

A person in a dark suit is running on a modern architectural structure with a grid-like ceiling and concrete steps. The background is a bright, overcast sky. The overall tone is professional and dynamic.

Turning Compliance into a Profession

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13th International Pharmaceutical and Medical Device Compliance Congress

Athens, Greece
April 10, 2019

Article 3

L 255/22

30.9.2005

Definitions

1. For the purposes of this Directive, the following definitions apply:

- (a) 'regulated profession': a professional activity or group of professional activities, access to which, the pursuit of which, or one of the modes of pursuit of which is subject, directly or indirectly, by virtue of legislative, regulatory or administrative provisions to the possession of specific professional qualifications; in particular, the use of a profes-

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Architects Code: Standards of Conduct and Practice



Solicitors Regulation Authority

Version 21 of the Handbook was published on 6 December 2018.

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Code of Ethics

IEEE-CS/ACM Joint Task Force on Software Professional Practices

DES BONNE PRATIQUES



ABOUT US

JOIN | RENEW | UPDATE

MEMBER BENEFITS

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Architects Code: Standards of Conduct and Practice

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Solicitors Regulation Authority

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Codes of Conduct

Section 13 of the Architects Act 1977 (the Act) requires the Architects Registration Board ("the Board") to issue a code of laying down the standards of professional conduct and practice expected of persons registered as architects under the Act.

Cette Charte, fruit d'un travail de rédaction commun avec la Direction générale de la création artistique (DGCA - ministère de la Culture) acte officiellement et pour la première fois la reconnaissance de la galerie d'art comme interlocuteur incontournable lors de toute négociation entre un artiste et un établissement public, dès lors que l'artiste est notoirement représenté par la galerie.

CHARTRE DES BONNES PRATIQUES

ABOUT US

JOIN | RENEW | UPDATE

MEMBER BENEFITS

Code of Ethics 1

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Code of Conduct for ETHICS Members Version 01 (2017)

Letter from ETHICS founding members Dominique Laymand and Roeland van Aelst: in memoriam of Gabor Danielfy

Dear ETHICS Members,

Gabor Danielfy has been a great inspiration for us and the international Ethics & Compliance community. He was a true and authentic leader who continuously strived towards excellence in Ethics & Compliance and how we can become as a Profession, a strategic partner and advisor to the business in ethical business decision making. We remember well his great sense of humour, his friendly nature, his talent for networking and his openness to share experiences and coach other Healthcare Compliance Professionals in their professional and personal development, through which he earned great respect from the Healthcare Compliance community and beyond.

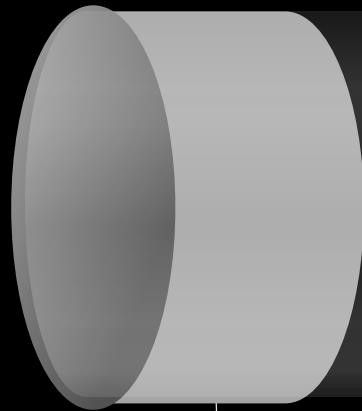
What are the expectations from
the authorities for our
profession?

Compliance Program Guidance: Evolution of “Culture”

David HESS: Ethical Infrastructure and Evidence-based compliance programs: policy implications from the empirical evidence. NYU Journal of Law and Business vol. 12, 2, 2016.

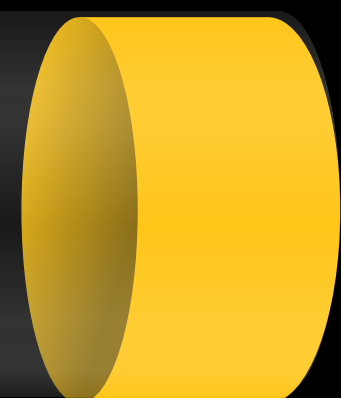
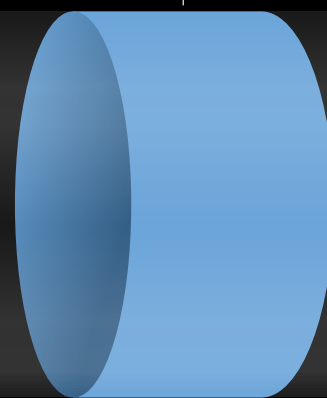
2004 OSG AMENDED

Reference to “compliance **AND ETHICS** programs”. Promote an **ORGANIZATIONAL CULTURE** that encourages ethical conduct and compliance with the law.



