Confederation of Indian Industry

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Quality systems roadmap

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Foreword by CII

The Indian pharmaceutical industry has emerged as a significant part of the manufacturing and export sectors of the country. Aligned with the Make in India vision, it is undergoing remarkable change and adapting to the shifting dynamics of global consumer markets. As a sector which directly impacts health and well-being, the quality of products is of utmost importance.

The pharmaceutical industry is aware of the increased regulatory focus on quality. Over time, with increased regulatory scrutiny, quality has moved from the fringes of Indian pharmaceutical strategy to the very centre. The quality focus is increasingly going beyond regulatory compliance to all-time readiness, a critical pivot that will enable India to build on its global leadership in pharmaceutical manufacturing.

This report provides a roadmap for Indian pharmaceutical companies to capture opportunities for enhancing quality outcomes in manufacturing. The report aims to define the actions needed from all stakeholders, including the government, regulators, industry and academia, to strengthen and build India's quality attainments in the pharmaceutical industry.

I am confident that this report will prove to be a useful guide for the different stakeholders in the pharmaceutical ecosystem and will help the industry to create a new quality vision that will further drive its growth as a global leader.

Chandrajit Banerjee
Director General CII

Foreword by CII National Committee on Pharmaceuticals

Despite being the largest provider of generic drugs globally, the Indian pharmaceutical industry is highly fragmented, with varying degrees of capabilities. It comprises big players who are compliant with multiple global regulatory standards such as those of the USFDA and MHRA, along with a large number of small players who are still struggling with Schedule M compliance.

Though significant efforts have been taken to get the 'process' right and achieve parity with the best manufacturing practices observed in other sectors, the Indian pharmaceutical industry still has a long way to go in order to meet global standards on the whole.The industry has already started showing signs of considering quality as an important bottom line driver.

This is an intermediate step in the evolution of industry manufacturing systems and business models where quality becomes a revenue driver.With a little hand-holding of smaller players to achieve compliance, policy support from the government, and an emphasis from leaders on quality to trigger a cultural change in organisations, India can unlock its potential to achieve the pharma vision of becoming a global leader in end-to-end drug manufacturing. In the ever-evolving pharmaceutical landscape, investment in quality brings excellent return on investment. This report strongly advocates that quality is no longer an expenditure that companies incur to procure a licence in order to be in the business but is a way of life that drives revenues and separates winners from losers. It has direct imperatives on a company's margins, brand image, working capital and return profile.

I thank PwC for collaborating with CII and participating in shaping the roadmap to achieve Quality Vision 2020. I am also thankful to all members of the CII National Committee on Pharmaceuticals 2017-18 for their valuable contributions to this report.

Dr. Rajiv I Modi
Chairman, CII National Committee on Pharmaceuticals
Chairman and Managing Director, Cadila Pharmaceuticals

Foreword by PwC

'What got us here will not take us there' would be an apt maxim to describe the current dilemma that the Indian pharmaceutical sector is grappling with. The Indian pharmaceutical industry has shown tremendous growth over the last two decades—graduating from manufacturing API for the domestic market to API and subsequently formulations for developed markets. While the shift to manufacture specialty products for developed markets is ongoing, pharma companies continue to struggle with regulatory issues.

Data from FDA presentations and citations show an increased shift in the regulator's stance from a compliance-centric to a risk-based approach in assessing quality readiness. 'Process'-related shortfalls have been the fastest growing citation bucket in FDA 483 observations over the last four years. Ongoing harmonisation among global regulators compounds the issue as quality shortfalls at manufacturing sites get shared internationally. Against this backdrop of rising regulatory oversight, the importance of quality as a risk mitigator gets amplified.

India needs to accelerate infrastructure upgrade, shift the weight of quality from getting the product right to getting the process right consistently, invest in building capabilities to make quality culture a 'way of life', and match the global regulatory standards to gain leadership in end-to-end drug manufacture.

Quality focus is no longer a matter of hygiene but a clear competitive edge that companies will leverage to gain and retain market share at enviable profitability. Procrastination may cost us the next decade.

