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Ethics Mirror Survey CCO & CEO

**“Doing the right thing
when no one is watching you”**



Mirror Survey sponsored by ETHICS and conducted by DAY ONE and HEIDRICK & STRUGGLES



■ Context:

- ETHICS, the International Society of Healthcare Ethics and Compliance Professionals (www.ethicspros.com), has decided to conduct a study with pharmaceutical and medical device manufacturers to help its members to better understand:
 - the issues and challenges of Ethics / Compliance functions;
 - their positioning in organizations;
 - the outlook for these functions in the years to come.

■ Methodology:

- The study, called “mirror”, has been conducted during the months of September, October and November 2015 by the Management Consulting firm Day One and the Executive Search Firm Heidrick & Struggles.
- A panel of CEOs (or multi-country / regional operational managers, members of Executive Committee) and senior managers (global or regional) of the Ethics / Compliance function from various leading international pharmaceutical and medical devices companies, have been interviewed.
- Only anonymous data and information are aggregated and published in fine.

HEIDRICK & STRUGGLES



19 participants... so far!

- Ann Beasley, Chief Compliance Officer, **Biogen**
- Johanna Friedl-Naderer, SVP Head Europe & Canada, **Biogen**
- Dipti Amin, Chief Compliance Officer, **Quintiles**
- Anand Tharmaratnam, President & Head of Asia Pacific, **Quintiles**
- Jacques Fontas, Compliance Chief Officer, **GE Healthcare Europe**
- Jean-Michel Malbrancq, President and CEO, **GE Healthcare Europe**
- Dominique Laymand, Compliance Chief Officer, **Ipsen**
- Marc de Garidel, President & CEO, **Ipsen**
- Stephen Nguyen, Regional Director Ethics & Compliance W. Europe Israel & Canada, **AbbVie**
- Pascale Richetta, Vice-President W. Europe & Canada, **AbbVie**
- Anne-Sophie Bricca, Director Legal Affairs & Compliance EMEA, **Terumo BCT Europe**
- Régis Leonard, Vice-President EMEA Commercial Operations, **Terumo BCT**
- Anthony Mcquillan, Vice-President Legal & Compliance EMEA, **Medtronic International**
- Fabrice Dubois, Director International Legal Coordination, **Servier**
- Eva Gardyan Eisenlohr, Chief Compliance Officer, **Bayer Pharma**
- Dante Beccaria, VP Global Compliance, **Sanofi**
- Dominik Geller, Head Healthcare Compliance Office, **Roche**
- Thomas Hauser, Global Chief Compliance Officer, **Siemens Healthcare**
- Suzanne Durdevic, Senior Director, General Counsel EMEA, **Boston Scientific**

Thinking compliance

- The words that embody « compliance » at best:



According to CCO*



According to CEO*

*We extracted the most recurring themes from the answers given to the question "What are the three words coming to your mind when compliance is at stake?"

Defining compliance... in 30 seconds

“Compliance is doing the right thing when no one is watching you.”

CCO

CEO

Follow the law and foster internal ethics culture CCO 77%* - CEO 80%	Understand and assist the business CCO 46% - CEO 0%	Protect the employees and the patient CCO 31% - CEO 80%
<ul style="list-style-type: none"> • “Ensuring adherence to all policies, standards, laws and regulations which concerns our business through the creation of a culture of ethics“ • “Compliance is integrity in decision making” • “Disseminate behaviors, ethics and integrity standards throughout the group.” • “Set up procedures to diminish risks.” • “Governance and risk management” 	<ul style="list-style-type: none"> • “Link between our business and our company code of conduct” • “Compliance is a business partner organization to enable our sustainable business success.” • “Ensure the business is compliant with rules” • “Supporting the business helping it to achieve its business objectives by providing tools. Main task is to support the business.” 	<ul style="list-style-type: none"> • “To protect the company and every employees with an effective and compliance function which present, detect, respond and issue in the world on anti corruption (anti Bribery), anti trust, AML, data privacy and on pharma laws.” • “Assist the business understand risks that could affect the company and put controls to them manage that risks and operate confidentiality.” • “Support our patients, community” • “To protect the professionals”
<ul style="list-style-type: none"> • “To work while complying with local and internal rules” • “Compliance is in everything we do our highest priority. ” • “To make sure that we operate everywhere in accordance with market rules, antitrust law (...)” 	<p>?</p>	<ul style="list-style-type: none"> • “A company and personal undertaking in charge of reminding to everyone that there is a set of rules to respect. It is of a tremendous importance for us as we operate in the pharmaceutical industry. We have to protect our patients.” • “To make sure our success is made with respect to the environment and the patient.” • “Ability to deliver quality to our customer/patient safety.” • “To make sure that we operate everywhere (...) with respect to the individual.”