1991 OSG ISSUANCE

Organizational Sentencing Guidelines are first issued by the Sentencing Commission. Corporations are offered an opportunity for a **REDUCED SENTENCE** if they have implemented a compliance program.



2017 DOJ/OIG GUIDES

DOJ issues Evaluation of Corporate Compliance Programs: management’s actions and statements demonstrating their leadership in the company’s compliance efforts. OIG issues Measuring Compliance Program Effectiveness Resource Guidance, includes **CULTURE SECTIONS**.

The impact of this "Culture" evolution on our profession?

Institutions expect us to move beyond the assigned role of technical compliance experts and focus on ethical culture

Assert and develop skills to impact corporate ethical culture, one brick at the time

Raise beyond simple influencing and turn into a cultural architect, helping building the corporate ethical culture, fearlessly

Public expectations are favourable to this transformation and so are new generations of businesspeople

Develop creative communication skills to help impacting culture

Kohlberg's Cognitive Moral Development Scale applied to the Evolution of Compliance Programs

Adapted from L. Kohlberg "Moral Development and Behaviour", ed. T Lickona, New York



1 Obedience & Punishment

EXTRINSIC MOTIVATION



Compliance programs are implemented to help **avoid punishment**




2 Instrumental Opportunism & Exchange

EXTRINSIC MOTIVATION



Compliance programs are implemented as they are believed to **give competitive advantage**



3/4 Conformity & Mutual Expectations

EXTRINSIC MOTIVATION



Compliance programs are implemented under **peer pressure**



5/6 Universal Ethical Principles

INTRINSIC MOTIVATION



Compliance programs are implemented to support the **intrinsic value of complying**

Programs aimed at *AVOIDING PUNISHMENT*

The role of our function

- Us vs. them, “otherness” of compliance
- Fear and mistrust
- Legal requirements imposed externally: a constraint
- Sanctions are king
- We must comply, otherwise...
- The law, the law, the law...
- Compliance team perceived as the police
- Compliance is owned by Compliance
- Run by lawyers

Programs aimed at supporting

COMPETITIVE ADVANTAGE

The role of our function

- Compliance is not a burden but a tactic
- “What’s in it for me?”
- Compliance is publicized as part of the corporate strategy
- Positive aspect to be integrated into organizational life
- Compliance team as “business partner”
- Business sees advantages of owning compliance as a desired leadership skill
- Incentives to comply
- Tone at the top is perceived but truly trusted all the way down?
- Business’s interest and awe but real intrinsic belief and ownership?

