Towards Quality Excellence: Journey of the Indian Pharmaceutical Industry

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GOVERNMENT OF INDIA

MESSAGE

It is a matter of great pleasure to share my blessings and good wishes with the pharmaceutical fraternity through this message for the Knowledge paper titled **"Towards Quality Excellence – The Journey of the Indian Pharmaceutical Industry"**. I express my best compliments on the release of the Knowledge paper during the **'India Pharma-2017'** – 2nd International Exhibition and Conference on Pharmaceutical Sector, scheduled to be held from 11th February to 13th February, 2017 at Bangalore International Exhibition Centre (BIEC), Bengaluru.

In 2016, the focus of the Knowledge paper was strengthening India's position in pharmaceutical manufacturing through the 'Make in India' initiative. During the deliberations, excellence in quality emerged as one of the major topics to address, going forward.

My best wishes to the Indian Pharmaceutical sector for undertaking this journey of establishing a culture of quality. I appreciate that the current paper addresses these larger concerns and offers suggestions on taking quality excellence to the next level across the Pharmaceutical sector. I am confident that the deliberations at the event would help strengthen India's position in the Pharmaceutical manufacturing landscape and help to achieve the desired growth.

I wish the Conference a grand success.

(AnanthKumar)

31 January, 2017

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Foreword

India is already an attractive destination for the manufacturing of pharmaceuticals owing to its strong capabilities across the value chain. We export vital medicines to over 200 countries including the highly regulated markets in the US, Western Europe, Japan and Australia as well as multiple emerging or small economies. The Indian pharmaceutical industry has demonstrated a strong commitment towards ensuring affordable and accessible medicines globally. As the third largest pharmaceutical industry worldwide by volume of production and 13th by value, the Indian pharmaceutical industry is a major contributor to the "Make in India" initiative. Pharma exports from India are expected to touch USD 30 bn by 2020. The pharma sector is the fourth largest contributor to Indian exports and has maintained a high rank as a fast-growing export contributor among the top 10 export categories over the last five years. Almost 60 percent of the world's vaccines come from India. The largest number of FDA approved plants outside the US are from India—Indian pharma companies have more than 20 percent of the prescription market share in the US.

The January 2016 FICCI report—"Realizing 'Make in India': Journey to become the most preferred manufacturer of high quality affordable medicines"—identified a number of opportunities and challenges for the industry going forward. While pharmaceutical manufacturing in India has multiple opportunities for growth across formulations, biologics, indigenous vaccines manufacturing, active pharmaceutical ingredients (APIs) and contract manufacturing, quality issues affecting supply reliability were seen as a challenge.

The global pharmaceutical industry faces the challenge of upgrading quality systems as per the evolving regulatory standards while delivering life-saving medicines simultaneously. India is no exception. While the industry is moving towards complex products and integrating new technologies, there is also a need to make quality processes more robust to meet the changing regulatory norms.

This knowledge paper describes the journey towards building quality excellence and imperatives for pharmaceutical companies, the industry as a whole and the role of the government and regulators.

We are grateful to McKinsey & Company for being a knowledge partner in this initiative once again and for their continued support through various insights and analytics.

Mr Pankaj Patel
President, FICCI

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Executive Summary

The Indian pharmaceutical industry is an immense contributor to healthcare around the world—it supplies medicines to the developed and developing world at affordable prices worldwide. It has built a sustainable foundation for success—in particular, strong manufacturing, product development and process innovation capabilities have led to significant impact. Even the level of collaboration seen across stakeholders has been remarkable.

Currently, however, driven by evolving current good manufacturing practices (cGMP), regulatory expectations and the complexity of operations, the global and the Indian pharmaceutical industry together face the dual challenge of upgrading quality and delivering life-saving medicines at affordable prices. In particular, quality issues affecting supply reliability were identified a major challenge for the industry.

To address these issues, pharma companies could develop a quality culture, embedded in their systems and championed by their leadership. Currently, some of the key challenges being addressed by the industry include:

- Building robust data reliability systems by leveraging technology
- Upgrading systems and capabilities in investigations
- Strengthening management systems to manage quality
- Embedding quality into product design
- Building a culture of quality across the organization
- Expanding and upskilling the quality and operations talent pool

To address these challenges comprehensively, different stakeholders such as the government, regulators, industry associations and individual companies could collaborate to create an ecosystem that would foster quality excellence. Regulators and pharmaceutical companies could leverage this ecosystem to build quality excellence across their operating, management and people systems.

New emerging digital technologies could also help to resolve major quality challenges by effectively addressing some of the more serious concerns and driving breakthrough improvements in quality.

Finally, the role of the leadership is crucial in setting a high aspiration, role modelling the right quality behaviours and mind-sets, and providing the right resources and infrastructure for quality. Organizations that commit to quality excellence reap the benefits of this effort, often significantly boosting their production, branding and customer loyalty.