*the total % is greater than 100% as CCOs and CEOs often integrate several characteristics in their definition of “compliance”

CCO & CEO aligned on the difference between compliance and ethics

Compliance

- *“Follow all the rules and regulations”*
- *“Imposed by the outside”*
- *“Compliance is how you implement your values”*
- *“Compliance it’s about standard, HR standard, Financial Standard...”*
- *“A way to act in a defined framework.”*
- *“Compliance is more about rules and the way to operate.”*
- *“Compliance is more law oriented than ethics but they’re the same when it comes to grey zone in terms of integrity.”*

Ethics

- *“Close but ethics goes beyond. Would you be proud of what you did? The stomach ache test.”*
- *“It’s more than law even if you comply with the law you may not be perceived very ethical”.*
- *“Our philosophy”*
- *“Help us to deal with the grey zone.”*
- *“We don’t use the word “ethics” we rather use the word “integrity” which means doing the right thing even if no one is watching”.*
- *“Ethics is more about behavior.”*

CCO: “The main difference for us is not what you must do (it’s a given) but what we should do : “from doing things right to doing the right things”

Compliance as a strategic tool

“Compliance is even a sales weapon.”

- 100% of **CEOs** consider Compliance as a strategic tool
- 85% of **CCOs** think Compliance is a strategic tool and 15% consider it as both a strategic tool and a compliance tool

CCO

CEO

Integration with the business at every stage CCO 62% - CEO 50%	Reputation CCO 38% - CEO 33%	Up front participation CCO 23% - CEO 17%	Talent retention CCO 15% - CEO 33%
<ul style="list-style-type: none"> • <i>“Strategic : in every aspect of our business. Even in our new entity with new business model due to digitalization there is compliance”</i> • <i>“Compliance is the way you do business. It is totally included in the strategy.”</i> 	<ul style="list-style-type: none"> • <i>“Major impact on the reputation.”</i> • <i>“We are consulted about how to interact with patients.”</i> • <i>“How to show patients a different image.”</i> • <i>“Compliance is even a “sales weapon” because doing business with us means the business is clean”</i> 	<ul style="list-style-type: none"> • <i>“Need to change our mind set and be part of strategic meeting “Be at the table early””</i> • <i>“Compliance is built in our business and compliance needs to participate up front part”</i> • <i>“Strategic Tool : our compliance team is consulted upfront for strategic issue”</i> 	<ul style="list-style-type: none"> • <i>“Interactions between individuals.”</i> • <i>“New risk: burnout, employees stress. We can detect and help them. Compliance is a strategy of talent retention.”</i>
<ul style="list-style-type: none"> • <i>“It’s a strategic tool. Managing compliance is key for our business.”</i> 	<ul style="list-style-type: none"> • <i>“We’re obliged to serve the patient the best we can and be highly respected “</i> • <i>“Brand image of our company.”</i> 	<ul style="list-style-type: none"> • <i>“We need a multi disciplinary approach to face new challenges.”</i> 	<ul style="list-style-type: none"> • <i>“Brand image of our employees.”</i> • <i>“From an internal perspective : great place to work, retention”</i>

**the total % is greater than 100% as CCOs and CEOs often integrate several features in their conception of compliance as a strategic tool*

Compliance as a competitive tool

According to you, what would make compliance a competitive tool?

