Managing growth through better compliance management
A survey report

June 2015
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The Indian Pharmaceutical sector is the third largest in the world, growing at a CAGR of 14-15 percent between 2012-16, and is expected to generate revenues worth USD 55 billion by 2020. With exports constituting 53 percent of these total revenues, the industry has made significant investments in upgrading their manufacturing plants to international standards set by regulatory bodies such as the United States Food and Drug Administration (USFDA), UK’s Medicines and Healthcare products Regulatory Authority (MHRA), European Directorate for the Quality of Medicines (EDQM), and Australia’s Therapeutic Goods Administration (TGA), among others.

India today has about 546 facilities approved by the USFDA, 857 facilities approved by the UKMHRA and 1295 facilities approved by the WHO-GMP. These impressive numbers give India the distinction of having one of the highest number of USFDA, MHRA, WHO-GMP approved manufacturing facilities outside of the US and Europe, exporting large volumes of medicines to these regions. To manage such a high number of facilities and their compliance standards, the USFDA has opened two local offices with investigators based in India to facilitate inspections (surprise checks as well as notified ones).

Additionally, the European Union regulatory bodies and the US FDA now collaborate closely to share inspection findings and compliance gaps they identify.

These coordinated efforts by foreign regulators have uncovered several instances of non-compliance among Indian life sciences companies pertaining to manufacturing practices, data management, quality control practices, as well as overall questionable industry practices (tipped off by whistleblower complaints). These instances of non-compliance have been penalized by levying large fines, import bans (in the last two years, import ban orders have been issued by the USFDA and Canada’s Health Canada to more than 25 Indian API and formulations), and posing threats to business, forcing companies to re-look at their compliance management processes.

To understand the perception of life sciences companies in India on managing the challenges of regulatory non-compliance, and their views on the state of internal controls as well as drug production standards, Deloitte Forensic, released a survey questionnaire in August 2014 seeking responses from risk and compliance professionals in the industry. The findings of the survey have been developed into this report.

The majority of our survey respondents have identified compliance challenges and shortage of skilled resources as hampering their company’s growth. In our opinion, these concerns have existed for some time within the industry, but recent strong enforcement action by regulatory bodies has brought these issues to the forefront. This report provides pointers for companies to assess and take action in the area of product and process compliance and also provides some practical insights on building a resource pool to manage forthcoming compliance requirements.

We hope you find this report useful.

Foreword

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Director

3 Source: http://indiaratings.co.in/upload/research/specialReports/2014/5/7/india07impact.pdf
4 Source: Pharmexcil Report - http://www.pharmexcil.com/circulars/list-of-whogmp-usfda-mhra-edqm-approved-indian-companies-products/893/239f2813416dafa5c3ef5c8ed90734a0d.html
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Non-compliance - A serious challenge to growth

Challenges in compliance management

Deloitte's point of view

We believe that for organizations to minimize the risk of compliance failure, they need to have a 360 degree approach to managing compliance and fraud risks.

Detecting fraud and managing non-compliance and malpractice

Conclusion
Non-compliance
A serious challenge to growth

Regulatory non-compliance is a challenge that can hinder the life sciences sector’s growth in India. Around 64 percent of survey respondents have attributed non-compliance to shortage of skilled staff (in their risk and compliance teams), followed by challenges in implementing cGXP guidelines (52 percent), complying with professional association guidelines (42 percent), and poor fraud risk management systems (36 percent).

The fast pace of growth in the Indian life sciences sector has resulted in scarcity of talent at several levels and across functions within a life sciences enterprise. However, this scarcity is relatively higher in the compliance management function, due to frequently changing regulatory requirements and increasing number of approved facilities. For instance, in the last two years, most regulatory bodies have introduced new areas of scrutiny beyond just testing drug efficacy and now involve risk management and mitigation programs for R&D laboratories, manufacturing facilities and procurement functions. For compliance management professionals to familiarize themselves with these changes and become adequately trained in them requires time. In the interim, companies could be exposed to vulnerabilities arising from non-compliance. About 55 percent of survey respondents have indicated that their compliance teams were not adequately trained to address the regulatory requirements.

