



Dr. Detlef Geiges



## Compliance **C**oaching & **C**onsulting

Pragmatic and efficient support to boost your  
Governance & Compliance framework



## My Expertise

- 24 years experience in the pharmaceutical industry, thereof 20 years in different senior management positions at AstraZeneca.
- 9 years experience in the area of Corporate Governance and Compliance, initially in Germany, later responsible for Europe, Middle East, Africa, Russia and Eurasia.
- Global Methodology Lead for Compliance Assurance.
- Conception, lead and implementation of national and global projects, e.g. development of a Compliance App, establishment of a cost-efficient Compliance hub structure in Europe.
- Extensive experience in recruitment, coaching and development of employees.

## My approach

- Value-driven, pragmatic, efficient.
- I see Compliance as an essential success factor. Ethically acting companies with a positive reputation perform significantly better on the market compared to standard indices. A crucial driver of this is the sustainability of the Compliance Management System and the Compliance mindset of each individual employee. Because every interaction counts!
- My motivation for Compliance starts where the legal framework is established. It comprises questions about
  - the efficacy and efficiency of the Compliance Management System,
  - the nature and quality of interactions between Compliance and the business,
  - the integration of the risk management process into Compliance and business activities,
  - and finally the creation of an ethical company culture as a competitive advantage.
- With my experience from the reputationally weak and at the same time strongly regulated pharmaceutical industry I develop solutions tailored to your needs and help you to boost your Compliance framework to the next level.
- As a passionate Darts player I act in analogy to the Darts game: Unexperienced players hit the board not very targeted and in different fields including those with low value. The experienced Darts player is focussed on the fields with the highest value. An experienced monitor, as an example, acts in the same way: focused on the activities that carry the highest risk and thereby the highest value of the control.
- Compliance does not end in itself but lives and grows in the organisational context. Hence, the success of many Compliance projects is critically dependent on the acceptance in the company's functional interfaces. This is why besides the interaction with the sponsoring function – dependent on the project scope – I consider an exchange with the involved stakeholders as important. Because only with a maximal buy-in a Compliance measure gets sustainable and therefore successful.



# My Consulting Portfolio

## ASSESSMENT, ESTABLISHMENT AND ENHANCEMENTS OF THE COMPLIANCE MANAGEMENT SYSTEM (CMS)

- Heatmap-Analysis, identification of weak areas and optimisation potential
- Targeted analysis of single CMS elements
- Establishment or enhancement of a CMS

## COACHING & RECRUITMENT SUPPORT

- Coaching of Compliance personnel and managers
- Support for recruitment of Compliance personnel

## COMPLIANCE TRAINING

- Delivery of Compliance trainings, internally or for 3<sup>rd</sup> parties
- Analysis of the Compliance training concept and existing training materials
- Development of concepts to improve the Compliance mindset

## CONTROLS, MONITORING

- Assessment of efficiency of 1<sup>st</sup> line controls
- Optimisation of 2<sup>nd</sup> line controls
- Check and/or revision of control plans
- Data Analytics
- Auditing

## RISK MANAGEMENT

- Analysis of the risk management processes, the risk management plans and – if need be – specific risks (e.g. corruption, fraud)
- Analysis of the 3<sup>rd</sup> party risk management

## CRISIS PLAN & BUSINESS CONTINUITY PLAN

- Advice on the optimisation of the Crisis plan and Business Continuity plan

## SOPS

- Analysis of the SOP Management system, advice on the role assignment of single SOPs
- Content analysis of existing SOPs and Standards, identification of optimisation potential
- Simplification & visualisation of processes in SOPs
- Development of paperless, digital SOPs/ SOP-App

## PROCESS MANAGEMENT

- Development of new processes
- Analysis and advice on process weaknesses
- Identification of options for process simplification

## INTERNAL INVESTIGATIONS

- Support for the conduct of internal investigations
- Training on the conduct of internal investigations

## INTERIM COMPLIANCE MANAGEMENT

- for short-term vacancies, e.g. maternity/parental leave
- project-driven



# The elements of a Governance/ Compliance Management System



My consulting service covers all or single elements of the Governance/ Compliance Management System.