CCO: *"It increases our brand in the market, help us attract talent"*

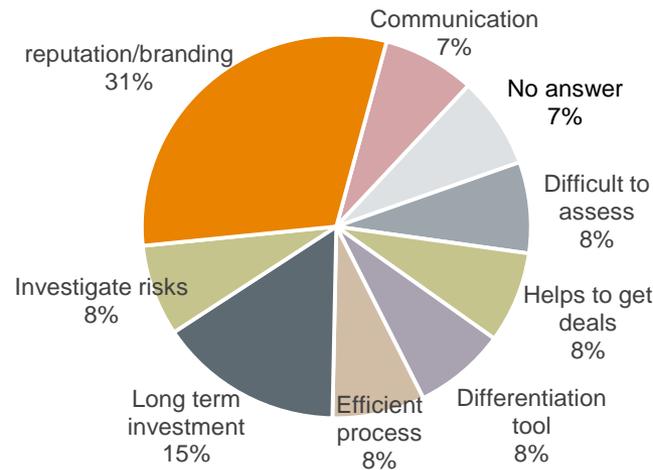
CCO: *"Our ability to investigate risks is a competitive advantage"*

CCO: *"Competitive advantage: in public tenders it helps because it proves that our business is clean even if we're not the cheapest."*

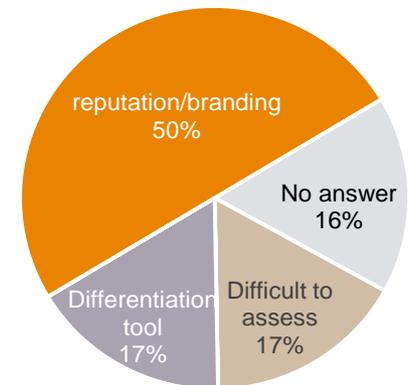
CCO: *"Key to have a strong reputation"*

CEO: *"It's a competition advantage, because it helps you to be trusted and highly regarded as a company."*

According to CCO



According to CEO



*% of answers given to the question "According to you, what makes compliance a competitive tool?"

Compliance and its partners

CEO: *“When there is a crisis all these functions come together to solve it”*

Compliance

Legal

Risk management

Internal control

Internal audit

CCO	CEO
<ul style="list-style-type: none"> • <i>“Create transparency in the way the business is doing, we’re here to prevent issue and create a culture when people can speak up to us”</i> • <i>“Update of rules and trainings”</i> • <i>“What you should do”</i> • <i>“Compliance is a more governance function”</i> 	<ul style="list-style-type: none"> • <i>“Compliance is about collective effort even though it deals with clear matters: i.e. probes, whistleblowing, local laws...”</i> • <i>“It is more about internal behaviors”</i> • <i>“How to do it well, under moral principles”</i> • <i>Legal and compliance work a lot together, especially about proactivity to create our framework”</i>
<ul style="list-style-type: none"> • <i>“It’s about transactions, contracts, legal opinion”</i> • <i>“What you can do”</i> • <i>“legal is a more consulting function, technical, black or white”</i> • <i>“is more contractual work and negotiation, we have also in house lawyers within the compliance function working on investigation (50% of the team) because of the pharma compliance environment”</i> 	<ul style="list-style-type: none"> • <i>“legal and compliance shall be true partners”</i> • <i>“It is more about external matters: laws, regulations...”</i> • <i>“legal advisors, understanding the legislation working on contract and collaboration with third party”</i> • <i>“About what you can do”</i>
<ul style="list-style-type: none"> • <i>“Mostly about risk mapping and prioritization”</i> • <i>“The risk management and internal audits are checkpoints to control the vehicle driven by the business, legal and compliance are more like co-pilots”</i> 	<ul style="list-style-type: none"> • <i>“Risk Management : is part of the risk committee and at board level doing the risk assessment”</i>
<ul style="list-style-type: none"> • <i>“It is a business process that implements control”</i> • <i>“Report to the CFO”</i> • <i>“Internal control are embedded in the risk management system”</i> 	<ul style="list-style-type: none"> • <i>“Under the CFO”</i> • <i>“Quality assurance is a stand alone function like the compliance”</i>
<ul style="list-style-type: none"> • <i>“We collaborate very closely with our audit function through reporting to the audit committee risk management”</i> • <i>“Internal audit is assessing, investigating in order to understand what went wrong whereas compliance try to make sure things don’t go wrong”</i> • <i>“Report to the CEO”</i> 	<ul style="list-style-type: none"> • <i>“It is the only function which is doing request audit and measure how good we are in terms of compliance”</i> • <i>“coercive action plan”</i>

