







INTERNATIONAL
SOCIETY OF
HEALTHCARE
ETHICS AND
COMPLIANCE
PROFESSIONALS

Healthcare Ethics & Compliance Competency Model Working Group

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Healthcare Ethics and Compliance Competency Model

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

business decision making with a focus on mitigating risks of non-compliance

Mission: HCC Professional advances and promotes culture of business accountability of ethical

Strategic Pillars of the HCC Professional Function

STRATEGIC PARTNER

transparency

For internal stakeholders/business leaders understands business strategy and market

To get alignment on ethical behavior, integrity and

- trends · aligns on present and future compliance risks related to their business
- advises business leaders on compliant business solutions, including changes tobusiness models
- facilitates development of compliance SWOT/strategy
- fosters candid discussions business compliance fosters adequate actions in case of incidents

- For external stakeholders • either via supporting/advising the relevant
- business representative and/or via active personal participation policy

makers' groups (e.g. industry associations)

CHANGE MANAGER

Facilitates re-positioning of the compliance

function "from policing to business partnering" (if

needed, if not: ensures the value based positioning) Facilitates competency development for compliant business if needed based on insight into

business decision making and customer facing

emotional identification around values

interactions

Fosters business accountability Translates HCC into business benefits fosters visionary, inspires and motivates stakeholders **Embeds compliance requirements** in a simple, easy to understand way into business processes

COMPLIANCE LEADER/ADVISOR

Leading by example & without authority

Acts as a role model for compliance and a

Monitors / tests adherence to compliance programs/local rules and regulations as part of risk assessment,

Informs stakeholders / business leaders and ensures relevant actions are taken

Leads/facilitates cooperation across different functions to align on compliant and ethical business standards / competencies / strategies / resources / communication

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HCC Professional Core Competencies v2.0 **Compliance leader/advisor** Strategic partner **Change manager Communication skills Leadership skills - leading without** Strategic skills Business acumen, understand and listening, asking the right questions, authority self-confidence / courage, self awareness, develop strategy (analytical skills, assertive communication, presentation synthesis), planning, seeing hidden skills, negotiation skills, identifying & motivate & inspire, delegate & empower, problems, differentiating between facts managing manipulative communication ability to receive & give appropriate feedback, making decisions, managing and assumptions, understanding the /hidden agendas context/big picture, aligning on & complexity & ambiguity, facilitate ensuring compliance controls in business Impact/influencing skills development of company competencies, ability to learn & adapt, develop oversight processes selling skills, identifying / managing body language, engagement, coaching, conflict Stakeholder management (internal & management, manage difficult discussions **Ethical role model - leading by** external) example understanding and impacting decision **Project management skills** being open / approachable, patience & making, networking, connecting / stakeholder & resource management, resilience, integrity & reliability, bridging, customer orientation, strategic alignment, implementation accountability, walk the talk, learn & facilitate learning from mistakes alliance, organizational intelligence, working in teams, sensitivity for multicultural aspect Governance understand and become part of the governance structure, keep independence **HCC=** Healthcare Compliance **Personal skills Self management:** prioritization, stress management, work-life balance **Positive attitude:** celebrating success (self & team), sense of humour Use of common sense Content owned by ETHICS. Members may use materials for their personal development, or for any not-for-profit activity within their employing organisation. All other rights reserved.

Content knowledge (experience & training)

Non-HCC knowledge: business strategy / process / systems, budget planning, finance for non-finance

HCC knowledge: HCC strategy / processes / systems, monitoring/testing/auditing, regulatory environment

Self Assessment Tool Objective



To provide a simple, easy to use, flexible tool based on the agreed competency model

For assessment purposes:

- o for self-assessment
- o for giving feedback by the line manager
- o for collecting feedback from stakeholders

For agreement on development areas:

- o proposal is to select the areas of improvement / strength
- o as a general rule select max. 3 based on what could best contribute to performance improvement / enhancement and / or career development
- remember that one should not only focus on the improvement areas but also on the areas of strength



Thank you for the core group testing & feedback: Enno Behrendt, Nys Vincent, Giota Papamarkou

