

An Empirical Study on the Cost of Compliance in Manufacturing Industry

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Abstract

This paper attempts to study how rising costs of **compliance in manufacturing industry** and how new technologies can reduce costs and offer foresight into emerging risk issues. Due to the stringent and increasingly demanding Good Manufacturing Practice (GMP) and customer requirements, companies within the chemical–pharmaceutical sector share the enormous challenge of evaluating and measuring compliance and costs. The need for implementing a compliance measuring tool for production was identified within the Schering AG and activities were undertaken. The established compliance evaluation system and the first model for a compliance cost system proved to be well-structured and suitable for the production. After independence, India adopted a socialist, mixed economy model with the state retaining control over the important components of the economy like heavy industries and utilities. While private sector activity was allowed, the government controlled it through licensing and quotas complemented by high tariff barriers. Accordingly, the government policies and regulations were made to suit the business environment that was in vogue at that time. After 1985, the Indian government embarked on a process of reforms which involved the elements of de-licensing of industries, abolition of output quotas for firms, permission for private entry into sectors which were hitherto the monopoly of the government, and liberalization of quotas and tariffs on capital goods imports.

The existing regulatory framework in India seems to have evolved in an uneven way across and within sectors of the economy, resulting in time consuming and expensive processes at the firm level. Due to the federal nature of Indian governance as well as the consensual nature of decision making in the Indian democracy, the regulatory reforms process has been slow. While the economic reforms, in general, have improved the overall business environment through market oriented policies, the old paradigm of seeking to control businesses through a multiplicity of procedures and inspections have impacted the manufacturing sector. On an average, a manufacturing unit needs to comply with nearly 70 laws and regulations. Apart from facing multiple inspections, these units have to also file as many as 100 returns in a year. The national manufacturing policy points out that even though a number of efforts have been made in the past (e.g. single window systems, fast track approvals, e-filing of forms etc.) to bring down this compliance burden, they have been only partially successful as different government departments are not willing to shed or reinvent their roles

Key words: Democracy, politics, participation, Islam, India, Muslims, General Elections

Introduction

Over the past two decades, there have been changes in the Indian economy which has progressed from a government controlled, quota regime to a more liberalized business environment. However it is widely believed that the reforms relating to the legal and regulatory compliances have not kept pace with the change and are seen to be cumbersome and business unfriendly. Outdated requirements, unfriendly procedures and lack of clarity in rules / legislations have been identified by the respondents as the key issues faced across company structure, employee, environmental, and factory related compliances. Simplification of laws/procedures, increasing selfcertification/ self-regulation, increased automation of processes, and managing the discretionary powers of government officials in a more effective way are the key recommendations by the respondents to reduce compliance related load. A high level of compliance including continuous improvement for quality, environmental protection and occupational health and safety topics is a prerequisite for international competitiveness in the production of pharmaceutical drug substances and drug products. Poor compliance on one hand and excessive compliance measures on the other hand will negatively affect the ability to compete. Consequently, the evaluation of the compliance level, the investigation of compliance costs and the connection of compliance level and its operational measurement within a company are increasingly important. In addition, there was an increased focus on attracting foreign capital to be invested in manufacturing. However the policy recognizes that the compliance burden on industry arising out of procedural and regulatory formalities needs to be reduced through rationalization of business regulations in order to achieve the stated objectives.

- Simplification of laws/procedures: Lack of clarity in interpretation leads to litigations, and considerable time / energy of senior management being spent. In addition, bringing in certainty in laws would help companies in reducing compliance challenges
- Increasing self-certification/ self-regulation: The Indian compliance regime lays increased importance to inspection and monitoring, however, some of the government departments are not adequately staffed to handle this. The respondents opined selfcertification may be introduced in a phased manner in greater number of areas of compliance.
- Automation of processes: Automation of processes has resulted in reducing the time and cost involved in the compliance process. Initiatives such as e-filing at the MCA (Ministry of Corporate Affairs) are often cited by the respondents as the way forward to reduce compliance burden.
- The time taken for the legal processes is another area where the respondents believe that the businesses are significantly impacted.

Objective:

This paper intends to explore and analyze **compliance cost in manufacturing industry** that refers to all the expenses that a firm incurs to adhere to industry regulations.

Manufacturing compliance: cost of compliance

Manufacturing compliance comprises the technical, legal and corporate requirements, regulations and practices manufacturers must comply with in order to produce and market products. The risk of non-compliance has become an increasingly major concern in recent years, particularly for manufacturers with operations in multiple countries and jurisdictions. This development has been further heightened by the increasing role of governmental regulatory bodies in certain industry sectors, along with the emergence of global standards to address the increasingly global nature of manufacturing.

