

# Pre-Conference I – ETHICS Association Highlights on Current Compliance Issues

14 May 2018



# Why ETHICS?

- ☉ An **informal "Ethics Group"** had been created between professionals from different Healthcare companies
- ☉ From the creation, the possibility to **formalize the existence** of this Group through the creation of such an Association was foreseen
- ☉ Permanently **increasing complexity** and **importance of tasks** of Ethics and Compliance Professionals justified the move to this next step be achieved quickly
- ☉ Need to be **resourced** to be sustainable
- ☉ There was a **vacuum** as far as a Professional Society for Healthcare Ethics and Compliance professionals is concerned



# ETHICS Vision

“We aim to be recognized as an independent international association of professionals, which sets standards of Ethics and Compliance and shapes and influences strategies in the changing Healthcare environment for the ultimate benefit of Patients and Society at large.”



# ETHICS Mission

- ☞ **Visible and transparent network** and a **think tank** of diverse International Ethics and Compliance professionals in the Healthcare sector
- ☞ **Add sustainable value** to Ethics and Compliance professionals by enabling them to **manage their professional responsibilities** and supporting them in the **development of their careers**
- ☞ **Developing and sharing best practices** to anticipate and **facilitate new business models** in the healthcare sector including through effective education and training, closer collaboration between MedTech and Pharma and other initiatives
- ☞ Delivering Ethics and Compliance perspectives to **multiple external Healthcare sector stakeholders**, as well as to Ethics and Compliance professionals from other sectors
- ☞ **Independent, not-for-profit association** governed by a Code of Conduct



# Legal Organization

With the help of Clifford Chance Law firm

- Ⓢ Creation of an Association governed by the French law of 1901
- Ⓢ Headquarters in Paris (hosted by Clifford Chance)
- Ⓢ Article 1 defines the association as "*the convention by which two or several people share, in a permanent way, their knowledge or their activity with a different aim than to share benefit*"



# Members and Funding

- ☞ Currently around 100 members from different (mainly European) countries
- ☞ Membership per individual – not per company
- ☞ The Association is essentially funded by members' fees and contributions
- ☞ 3 different categories of membership fees:
  - Founding and Contributing members pay €1,500
  - Active members pay €250
  - Honorary members (proposed by the Board) do not pay any membership fee
- ☞ All members treated equally, regardless of fees paid



# Governance

## ☞ **Board**

- Meets at least twice a year
- Broadest powers to act in the name and on behalf of the Association
- **Bureau of the Board** composed of (at least) President, Secretary General and Treasurer of the Association

## ☞ **Strategic Committee**

- Meets face to face at least once a year
- Around 20 members
- Determines the main guidelines, field of actions and priorities of the Association

## ☞ **General Assembly of members**

- Meets at least once a year
- Possible extraordinary meetings of the members, as needed



# Pre-Conference Discussion

## Session host:

Dante Beccaria

ETHICS member and Senior Vice President, Global Compliance Officer, Head of Ethics and Business Integrity Department, Sanofi

- 🕒 Topic leader introduces topic
- 🕒 Tables discuss the topic with their table facilitator
- 🕒 Cross-table discussion – key points shared with topic leader
- 🕒 Move on to the next discussion topic





# Discussion Topics and Leaders

- ☞ Tone at the Top – Dominique Laymand
- ☞ Compliance Officers Development – Stephen Nguyen-Duc
- ☞ Writing Policies and Procedures – Cécile Gousset
- ☞ Future of Compliance and Code Convergence – Roeland van Aelst
- ☞ Code of Conduct for Compliance Officers – John McLoughlin



# Tone at the Top

Topic introduced by:

Dominique Laymand Esq

Honorary President ETHICS and Executive VP – Chief Compliance Officer, Ipsen

- ☞ Who sets the tone?
- ☞ What is “Tone at the Top”? Is compliance enough?
- ☞ How to measure Tone at the Top



# Compliance Officers Development-1

Topic introduced by:

Stephen Nguyen-Duc

Co-Chair ETHICS Strategic Committee

Typical approach : **LEARN-PERFORM-GROW**

**1.LEARN:** skills, capabilities ... also rules, regulations, environment ...

**2.PERFORM:** Criteria? Competency Model?

**3.GROW:** Next level scenario e.g. individual contributor to team lead, local to regional, regional to global, in Compliance or outside of Compliance?



# Compliance Officers Development-2



Typical approach : **LEARN-PERFORM-GROW**

- 1.LEARN:** How do you learn today? What are the sources? How do you get access / support for soft skills development? How do you get access / support for technical skills? What is potentially missing?
- 2.PERFORM:** What should “good” look like? How do you / your supervisor know that you are performing well?
- 3.GROW:** Do you have clarity around your potential next level career scenario? Why?