And for feedback and input received during and after the General Assembly 2016, including



Self Assessment Tool Structure



5 tabs: 4 for Core Competencies (Strategic partner, Change manager, Compliance lead, Personal)

1 for Content knowledge

same coloring as in the model PowerPoint (orange, grey)

Content per sheet:

key skills (sub-skills as relevant)

short description of indicators of competence level in key skills (sub-skills)

simple assessment options (none, some, full) with comment opportunity

		Sub-skills (where			ASSESSMENT					
ENCE	KEY SKILLS	relevant)	DESCRIPTION	None	Some	Full	COMMENTS			
GIC PART	TTNER: gets alignment on ethical behavior, integrity and transparency									
	BUSINESS AC	JMEN/STRATEGIC SKILLS: al	bility to understand, develop strategy and get it implemented							
		Analytical ability	1 Open minded, looks for different perspectives/sources for analysis							
			2 Differentiates between facts and assumptions and understands relevance							
			3 Performs risk analysis (retrospective, prospective; with weighting of risk/feasibility)							
			4 Identifies root causes, including hidden problems							
			5 Business acumen (understands how business/functions work, knows competition, understands how strategy translates into operations)							
			6 Understands big picture (and also details), strategy and trends (business, Ethics & Compliance/Healthcare Compliance, environment)							
		Strategic skills	1 Sets priorities based on the analysis							
			2 Develops options based on risk assessment (prevention, resolution, management)							
			3 Develops mission, vision, objectives, strategy, positioning of compliance based on business acumen							
			4 Embeds compliance controls into business processes							
			5 Translates strategy into SMART (specific, measurable, actionable, realistic, time bound) plan to ensure compliant business decisions							
			6 Ensures timely implementation, including follow up, measurement and corrective actions							
	STAKEHOLDE	R MANAGEMENT (internal &	external): understands and impacts the decision making process towards ethics (within & outside the company)							
		Understands the decision	1 Identifies/maps key stakeholders and stakeholder groups (understands attitudes/behavior & relative importance: roles, relations, organizational & functional power	·)						
		making process	2 Uses networking, individual and team meetings and other sources to collect proper stakeholder insight (including their interest)							
			3 Understands organizational politics & behavior (culture, formal & informal networks, power, dynamics)							
			4 Identifies cultural differences relevant for the Ethics & Compliance/Healthcare Compliance program							
Im		Impacts the decision	1 Influences individual & account mindsets toward ethical decision making based on stakeholder mapping							
		making process	2 Manages cultural differences to get the compliance messages through effectively							
			3 Influences politics and power structures appropriately to achieve the right outcomes							
			4 Builds and maintains strategic alliances							
			5 Builds trust within and outside the company							
	GOVERNANCE									
			1 Understands organizational/corporate governance structure							
			2 Becomes influential in the organizational/corporate governance structure							
			3 Keeps independence							



Self Assessment Tool Strategic Partner



CORE COMPETENCE	KEY SKILLS	Sub-skills (where relevant)	DESCRIPTION						
COMPETENCE		relevant)							
STRATEGIC PAR	TNER: gets alig	nment on ethical behavior	, integrity and transparency						
	BUSINESS ACUMEN/STRATEGIC SKILLS: ability to understand, develop strategy and get it implemented								
		Analytical ability	1 Open minded, looks for different perspectives/sources for analysis						
			2 Differentiates between facts and assumptions and understands relevance						
			3 Performs risk analysis (retrospective, prospective; with weighting of risk/feasibility)						
			4 Identifies root causes, including hidden problems						
			5 Business acumen (understands how business/functions work, knows competition, understands how strategy translates into operations)						
			6 Understands big picture (and also details), strategy and trends (business, Ethics & Compliance/Healthcare Compliance, environment)						
		Strategic skills	1 Sets priorities based on the analysis						
			2 Develops options based on risk assessment (prevention, resolution, management)						
			3 Develops mission, vision, objectives, strategy, positioning of compliance based on business acumen						
			4 Embeds compliance controls into business processes						
			5 Translates strategy into SMART (specific, measurable, actionable, realistic, time bound) plan to ensure compliant business decisions						
			6 Ensures timely implementation, including follow up, measurement and corrective actions						
	STAKEHOLDER	R MANAGEMENT (internal	& external): understands and impacts the decision making process towards ethics (within & outside the company)						
		Understands the decision	1 Identifies/maps key stakeholders and stakeholder groups (understands attitudes/behavior & relative importance: roles, relations, organizational & functional	power)					
		making process	2 Uses networking, individual and team meetings and other sources to collect proper stakeholder insight (including their interest)						
			3 Understands organizational politics & behavior (culture, formal & informal networks, power, dynamics)						
			4 Identifies cultural differences relevant for the Ethics & Compliance/Healthcare Compliance program						
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		making process	2 Manages cultural differences to get the compliance messages through effectively						
			3 Influences politics and power structures appropriately to achieve the right outcomes						
			4 Builds and maintains strategic alliances						
			5 Builds trust within and outside the company						
	GOVERNANCE								
			1 Understands organizational/corporate governance structure						
	2 Becomes influential in the organizational/corporate governance structure								
	3 Keeps independence								
Strategic	partner (Change manager	Compliance leader advisor Personal skills Content knowledge						



