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Mitigating compliance risks in the Life Sciences sector

Maintaining a cost effective balance between compliance and risk

The Global Life Sciences industry[1] is undergoing major changes driven by changing business and consumer needs that are closely mirrored by regulatory changes. While cost pressures have shifted the focus from branded and innovator drugs to generic drugs, new concerns pertaining to the consistency in quality, efficacy and safety of these generic products have persistently challenged regulators, and manufacturers on an on going basis. In addition to these quality related challenges, the sector has been in the news for adopting unethical and allegedly fraudaulent manufacturing practices to achieve business objectives.

All these adverse findings have prompted key regulatory bodies like US FDA, EMA, DoJ, SFO etc to increase and extend their scope of overview beyond the traditional risk parameters and now include quality systems among others. Any action by these agencies for non-compliance with guidelines could result in Life Sciences companies risking erosion not just in their profit margins but brand image too. In the context of ever reducing margins, any negative regulator action could result in financial closure for some companies.

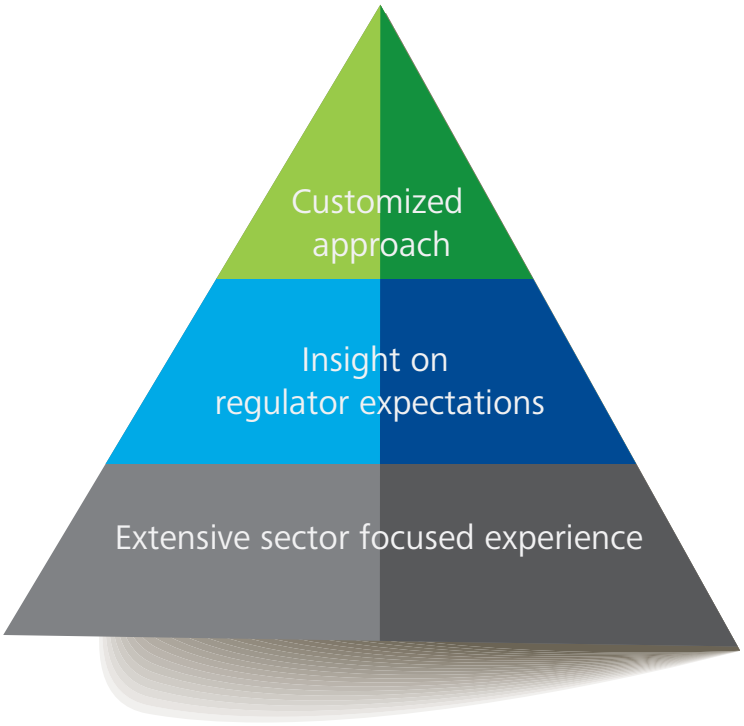
We at Deloitte Touche Tohmastsu India Private Limited (Deloitte) can help you prepare and manage your global compliance obligations and tackle fraud risks better. We can provide you access to our global teams consisting of professionals drawn from industry and regulators. These teams come with indepth operational knowledge and skills of various functions across the pharma value chain.

[1] Comprising of the Pharmaceutical, Biotechnology, and Medical Device industries

Our Approach

We engage closely with Life Sciences organizations to identify, assess and manage their fraud and compliance risks with a three tier strategy (represented below).

This helps us offer a range of services that are integrated with the company's overall fraud risk and compliance management initiatives.



Our Leading Services

Regulatory Impact Assessment
The key objective of this Deloitte Assessment tool is to help experienced regulatory practitioners with assessment of the impact that a defined set of regulations (e.g. cGMPs, 21 CFR Part 11, 210, 211, 820) would have on their business. These assessments are generally undertaken when regulations, applicable to a client's existing operations, are being reviewed and amended and the client needs to understand the depth of impact on the overall business. It could also be useful to assess impact of regulatory burden on a new operational set up.