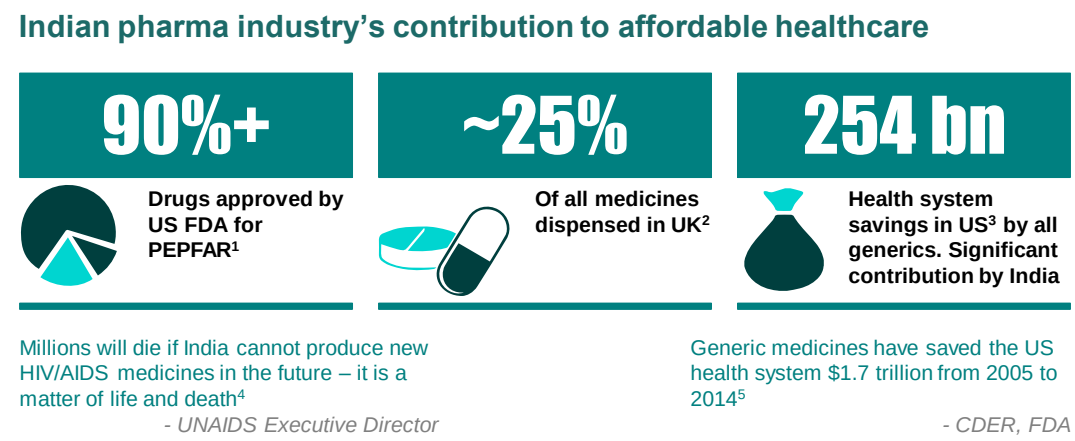
1. Journey of the Indian Pharmaceutical Industry

As the third largest pharmaceutical industry worldwide by volume of production and 13th by value[1], the Indian pharmaceutical industry is a major contributor to the "Make in India" initiative. The industry has been on a tremendous growth journey. The domestic market is worth more than INR 100,000 crore and has been showing double digit growth across therapeutic areas over the last five years[2]. Pharma exports from India exceed USD 16 bn[3] and the Indian industry is poised to be the third largest contributor to incremental global pharma growth[4].

As a major supplier of affordable and quality medicines to the developed and developing world, the Indian pharmaceutical industry plays a crucial role in ensuring health outcomes. Generic drugs contribute immensely to healthcare systems in the developed world by reducing costs and easier access (Exhibit 1).

The scale of impact on patients is staggering. India accounts for 60 percent of global vaccine production and 90 percent of the WHO demand for the measles vaccine[5]. Affordable anti-retroviral (ARV) drugs from India were a major factor in driving greater access to treatment for patients with AIDS. Those receiving treatment increased from just 2 percent in 2003 to 37 percent in 2009[6]. In fact, India supplies 60 percent of global ARV drugs and 30 percent of the annual UNICEF.

Exhibit 1



1 US FDA website's international programs section
2 UK and India regulators agree deal for closer collaboration to improve public safety
3 Generic drug savings in the US report 2015, GPhA
4 'UN welcomes India's decision to continue making generic HIV/AIDS drugs', 6 July 2011, UN News center
5 Congressional testimony, Director CDER, US FDA, Feb 4 2016

1 OPPI Publication – 'Healthcare in India – New Milestones ...New Frontiers' 2016,
2 AIOCD Data, FY16, CAGR 2012-2016
3 Pharmexcil data, FY16
4 Pharmaceutical March-2015, IBEF report
5 Press Information Bureau; "Affordable Efficacious Medicines - All roads lead to India", report by IDMA
6 Pharmaceuticals: India's generics flow into Africa, African Businesses Magazine, 19 January 2012

Within India, the industry supplies medicine at some of the most affordable prices globally. There was a time, nearly a decade ago, when first-generation HIV medicines came with a price tag of USD 10,000. Today, many Indian generic manufacturers in India provide these medicines at around USD 100, a reduction of more than 99 percent[7].

The industry is a major source of employment—estimates suggest that India's pharma industry directly and indirectly employs nearly 2.5 mn people[8]. Many of these jobs are in high skill areas of R&D and manufacturing. The industry generates around USD 10 bn of trade surplus every year and is the third-largest contributor to reducing India's trade deficit[9].

The journey continues—India accounted for 34 percent of abbreviated new drug application (ANDA) filings in 2016[10] and more than 50 percent of drug master files (DMFs) submitted in Q1 2016[10] were from India. Indian companies accounted for more than 1,200 UK MHRA (Medicines and Healthcare products Regulatory Agency) market authorizations by May 2014[11].

The industry, with support from the government and other stakeholders, has built a sustainable foundation for success, especially distinctive capabilities in key areas of the value chain. In particular, strong manufacturing, product development and process innovation capabilities have enabled Indian companies drive significant efficiencies.

Over the last two decades, the industry has invested heavily in world-class manufacturing facilities to serve the international market. India has the highest number of US FDA-registered[12] sites outside India. The industry has significantly expanded capabilities across dosage forms and technologies and is increasingly focused on innovation (Exhibit 2).

7 amFAR, Foundation for AIDS research, Doctors Beyond Borders (MSF)

8 "Indian Life Sciences:Vision2030", FICCI June 2015

9 Export Import Bank of India; Reserve Bank of India

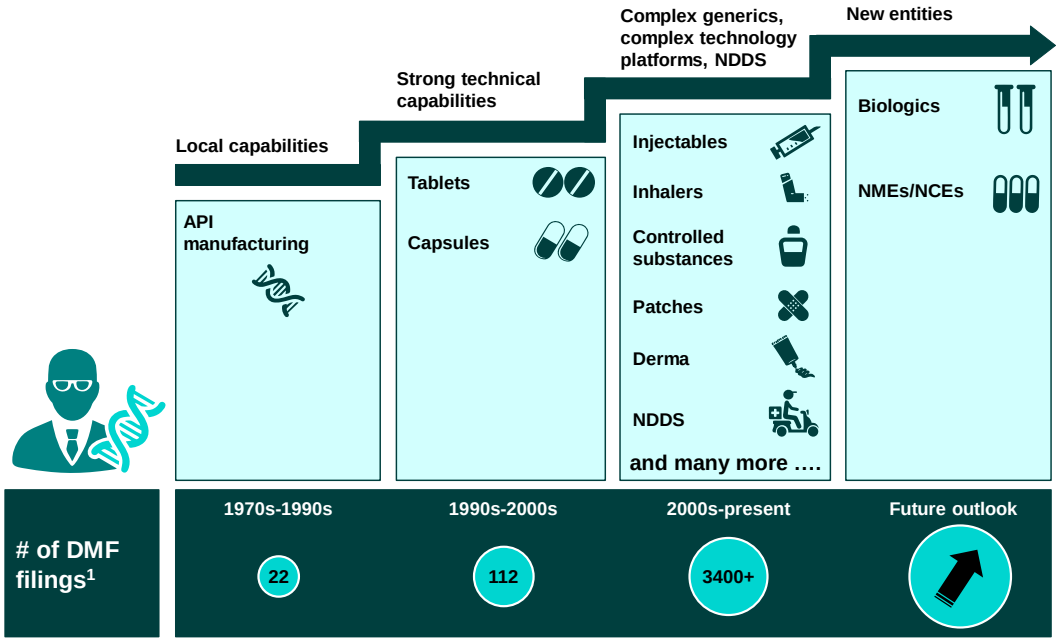
10 Pharmabiz, India industry equity research reports