2



Programs aimed at supporting complying because *"IT IS THE RIGHT THING TO DO"*

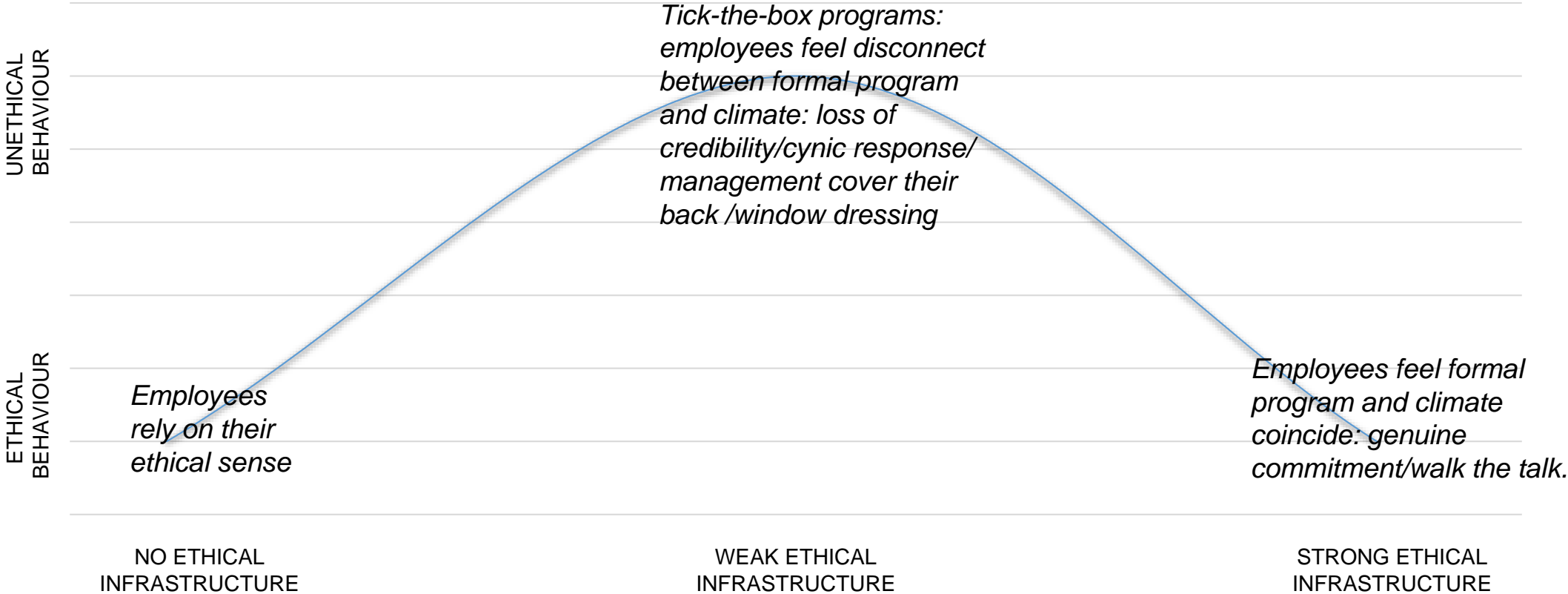
The role of our function

- Doing the right thing is the right thing to do
- Compliance is part of "who we are"
- Positive aspect integrated into organizational life
- Values are integrated
- Compliance rules are followed as business processes
- It is not just that we "must" comply, it is a natural choice ▷ "we comply"
- Compliance as team members, adding value as equals in network
- Compliance is a punctuation in the business narrative
- Business owns compliance
- Written program and ethics culture are one and the same

4/5



Tenbrunsel: Curve Ethical Infrastructure



Ann. E. TENBRUNSEL: Building Houses on the Rocks: The Role of Ethical Infrastructure in Organizations, 16 Soc. Just. Res. 285 (2003).

What are the evolving
professional competencies for
our profession?

Vision: Healthcare Compliance (HCC) Professional facilitates regaining and sustaining of stakeholder, governmental and public trust of Health Care/Life Science Industry as valuable partner in finding treatment solution for patients

Mission: HCC Professional advances and promotes culture of business accountability of ethical business decision making with a focus on mitigating risks of non-compliance

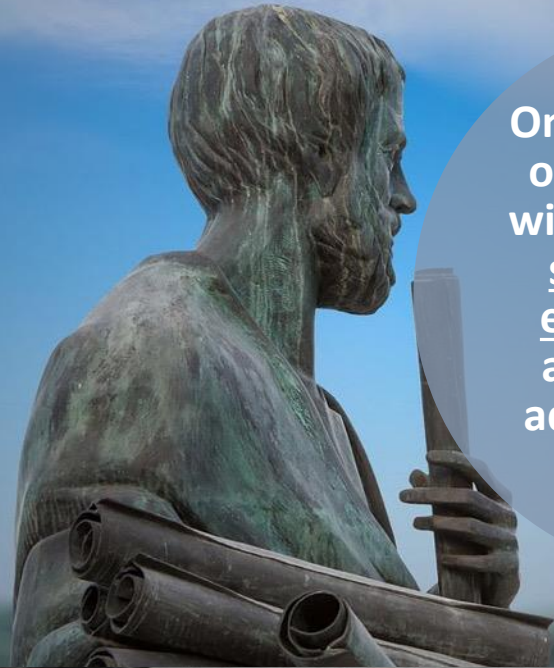
Strategic Pillars of the HCC Professional Function