# Writing Policies and Procedures-1

Topic introduced by:

Cécile Gousset

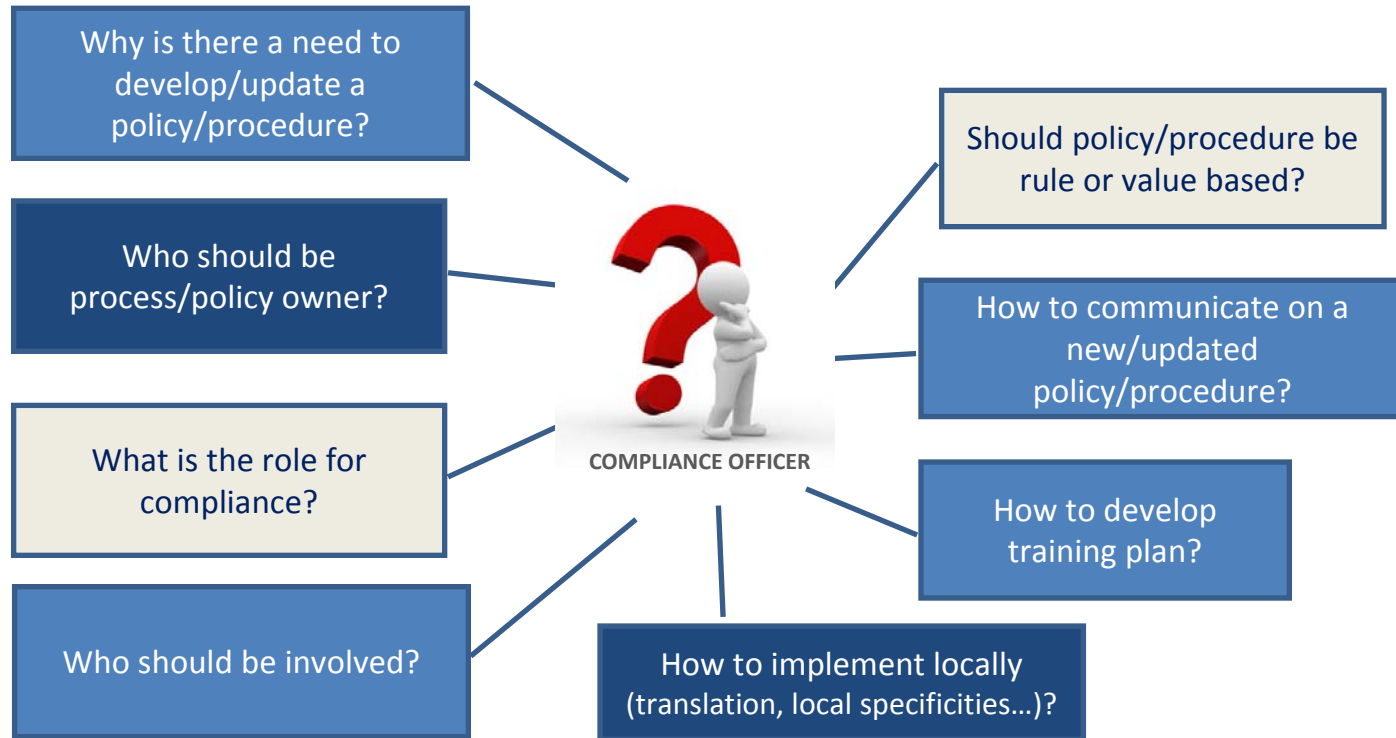
ETHICS member and Head of Compliance Risk Assessment, Policies and Education, Global Ethics and Business Integrity, Sanofi



- 🕒 Implementing written policies, procedures and standards of conduct is one of the 7 elements of an effective compliance program
- 🕒 But how to define there is a need for new/updated policy/procedure, to ensure relevant stakeholders feel accountable and responsible for application, and what is the role for compliance in this process?



# Writing Policies and Procedures-2





# Future of Compliance and Code Convergence-1

Topic introduced by:

Roeland van Aelst

President ETHICS and Regional Vice President, HCCO MD&D EMEA, Office Health Care Compliance and Privacy, Johnson & Johnson

- 🕒 The environment is changing
  - New business models (from product toward end-to-end, risk sharing, outcome based )
  - New players ( Google, Amazon, .... )
  - New technology ( A.I., digital health care, personalised medicine )
- 🕒 Code convergence
  - Change in decision maker to more centralised
  - We all play on the same field



# Future of Compliance and Code Convergence-2

- The environment is changing
  - What will be the impact on Health Care Compliance
    - Regarding regulation, what are the new risks
    - Regarding the role of the officer, new tasks
- Code convergence
  - Can we keep explaining the differences
    - To customers
    - To authorities
  - How do we get closer
    - Globally
    - Cross-sector







# Code of Conduct for Compliance Officers

Topic introduced by:

John McLoughlin

Editor, ETHICS in Action

- ☞ Do we need a separate Code of Conduct for Compliance Officers?
- ☞ Why / why not?
- ☞ If we did have a separate Code of Conduct what would be included?