In our view, creating a long term training program to keep industry professionals updated with much needed skills across functions in the Life sciences sector life cycle would help tackle the issue of talent shortage. Companies can work together with regulatory bodies to set up training and development courses that professionals can be certified in. The India Skills Report 2014 notes that unlike other industries where multinational companies have established alliances with academic institutions on endeavors such as research incubation, faculty development, internships, curriculum revision programs etc., the life sciences industry is found lagging in such initiatives.

Further, about 25 percent of survey respondents representing small sized companies in the sector (revenues below Rs 100 Crore) indicated that the level of non-compliance in the life sciences sector was less than any other regulated sector. In our view, this could indicate lack of understanding of regulatory obligations at a senior management level, which could directly impact the ground level implementation of regulatory compliance measures.
Poor internal controls facilitate malpractice

Around 61 percent of survey respondents felt that there was a lack of internal controls and compliance processes to proactively manage and mitigate the risk of non-compliance. This has also been indicated in multiple inspectional findings by various regulatory authorities and details are available on their respective websites.

In our view, this can be attributed to the lack of a zero tolerance approach to non-compliance and malpractice among senior management, as endorsed by 30 percent of the survey respondents. In the past, the life sciences sector in India has come under scrutiny for several malpractices such as bribery and corruption, financial misrepresentation such as inflated sales numbers, diversion and theft of assets, counterfeiting and misuse of funds. For a long time these were acceptable business practices, until the Indian regulatory bodies intervened to create guidelines around sales and marketing. However, we continue to observe these malpractices in the sector, although close to half of survey respondents felt otherwise.

About 55 percent of respondents indicated that weak enforcement action by regulatory bodies, such as USFDA, MHRA, TGA and others, is likely the cause for repeat incidents of noncompliance. In our understanding inspections by regulatory bodies in the past were inconsistent. While it was recommended by regulatory authorities that inspections happen every two years, there have been cases where the gap between inspections was as much as four years. At times, the duration of each inspection may have also been insufficient to comprehensively cover non-compliance. However, today, the situation is changing. With regulators setting up local offices and equipping themselves to conduct spot audits, weak enforcement action is unlikely to be a reason for repeat incidents of non-compliance in the future.

Around 45 percent of survey respondents also felt that organizations did not invest in available technology to manage quality risk related processes and controls. This could be attributed to a lack of understanding of how technology can help in improving compliance management, especially as regulators in the past did not insist on electronic data verification during inspections. Only one third of survey respondents pointed to the pressure of achieving unrealistic targets as a reason for malpractice. We feel this is a conservative estimate, as other surveys conducted (by us and other organizations) have indicated this factor as key to the rising levels of non-compliance and fraud in India.

KEY CONTRIBUTORS TO MALPRACTICE AND NON-COMPLIANCE IN THE SECTOR

<table>
<thead>
<tr>
<th>Lack of an efficient internal control/compliance system</th>
<th>Weak regulatory enforcement/action taken against fraudsters</th>
<th>Inadequate utilization of technology tools available to identify red flags</th>
<th>Inadequate due diligence on employees/third party associates</th>
<th>Unrealistic targets/goals linked to monetary compensations</th>
<th>Senior management override of controls</th>
<th>Inadequate oversight by the Board/Audit Committee</th>
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<td>61 PERCENT</td>
<td>55 PERCENT</td>
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<td>36 PERCENT</td>
<td>33 PERCENT</td>
<td>24 PERCENT</td>
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*Source: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm401451.htm*
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Despite recognizing non-compliance as a challenge, about 45 percent of survey respondents indicated that their organizations had not experienced any fraud or malpractice in the last two years. Further, only 30 percent of survey respondents confirmed that their organizations had experienced non-compliance with obligations during regulatory authority inspections and/or other agency audits.

Absence of fraud/ non-compliance could indicate that these organizations were either fully compliant with the minimum critical requirements or regulatory bodies were yet to conduct inspections. It is also possible that many respondents felt uncomfortable sharing details of any non-compliance (detected or undetected) in their organizations.

Further, the US and the UK have proactive and well managed pharmacovigilance programs such as MedWatch and EurdaVigilance which help them track not just adverse events and reactions caused by medicines, but also track short and long term impact of medicines on patients. Unlike these highly regulated pharmacovigilance programs, India’s pharmacovigilance program is relatively nascent, having been initiated in recent years.

