

Building a strong, risk-based
technology compliance
foundation to create
competitive advantage

Moving forward

Industry challenges require new technology solutions

The pharmaceutical and life sciences industry is currently facing unprecedented compliance challenges, and the close regulatory scrutiny of the industry is unlikely to abate anytime soon. Globalisation, information protection requirements (privacy, security), business partnerships, heightened transparency expectations, external reporting obligations, and other drivers force companies to re-examine their enterprise approach to IT governance, risk, and compliance.

New and different risks and compliance requirements are emerging as companies increase their reliance on technology to achieve the necessary transformation of commercial and R&D processes, extend the walls of the virtual organisation, automate business processes, share increasing amounts of sensitive information and data on a global basis, and to ultimately create a competitive business advantage for the company.

To help our clients explore the challenges of this changing landscape, PwC recently surveyed 17 pharmaceutical companies on the issues surrounding information technology (IT) governance, risk, and compliance management.

What we learned: a PwC survey on risk and compliance

PwC's IT governance, risk, and compliance (GRC) survey of pharmaceutical and life sciences companies reveals a consistent challenge across the industry: a siloed approach to IT organisation, process, and technology has resulted in reactive and costly technology compliance efforts that are based on functional or regulatory requirements rather than an efficient and cost-effective risk-based approach that provides a foundation for innovation and competitive advantage.

Among the survey highlights:

Organisations have broad and varying definitions of risk. All respondents indicated they have a sustainable IT risk management process in place to identify risk. However, only 60 per cent have consistently defined risk and applied that definition to decision-making.

Nearly all of the survey respondents have deployed a documented IT strategy and vision that clearly articulates IT goals; however, only slightly more than half of the respondents indicated that IT governance groups include both IT and business representatives.

Most survey respondents said IT policies and standards have been defined based on key IT risks, and that procedures align with and support policies. However, in many cases companies have established overlapping and redundant policies, standards, or procedures, and they do not follow a consistent set of documents.

Many pharmaceutical companies see IT compliance as a necessary evil; about 30 per cent see IT compliance as a process that can help the business better manage its processes, increase efficiencies, and ultimately create a competitive business advantage.

Data management is a significant area for improvement within the industry, particularly in areas of defining data owners, establishing a sustainable data cleansing process, and protecting data based on its associated business value and sensitivity.

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Implementing an integrated approach to IT risk and compliance

The complex layers of IT GRC cannot effectively operate in silos if companies hope to achieve the innovation that will keep them ahead of the competition. The industry's transformation will require that pharmaceutical companies first build a strong foundation for compliance that acts as a springboard for distinctive and innovative business solutions.

PwC can help your company develop an integrated IT GRC programme. To do so successfully, companies should consider a number of actions, including:

Establish a process to define and organise key risks, determine the impact and likelihood of the risk, evaluate the adequacy of existing controls, and assign appropriate owners for each risk

Establish a process to make decisions on the level of risk that is acceptable, aligned with the organisation's business objectives and the overall enterprise risk management programme

Establish focused policies that target management's key risk areas, along with supporting standards and procedures where necessary

Align audit activities and functions based on the results of the risk assessment and GRC framework

Create a continual improvement process that identifies the root cause of compliance gaps, anticipates and addresses potential risks, evaluates trends, anticipates future risks based on emerging changes in regulation or business conditions, and establishes timely solutions

Select and deploy appropriate tools to monitor the effectiveness of compliance on a consistent and ongoing basis across locations

Benefits to your business

There are several benefits of taking an integrated approach to risk and compliance:

Management can establish a defined method for decision-making regarding risks, controls, and compliance that ensures the organisation considers key risks

Companies can better anticipate and manage risks before they become problems and mitigate potential reputation damages, fines, penalties, or lost revenue

A focussed set of controls that addresses risk can help manage the cost of compliance.

Improved alignment between management and internal/external audit groups can simplify the audit process and allow redeployment of resources for other strategic initiatives and activities

The time and money that can be saved will become more important as IT shifts its focus to automating business functions, managing data, and enabling the innovation essential to discovering the preventive medications for the future

Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 161,000 people in 154 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.