



**SEVENTH ASIA PACIFIC PHARMACEUTICAL AND MEDICAL DEVICE
COMPLIANCE CONGRESS**

Sept 13 - 15, 2017

InterContinental Shanghai, China

Mini Summit: The Evolution of Compliance Organizations

Thursday Sept 14, 2017: 1.00-2.15 PM

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AREAS TO BE DISCUSSED

- Awareness of changes in the elements of effective compliance programmes – what does this mean and what are we doing about it?
- Impact of technology and digitalisation on the evolution of the compliance function / programme – perspectives/challenges!
- What about the role of ethics? What changes or additional requirements are we seeing?
- Evolution of Compliance leadership within organisations, change in dynamics and expectations – what does this mean for us?

The (Original) Seven Elements of an Effective Compliance Program

1. Senior Management Oversight
2. Written Policies & Procedures
3. Training & Awareness
4. Communications hotline – Speak Up/Listen up culture, whistleblower provisions
5. Investigations / Non-Retaliation / Disciplinary Actions
6. Auditing & Monitoring
7. Corrective Actions

Evaluation of Corporate Compliance Programs – what is new?

- 2015: The US Department of Justice (DOJ) hired a compliance consultant to help evaluate compliance program (left after the US Presidential elections)
- February 8, 2017: additional Evaluation Guidance
- Issued by the DOJ Fraud Section
- First document issued by the DOJ on corporate compliance matters
- Contains 11 topics
- Some of the topics overlap with the seven elements of an effective compliance program
- A few topics are new but address on going concerns both for companies and for regulators

Evolution of Compliance Organizations

Previous guidance 7 Elements		New Guidance* – Feb 2017 11 Elements	
1	Senior Management Oversight	2	Senior and Middle Management
2	Written Policies & Procedures	4	Policies and Procedures
3	Training & Awareness	6	Training and Communications
4	Whistleblower hotline	7	Confidential Reporting
5	Investigations / Non-Retaliation / Disciplinary Actions	7	Investigation

* <https://www.justice.gov/criminal-fraud/page/file/937501/download>

Evolution of Compliance Organizations

	7 Elements		11 Elements
6	Auditing & Monitoring	9	Periodic Testing and Review
7	Corrective Actions	9	Continuous Improvement
		1	Analysis and Remediation of Underlying Misconduct
		3	Autonomy and Resources (Compliance)
		5	Risk Assessment
		8	Incentives and Disciplinary Measures
		10	Third Party Management
		11	Mergers and Acquisitions

Evolution of Compliance Organizations

	Additional Elements?
3	Autonomy and Resources (Compliance)
5	Risk Assessment
8	Incentives and Disciplinary Measures
10	Third Party Management
11	Mergers and Acquisitions

3. Autonomy and Resources (Compliance)

- ▶ independence, experience and qualification of compliance
- ▶ Scaling for growth and adapting to continuous change
- ▶ Innovative budgeting to sustain and grow the compliance function
- ▶ Think about
 - ... technology and digital tools and alignment with IT systems
 - ... what about the role of ethics and ethical decision making?
 - ... how to evolve the compliance function with changing times?
 - ... what are the expectations now and over next 5 year horizon?