Self Assessment Tool Change Manager



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CORE COMPETENCE	KEY SKILLS	Sub-skills (where relevant)				DESCRIPTION			
CHANGE MANA	GER: fosters	relevant changes to ϵ	ensure pro	pper accountability, clear roles and responsibi	ilities, competences, resou	urces and positive attitude for eth	nical business		
4	COMMUNICATION SKILLS								
1			1 Listens actively with right attention; interested in and understands different views/opinions						
			2 Asks th	2 Asks the right questions (asks, manages a mixture of closed and open questions as relevant, clarifies)					
			3 Comm	unicates clearly to achieve the desired outcome	es				
			4 Identif	ïes and manages non-verbal communication ele	ements (body language/voi	ice)			
		J	5 Presen	tation skills: presents info clearly and effectivel	ly, adapting to audience size	e and composition			
		J	6 Comm	unicates assertively (able to represent opinion i	in a calm & positive way wi	thout being aggressive or submissi	ve)		
			7 Selects	appropriate communication channels for optir	mal messaging in accordanc	ce with stakeholder management (s	see Strategic Partner tab)		
		J	8 Transla	ates complex issues into simple, understandable	e messages				
	IMPACT/INFLUENCING SKILLS								
	1 "Sells" compliance (selling skills: identifies needs, finds & communicates benefits of compliance, bridges needs & benefits, identifies "buy-in" signal, follow						enefits, identifies "buy-in" signal, follows up)		
			2 Identifies & manages different communication styles (e.g. manipulative behavior or indifference of partners; manages difficult discussions)						
	3 Negotiates effectively (clear objectives, understands boundaries, willing to give & take, identifies common goals, recognizes partner as a partner)						cognizes partner as a partner)		
	4 Creates engagement (joy, alignment, recognition) around compliance								
			5 Coachi	ng skills (improves performance/competences	of others as a facilitator of	learning, helps to find the right ans	swers)		
			6 Manages conflicts (prevents, accepts, resolves as relevant)						
	PROJECT MANAGEMENT SKILLS								
			1 Develops projects (identifies needs/objective, stakeholders, resource needs, deadlines, key success factors, deliverables, risks and preventive measures, controls)						
			2 Leads projects towards agreed objectives (manages stakeholders, resources, risks, reports, monitoring, interrelationships, corrections, change)						
Strategic	partner	Change man	ager	Compliance leader_advisor	Personal skills	Content knowledge			



