Mahesh Kumar Mittal & Co.

Navigating Internal Audit Dynamics in the Pharmaceutical Landscape

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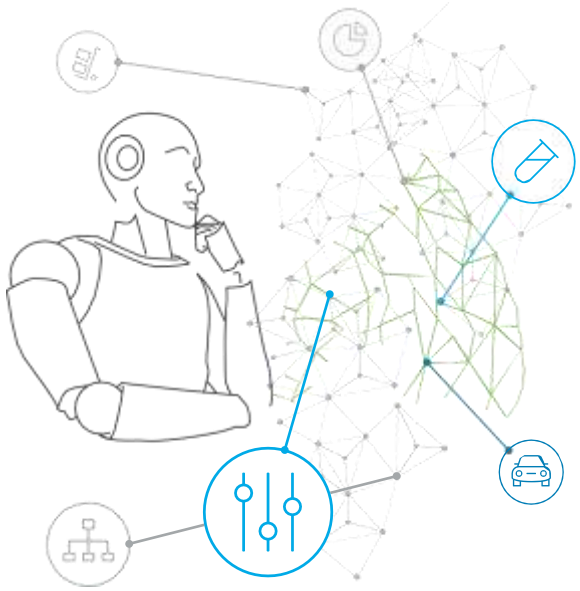
Preface

Today, The **Indian pharmaceutical industry** has evolved from its inception to become a global leader in providing affordable and high-quality healthcare solutions.

Rooted in a legacy of innovation and resilience, it has thrived on the production of generic medicines, earning the reputation of being the "pharmacy of the world." With a focus on research, development, and stringent regulatory compliance, Indian pharmaceutical companies have expanded their reach across the globe, supplying essential medications to diverse markets.

Internal audits are the backbone of regulatory compliance and operational excellence in the pharmaceutical industry. They serve as a robust mechanism for verifying adherence to the myriad regulations governing the sector, encompassing everything from manufacturing processes to distribution channels. Given the high stakes involved in pharmaceutical operations, where even minor deviations can have significant consequences, internal audits take on added importance. They are not just routine checks but strategic endeavors aimed at detecting and addressing non-compliance issues promptly. By scrutinizing processes and systems, they identify areas for enhancement, leading to improved product quality and operational efficiency. Moreover, in an industry characterized by complex supply chains and evolving regulatory landscapes, internal audits play a pivotal role in risk management. By assessing risks associated with various aspects of operations, from raw material procurement to final product delivery, they enable companies to implement robust risk mitigation strategies.



Indian Pharmaceutical Industry (Market Overview)

Low cost of manufacturing (30%–35% lower than in the US and Europe), cost-efficient R&D (about 87% less than in developed markets)

