallee 59, 40215 Düsseldorf, Germany

© Clifford Chance 2021

Clifford Chance Partnerschaft mit beschränkter Berufshaftung von Rechtsanwälten, Steuerberatern und Solicitors · Sitz: Frankfurt am Main · AG Frankfurt am Main PR 2669

Regulatory information pursuant to Sec. 5 TMG and 2, 3 DL-InfoV: [www.cliffordchance.com/deuregulatory](http://www.cliffordchance.com/deuregulatory)

**[WWW.CLIFFORDCHANCE.COM](http://WWW.CLIFFORDCHANCE.COM)**