STRATEGIC PARTNER	CHANGE MANAGER	COMPLIANCE LEADER/ADVISOR
<p>To get alignment on ethical behavior, integrity and transparency</p> <p>For internal stakeholders/business leaders</p> <ul style="list-style-type: none">• understands business strategy and market trends• aligns on present and future compliance risks related to their business• advises business leaders on compliant business solutions, including changes to business models• facilitates development of compliance• SWOT/strategy• fosters candid discussions on business compliance• fosters adequate actions in case of incidents <p>For external stakeholders</p> <ul style="list-style-type: none">• either via supporting/advising the relevant business representative• and/or via active personal participation policy makers' groups (e.g. industry associations)	<p>Facilitates re-positioning of the compliance function "from policing to business partnering" (if needed, if not: ensures the value based positioning)</p> <p>Facilitates competency development for compliant business if needed based on insight into business decision making and customer facing interactions</p> <p>Fosters business accountability</p> <p>Translates HCC into business benefits fosters emotional identification around values</p>	<p>Leading by example & without authority</p> <p>Acts as a role model for compliance and a visionary, inspires and motivates stakeholders</p> <p>Embeds compliance requirements in a simple, easy to understand way into business processes</p> <p>Monitors / tests adherence to compliance programs/local rules and regulations as part of risk assessment,</p> <p>Informs stakeholders / business leaders and ensures relevant actions are taken</p> <p>Leads/facilitates cooperation across different functions to align on compliant and ethical business standards / competencies / strategies / resources / communication</p>
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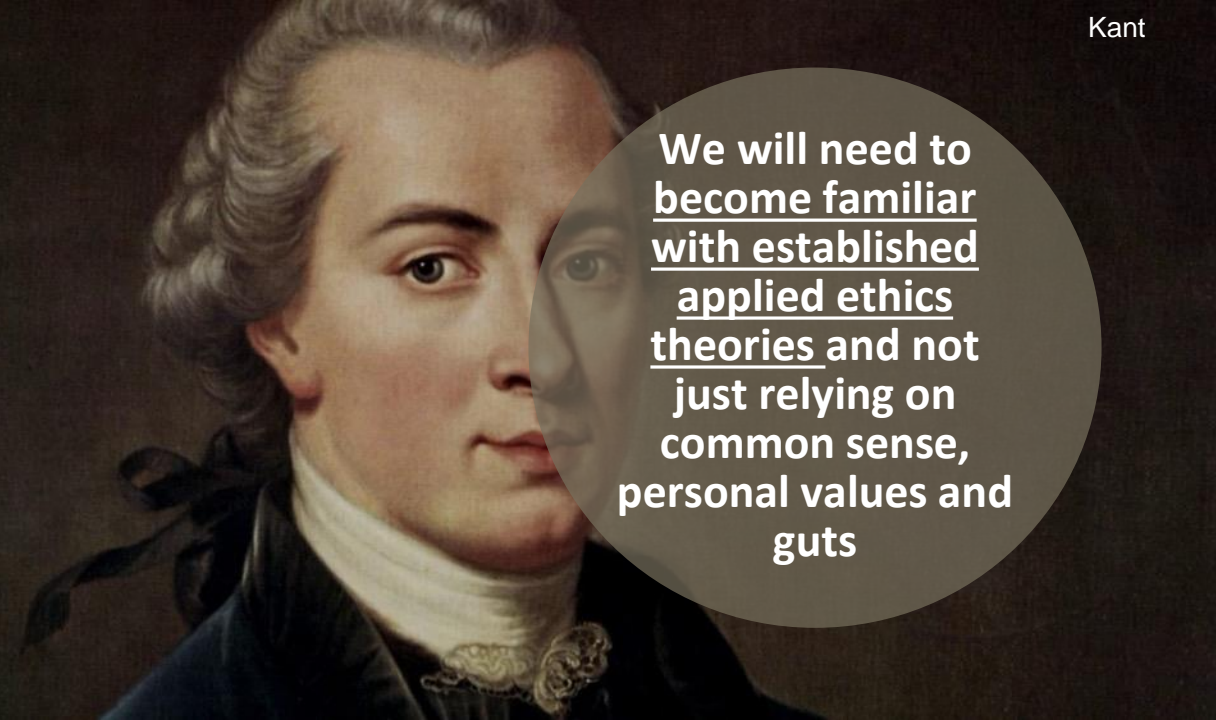


Evolution of the business model

- Increasingly complex models and transactions, driven by access needs and big data
- Artificial Intelligence plays a growing role in healthcare
- Policies and procedures run out of relevance very quickly and cannot cope with the pace
- What is the impact on our profession and its competency expectations?