Sujay Shetty
PwC India Partner and Health Industries Leader
Pharma and Life Sciences Leader – Asia Pacific

Executive summary

Summary

- The Indian pharmaceutical industry has shown tremendous growth over the last two decades—graduating from manufacturing API for the local market to API and subsequently formulations for developed markets.
- While the shift to manufacture specialty products for developed markets is under way, pharma companies still struggle with regulatory issues.
- In the background, regulators across the globe are shifting their stance from compliance-based to risk-based audits along with sharing of information to drive harmonisation; however, there is much ground to be covered on this goal.
- Since quality mitigates risk, manufacturers that embrace quality as their key driver stand to benefit significantly. This requires organisation-wide change and process re-engineering but the payoff is material enough to pursue this investment.
- The 'Pharma Vision 2020' of the government's Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery.
- CII and PwC joined hands to conduct a survey of senior quality leaders to identify the roadmap that the stakeholders should follow to achieve 'Pharma Vision 2020'.
- This roadmap aspires to serve as a guideline along which the Indian pharmaceutical industry can design and benchmark its progress. We break this migration into the following buckets:

Infrastructure 'Aggressive augmentation of current infrastructure and human capital capacity building'	• Ensure **availability of quality infrastructure** (e.g. power, raw water, connectivity for pharma hubs). • Establish **academia and industry interface** to update curriculum and establish avenues for imparting basic domain experience to pharma graduates and diploma holders. • Encourage **learning and development investment** in all pharma mega parks.
Operations 'Quality-focused reengineering of manufacturing process and a unified view of supply chain'	• **Simplify and harmonise SOPs across the industry** to reduce training time, save cost and increase compliance. • Implement a **hands-on training programme** such as on the job training (OJT) to improve the comprehension of followers. • Leverage **automation, big data and the cloud** to achieve full transparency of data across suppliers, manufactures and channels. • Increase **R&D effort** through government, academia and industry collaboration; also encourage smaller pharma firms to engage in the same. • **Safeguard domestic bulk drug and API manufacturing** against cheap imports; provide impetus for the CRAMS and CRO sector.
Capability and culture 'Organisation capacity building to embrace quality as a way of life'	• Make quality a **key CxO agenda**. • Permeate **quality ownership from the board** level down. • Make quality an **integral part of the company's mission and vision.** • Empower quality personnel to **express disagreement** with scientific evidence. • Leaders should **walk the floor** to talk to and understand the pulse of people touching the product.
Regulation 'Regulatory agencies to create a level playing field'	• Aim for **global alignment of the regulatory expectations** and perspectives and help the industry develop common knowledge. • Train inspectors in **Indian FDA to achieve parity with US standards.** • Participate in the drive for **global harmonisation of regulations.** • **Harmonise inspection and enforcement** across firms of all size in India and abroad. • Articulate a clear **glide path to achieve WHO compliance** with adequate hand-holding.

The incredible rise of the Indian pharmaceutical sector

India aspires to be a global leader in the pharmaceutical industry…

- The Indian pharmaceutical industry was worth 20 billion USD in 2015 and is expected to expand at a compound annual growth rate (CAGR) of 15.92% to 55 billion USD by 2020.[1]

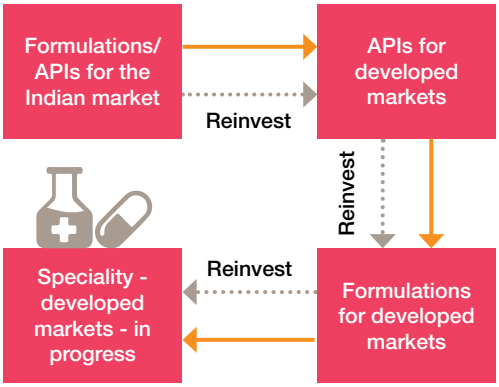
3rd
Rank of India by volume of pharma production