11 11th Annual Report 2014–15, Pharmaceutical Export Promotion Council of India (Pharmexcil), Set up by ministry of commerce and industry, Government of India

12 Manufacturing sites with a unique Facility Establishment Identifier (FEI) number assigned by FDA to monitor and track inspections of regulated firms

Exhibit 2

Evolution of the Indian pharmaceutical industry



1 Includes active type II DMF filings
SOURCE: US FDA (for number of DMF filings)

With this strong foundation, the opportunities for the Indian pharmaceutical industry are immense. FICCI's 2016 knowledge paper—"Realizing 'Make in India': Journey to become the most preferred manufacturer of high quality affordable medicines"—identified a number of avenues for growth across formulations, bulk drugs, indigenous vaccines manufacturing and contract manufacturing. The paper also identified a number of issues including:

- Growing dependence on external markets for raw materials
- Challenges in sustaining cost competitiveness in traditional generic formulations
- Competition in complex generics and new technologies
- Quality issues affecting supply reliability

Following on from 2016, quality is a major focus area of the current knowledge paper. As cGMP, regulatory expectations and complexity of operations evolve, this paper describes the approach to continue the journey towards quality excellence and the potential roles of different stakeholders.

2. Achieving Quality Excellence

In the last few years, like their global peers, Indian pharmaceutical companies have faced an increasing number of quality-related issues, especially in the US market. Globally, between 2008 and 2014, the number of product recalls and warning letters to pharma companies tripled[13]. In India too, the number of warning letters from US FDA to Indian manufacturing sites increased from an average of five letters between 2011 and 2014 to 10 in 2016[14].

As the industry continues to expand in scale and complexity, it is crucial to pursue quality excellence relentlessly. To do so, pharma companies could continuously nurture a culture of quality, deeply embedded in their systems and advocated by their leadership. There are also lessons to learn from the journey so far. Stakeholders could play a role in helping individual companies by creating an ecosystem to support quality excellence.

2.1 AREAS OF IMPROVEMENT

What does it take to do this? One challenge is strengthening the case for consistent quality excellence through market mechanisms, i.e., reward quality excellence and penalize poor quality. Potential issues could be building greater transparency on quality performance of individual companies, e.g., through metrics or accreditation, ensuring consistency of enforcement and connecting business outcomes to quality performance.

For individual pharmaceutical companies, the first step would be to build a shared understanding of the key systemic challenges and focus all stakeholders' resources in solving them. Six areas of improvement could be explored by the industry, that is:

1. Building robust data reliability systems by leveraging technology
2. Upgrading systems and capabilities in investigations
3. Strengthening management systems for quality, even with the increasing operational complexity
4. Embedding quality into product design
5. Building a culture of quality across the organization
6. Expanding and upskilling the quality and operations talent pool

13 Analysis of multiple issues of Gold Sheet

14 Analysis of USFDA data from http://www.accessdata.fda.gov/scripts/warningletters/wlSearchExcel.cfm

2.1.1 Building robust data reliability systems by leveraging technology

Data reliability is a major driver of quality issues globally. Up to June 2016, 14 quality-related warning letters issued globally cited data reliability concerns[15]. Reflecting these concerns, a number of regulators, e.g., UK MHRA, US FDA, WHO, have issued guidelines which describe and clarify the key principles of data reliability.

Many companies have significantly upgraded laboratory systems to these requirements. However, implementing systems, which help ensure strong data reliability outcomes, continue to require constant vigilance and focus from the top management. Efforts are already underway to enable companies to strengthen data reliability further. For instance, a major pharmaceutical industry body is developing implementation - oriented guidelines consistent with global regulatory guidelines to help companies implement data reliability.

2.1.2 Upgrading systems and capabilities in investigations

It has been observed that weak investigation systems in pharmaceutical companies have led to recurring deviations that impact product quality adversely[16]. As per a global pharmaceutical industry benchmark, top quartile companies face only 5 percent recurring deviations, while for median companies it is 13 percent[17]. Areas of improvement across investigation systems include defining the problem, performing an effective root-cause analysis and introducing a comprehensive risk-management processes.

As the industry continues to grow, it becomes even more important to develop and build on best practices across the following six stages of quality investigations:

- Identification of deviation or incident
- Investigation and root-cause analysis
- Corrective and preventive action (CAPA)
- Implementation
- Verification
- Effectiveness of monitoring

While doing so, the organization could develop the right tools, define the right success metrics and identify the right team.