Self Assessment Tool Compliance Lead/Advisor



CORE COMPETENCE	KEY SKILLS	Sub-skills (where relevant)	DESCRIPTION			
COMPLIANCE LE	ADER/ADVISO	OR				
	LEADERSHIP	SKILLS - leading without auth	ority			
			1 Self confident and courageous, ready to raise concerns			
			2 Has self-awareness, proper insight to learn and adapt if needed			
			3 Motivates & inspires self & others			
			4 Delegates & empowers others to create proper level of accountability			
			5 Makes decisions			
			6 Able to give and receive appropriate feedback			
			7 Manages complexity and ambiguity			
	8 Facilitates development of relevant company competencies					
	ETHICAL ROL	E MODEL - Leading by examp	le			
			1 Walks the talk, demonstrates high ethics & integrity standards, honest, transparent			
			2 Learns and facilitates learning from mistakes			
			3 Reliable partner, takes accountability for actions and decisions			
			4 Is a trusted partner			
			5 Has an open door policy, is accessible			
			6 Passionate about ethics, integrity & compliance			
Strategic par	tner Cha	nge manager Complian	ce leader_advisor Personal skills Content knowledge			



Self Assessment Tool Personal Skills



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CORE COMPETENCE	KEY SKILLS	Sub-skills (where re	:levant)			DESCRIPTION			
PERSONAL SKILI	ERSONAL SKILLS								
	SELF-MANAG	GEMENT							
				1 Sets and follows priorit	ties, does not get bur	ied in transactional/ad hoc	tasks		
<u> </u>			Ţ	2 Manages stress (preven	nts, dissolves, reduce	es)			
			Ţ	3 Keeps a good work-life	balance				
			J	4 Keeps good sense of hu	umour (even in mom	ents of hopelessness)			
			J	5 Self-calibration and ten	nperance; controls di	isruptive impulses and moo	ods/emotions		
			Ţ	6 Trigger frequent and honest reality checks (self-awareness)					
				7 Keep actions appropriate to challenges					
	POSITIVE ATT	TITUDE							
				1 Stays constructive, stay	ys polite, looks for so	olutions & positives, avoids	being overly critical		
<u> </u>			Ţ	2 Acknowledges and cele	ebrates success (self	& others)			
4				3 Uses humour to positively influence (even in moments of hopelessness)					
4	COMMON SE	ENSE							
<u>i</u>				1 Does not overcomplica	ate, is pragmatic				
il .			Ţ	2 Is able to translate com	nplex matters into a la	anguage that makes sense t	to the audience		
				3 Uses common sense to receive buy-in from key stakeholders					
Strategic pa	rtner Ch	ange manager (Compli	iance leader_advisor	Personal skills	Content knowledge			



Self Assessment Tool Content Knowledge



CONTENT KNOWLEDGE	CONTENT TYPE	ELEMENTS
	HCC knowledge	
		1 Company Ethics & Compliance/Healthcare Compliance/Bribery and Corruption Prevention strategy (mission, vision, strategic objectives) long & short term
		2 Company HCC written standards, policies, processes and procedures including guideline (Ethics statement, if separate)
		3 Company risk based monitoring, testing, audit guidelines/processes
		4 Company HCC analytics (key performance indicators, dashboards, trends)
		5 Company HCC related systems including internal control systems and framework
		6 Risk Management Knowledge including risk assessment, mitigation and prevention
		7 Regulatory environment (laws, codes, regulations - local & applicable international ones)
		8 Follows HCC related news/publications (like FCPA, CEB, others)
	Non-HCC knowledge	
		1 Company business strategy (mission, vision, strategic objectives) long & short term
		2 Business plans & mid term forecasts of the company
		3 Relevant business processes of the company (e.g. marketing, medical, HR, procurement, finance, communication)
		4 Key products, services & therapeutic areas of the company
		5 Relevant business systems of the company
		6 On-boarding & development content for customer facing employees & managers
		7 Finance for non-finance
		8 Insight on business dynamics, including trends & role of players in the company and the market
		9 Awareness of the product life cycle, distribution channels, payment methods

Strategic partner

Change manager

Compliance leader_advisor

Personal skills

Content knowledge







Actions agreed at the General Assembly 2016 – status overview



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- ✓ Develop a Communication Plan & Strategy
- ✓ Consolidate feedback on Self-Assessment Tool
- **✓ Finalize Self-Assessment Tool**
- **✓** Endorsement from ETHICS Strategic Committee & Bureau
- ✓ Webinar Sessions with Q&As now
- ✓ Website Update
- Healthcare Ethics & Compliance Competency Model next version