## ASSESSMENT, ESTABLISHMENT AND ENHANCEMENTS OF THE COMPLIANCE MANAGEMENT SYSTEM (CMS)

### Heatmap-Analysis along the 7 CMS elements, identification of weak areas and optimisation potential

*You want to know how your organisation and/or single departments have implemented the Governance and Compliance requirements?*

*By means of a specifically developed questionnaire including the recording of the respective evidence, the results will be visualised and you quickly see the status of your Governance system and which elements, or which departments require improvements.*

		Improvement plan & deadline
Organisation & Culture	8	
Standards & Processes	9	
Training & Communication	7	
Risk Management	5	
Controls	6	
Documentation & Reporting	9	
Investigation & Remediation	7	

### Targeted analysis of single CMS elements

*With the same methodology also single CMS elements can be analysed either for the organisation as a whole or as a department comparison.*

### Establishment or enhancement of a CMS

*Your business is growing, and you face the challenge to implement a comprehensive Compliance Management System? Or you see the need to refine your existing CMS?*

*I will support you to develop and implement an efficient Compliance framework. My approach: no administrative hydrocephalus but a business-integrated, value generating and sustainable CMS.*



## COACHING AND RECRUITMENT SUPPORT

### Coaching of Compliance personnel

*You want to support your Compliance staff to contribute more effectively to the company success?*

*Through targeted Business Partnering and/or Assurance Coaching following the „WHY, HOW, WHAT“-model, I support the development of your Compliance staff, e.g.*

- to optimise the advice for and interaction with the business*
- to improve the efficiency of risk-based Assurance controls*

### Coaching of managers

*Your leaders ultimately determine the Compliance mindset of the whole organisation.*

*By means of individual or group coaching I support your leaders to establish a sustainable Compliance culture, to harmonise ethical and business requirements, and to implement and maintain an efficient 1<sup>st</sup> line control framework.*

### Support for recruitment of Compliance personnel

*You have already identified candidates for a Compliance position and would like to get an independent, external assessment of their specific Compliance competencies and behaviours?*

*With my experience from numerous recruitments of Compliance staff I support you to combine your expectations with the required Compliance competencies and behaviours and to make the best selection.*



## COMPLIANCE TRAINING

- **Delivery of Compliance trainings, internally or for 3<sup>rd</sup> parties**
- **Analysis of the Compliance training concept and existing training materials**
- **Development of concepts to improve the Compliance mindset**

*Is your Compliance training efficient and sustainable enough? Do you want to remodel your Compliance training? Do you ask yourself which training, and communication measures could sustainably improve the Compliance mindset of your organisation?*

***I assess your existing Compliance training and communication concept and suggest options for improvements.***

***I also deliver Compliance trainings for your staff or your 3<sup>rd</sup> parties on-site or online.***



## CONTROLS, MONITORING

*Regular, risk-based controls of business activities and transactions are not only a key element of a functioning Compliance Management System. They also help to identify areas for process optimisation and to continuously update your risk management plan. Not least – if working well – they contribute to your healthy night sleep.*

**I offer support for different control levels/ lines of defence:**

1 <sup>st</sup> line Business	2 <sup>nd</sup> line Compliance	3 <sup>rd</sup> line Audit
Continuous risk management and operational controls by the line management	Risk-based monitoring by the Compliance department	Independent, detailed controls by internal audit department or external audit firms

### Assessment of efficiency of 1<sup>st</sup> line controls

*Controls of the own business activities always carry the risk of bias and lacking objectivity and transparency.*

**I assess the efficiency of your 1<sup>st</sup> line business monitoring and develop options for optimisation.**

### Optimisation of 2<sup>nd</sup> line controls

*2<sup>nd</sup> line controls by the Compliance department usually follow a monitoring plan. Is the plan aligned to the current business risks? Is the plan flexible enough to react on emerging risks? Which criteria determine the sample selection? How are 2<sup>nd</sup> line monitoring observations transformed into learning and improvement?*

**In close collaboration with your Compliance department I analyse the existing monitoring processes and develop options for optimisation.**

**In doing so, I consider the following monitoring approaches:**

explorative	transactional	Deep dive
Questionnaire/ checklist to determine the risk and the control efficiency. The results inform the scope of transactional controls. Is usually applied for new business processes and activities.	Risk-based sampling and monitoring Different criteria for sample selection (not only quantitative) can be applied.	Detailed controls, higher sample numbers combined with questionnaires and interviews with staff involved in the respective business process.





