



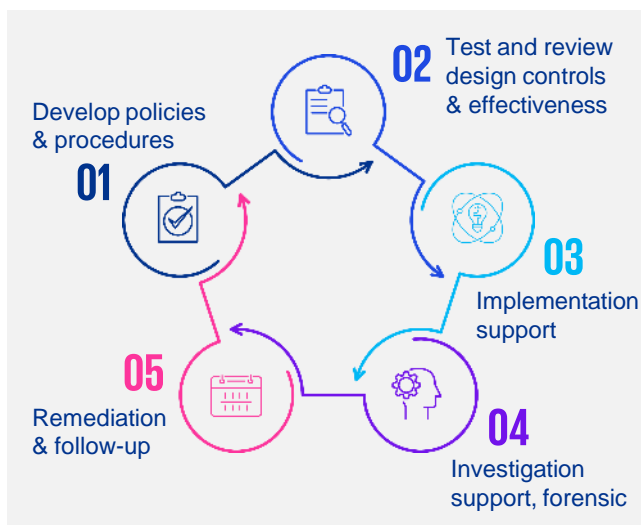
Internal Audit and Forensic Services

Pharmaceutical Industry

KPMG in Hungary

Changing regulatory framework and circumstances create challenges for pharmaceutical industry. Resilience to new conditions is crucial for ensuring ethical and transparent business conduct and compliance with the regulatory requirements.

Essential elements of effective compliance, as the second-level, and internal audit, as the third-level control functions, as well as of their ability to respond in time to constantly changing regulatory and macroeconomic challenges are independence, qualified professionals, sufficient sources, adequate control environment and risk assessment.



How we can help

- Supporting the preparation for compliance assessment
- Internal audit services, control testing (outsourcing, co-sourcing, ad-hoc)
- Assessment and implementation support (e.g. trainings and communications)
- Anti-corruption and anti-bribery framework assessment
- Fraud and misconduct investigations, regulatory investigations
- Supporting remediation and follow-up actions

Challenges for the sector

- Regulatory changes
- Inefficient controls and processes
- Third party risk management
- Fraud, misconduct, or other violations of laws, regulations or company policies
- Temporary resource management challenges (difficulties in hiring, peak seasons, ad-hoc and regular procedures of the competent authorities)
- Lack of knowledge required for the internal audit (IT, HR, Finance)

Improving competitiveness by enhancing internal control environment

Internal audit, compliance and forensic services provided by KPMG can contribute to ensuring compliance with the applicable regulation, in preparation for (group) internal audits, in improving effectiveness, and in mitigating compliance risks (reputational risk, risk of financial loss, risk of fines and sanction) by continuous and independent control activity.

An enhanced internal control system is an element of compliant and ethical business operation.

Examples for relevant rules and regulations which we rely on when working on anti-bribery and corruption engagements:

National:

- Local laws
- Regulation of the National Authority of Pharmacy
- Company-level EFPIA Transparency Disclosure Report
- Company-level regulations, policies and standard operating procedures (SOP)

International:

- OECD Anti Bribery Convention
- US Foreign Corrupt Practices Act (FCPA)
- European directives and regulations
- EFPIA Code (European Federation of Pharmaceutical Industries and Associations)
- UK Bribery Act
- PhRMA Code
- Industry codes, other standards

KPMG Hungary has extensive, cross-sectoral experience in providing internal audit, compliance & forensic services

1

Internal Audit Support

- Financial audit
- Compliance audit

2

Regulatory Enforcement & Compliance Services

- Pharmaceutical and life sciences regulatory services
- Consumer protection services
- Other regulatory enforcement and compliance services

3

Internal Investigations

- Fraud and misconduct
- Investigations support

4

Forensic Technology

- Digital evidence recovery
- Evidence and discovery management
- Forensic data analytics
- Records information management

5

Anti-Bribery & Corruption Services

- Anti-bribery and corruption proactive services
- Anti-bribery and corruption reactive services

6

External Dispute Advisory Services

- Expert witness
- Dispute consulting
- Arbitrator, mediator or independent expert
- Litigation support

Our references from the pharmaceutical industry



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