10%
Volume share of world's total pharma output

1st
India's rank in global generic exports

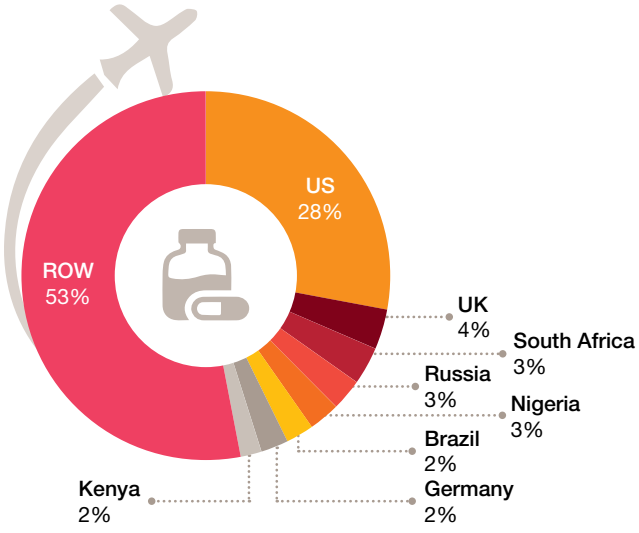
3rd
India's rank in production of APIs and dosage formulations

- Indian pharma growth is a culmination of three decades interspersed with two key pivots.
- The industry is now in the midst of the third pivot by getting ready with a pipeline of specialty drugs for developed markets.



- The Government of India plans to set up a 640 million USD venture capital fund to boost drug discovery investments and strengthen pharmaceutical infrastructure to help the industry achieve global leadership in pharma manufacturing.[2]
- Both MNCs and local companies continue to make significant investments in the manufacturing for:
  - Captive plants by export markets
  - Same plant to supply to different export markets
- Indian drugs are exported to more than 200 countries, which accounts for around 50% of its revenues. The US is its biggest export market.[3]
- Exports still remain a key growth driver as India aspires to be a global leader in 2020.
  - India is expected to rank amongst the top three pharmaceutical markets in terms of incremental growth by 2020.
  - Pharmaceutical exports from India were worth 16.84 billion USD in 2016–17, and are expected to reach 20 billion USD by 2020.

Percentage of pharma exports in USD (2014–15)



Source: Pharmaceuticals Export Promotion Council of India

For India to realise its aspirations, quality will be a key success factor.

1. Source: IBEF (https://www.ibef.org/industry/pharmaceutical-india.aspx)
2. Source: IBEF (https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation)
3. Source: IBEF (https://www.ibef.org/exports.aspx)

…however, there is considerable distance to cover in order to achieve parity with global standards.

While significant progress has been made on the quality front, a lot more is needed to gain industry leadership.

- Indian companies have experience with multiple regulatory agencies such as:
  - USFDA (US)
  - MHRA (UK)
  - TGA (Australia)
  - MCC (South Africa)
  - ANVISA (Brazil)
  - EMEA (EU)
  - MHLW (Japan)
  - Health Canada
  - NAFDAC (Nigeria)

India has the highest number of USFDA-approved plants outside of the US.

# of USFDA approved sites 2017: 546
# of WHO GMP approved sites 2017: 1,295

- However, there is still scope for improvement:

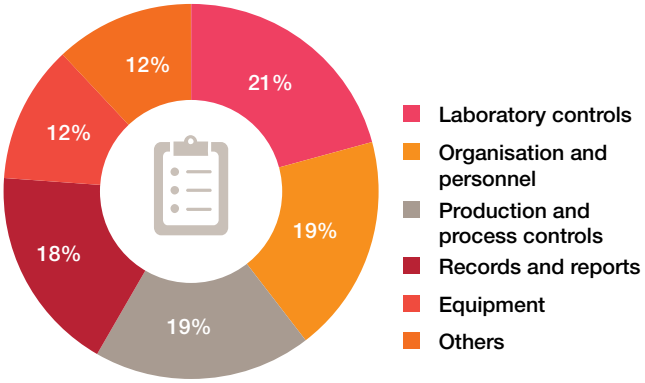
Key observation themes

- Conclusions based on lab results are not established scientifically using appropriate standards/sampling plans.
- Major responsibilities and procedures applicable to the quality control unit are not clearly written or fully followed.
- Major discrepancies arise due to failure to thoroughly investigate and review records.
- Procedures are lacking detail or are overly complicated and hence not fully followed.