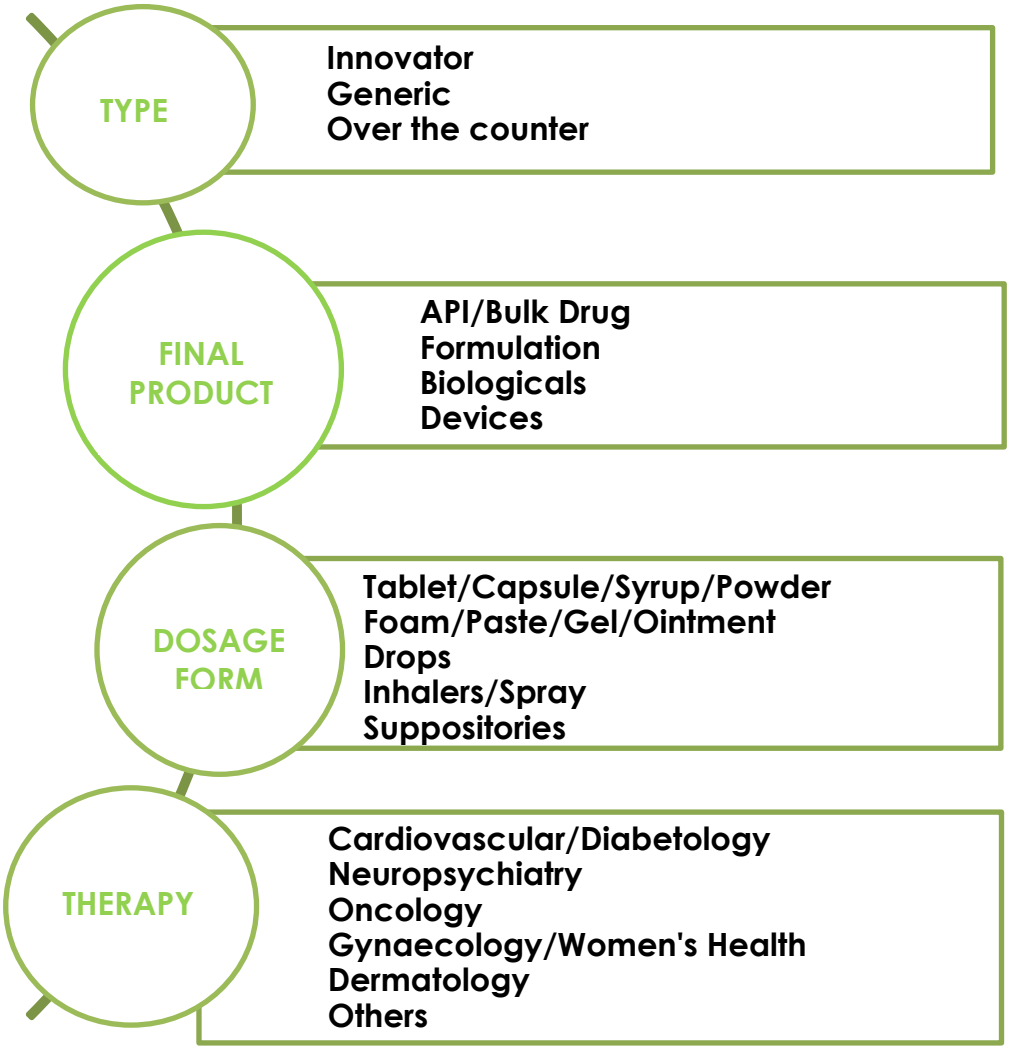
Serving demand from 150+ countries worldwide, with 10,500+ manufacturing facilities

Supplies over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK.