Compliance cost system In 2003, activities commenced to define compliance costs in order to measure such costs at the different production sites. The results of the discussions between production, quality assurance and controlling personnel showed that the largest proportion of compliance costs could be attributed to personnel expenditures (Table 2). Due to the fact that those personnel costs arise in different departments and employees could be responsible for different compliance activities it turned out to be challenging to establish measuring methods for personnel costs, whereas material and equipment costs can be evaluated very easily

The strategic goals of most manufacturing companies are to manufacture competitive products, operate profitably, and grow their business in an environment of increasing globalization and elevated product development costs. This is challenging enough in itself; but in market sectors such as medical device and biotech manufacturing, the task is even more daunting due to the additional burden of dealing with the various facets of manufacturing compliance originating from the FDA, EPA, and SEC, among others.

Numerous areas of compliance can come to bear on manufacturers directly or indirectly, including:

- Product safety
- Health, safety, and environmental impact
- Data protection
- Export controls
- Anti-corruption
- IT safety and security
- Fair competition
- Employment law

The core mandate guiding FDA regulatory oversight is consumer safety. As a result, the FDA has defined Good Manufacturing Practices (GMP) for both device and drug manufacturers that dictate the necessary measures that must be taken to ensure that quality systems and processes are in place to consistently produce safe, quality

products. Therefore, manufacturers in these sectors seek a manufacturing certificate of compliance indicating that they meet GMP.

Meeting the challenge of manufacturing regulatory compliance requires establishing a consistent top-down strategy for ensuring compliance across the enterprise. Software developers have responded to this need by creating solutions for managing regulatory compliance within [manufacturing execution systems \(MES\)](#). For those in manufacturing sectors regulated by the FDA, these solutions must be compliant with Title 21 CFR Part 11 and Part 820. Part 11 requires pharmaceutical manufacturers, medical device manufacturers, biotech companies, biologics developers, contract research organizations, and other FDA-regulated industries (with some specific exceptions) to implement controls. These controls include audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data that are (a) required to be maintained by the FDA predicate rules or (b) used to demonstrate compliance to a predicate rule.

Key recommendations for Compliance

Outdated requirements, unfriendly procedures and lack of clarity in rules / legislations have been identified by the respondents as the key issues faced across company structure, employee, environmental, and factory related compliances.

Simplification of laws/procedures, increasing self-certification/ self-regulation, increased automation of processes, and managing the discretionary powers of government officials in a more effective way are the key recommendations by the respondents to reduce compliance related load.

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Increasing self-certification/ self-regulation: The Indian compliance regime lays increased importance to inspection and monitoring, however, some of the government departments are not adequately staffed to handle this. The respondents opined self-certification may be introduced in a phased manner in greater number of areas of compliance.

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Biggest challenges for compliance officers and the board

Compliance practitioners continue to identify managing and coping with continuing regulatory change as their biggest challenge. For 2018, data privacy and the global ramifications of the implementation of the European General Data Protection Regulation (GDPR) have been specifically highlighted as a key concern, which is a distinct shift from the challenges highlighted for 2017. The biggest challenges facing boards this year have again been highlighted as continuing regulatory change and the intensity of supervisory scrutiny. In line with compliance challenges, data privacy and GDPR have been specifically highlighted as a key board challenge for 2018.

Misconceptions about compliance

The biggest and most dangerous misconception regarding compliance is that it is easy to manage. Many people think compliance is only filling out a few forms every year and then they are finished. But that couldn't be further from the truth. Compliance laws are not only different in every jurisdiction, but regulations can change rapidly in some areas.

Another misconception is that everything can be submitted in English. 85% of the countries researched in our Compliance Complexity Index 2018 require the forms to be filled out in the local language. Understanding the local nuances of compliance is imperative to successfully comply in all jurisdictions where your business operates.

Costs of non-compliance

Mistakes in compliance can not only cost your company financially, personal liability is a real concern for compliance officers who are taking on risks as they are accountable for compliance at their company. Proper conduct and ethics are a big part of compliance and individuals are responsible for following the rules for their business. In 56% of the countries researched in our Compliance Complexity Index 2018, the failure to comply with corporate secretarial requirements is subject to either fines of more than 5,000 USD or prison sentences for the officers.

Too often compliance is limited to a couple of departments or even individuals but following certain regulations can require input from additional functions. Not counting on a team of experts can have detrimental costs to your business. Ideally, everyone should be educated on what compliance means and how it can affect their role and how it fits into the bigger picture.