Potential measure

- Robust procedures that have a sound scientific rationale
- Clarity in roles and responsibilities and ownership of quality across functions
- Drive quality culture through a holistic approach to execution
- Simplification and harmonisation of procedures to enable ease of execution; effective training

Percentage area quoted in 2016 USFDA 483s



It is important for pharma companies to comprehend the subtle yet critical migration of regulators towards promoting organisations that demonstrate all-time readiness on a sustained basis. The offshoot is that companies are mandated to invest in instituting a quality culture and architecting a organisation-wide transformation to embrace quality.

Regulatory developments

Shift of regulatory stance – going beyond compliance

Three major trends are shaping the regulatory stance in pharma manufacturing:

A. Shift from compliance-based to risk-based audits

B. Use of quality data to make informed decisions

C. Collaboration across regulatory agencies

A. Shift from compliance-based to risk-based audits

- The MHRA was one of the first drug agencies to move to this concept, followed by many other agencies, including the USFDA.
- The USFDA is attempting to move towards reducing regulatory oversight of participants that perform above average on quality metrics and ensure that good products drive bad products out of the markets.
  - Identify those performing above the requirements and reduce regulatory oversight.
  - Remove poor quality products from the marketplace.
  - Use quality metrics as an additional tool in the surveillance toolbox.

B. Use of quality data to make informed decisions

- FDA is soliciting data on quality metrics from the industry that will be used to ascertain pointers towards organisation preparedness for delivering consistent quality products.

	Example quality metrics data	Calculated metrics
	Lot acceptance rate	Robustness of commercial manufacturing process
	Invalidated out-of-specification rate	Robustness of laboratory operation
	Product quality compliance rate	Voice of the patient/ customer

Shift of regulatory stance – leveraging quality data

The USFDA has already begun incorporating quality metrics in its audit decision making as is evident from the following initiatives:

Initiative	Description
FDASIA Metrics Initiative	• Shift from compliance-based to risk-based enforcement actions • Focus on product and process robustness
FDA's Office of Pharmaceutical Quality	• Leverage quality history to inform decisions related to approval of new products • Ensure end-to-end integration of quality throughout the product's life cycle
FDA's New Inspection Protocol Project	• Proactive and consistent approach to determine the state of quality during production • Assess site's ability to consistently deliver quality
Quality-based inspection approach	• Simultaneous assessment of quality system effectiveness and organisational efficiency • Focus on driving continuous improvement
GMP Intelligence Program	• Monitoring of enforcement actions like FDA form 483, warning letters, recalls, import alerts, consent decree agreements, EU reports and inspection summaries

Shift of regulatory stance – regulatory collaboration

C. Collaboration across regulatory agencies

- Regulatory collaboration to exchange information under confidentiality agreements benefits all stakeholders.

Regulatory collaboration

Patient	Regulators	Industry
Provides access to high-quality medicine at the best possible rate.	Optimises resources, reduces training cost of inspectors and reduces compliance evasion.	Reduces compliance cost and bureaucracy.

- The EU and the US signed the revised mutual recognition agreement for Good Manufacturing Practices (annexure) this year to exchange information on GMP inspection and facilitate cross-trade of medicinal products.
- In 2014, the EU launched its information-sharing pilot—the International Generic Drug Regulators Programme (IGDRP)—as a model for sharing of information during scientific assessment phases.
  - Currently, the pilot involves EU authorities as well as Health Canada, Swissmedic, the Taiwan Food and Drug Administration (TFDA) and the Therapeutic Goods Administration (TGA) of Australia.
- The MHRA co-operates with the FDA to facilitate the sharing of otherwise non-public documents and information that includes but is not limited to:
  - Post-authorisation pharmacovigilance data held by an authority which raises safety concerns about a product manufactured or distributed in the territory of the other
  - Information on quality defects or product recalls held by an authority in relation to medicinal products which are distributed or have been manufactured in the territory of the other
  - Information contained in marketing authorisation applications which is of significant public health interest to the authority to which it is disclosed

Companies that do not align their processes and culture to this new regulatory reality will endanger their competitiveness and future in pharma manufacturing.