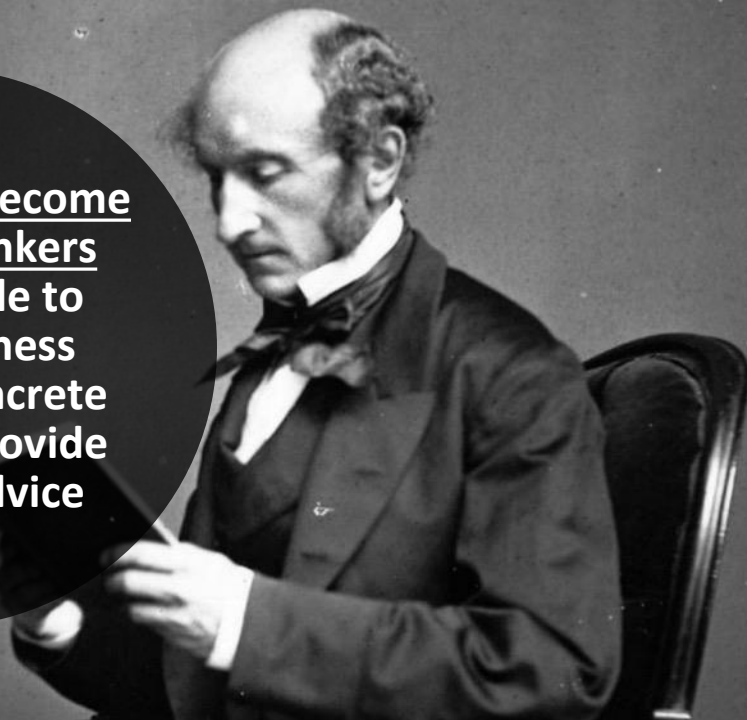


Once rules run out,
our professionals
will need to rely on
sound business
ethics judgment
and knowledge,
adaptable to ever
new scenarios



We will need to
become familiar
with established
applied ethics
theories and not
just relying on
common sense,
personal values and
guts

We need to become
creative thinkers
that are able to
apply business
ethics to concrete
cases and provide
practical advice



Achieve
transformation
from compliance
technicians to
business ethics
professionals



**ARTIFICIAL
INTELLIGENCE** as a
major business
strategy means we
need to understand
its mechanics

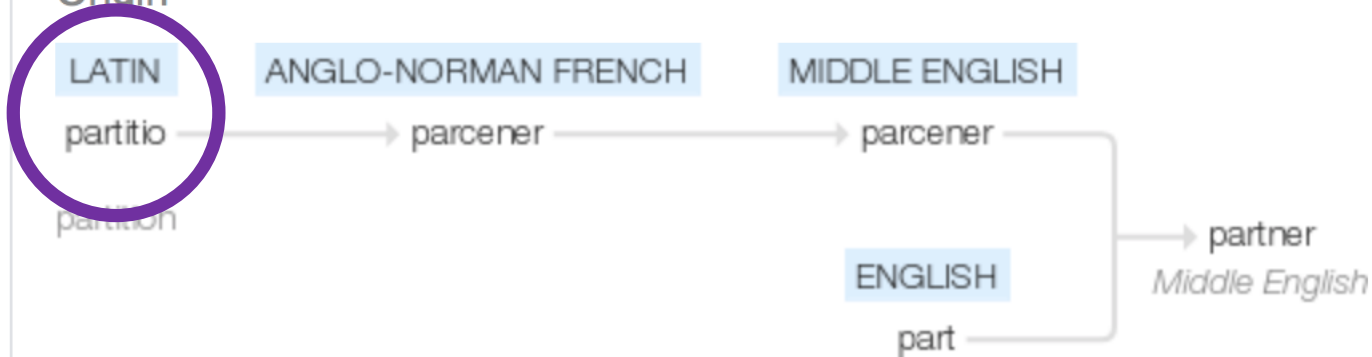
Availability of **BIG
DATA** from internal
processes means
we have a duty to
use it

Develop
technological skills
to understand the
business, provide
advice, build
infrastructure and
detect issues:
**COMPLIANCE BY
DESIGN**

About 3,090,000 results (0.37 seconds)

 **partner**¹
/ˈpɑːtnə/

Origin



Middle English: alteration of *parcener* 'partner, joint heir', from Anglo-Norman French *parcener*, based on Latin *partitio(n-)* 'partition'. The change in the first syllable was due to association with [part](#).



Translations, word origin, and more definitions



Can we move beyond a title where we are defined in relation to another function, regardless of their important role?

Other functions also use “business partners”, as if everyone looks bilaterally at our revenue-generating colleagues in deference and as “support”

Based on its etymology, “business partner” may suggest a binary power relation and a strong concept of “otherness”

Can we look at a title where our value is recognized positively and intrinsically? All members of the same team



Our role is significantly broader than just being partners to the commercial function

It involves a rhizomatic network where we learn from and provide advice to many functions

Constantly collaborating with all roles and functions for the common benefit of the company, as equals

If we do not succeed in elevating our profession, the risk is that the values we represent will also not be elevated

Conclusion

Process expert

Culture architect
& communicator

Advisor on policies

Thinker & ethics
theory savvy

Laws, regulations
and codes

Technology savvy

Technical
Compliance

Business Ethics

Thank you

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