## CONTROLS, MONITORING

### → Check and/or revision of control plans

*The internal monitoring plan describes which business activities are monitored at which frequency by the business and by the Compliance department. The plan should be aligned to the risk of the respective activity.*

*I support you in the development of monitoring plans or by analysing existing plans and their alignment with the risk management plan.*

### → Data Analytics

*You want to improve your monitoring efficiency by making better use of existing data systems?*

*I provide advice for the development of a data analytics concept that allows you to analyse the entirety of transactions of a business activity, to quickly identify outliers and to visualise trends.*

### → Auditing

*You want assurance that specific business processes are executed in a compliant manner, even those of your 3<sup>rd</sup> parties?*

*Or do you face the challenge of being audited yourself?*

*With my long-lasting experience in supervising and commissioning independent audits I support you with the selection of suitable audit service providers, the determination of the audit scope, and the preparation of a remediation plan.*

*Is your organisation being audited I support your audit-responsible person and provide coaching for the involved functions and for the management.*



## RISK MANAGEMENT

### → Analysis of the Risk Management Process, the Risk Management Plan and – if need be – specific risks (e.g. corruption, fraud)

*Clarity on the responsibilities, completeness and relevance, awareness, understandability, and verifiability are the key elements of a good risk management process and plan.*

*I provide advice for the development and revision of your process and plan, train relevant staff, or analyse the effectiveness of your risk management process and plan.*

### → Analysis of the 3<sup>rd</sup> party risk management

*As purchaser of external services you remain responsible for the compliant behaviour of your 3<sup>rd</sup> party service provider.*

*I analyse your risk management of 3<sup>rd</sup> parties, both conceptionally as well as for specific service providers. I also assess the risk awareness of your employees in dealing with 3<sup>rd</sup> parties and I support you to optimise the efficiency of your 3<sup>rd</sup> party risk management process.*



## CRISIS PLAN UND BUSINESS CONTINUITY PLAN

### → Advice on the optimisation of the Crisis plan and Business Continuity plan

*The crisis plan should capture operating procedures for events that constitute a danger for life, public health, or the environment, that could lead to production or supply outage, could result in prosecutor investigation, put your IT infrastructure at risk, or that could seriously damage the reputation of your company. The plan helps to react quickly and comprehensively in case of a crisis. A good Business Continuity Plan helps you to continue with your business without major interruptions.*

***I provide advice for the development or optimisation of your plans, help to develop scenarios, or support you with crisis testing on-site.***



## SOPs

- **Analysis of the SOP Management system, advice on the role assignment of single SOPs**
- **Content analysis of existing SOPs and Standards, identification of optimisation potential**
- **Simplification & visualisation of processes in SOPs**
- **Development of paperless, digital SOPs/ SOP-App**

*Policies, Guidelines and Standard Operating Procedures are essential for a standardised, compliant and law-conforming execution of your business activities. However, often the process descriptions are perceived as bloated bureaucracy, are written in a too complicated manner, and it is unclear which employees need to read and know which SOPs.*

***I support you to optimise your SOP system and to sustainably shape your process descriptions through improved end-user friendliness.***

## PROCESS MANAGEMENT

- **Development of new processes**
- **Analysis and advice on process weaknesses**
- **Identification of options for process simplification**

*You face the challenge to implement new regulatory requirements? You are unsure if you haven't missed an important control step given the high number of processes? You are seeking options to improve your efficiency through process simplification?*

***I provide advice to all this aspects. Usually I follow a workshop approach with all functions involved in the process in question.***



## INTERNAL INVESTIGATIONS

### → Support for the conduct of internal investigations

*You have a suspicion or first indications of a serious Compliance breach in your organisation and want to provide the internal investigating staff with external expert support?*

*With my long-time experience in conducting internal investigations I go along with the investigation, provide advice to the investigation lead and help to complete the case objectively and efficiently.*

### → Training on the conduct of internal investigations

*You see the need for a (refresher-) training for the function(s) involved in internal investigations (Compliance, HR, Finance) and want to get an external expert view?*

*I would be pleased to conduct an online or on-site training with case examples and exercises.*

## INTERIM COMPLIANCE MANAGEMENT

*I also assume interim Compliance Management tasks, for maternity/parental leave, other short-term vacancies, or to support your Compliance team in case of resource shortage.*



# CONTACT

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