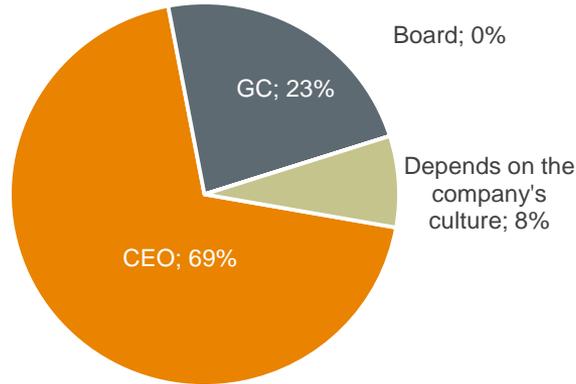
CCO's most appropriate person to report to

CCO: "It depends on the culture as soon as compliance has a different team from legal. I could report to legal without problem."

CCO: "Reporting to the CEO is mandatory in order to be independent and have the authority"

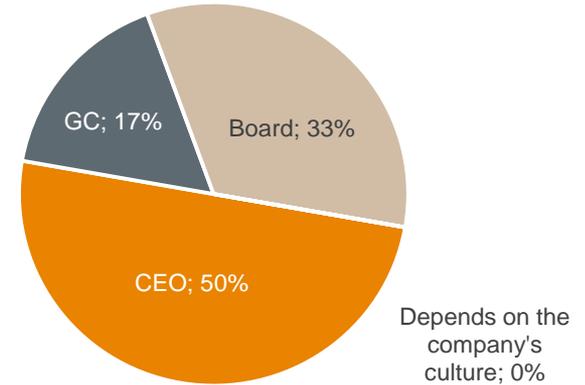
CCO: "In order to integrate compliance within the company culture and decision making, the CCO shall report to the CEO."

According to CCO*



CCO: "Compliance and legal should be aligned they are both side, of a flip coin. So CCO should report to GC into reports to CEO."

According to CEO*



CEO: "CCO and GC should both report to the CEO"

CEO: "CCO should report to the board"

*% of answers given to the question "From an organizational point of view, what is according to you the most appropriate hierarchical link to the compliance function?"

Skills required to be a good CCO

According to CCO*



According to CEO*



*We extracted the most recurring themes from the answers given to the question "What are the skills required to be a good CCO?"

CCO and CEO's interaction

CCO

CEO

	Informal CCO 69% - CEO 83%	Formal CCO 69% - CEO 100%
CCO	<ul style="list-style-type: none"> • “Preferable informal with CEO and formal with Comex” • “Formal and informal meetings” • “Informal: at any time” • “One on one calls” • “One on one meeting with CEO” 	<ul style="list-style-type: none"> • “Audit committee meeting 4 times a year” • “Once a month our CEO talks about one business issues and one value issue that is part of our code of conduct” • “Formal monthly meeting” • “CEO - CCO interact on a regular basis” • “Constructive and regular dialogue, you should be able to challenge each other” • “In constant engagement, contact or dialogue in order to know their plans, their concerns”
CEO	<ul style="list-style-type: none"> • “To make sure that we operate everywhere in accordance with market rules, antitrust law (...)” • “A lot of informal interactions” • “Frequent one on one.” • “Just pick up my phone and speak to my CCO any time” 	<ul style="list-style-type: none"> • “CCO is be a member of the strategic committee” • “Compliance review board: the agenda is prepared by the Compliance Officer.” • “Interact regularly to keep pace with each other.”