Quality vision and roadmap

Quality vision

Vision 2020 – Global leader in end-to-end drug manufacture

- The clarion call for the industry is to achieve 'peak performance' across the key pillars for it to record sales worth 55 billion USD by 2020. Every stakeholder of the pharma ecosystem—the government, regulators, and the industry—needs to come together and voluntarily cut down slack to power the industry's next leap.

Pillars

1. Infrastructure

- Shared facilities that ease manufacturing bottlenecks and allow more time to be invested in getting quality right
- Investments in building human capital

2. Operations

- Research-driven production culture
- Decluttered and transparent supply chain
- Consolidation among contract manufacturers
- Perceptive organisation that anticipates where quality may get compromised

3. Capability and culture

- Leadership-driven quality culture which focuses on the empowerment of all those who touch the product
- Capability building to embrace quality as way of life
- Quality inculcated as a continuous best effort function rather than a reactive inspection passing unit

4. Regulation

- Efforts towards driving down approval timelines
- Inspection approach move from 'check to penalise' to 'collaborate to improve'
- Hand-holding by bigger players in making India achieve WHO compliance universally

Quality roadmap – how to achieve the future

		Current state	Future state	
			Mid term	Long term
Infrastructure	1. Infrastructure	• Shortage of NABL accredited labs • Inadequate infrastructure (water, power)	• Strict enforcement of NABL accredition • Cluster development with common facilities such as effluent treatment and pollution control	• Enhanced network of NABL labs • Acceleration of infrastructure development
Infrastructure	2. Academia	• Acute shortage of skilled manpower in research and operations • Severe shortage of skilled resources by 2022 – forecasted by NSDC	• NIPERS extended as innovation hub • Internship for diploma holders and ITI graduates; mentorship by senior leaders at organisations • Curriculum revamp along with industry-academia collaboration	• Learning and development infrastructure in pharma mega parks
Operations	3. Product development	• Insufficient R&D spending • Low penetration of concepts like QbD, design space, CtQ and CPP • Prioritisation of time to launch over robust process development	• Collaborative research by academia and industry • Policy support for SMEs to invest in R&D • Use of technology for in-depth process and analytical understanding	• Incentives for R&D to encourage innovation • Adoption of Six Sigma process capabilities
Operations	4. Manufacturing	• Excessive focus on production throughput and volume • Complicated SOPs that increase compliance burden • Basic level of process measurement done manually	• Process optimisation to cut costs • Simplification of SOPs and practical training (OJT) deployment • Automation-enabled process measurement that anticipates failures and slippages	• Big data and cloud used for process optimisation • Harmonisation of general SOPs across the industry • Technology-enabled dashboards to do away with product testing
Operations	5. Supply chain management	• Highly fragmented supply chain –quality control outside of manufacturing unit is difficult • Multiple pain points such as quality issues with suppliers, different regulatory requirements across export markets, poor technology penetration, unequipped distribution network and infrastructural gaps	• Tighter quality control over imported bulk drugs and intermediates • Full data transparency across supplier, manufacturer and channel • Clearly defined logistics requirement with active control over service providers	• Policy support such as minimum import price for bulk drugs • Benchmarking with best in class procurement industries through technology-enabled processes • Development of specialist logistics providers with end-to-end capabilities • 24x7 logistic operations through schemes like Bharat Mala