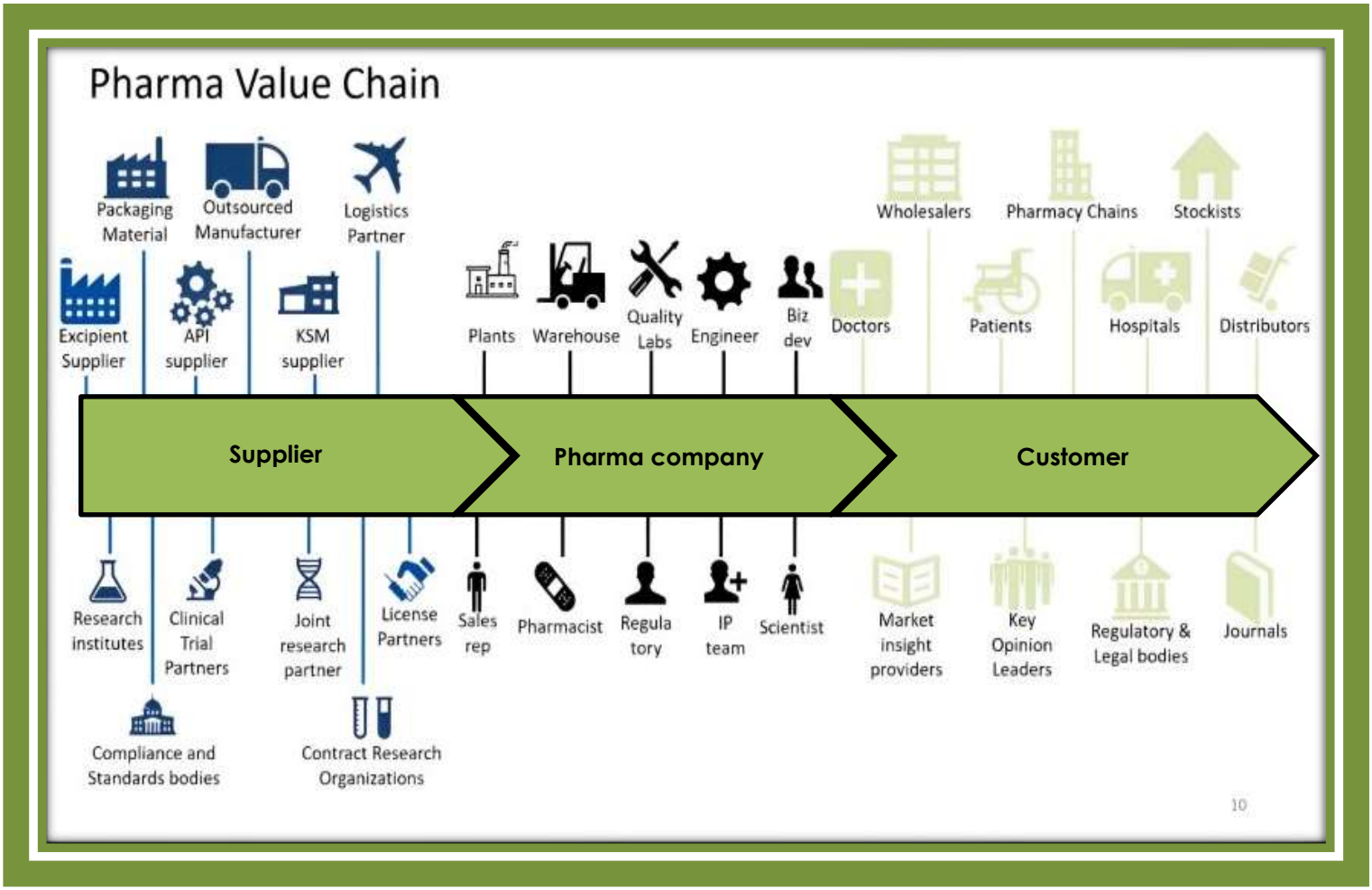
India's Pharma exports USD

12th largest exporter of medical goods in the world 3rd largest in in the world in terms of volume and 14th largest in terms of value.

Pharma Panorama: A Comprehensive Overview of Industry



Pharma industry supply chain



The pharmaceutical supply chain in brief involves:

1. Supplier: Provides raw materials and active pharmaceutical ingredients (APIs).
2. Pharma Company: Manufactures, tests, and packages the medications.
3. Customer (Patients): Receives the final product through pharmacies or healthcare providers.

Compliance with various law

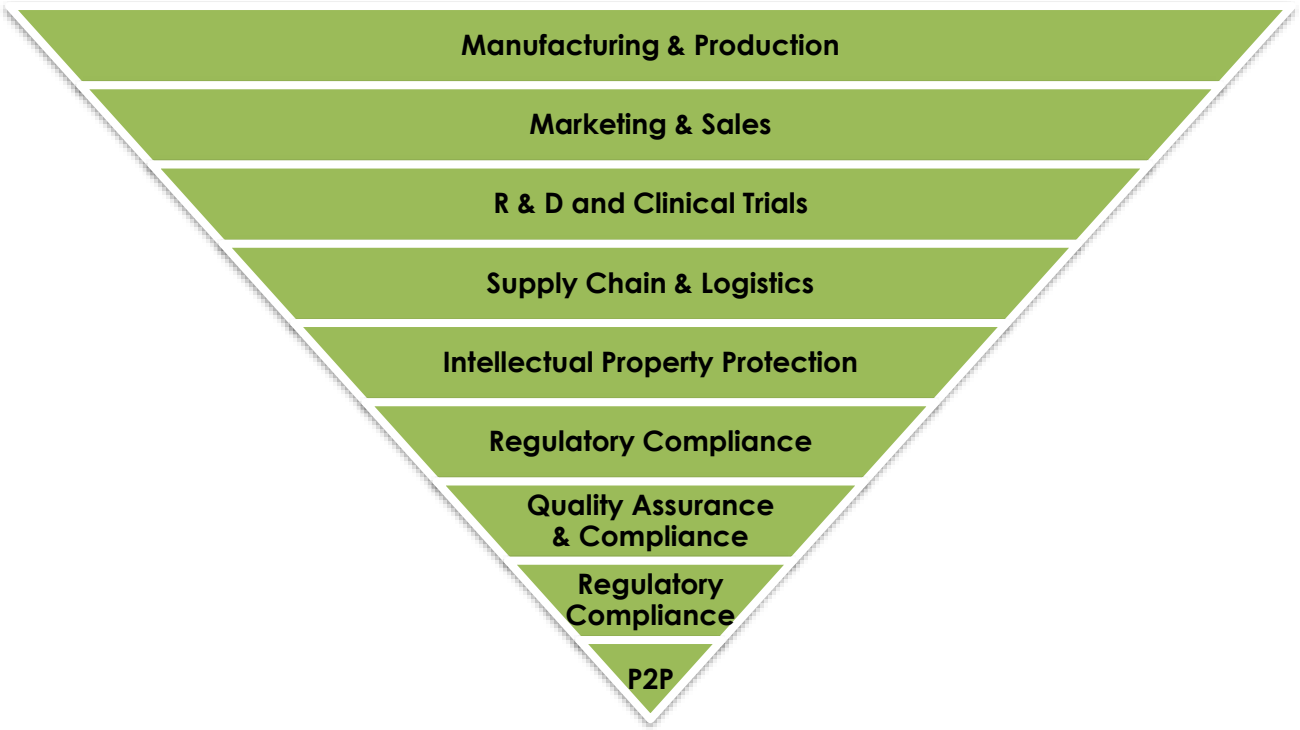
Law/Regulation	Compliance Focus in Internal Audit
Drugs and Cosmetics Act, 1940	Verification of adherence to requirements for drug import, manufacturing, distribution, and sale.
Drugs and Cosmetics Rules, 1945	Review of compliance with specific rules regarding manufacturing standards, labeling, and licensing
Central Drugs Standard Control Organization (CDSCO) Guidelines	Assessment of compliance with CDSCO guidelines for drug approval, clinical trials, and quality control.
Good Manufacturing Practices (GMP)	Audit of adherence to GMP guidelines for manufacturing processes, facility standards, and personnel training.
National Pharmaceutical Pricing Authority (NPPA)	Assessment of pricing practices to ensure compliance with NPPA regulations, including pricing notifications and controls.
Good Distribution Practices (GDP)	Evaluate storage and transportation conditions. Assess documentation and traceability of distribution activities.
The Pharmacy Act, 1948	Verify that pharmacy operations are conducted by registered pharmacists and pharmacy technicians in accordance with the Act's provisions. Ensure that the organization maintains accurate records of pharmacy licenses and registrations, and that renewals are conducted in a timely manner.