“Continuously even though you can have fixed meetings : in constant engagement, contact or dialogue in order to know their plans, their concerns”

**the total % is greater than 100% as CCOs and CEOs often answered that CCO and CEO's interactions shall be both formal and informal*

Compliance departments future challenges

“To do the right thing, we need to pay more attention at what we do and how we do it”

Manage external stakeholders

Regulatory matters and third parties

Integrate, structure and measure the added value of the compliance department

CCO	CEO
<ul style="list-style-type: none"> • “Key Challenges : understanding more government affairs, policy making” • “Deal with new stakeholders (patients, gov, officials...)” • “Wisely strengthen transparency towards health professionals” 	<ul style="list-style-type: none"> • “Ability to deal with innovation and stake holders new concerns” • “Relation with government (In reimbursement) and innovation pipelines i.e. more collaboration and partnership with government” • “The civil society is more and more demanding” • “Public perception, reputation” • “Social media and communication channels”
<ul style="list-style-type: none"> • “Anti corruption, conflict of interest, Data privacy, Transparency” • “Anti corruption and data privacy are the two main topics” • “manage risks” • “Third party vendors” • “Service providers and suppliers are a major matter for the industry” 	<ul style="list-style-type: none"> • “Stay compliant with new regulations”
<ul style="list-style-type: none"> • “Still an issue to value the contribution. How to further build the function” • “Successfully integrate compliance with our entire organization after our last acquisition” • “Articulate our action with internal audit on monitoring issues” • “Work more on the strategic and value added component of compliance and really stop the “check list-tick the box” approach” • “Keep trying to find out where we belong in the organization v.legal and audit” • “To be recognized in a profound and homogeneous way” • “To get credibility” • “To shape tomorrow’s CEO” 	<ul style="list-style-type: none"> • “Get in the DNA of the company” • “Get integrated in our teams DNA”

How to evaluate compliance's success?

“To do the right thing, we need to pay more attention at **what** we do and **how** we do it”

CCO

CEO

Qualitative evaluation	Quantitative evaluation
<ul style="list-style-type: none"> • “Lack of fines or verdicts” • “No crisis” • “Internal survey to measure the evolution of the culture” • “Extremely difficult. Audit. Monitoring exercise” • “Compliance success is deeply linked with the business success. No other way.” • “How often our employees come to us directly to settle a question. Not only through our formal hotline” • “To take part in the corporate strategic matters.” • “Tracking the calls on our hot line : quantity, quality : more reporting” • “Prevention, training, monitoring. Not easy to develop a dashboard” 	<ul style="list-style-type: none"> • “Number of cases coming out abroad” • “Measuring the number of compliance issues we track in our database and look at their results” • “Training metrics” • “Budget : spend less on law firms and authorities on these cases” • “I refuse to use KPIs as it is mostly a cultural matter.” • “It’s difficult to have KPI, but it’s even more difficult to have kpis that make sense. The more cases the better or the less cases the better ? No public prosecutions ? Nobody is in prison? Is my CEO is happy ? It’s very difficult.” • “KPIs on training and actions.”
<ul style="list-style-type: none"> • “Small signs: acceptance of the compliance department, taking part to committees, integration within the culture.” • “To have an up front approach” • “How we work together as a team to solve our patients problem in a collaborative way. How well do we do in training our people. How people speak about compliance. Setting clean timeframe.” • “Dialog, culture, behavior.” 	<ul style="list-style-type: none"> • “Big signs: number of crisis” • “Decreasing number of cases.” • “Our distributors evaluation and number of cases.” • “Findings from our audit. Number of employees issue per 1000. We don’t really have formal KPIs. Though it is important. It’s what coming next, it has to be linked to patient safety at the end of the day.”

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