		Current state	Future state	
			Mid term	Long term
Capability and culture	6. Quality unit capability	• Quality unit is a compliance-centric reactive unit that operates on the philosophy of 'fix when broke'	• A better trained organisation that uses global best practices and anticipates potential risks	• Quality capabilities are well distributed from the operating to leadership level • Deeper quality expertise and practice leads to accelerated career progression
	7. Academia	• Operational metrics are preferred over quality metrics	• Automation-enabled predictive analysis of quality metrics to identify and mitigate risks proactively	• Balanced set of operational and quality metrics are used to set firm's priorities
	8. Culture	• Quality is viewed as a cost centre • Culture of avoiding bad news • Quality viewed as a 'license to operate' rather than a value driver	• Quality is the responsibility of everyone in an organisation • Quality is a part of the company vision and mission • Organisation empowers employees who advocate quality	• Company's culture promotes 'all-time readiness' with structured continuous improvement programmes
Regulation	9. Minimum compliance standard	• Small-scale industries struggle with space requirement, air handling units and lengthy documentation of Schedule M compliance	• Centre of Excellence for SSI to address non-capital intensive points of Schedule M compliance • Government budgetary support for capital-intensive points	• Clear guidance path to achieve universal WHO compliance • Incentives for WHO compliance such as procurements from the National Health Mission funds from GMP/GLP compliant manufacturing units only
	10. Regulatory inspection	• Inspections still focus on compliance adherence • Irregular audit of NABLs and long approval timelines raise quality concerns and slow down the entire supply chain	• Product-centric approach through quality index and risk rankings • Gradual reduction in inspection rigour for those who demonstrate adherence to quality metrics • Regular annual audit of labs	• Rewards for continued quality adherence by decreasing the frequency and duration of inspections • Mandatory bioavailability and bio-equivalence tests for all drug manufacturing permissions
	11. Global regulatory landscape	• Global regulations continue to become more complex and difficult to comply with • Regulatory skill-building efforts are picking up speed	• Active collaboration to achieve global harmonisation (MD-SAP, FDA/MHRA, Q12, PIC/S) • MoU with the USFDA and the UK's MHRA to cross-pollinate best audit practices	• Regulation amendments to encourage innovation and continuous improvement • Capacity augmentation to conduct annual inspections by augmenting inspector counts and upgrading their skills

Stakeholder actions to achieve the quality vision

Actions to achieve the vision

The government

	Short term	Long term
Infrastructure	• Accelerate the Cluster Development programme unveiled in the Make in India initiative for creation of common facilities such as pollution control and effluent treatment plants near a major pharma manufacturing zone. • Transform the National Institute of Pharmaceutical Education and Research (NIPERS) into an innovation hub to increase the number of R&D professionals available in the country.	• Continue acceleration in infrastructure development, especially in the areas of water and power generation. • Encourage more NABL accredited labs to come up in the country. • Set up learning and development programmes at pharma mega parks to create a ready pool of talent that companies can hire from.
Operations	• Provide fiscal incentives and tax sops to small and medium enterprises in order to stimulate investments in innovations and R&D. • Encourage rapid entrepreneurship in the cold chain/temperature controlled logistics industry. • Get rid of unfavourable policies such as small-scale reservation policy for drugs such as paracetamol which makes Indian players loose economies of scale over Chinese manufacturers. • Revive public sector units to ensure a manufacturing base for APIs and intermediates.	• Incentivise R&D by strong IPR and legally enforceable out-licensing contracts for innovation to bloom. • Implement uniform pricing structure for imported API and intermediates. • Materialise plan to implement peak customs duty on the import of APIs, identify drugs for import substitution and set up mega drug parks to give a boost to domestic production. • Become a 24x7 continuous operations country through schemes like Bharat Mala, which will bring down lead times by reducing slack in the supply chain. • Drive consolidation of the contract manufacturing sector.
Regulation	• Implement regulatory skill building as part of the Make in India campaign to have CDSCO sign an MoU with the USFDA and UK's MHRA to cross-pollinate best audit practices. • Provide budgetary support to the SSI to comply with the capital-intensive requirement of Schedule M.	• Ensure WHO standards are adopted by all manufacturing units by incentivising small-scale industries to become compliant and by mandating procurements from the National Health Mission funds to be from GMP/GLP compliant manufacturing units only.