Regulatory Gap Assessment
The Regulatory Gap Assessment is a tool that our team uses to assist clients in assessing the gap between their current state of operations and that of a defined set of regulations (e.g., cGMP/GDP/GLP/GPvP). This type of assessment is undertaken when a client needs to understand whether they meet compliance with existing regulations and/or any upgrades that may be required to achieve acceptable levels of compliance with the authority regulations

Process Validation Requirements
This is in-depth assessment of existing validation programs and strategy to help clients measure compliance with current guidance. The USFDA defines validation as a documented process of demonstrating, that a process, procedure, method, piece of equipment, or facility will consistently produce or deliver a product or result that meets set specifications and quality standards.

Assessement and resolution of current inspection findings
We can review and assess inspection findings of competent regulatory authorities and suggest action plans to prevent future risks and evolve the systems.

Assessement of compliance technology systems
Our professionals can review technology systems that

process various aspects of the quality system, including Deviations, Corrective Actions and Preventive Actions (CAPA), Change control, and complaint handling. Our global team can suggest and support in vendor selection for supply of Quality Management software such as TrackWise , SOLABS, and Smartsolve. These software are now the mainstay of managing and minimizing risks associated with data integrity effectively and efficiently.

Internal QA Audits of Manufacturing and Quality
We can review and assess the Standard Operating Procedures (SOPs), current training programs, CAPA protocols, change control, self-inspection programs and management protocols for internal/ external audits. We also recommend/suggest improvement actions and provide reports to the Management on identified high risk areas.

GMP Gap Assessment
We can review existing controls and procedures to measure compliance with competent authority regulations and guidelines. We can also help with setting internal benchmarks for future state of compliance with Competent Authority regulations, besides reviewing recent FDA inspection trends to assist organizations with evolved compliance and operational strategies.

Pharmacovigilance
We provide 360 degree services across the Pharmacovigilance and Drug Safety value chain. Our team consists of global Pharmacovigilance practitioners with hands on experience of managing complex and global operations.

Compliance Strategy and Transformation
The compliance landscape has been evolving over the years and only companies with a robust well-designed compliance program are in a position to manage their compliance needs. We can support and help clients design, implement and monitor such programs so that they can stay ahead of the obligations curve and quickly adapt to the challenging environment.

Regulatory due diligence
In the past many investors have suffered financial losses and continue to do so, on account of not having an independent regulatory diligence report which would have provided them with a true picture of their investee company's regulatory compliance. We can review critical documentation pertaining to product, manufacturing licenses, inspection findings reports etc and provide the clients with a status report.

Managing Anti-bribery and corruption compliance
We help you manage risks arising from non-compliance with global regulations such as the Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act (UKBA) as well as local legislations in this area. We also help create a framework to manage these risks proactively which involves review, evaluation and recommendations on code of conduct, ethics policy, gifts policy, and accounting of such transactions. We also conduct workshops and awareness programs to help employees of Life Sciences companies to understand the impact of their potential actions pertaining to bribery and corruption. This includes managing third party compliance also such as by vendors and business partners.

Whistleblower services
Non-compliance is increasingly being reported via whistleblower complaints and regulatory bodies across the world have mandated that companies offer a safe, secure, confidential and anonymous channel to employees, business associates and parties to report any suspicious concerns. We can help life sciences companies establish and manage their whistleblower channels. We can also offer support in reviewing whistleblower complaints and recommending suitable actions including remediation, third party investigations, and legal recourse.

The Deloitte difference
Deloitte Forensic services in India bring together individuals from across geographies with significant local and global Life Sciences industry and regulatory experience. Globally, we are recognized as a leader in end-to-end compliance management services. Our India leadership has strong Forensic experience exceeding 10 years on average for every leader. We follow a flexible and cost-effective approach, thereby avoiding the negative implications of rigid, one-size-fits all solutions.

Contact us

To discuss your business challenges and possible solutions, please contact:

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