This limited extent of a proactive pharmacovigilance program in India, may allow organizations and regulators to view non-compliance with quality standards with less severity than it deserves, since consequences are not consistently tracked. For instance, there is limited data on the number of adverse events caused by standard or sub-standard medicines that have led to patient death. In contrast data available in the US and UK encourages, tracks and investigates every adverse event that occurs to its very end.

Considering the large volumes of medicines being produced and consumed in India, non-compliance with drug standards makes for a serious concern that needs to be addressed by the government immediately.

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10A pharmacovigilance system measures the effect of adverse events and adverse drug reactions on consumers due to sub-standard and inefficacious generic and/or branded medicines.
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Common non-compliance scenarios observed in the Indian life sciences industry

<table>
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<th>USFDA findings trends⁸</th>
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<tr>
<td>Area</td>
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<td>Laboratory controls</td>
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<td>Computer system controls</td>
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<td>Quality control operations</td>
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<td>Investigation system</td>
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<td>Production operations</td>
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<td>Training system</td>
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<th>EU/MHRA findings trends⁹</th>
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<td>Area</td>
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<tr>
<td>Contamination prevention system</td>
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<td>Investigation failure</td>
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<td>Documentation controls</td>
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<td>Environmental monitoring</td>
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<td>Validation</td>
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<tr>
<td>In process controls</td>
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<tr>
<td>Equipment validations</td>
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⁸Source: US FDA Website - http://www.fda.gov/ICECI/Inspections/ucm250720.htm
⁹Source: http://www.gmp-compliance.org/eca_news_364.html
Challenges in compliance management

The key to managing any compliance framework is to create a matrix of concerns that affect compliance and rate these based on the organization’s understanding of their impact on the business. In the context of new and proactive compliance requirements prescribed by global regulators, survey respondents rated their concerns in terms of high risk to low risk.

Close to 50 percent of survey respondents indicated that data management systems and Pharma Quality systems were a concern, alongside investigation of anomalies (Corrective Actions Preventive Actions). This can largely be attributed to the skill deficit in the sector to handle these issues, as indicated by 52 percent of survey respondents. Further, in our view, a proactive self-driven mechanism that monitors compliance on an ongoing basis, can possibly help manage compliance concerns better within an organization.

About 52 percent of survey respondents indicated that there was lack of clarity and consistency on compliance expectations and 24 percent said reviews of product quality were irregular. Ambiguity in interpretation of guidelines is an inherent risk that all regulatory authorities attempt to manage, with varying degrees of success. A case in point is that manufacturing facilities deemed to be compliant previously are now being issued with manufacturing bans and import alerts.

Key Concerns in Compliance Management

- Data Management systems (48%)
- Pharma Quality Systems (45%)
- Investigation of anomalies – CAPA (45%)
- Lack of trained resources to address compliance needs (42%)
- Oversight of Raw material supplier (27%)
- Interpretation of regulatory guidelines (27%)
- Microbiological contamination (24%)
- Environmental monitoring and compliance with local laws (18%)
- Availability of skilled and trained consultants with a global perspective (15%)
- Availability of standard raw materials (6%)

Difficulties in managing quality related compliance requirements

- Poor vendor/third party management practices (45%)
- Budgetary constraints/lack of compliance planning (48%)
- Inadequate training to employees on quality and other aspects of compliance (52%)
- Lack of clarity and consistency on compliance expectations from regulators (52%)
- Availability of skilled and trained staff (39%)
- Focus on growth leading to compliance being relegated to the backburner (27%)
- Irregular review of quality indicators by management (24%)
- Incorrect timelines provided to complete resolution of negative inspection findings (6%)
We believe this is a result of increased scrutiny by regulators owing to the change in assessment standards. Regulators have been forced to relook at the assessment standards due to several cases of whistleblowers reporting large scale non-compliances to authorities.

As with any formal regulatory approval, the onus of compliance with all regulations is on the license holder and not the regulatory authority. This means that regulatory ambiguity can only be addressed through a very robust and proactive risk identification, assessment, management and mitigation system for quality process, system, product and people, among other factors. As per inspection findings reports of the USFDA and MHRA over last few years, organizations have been issued warning letters for lack of a documented training program, leading these authorities to believe that it has not been given the critical importance that is expected. With ever evolving regulatory compliance requirements, training form an integral part of risk mitigation and management. Lack of skilled resources to manage compliance could be a result of lack of well planned and executed training programs across the industry.