15 Analysis of US FDA Warning letters - http://www.accessdata.fda.gov/scripts/warningletters/

16 “Recurring deviations” can be defined as deviations that recur within two years from the first instance

17 McKinsey’s POBOS benchmarking that covers more than 600 plants worldwide

2.1.3 Strengthening management systems for quality, even with the increasing operational complexity

While pharmaceutical companies have scaled up, management systems have also evolved to manage quality across sites and across different dosage forms. Agile governance systems help to surface issues from the sites and drive strong decision-making at all levels. Strong processes, metrics-driving accountability and structured review mechanisms are seen as some of the enablers of strong management systems.

Good governance systems include metrics that define in detail (without ambiguity), provide a distinct calculation methodology with linkage to raw data and aid in consistent application of metrics across sites. These definitions and the calculation methodology is usually aligned with emerging regulatory requirements. Metrics could build in leading quality indicators, incorporate measures of culture and capture total risk from quality. Leading indicators help to anticipate quality issues. However, building a shared understanding of the definition and interpretation of metrics still proves to be a challenge.

2.1.4 Embedding quality into the product design

Using a product lifecycle perspective on quality reveals that building robustness into products and processes in the early stages in an important driver of quality. Greater process robustness could significantly reduce compliance risk, unnecessary costs, supply disruptions and wasted efforts during commercial manufacturing.

Many Indian companies are already addressing this area. Typical initiatives have included creating dedicated, highly capable teams of scientists and process engineers to manage the technology transfer process, introduction of process robustness metrics and structured product development.

2.1.5 Building a culture of quality across the organization

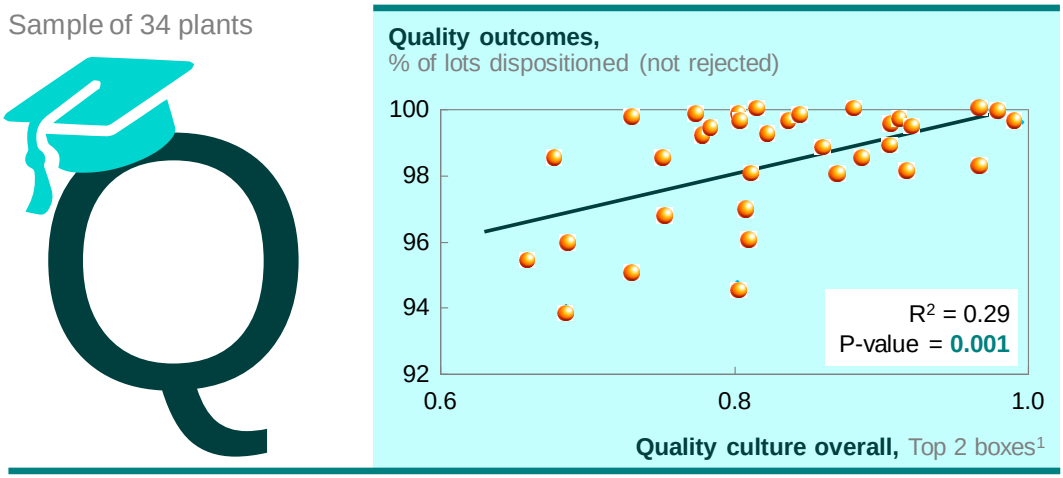
Extensive research on organizational health and performance has shown that companies with a stronger quality culture ultimately have better operational outcomes overall[18]. However, developing the right behaviours and mind-sets on the shop floor is often a bigger challenge as compared to developing the best processes, SOPs and technical systems.

18 Flawless; “The invisible but essential foundation: Fostering a culture of quality in pharma”, by Alessandro Delfino, Paul Rutten, Vanya Telpis, McKinsey & Company

According to a global pharmaceutical industry survey, there is a positive link between quality culture and performance as well as quality productivity (Exhibit 3)[19]. It is indeed feasible to measure quality through a combination of an employee-level survey, focus group discussions and deep-structured interviews. This survey has been deployed at more than 15 Indian manufacturing sites, covering more than 15,000 responses.

Exhibit 3

Quality culture is empirically linked to quality outcome: stronger culture scores lead to higher quality outcomes



R2 measures how well variability of given metric X explains variability of metric Y. It ranges from 0 (no relationship) to 1 (perfect linear relationship). **P**-value is probability that correlation is zero, value below 0.05 indicates significant results.

1 Scores calculated as "Top boxes" (share of "agree" and "strongly agree" responses) ratio

SOURCE: POBOS Quality survey, ISPE Quality Metrics pilot Jul 2014 – March 2015

2.1.6 Expanding and upskilling talent pool

With increase in scale and complexity of operations, there is a need for higher numbers of professionals as well as broader skill-sets of quality and operations. A supply-demand mismatch often leads to quality issues as a result of high attrition rates at multiple Indian sites, which leads to a vicious cycle of heavy workload, even high attrition and resource challenges in quality functions. Furthermore, as the industry's product portfolio shifts towards more complex products, the industry needs more and more expertise in areas such as sterility assurance.

A focused collaborative effort to build capabilities in new and emerging areas could help the industry scale up rapidly with excellent quality. For instance, a responsive capability-building institute for pharma quality could operationalize industry-wide "at scale" capability-building programs that go beyond just training people.

19 McKinsey's POBOS benchmarking that covers more than 600 plants worldwide

2.2 HOLISTIC APPROACH TO QUALITY EXCELLENCE

What would it take for the Indian pharma industry to address these areas of improvement and achieve great quality? The answer is multi-pronged. Individual stakeholders such as the government, regulators, industry associations and individual companies could collaborate to create an ecosystem, e.g., policies and guidelines, which would foster quality excellence. Pharma companies could leverage this ecosystem to build quality excellence into their operating, management and people systems. This would involve setting the right technical and management processes and mechanisms and driving adoption through a culture of quality.

