Manage Compliance and Ethic risks in Pharma Industry

Key principles to establish efficient compliance program in the organization

Kfir Manor, CPA

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Agenda

- Five key ethic risks in Pharma Industry
- What is the effect on the business?
- Do we have effective instructions
- Five key Compliance risks
- Efficient compliance and ethic program
- What should be our action plan for remediation?

Five key ethic risks in Pharma Industry

- Interstation with HCPs (Off label promotion, samples, Promotional Material etc.)
- Interaction with Patients (POP, Data privacy, Adverse Event, DTC etc.)
- Interaction with Public Official (Anti Bribery, Antitrust, Commercial interaction etc.)
- Interaction with Health Authorities (registration, re registration, labeling, Grants etc.)
- Supply chain (GxP, re call, batch release, drugs, special condition, lead time risk for life saving drug etc.)

What is the effect on the business?

- Poor health / safety conditions - Loss of time / money for remediation (**Reputation**, training, QA issue etc.) (2)
- Non-standardization / harmonization - No efficiency
- Business continuity / Risk Management S&MBs (10)
- Poor control environment, high risk for fraud (7)
- Low business management capability

Do we have effective instructions ?

- Commit before reading (training material, SOP, expense reimbursement, declarations etc.) [6]

- The instructions should be available and clear

- The structure of the instructions should be in accordance with the organization culture and needs (code / policy / SOP / Work Instruction etc.) – to keep the relevancy of the content to the audience

- Training should be on a frequent basis (frontal / web / R&U) – effectiveness: tests, record scores etc.

- A Policy of Consequences (no exclusions) should be in place – e.g. 'Three-strikes law' [8], 'implicit deterrence vs. specific deterrence' [10]

Five key compliance risk(1)

- Employee are not aware of the policies
- Policies are not clear / practical
- Executives should lead by example, but they don't
- Employee believe it's not their concern
- They know the policy won't be enforced

Efficient Ethic Program ₍₁₎

- Establish Compliance Committee, led by senior management cross functional
- Establish internal ethic code by adopting the Industry ethic code
- Defined detailed and efficient SOPs to enable standatization (e.g. define professional clearance process)
- Define Monitoring process (including enforcement and deterrence)
- Define Compliance and ethic training program

What should be our action plan for remediation?

- Ten Commandments principle – get people engaged (6)
- Babylon principle - avoid unnecessary / unclear instructions (simplification / right context) (4)
- An eye for an eye principle - Enforce oversights
- 1:98:1 principle – "Just give me a reason" – P&L
- Milgram principle (5) (experimental) – the unlimited power of authority (Nominate compliance champions / "train-the trainer" (9) and adopt efficient instruction training program)

References

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(4) Leading Global Projects (by Moran & Younghal)

(5) https://en.wikipedia.org/wiki/Milgram_experiment

(6) "The Dishonesty of Honest People: A Theory of Self-Concept Maintenance' Journal of Marketing Research (2008). Nina Mazar, On Amir and Dan Ariely

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(8) https://en.wikipedia.org/wiki/Three-strikes_law

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Contact details:
Manor-k@bezeqint.net
054-5211699