Around 48 percent of survey respondents confirmed that compliance strategy was not a key area earmarked for investment in their organizations, indicating that perhaps senior management did not consider this area as a high risk with serious consequences in the event of non-compliance.

Close to 45 percent of survey respondents felt that product quality issues and probable data manipulation was due to poor or non-existent control over raw material vendors. In this context the USFDA/MHRA observations note that organizations appear to have manipulated quality control records to help them pass the finished product for commercial sale. Such manipulation would not be required if the standard of raw material used in the manufacture of a commercial batch conformed to that used in test/validation batches11.

The adage, Prevention is better than cure is applicable to the life sciences industry not just in spirit, but in practice too. With every action across the life sciences value chain needing validation and approval to mitigate risk to human life, a proactive approach to fraud and compliance risk mitigation has been recommended by all stakeholders from within and outside the industry.

These are initiatives that the company must undertake to self-assess its preparedness to comply with regulations. Some leading practices include:

- Establishing a Corporate Quality Policy aligned with global quality and system requirements
- Implementing a Pharma Quality System framework tested by internal teams on an ongoing basis for compliance with current regulatory guidelines and as per ICH global risk management protocols
- Approved and documented job descriptions for all positions aligned with functional accountability
- Recruitment of qualified and skilled people as defined in the job description documents.
- Training and assessment programs for new and existing personnel conducted by internal trainers and assessors to help them keep abreast of regulatory changes ahead of time
- Zero tolerance by top management to any form of non-compliance
- Ongoing investments in technology solutions for quality assurance and control programs

These initiatives call for extending the existing internal programs to external stakeholders. Some of the leading practices include:

- Conducting a robust vendor/supplier quality compliance audit programs by internal and external assessors on an annual basis
- Cross functional training by external consultants on compliance matters
- Periodic quality system audits and overviews by recognized and qualified consultants
- Continuous validation program to validate technology solutions overseen by independent experts
- Stringent review and immediate resolution of non-compliant quality systems by non-executive directors and senior management
- Technical and commercial audits of R&D labs and review of objectives delivered within agreed timeframes

Though the above mentioned list is not exhaustive, we believe that these are bare minimum initiatives that could provide companies with a robust fraud and compliance risk mitigation process, helping them steer clear of negative regulatory actions, including financially expensive import bans.
Detecting fraud and managing non-compliance and malpractice

Upon detection of fraud 85 percent of respondents said they launched an internal investigation by a specially appointed committee, while 82 percent confirmed that some form of disciplinary action was initiated as per existing policies and fraud and compliance risk management frameworks.

About 94 percent respondents confirmed that a majority of non-compliance or fraud was detected during regulatory authority inspections or self-audits initiated either on account of remediation plans or proactive risk management. A very small percentage of the respondents engaged external consultants to detect/identify non-compliance in the organization. In our view, many actions by regulatory authorities can be avoided if external consultants are a part of the risk management and mitigation process.

Further, 76 percent of respondents indicated that their whistleblower hotlines were responsible in detecting non-compliance or fraud. Demonstrating action on whistleblower complaints can give employees confidence that their concerns are being addressed and also help the organizations safeguard themselves against possible regulatory action.

METHOD OF DETECTION
Conclusion

With the life sciences sector expected to grow rapidly over the next few years, evolving the compliance risk management processes would take equal precedence with business and commercial considerations, especially for organizations looking to grow rapidly in lucrative and highly regulated markets of the US, European Union and Latin America. These markets are developing complex quality compliance frameworks that function to protect their population from substandard medicines. Organizations are therefore expected to have proactive compliance management and risk mitigation frameworks that are aligned to the regulatory authority guidelines in the markets they serve.

While the life sciences sector in India is aligning with the changing compliance dynamics, there are many challenges it has to overcome, particularly in the areas of compliance management. Failure to address and overcome these challenges on a war footing may result in business stagnation or decline, allowing other countries such as China, Thailand, Indonesia, South Africa, and Russia to surge ahead and claim leadership position in this industry. The Indian government should support the industry to transform and align its vision and mission with global expectations over the next few years and help it attain its preeminent position of being the ‘pharmacy to the world’.

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