Another cost of non-compliance is time. There are some countries which allow businesses to submit filings online, but on average 44% of the countries require the forms to be submitted in person. Therefore, companies need the time of an expert to prepare the forms in the local language, and file all the appropriate paperwork at the local authority's offices.

Lastly, it is frequently forgotten that non-compliance may cost companies business opportunities. Compliance is fundamental for companies to participate in tenders, obtain specific licenses, render services to other companies, or even be sold to another group. Nevertheless, the path to bring a non-compliant subsidiary back to a compliant status may be filled with unpleasant surprises, such as appointed directors that left the company and were never replaced, and financial statements not being filed for extended periods. Some issues can take longer than expected to be solved causing important deadlines to be missed.

With the risks and penalties so high, it's important to outline the compliance costs and include it in your budgets and decide whether or not to handle it internally or use a trusted partner.

Keys to compliance programs

Multinational companies managing many entities across several countries can have a hard time establishing a unified compliance program that ensures all entities are in good standing and compliant with the ever-changing local regulations.

Enacting a strong compliance program with a knowledgeable team is essential to understanding all regulations and policies across all jurisdictions the business operates in. Companies need to decide if the processes can be managed in-house or if they will require support from an expert provider. There are some hidden costs for compliance departments to consider when making this decision:

- Training –making sure your staff is constantly up to date with the most recent regulations or trusting the compliance function to a global partner that already invests in their experts training;
- Technology – what systems do you need to use and where and how integrated are they?
- Service provider fees – working with multiple providers and legal firms can result in many invoices paid by different parties and sometimes even different departments. The costs can be very high when all invoices are calculated.

Compliance is becoming even more important for businesses everywhere and having sufficient local knowledge is the key to success along with being prepared and informed.

The difficulty of adhering to business regulations across 84 countries was surveyed and the results compiled in the [Compliance Complexity Index 2018](#). The report includes areas related to managing your local entities, as well as regulatory compliance, such as the ease of setting up a company; the information firms must report to local authorities; and the relative difficulty of complying with national legislation locally.

Benefits

Cut down of legal charges

The obvious direct benefit of complying with laws is mitigating risk of fines, penalties, legal hassles or cancellation of license.

Competitive advantage

Firms that follow proper processes, strictly adhere to compliance and discourage any kind of improper and unethical behaviour can attract government authorities, investors, shareholders, partners, employees and customers more, and gain in long run.

Business goodwill

Adding positive image towards employees, market, customers or public at large, and, thereby, building intangible asset is a certain by-product of following internal and external compliance.

Employee retention tool

Effective internal compliance of a company can be a motivating factor for employees to stick to the organization, because it acts as basic building block for safety, transparency and fairness.

Strengthening DNA of the organisation – can pave the way for paradigm shift

Proactive measures such as employee training, internal control, benchmarking and adoption of best practices will set foundation of robust framework for a future ready organization. Companies with strong access control, SOPs, processes and policies for remote operation have smoothly adopted work from home (WFH) situation imposed by COVID-19. Some of the Indian companies such as BPO and analytics firm EXL Service, insurance aggregator PolicyBazaar.com are now seriously considering WFH for long run as it gives them the opportunity of cost savings, convenience and productivity gains. Is it not a good idea?

Saving bandwidth of top management

With systems and processes in place, top management can make themselves free of anxiety related to compliance deadlines, verification of data, documentation and reports. Instead they may focus more on core operations and business growth.

All these add up to immense advantage for compliant companies...

A December 2017 study by Ponemon Institute and Globalscape (“Ponemon Study”) revealed that non-compliance costs 2.71 times the cost of maintaining or meeting compliance requirements.

Conclusion

The non-compliance costs come from the expenses associated with business disruption, productivity losses, fines, penalties, and settlement costs, among others.

As governments and regulatory bodies across globe are showing more interest towards latest technologies

such as artificial intelligence and real-time big data analytics to enforce compliance, non-compliance is not an option any more. Compliance is not optional: chemical–pharmaceutical companies have to face the challenges of increasingly challenging GMP requirements which indeed lead to rising cost pressure for the company. Therefore, a compliance evaluation system is essential in helping identify system weaknesses in compliance management and at the same time to define best practice in implementing measures to meet GMP requirements. Additionally, an effective compliance evaluation system stimulates communication on the observation of requirements and helps challenge internal and external standards. And last but not least, such a system enables the company to find an appropriate balance between compliance and costs. Since the compliance evaluation system is well-structured including general GMP requirements, it can be easily adopted and modified by other chemical–pharmaceutical companies. The high incidental costs within a company for complying with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) requirements demonstrate the necessity of developing such tools for research and development, too. The examples of the compliance evaluation and compliance cost systems for the GMP area can serve as a basis for similar tools.

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