2.2.1 Quality in the operating system: Product development and operations

Operating systems ensure that the technical solution is in place and the SOPs required to follow the solution are established. This requires upgrading SOPs and protocols in line with guidelines and best practices. In the long term, this would mean building quality into the product development and transfer processes, supported by a deep understanding of critical quality attributes, process parameters and material attributes.

2.2.2 Quality in the management system: Power of predictive metrics and effective governance

Strong management systems help the leadership to rapidly identify issues, design solutions and ensure effective implementation of solutions. A best-in-class management system anticipates and proactively resolves quality issues through predictive metrics. It also plays a critical role in ensuring that learnings are effectively transferred across sites and functions.

2.2.3 Quality in the people systems: Embedding a culture of quality and robust training infrastructure

People systems could be strenghtened to develop a culture of quality across organizations. This calls for capablity building, resourcing, work-planning and setting the right quality aspiration.

3. Continuing the Journey towards Quality Excellence

As the industry continues on the journey towards quality excellence different stakeholders could collaborate and create an ecosystem to facilitate this journey.

Government and regulators could help create market mechanisms that strengthen the case for quality excellence in line with global standards. Pharmaceutical companies could strive to continuously improve their quality systems and performance—by diagnosing and identifying challenges, designing solutions and offering implementation methods.

New emerging digital technologies could also be deployed to help solve major quality challenges rapidly and more effectively. These technologies could help companies effectively address some of the more serious challenges and drive breakthrough improvements in quality.

3.1 ROLE OF THE GOVERNMENT AND REGULATORS

As in other areas, the government and regulators could play a significant role in building the ecosystem to facilitate the journey towards quality excellence, efforts for which are already underway. Indian and international regulators and agencies have started a number of initiatives to enhance collaboration towards this objective[20]. This could help create a strong pool of suppliers and smaller companies who would be able to support future growth of the industry. The regulators, both Indian and foreign, have been supporting the industry by providing inputs and feedback on initiatives by industry bodies to ensure quality, and are also engaging constantly on any changes in regulations.

As the industry continues on the quality journey, the following options could be considered:

- Exploring opportunities to augment quality-related capacity and capability in the pharma ecosystem. These might include:
  - Creating provisions for using third parties, e.g., drug testing laboratories, accreditation to support greater oversight
  - Developing panels of experts in specific topics
  - Facilitating creation of industry centres of excellence to help ensure that recent graduates are industry ready, while existing employees build up quality skills
- Helping the industry standardize processes and approaches by:
  - Defining standard methodologies, e.g., for inspection or for testing procedures

20 http://www.cdsco.nic.in/writereaddata/WHO-CDSCO%201.pdf; http://blogs.fda.gov/fdavoice/index.php/2015/03/in-india-with-our-sleeves-rolled-up/

- Facilitating collaboration with international agencies to help build best practices

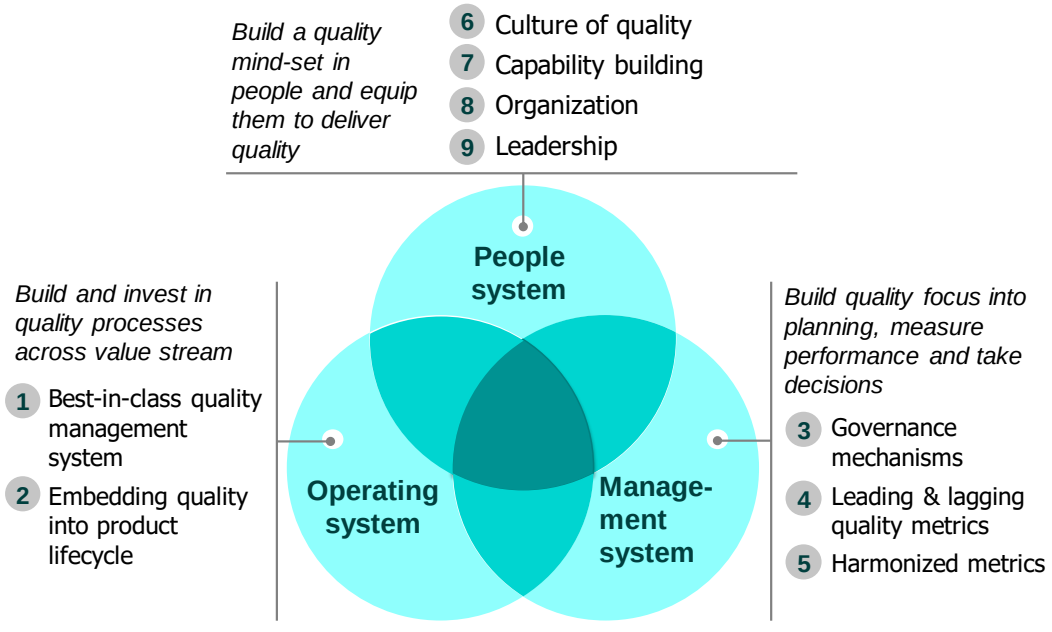
- Considering the possibility of consolidating the quality agenda under a common regulatory authority across product lifecycles and geographies
- Considering initiatives to create greater transparency in quality performance to help create market mechanisms that support quality excellence. This could be done by:
  - Providing greater data about quality performance, e.g., publish key metrics, actions taken, or by linking value to quality performance, e.g., through pricing regime
  - Creating mechanisms such as accreditation or rating of quality systems through third parties that can create potential differentiation based on quality

3.2 ROLE OF PHARMACEUTICAL COMPANIES

Individual companies and leaders could build quality excellence by resolving major quality challenges comprehensively across the operating, management and people systems. The operating and management systems could ensure that the right technical and managerial processes are designed to ensure quality. The people system could equip employees with capabilities to adopt and adhere to these processes (Exhibit 4).