Non-compliance in Pharmaceutical Industry

Area of Non Compliance	Examples	Corrective Actions
Documentation Issues	• Incomplete or inaccurate records • Outdated SOPs • Poor documentation of processes	• Update and verify records • Update SOPs regularly • Assign roles and responsibilities for document management, including document owners and approvers.
Manufacturing Non-conformities	• Departures from standard operating procedures • Malfunctioning or improperly calibrated equipment, lack of maintenance records or using equipment not meeting specifications. • Insufficient material inspections, or mislabeling of materials	• Adhere to approved processes • Implement regular equipment maintenance schedules
Quality Control Failures	• Inadequate testing • Deviations from established quality control procedures and standards	• Enhance testing protocols • Standardize quality measures
Supply Chain Management	• Non-compliance with supplier qualification	• Conduct supplier audits to assess compliance with quality standards and regulatory requirements
Storage and Distribution Problems	• Improper storage conditions • Poor tracking • Inadequate temperature control	• Maintain optimal storage conditions • Implement robust tracking systems • Ensure proper temperature control
Regulatory Non-compliance	• GMP(Good Mfg. Practices)/GDP (Good Distribution Practices)violations/ Good Clinical Practices (GCP) • Delayed adverse event reporting • Lack of proper licensing for manufacturing, distribution, or sales of pharmaceutical products. • Inaccurate or incomplete reporting to regulatory agencies	• Analyze internal processes, procedures, and controls to identify gaps or deficiencies contributing to the violation. • Implement preventive measures to reduce the likelihood of similar non-compliance in the future. • Ensure adherence to GMP/GDP • Timely report adverse events • Regular compliance reviews
Training Deficiencies	• Insufficient training programs • Lack of training documentation • Outdated training	• Develop comprehensive training programs • Document training sessions • Update training regularly
Risk Management Lapses	• Poor risk assessments • Lack of risk reviews • Ineffective risk management	• Conduct thorough risk assessments • Regularly review risks • Improve risk management strategies

Key Drivers of Pharma

COST DRIVER



REVENUE DRIVER

Pharmaceutical Process and Key Controls

Research & Development

- Ensure adherence to regulations & Bio-medical waste management SOP is monitored.
- Incidents are reported as per SOP on incident reporting and investigation.

Controlled Substances

- Perform Physical verification of controlled substances each quarter.
- Ensure controlled substances are stored in a separate storage vault/cage to ensure safetv.