CDSCO

	Short term	Long term
Infrastructure	• Enforce NABL accreditations strictly and comprehensively across lab infrastructure.	
Operations	• Tighten the regulatory control over Chinese suppliers.	
Regulation	• Initiate talent development programme for Indian FDA inspectors. • Develop quality index allotting risk ranks to companies on audit status. • Take a product quality-centric approach to inspection with deep understanding of critical quality metrics. • Reduce inspection rigour for manufacturers who demonstrate proven adherence to quality metrics in past inspections. • Participate in the ongoing regulation harmonisation efforts (MD-SAP, FDA/MHRA, Q12, PICS). • Build active forums for regulators and the industry to collaborate on a global basis to advance quality agenda.	• Link audit rigour with rank on quality index to incentivise companies in improving their quality adherence by reducing frequency and duration of inspections. • Make bioavailability and bio-equivalence tests mandatory for all drug manufacturing permissions. • Institute regular annual audit of labs which will conduct BA/BE tests and certify the results. • Imbibe a deep understanding of impact of quality on safety and effectiveness of the product in the inspection SOP. • Actively collaborate with manufacturers to improve access and patient outcomes. • Develop capacity to conduct annual inspections by augmenting inspector count and their skill. • Implement regulation amendments with the objective of continuous improvement in the quality of the manufacturing process. • Encourage innovation by prescribing in regulatory legislation what can't be done rather than what needs to be done to encourage innovation. • Keep annual targets to review and prune regulatory statutes to keep adherence strict but simple for manufacturers to comply with.

Academia

	Short term	Long term
Infrastructure	• Institute internship programmes for diploma holders and ITI graduates to make them job ready by the time of graduation. • Collaborate with the industry on research.	• Conduct immersive review of current Bachelor of Pharmacy curriculum and align with industry needs.

Industrial bodies

	Short term	Long term
Process and governance	• Harmonise SOPs across the industry to reduce training time which increases productivity; reduce training cost when employees move from one company to another and increase compliance by adopting best practices.	
Regulation	• Institute a Centre of Excellence around Schedule M compliance for small-scale pharma manufacturers to address compliance points that do not need capital investment. • Provide an active forum for regulators and the industry to collaborate on a global basis to advance the quality agenda.	• Prepare a guidance path for small-scale manufacturers to achieve WHO compliance.

Companies

	Short term	Long term
Infrastructure	• Establish a culture of seed and pollinate where senior leaders are rewarded for mentoring and coaching programmes. • Collaborate with academia on research.	
Operations	• Optimise processes to cut cost and increase compliance. • Simplify SOPs to make them consistent with operations and improve the comprehension of followers. • Implement OJT for better comprehension. • Increase lab optimisation. • Develop products with an in-depth process and analytical understanding that meet the patient's and society's needs while using relevant DfX concepts.	• Implement real time in-line analytical monitoring. • Link all the manufacturing data and provide the ability to provide real-time evidence by correlating batch information with patient's medical outcomes. • Consider having a fully functional cloud with all relevant development, manufacturing and quality information with the ability to trend and predict failures. • Focus on getting new molecules not just for the Western but for the Indian market too. • Target Six Sigma process capabilities. Automation and removing the human factor is critical. • Implement technology-enabled dashboards to do away with product testing by identifying failures proactively.
Capabilities and culture	• Quality should be owned by each operation function; make quality unit horizontal with R&D and manufacturing. • Stress test the process with observations reported in the past and with peers (national and global). • Submit mock quality internal audit report to the board biennially. • Engineer quality relay in the process to drive the practice of achieving the optimal output at each intermediate process stage. • Include quality in the company's vision and align it with the firm's strategy. • Encourage employees to express disagreement with evidence. • Managers should empower reportees to say 'no'. • Leaders should walk the floor to talk and understand the pulse of people touching the product.	• Make quality a part of the process design flow to ensure better process engineering. • Create career paths that encourage quality personnel to invest in themselves. • Make quality adherence and improvement a part of the board audit exercise. • Prepare quality dashboards and make them a part of management appraisal. • Use a balanced set of operational and quality metrics to set priorities and communicate to the larger organisation to hold development and operations accountable for quality. • Rotate senior management as quality champions driving quality adoption from top to down. • Promote a culture of all-time readiness with structured continuous improvement programmes.