Exhibit 4

Outstanding quality involves building quality into operating, management and people systems



3.2.1 Operating system

Pharma companies could focus on strengthening and delivering quality at the development phase itself, learning from global benchmarks and regulatory guidelines. To ensure that quality is built into the product, these companies could evaluate and improve the overall quality management system (QMS) by:

- **Continuously improving QMS:** As the nature of operations and cGMP evolve, it is important to ensure that the QMS is up-to-date and consistent with the new requirements. For instance, data reliability and ensuring the quality of data are increasingly important to the overall QMS.

  Other common areas of improvement include validation and technology transfer processes, risk management (including robust internal audit systems), sterility assurance, investigation and CAPA management. Industry bodies such as the IPA Quality Forum are already compiling best practices in some of these processes such as investigations and process validation.

  Many pharma companies have already established regulatory surveillance groups to make sure the QMS remains up-to-date and have also developed strong CAPA management systems, e.g., control towers to ensure sharing of learning across the network.

- **Strengthening quality during development and technology transfer:** A number of Indian companies have established Quality-by-Design (QbD) processes as well as technology transfer teams to improve robustness of products under commercial manufacturing. Organizations could continue to strengthen these processes and drive continuous improvement in process robustness. Key success factors include integrating operations from the early stages of process development and knowledge management across the lifecycle.

3.2.2 Management system

To ensure quality in the management systems, organizations could set up a governance system that balances quality and other objectives. Harmonization is a key enabler for the success of predictive quality metrics. Cascaded quality metrics from the CEO to the shop floor could help to drive accountability for quality outcomes, while shared metrics could help to drive effective collaboration across functions.

- **Using the power of metrics to quickly detect emerging quality issues:** There is a high degree of correlation between predictive metrics and eventual quality outcomes. It might be beneficial for the industry to move towards predictive metrics that could help to identify and resolve quality issues in time through

immediate action. Industry benchmarks like POBOS[21] commonly track predictive metrics such as right-first-time rate, yield, CAPA implementation time, investigation cycle time and recurring deviations.

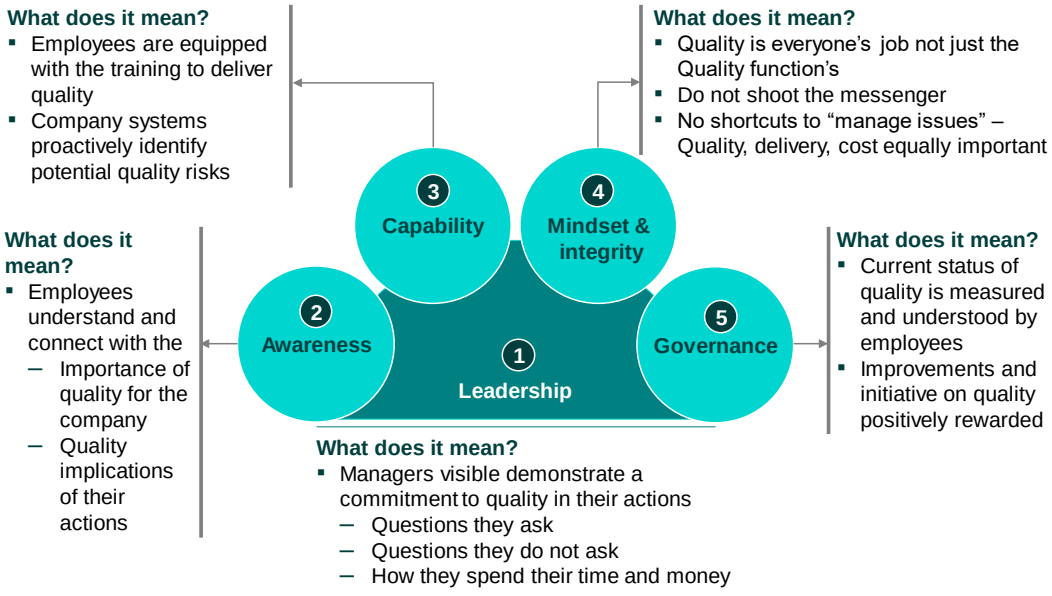
- **Improving governance mechanisms:** Multiple Indian pharma companies already have senior management forums, which could be further enforced and formalized as part of the company's governance mechanism. It could be linked to shop-floor review discussions through a set of common metrics. The role of strong top management support and its engagement in adopting and driving quality initiatives is quite essential. Some of the critical elements of managing for quality include conducting effective meetings, role-modelling the desired behaviours and ensuring accountability.

3.2.3 People system

It would be the leadership's responsibility to demonstrate commitment to quality and establish a culture of quality. Building the relevant capabilities is a crucial enabler in this context. Even the best designed processes and mechanisms need the support of the people aspect, in terms of mind-set and behaviours, for success. Leadership, governance, capabilities, mind-set and integrity, and awareness are the five important attributes that could define and help to measure a quality culture and its progress over time (Exhibit 5).

Exhibit 5

Culture could be assessed across five dimensions to identify focus areas and measure progress over time



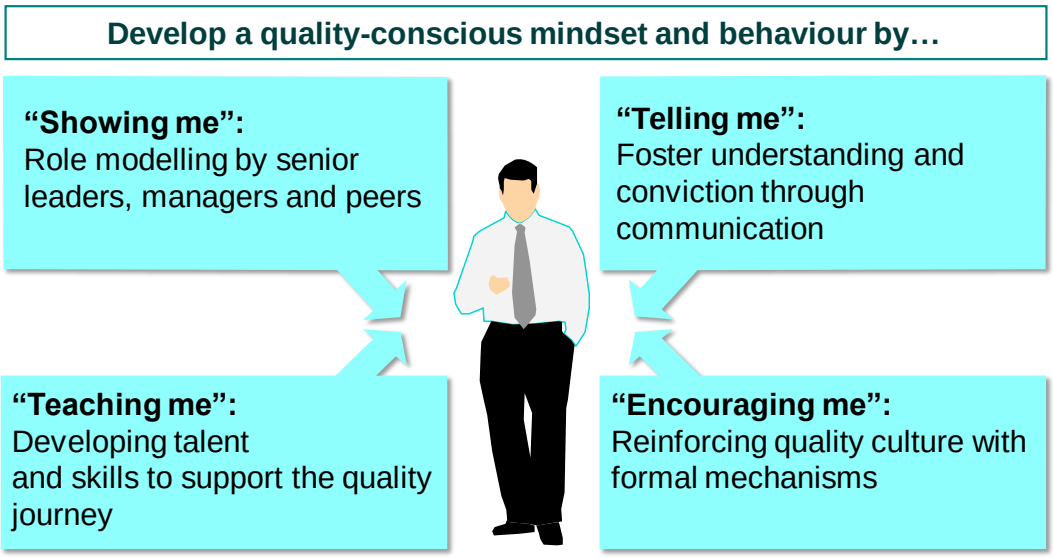
[21] McKinsey's POBOS benchmarking that covers more than 600 plants worldwide

- **Improving quality culture:** Companies could develop and implement a holistic plan across the four elements of culture change:
  - Extensive and multi-layered communication
  - Role-modelling by senior leaders, e.g., senior leaders' engagement at the site walk-through, Gemba, and coaching and problem-solving
  - Building skill sets
  - Adopting changes in the way performance is measured, i.e., balancing productivity and quality, and in the manner employees are rewarded, e.g., following systematic approaches to solving problems rather than one-time fixes.
- **Developing robust capability-building infrastructure:** For large-scale quality transformations, companies would have to build capability across the organization. Capability building usually involves using learning principles that combine classroom training and field work, including both mass and at-scale capabilities and targeted specialized topics like data reliability, sterility and assurance. Pharma companies could also follow an objective, metric-driven approach to measure training effectiveness. This would require close alignment between the QMS element and the quality training management process.
- **Strengthening the organization:** As the complexity and scale of operations evolve, companies may need to strengthen the organization by creating new specialist roles and upgrading competencies in existing roles, e.g., statistical expertise, quality and IT knowledge. Companies could build these specialist roles gradually based on the criticality of the function to the organization since these roles require specialized and cross-functional skill sets.

Finally, leaders play a crucial role in establishing a high aspiration for outstanding quality, setting goals and continuously revising the aspiration beyond visible frontiers. Leaders and CEOs would have to function like chief quality officers—that is, they would have to role-model desired behaviours and actions, instead of delegating the quality agenda to others in the organization. Leaders can inspire employees to imbibe a quality culture in four ways: by showing, by telling, by encouraging and by teaching them (Exhibit 6).

Exhibit 6

Leaders play an important role in building a culture of quality



3.3 LEVERAGING DIGITAL TECHNOLOGIES TO ACCELERATE THE QUALITY EXCELLENCE JOURNEY

Even following the three-system approach, transforming quality and building quality excellence could take years of effort and strong commitment from the senior management. Digital technologies provides a way (through proven approaches) to solve the bigger challenges in an accelerated manner and enable quality excellence (Exhibit 7).

Exhibit 7

Various digital tools available across the three systems

Operating system	▪ Advanced analytics for R&D to reduce development time
	▪ Simulations and rapid prototyping
	▪ Digital for automation of defect detection
	▪ Real time error correction using advanced analytics
	▪ Root cause analysis using advanced analytics
	▪ Breakdown prediction
Management system	▪ Real time performance monitoring
	▪ Remote monitoring using connectivity tools
	▪ Advanced analytics for connecting the dots and identifying quality risks
	▪ Improved quality governance through metrics and dashboards
People system	▪ Employee feedback on quality
	▪ Digital delivery for quality training and communication
	▪ Social media campaigns for communication of commitment to quality