Conclusion

Conclusion

- With 20% of the global export volume share of generic medicines, India is known as 'pharmacy of the world' and is working towards building its brand as the 'high quality pharmacy of the world'.
- Many initiatives have been launched by both the industry and the Government of India to give this sector a boost:
  - Patent protection
  - Best effort alignment of inspection guidelines with WHO
  - Policy support such as mega drug parks and 24x7 logistic operations through Bharat Mala
  - Cross-learning from other regulatory agencies such as CDSCO-US FDA workshop on GMP inspections for Indian inspectors
  - Accelerated adoption of automation and efforts to achieve the state of all-time readiness for inspections
- However, there are still areas for improvement in order to take the next ladder of growth:
  - Shortage of NABL accredited labs, inadequate utility infrastructure
  - Acute shortage of skilled manpower in research as well as operations
  - Attitude to trade off quality for production throughput, volume and time to market in process design
  - Highly complex supply chain that makes quality control difficult
  - Compliance-centric reactive quality unit that operates on the philosophy of 'fix when broke'
  - Struggle of smaller players with even Schedule M compliance
- In order for India to achieve Pharma Vision 2020 and become a global leader in end-to-end drug manufacturing, holistic and coordinated efforts are required from the government, academia and industry along the following lines:

Government

- Protect the sector against predatory import dumping.
- Incentivise learning and development to build capable human capital for the sector.
- Democratise research in the industry by strengthening the IPR regime.
- Invest in building regulatory capability by adopting the global best practices.

Regulatory

- Strengthen regulatory capacity by hiring more resources, better training of inspectors and strict target setting to enforce regulations by periodic audits.
- Work to change the perception of quality from a penalising exercise to a rewarding investment by easing regulatory oversight of firms that demonstrate continuous audit performance.

Industry

- Percolate quality change management from the top; understand the pulse of people who touch the product and sensitise them towards owning quality.
- Change from a culture of yes-men to one where employees freely express their disagreements with evidence.
- Begin the journey towards continuous manufacturing by leveraging modern technologies/equipment and achieving operations excellence on par with other sectors (e.g. automotive).
- Implement technology-enabled dashboards to do away with product testing at the end of manufacturing by identifying failures proactively.
- Reward employees at all levels for good quality adherence and observance.

Academia and industry bodies

- Actively pursue avenues for internship for ITI graduates and diploma holders.
- Expand opportunities for collaborative research with the industry.
- Revise *Bachelor of Pharmacy* curriculum to make it more industry relevant.

Geographical industry identifiers such as Japan for quality electronics and Germany for quality engineering have had significant payoffs for industry. Similarly, it is about time that India aspires to become synonymous with quality medicine.

Notes

Notes

About CII

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering industry, Government, and civil society, through advisory and consultative processes.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, playing a proactive role in India's development process. Founded in 1895, India's premier business association has over 8,500 members, from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 200,000 enterprises from around 250 national and regional sectoral industry bodies.

CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, healthcare, education, livelihood, diversity management, skill development, empowerment of women, and water, to name a few.

As a developmental institution working towards India's overall growth with a special focus on India@75 in 2022, the CII theme for 2017-18, **India@75: Inclusive. Ahead. Responsible** emphasizes Industry's role in partnering Government to accelerate India's growth and development. The focus will be on key enablers such as job creation; skill development and training; affirmative action; women parity; new models of development; sustainability; corporate social responsibility, governance and transparency.

With 67 offices, including 9 Centres of Excellence, in India, and 11 overseas offices in Australia, Bahrain, China, Egypt, France, Germany, Iran, Singapore, South Africa, UK, and USA, as well as institutional partnerships with 344 counterpart organizations in 129 countries, CII serves as a reference point for Indian industry and the international business community.

Confederation of Indian Industry

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