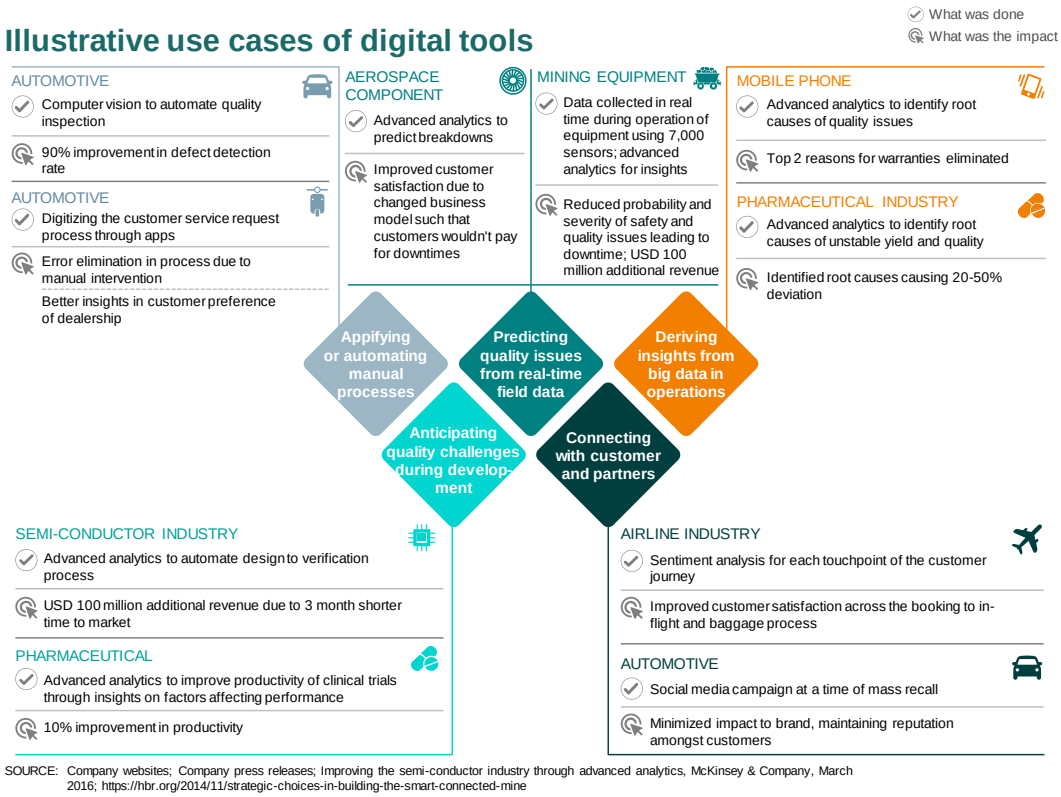
SOURCE: Company websites; press releases; McKinsey analysis

The broader digitization of organizations also profoundly impact quality. While well-implemented, robust enterprise software and other digital systems could improve quality, they might also create new and more complex risks. In this context, adoption of digital technologies and change-management processes are often seen as important challenges. For instance, a particular company that implemented a large automation software discovered that employees were maintaining duplicate manual records to ease daily operations, thus creating additional data reliability challenges.

Going forward, the next generation QMS could incorporate digital technologies, which might be restricted to elements like data reliability or documentation. Digital could also be integrated as a broader underlying theme in the organization's larger digital strategy. Quality functional organizations in pharma companies too need to build digital technologies or IT expertise.

Automation of manual processes and use of enterprise software are only an aspect of digitization. Large systems like warehouse management system, document management system and lab information management system could take years for full-scale adoption. While these are important enablers, other digital approaches like advanced analytics, big data and "appification" could also drive significant impact (Exhibit 8). As a first step, organizations could explore opportunities to use digital tools to solve quality issues across the operating, management and people systems.

Exhibit 8



SOURCE: Company websites; Company press releases; Improving the semi-conductor industry through advanced analytics, McKinsey & Company, March 2016; https://hbr.org/2014/11/strategic-choices-in-building-the-smart-connected-mine

3.3.1 Digital technology in the operating system

Apart from a broader digitization of the QMS, digital technologies offer opportunities to solve some of the major quality challenges at scale. A particular challenge is building quality into the design of products. Advanced analytics could be used to enhance process understanding which can be fed back into development.

Big data and advanced analytics have also been used to resolve recurring quality issues through better root-cause analytics. Predictive maintenance, anticipating breakdowns during product operations, real-time monitoring and error corrections during manufacturing could all help in improving overall product quality. Many Indian pharmaceutical companies are adopting advanced analytics to identify opportunities for yield improvement.

3.3.2 Digital technology in the management system

Governance standards and supporting metrics could help to embed the quality mind-set in the organization. They may also build a shared understanding of performance along various quality metrics across the organization.

Strong quality governance systems are able to make effective use of data by identifying quality risks via insights from disparate data sources, e.g., electronic data captured in the ERP system, lab data, manual investigation reports or Excel-based logs. This could also be extended to the field, patients and other partners through social media analytics. Additionally, sound governance could address important and emerging risks such as data reliability and cybersecurity.

Similarly, digital tools are increasingly being used to pull data from various sources to consistently calculate metrics, create transparency on the status of implementation of CAPAs and to streamline governance through visual dashboards. For instance, a major Indian pharmaceutical company deployed a single tool across more than 20 manufacturing sites to manage and track implementation of CAPAs.

3.3.3 Digital technology in the people system

Digital is also changing how employees engage with each other. For instance, at a large Indian pharmaceutical manufacturing site, instant messaging tools are being used to improve cross-functional coordination to reduce machine downtime significantly. Another company has deployed an app for employees to raise quality concerns and challenges.

Digital technologies would help to improve collaboration and provide an important channel to reach employees at scale through cloud-based virtualized environments

and information-sharing tools. They could also help cross-functional teams to experiment and innovate. These technologies offer real-time operating and quality information to frontline employees, allowing them to make quality improvement decisions, e.g., a leading pharma company provides connected iPads to factory workers for this purpose. Other tools offer employees risk-free channels to share their suggestions on quality improvement.

□ □ □

In the Indian pharmaceutical industry's growth journey, quality and compliance have emerged as areas requiring concerted action across stakeholders, including the government, regulators and industry associations. These stakeholders could help to build quality excellence by creating the ecosystem for quality. Individual companies could leverage this ecosystem to improve their operating, management and people systems. Emerging digital technologies and innovation could help resolve major quality challenges by accelerating the change and driving better and faster outcomes.

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