Government Pricing

- Material master should updated basis FDA letter, which is serially tagged and filed.
- Conduct regular reviews to ensure that government pricing calculations and submissions comply with applicable laws, regulations, and contractual obligations.

Regulatory Affairs

- Ensure compliance with regulatory standards such as Good Distribution Practice (GDP)
- Ensure that Confidentiality Disclosure Agreements (CDAs) are in place with local agents to protect confidential information and prevent unauthorized disclosure or use.
- Audit Pharmaco vigilance systems and processes to ensure timely and accurate reporting of adverse events.

Distribution, Supply Chain and Sales

- Goods are transported /stored in a temperature range as per SOP.
- System should prevent sale of plan near expiry or expired finished goods
- Implement controls to monitor and reconcile inventory levels, including regular physical counts, inventory tracking systems, and secure storage facilities.

P2P

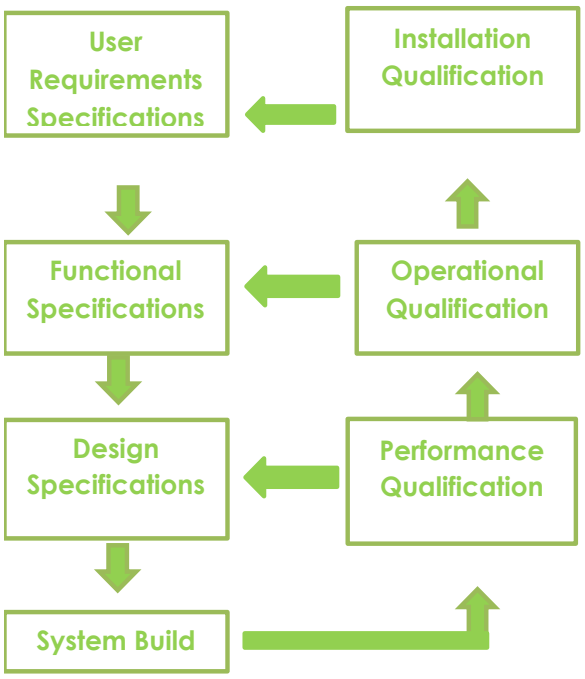
- Regular supplier assessments to ensure financial stability, reliability, and quality compliance. System does not allow users to raise PO where vendor technical qualification is overdue.
- Implement robust quality control measures including, quality assurance protocols, and compliance with Good Manufacturing Practices (GMP).
- Incorporate a quote comparison process to select the best procurement options for materials.
- Ensure that the requisition and PO are authorized and approved by relevant departments before proceeding with the purchase.
- Ensure regular updates and reconciliation of the inventory system with purchase orders, invoices, and delivery notes.

Quality

- System should restrict issue of expired/ short expiry materials.
- Audit trail for creation/change of inspection lots should reviewed monthly.

Pharmaceutical Controls: IT and Instrument Environment

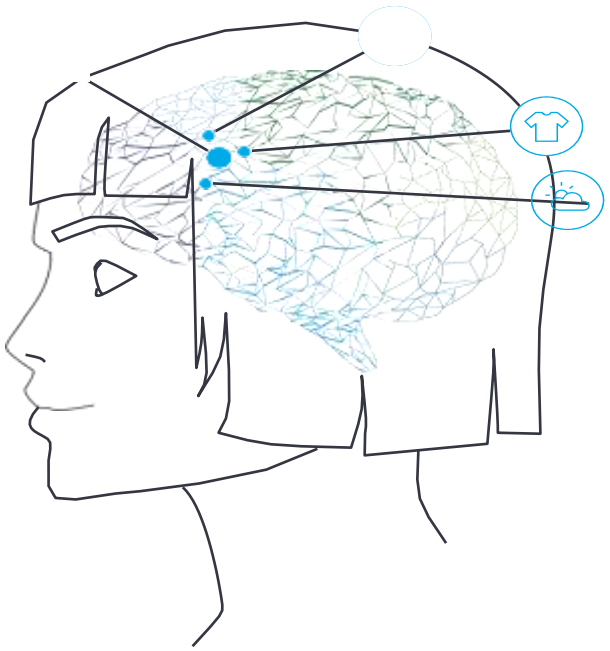
Computer System Validation - Validation or verification of system (equipment or software) is an essential part of a quality system.



Ensures that the installed system meets the specifications

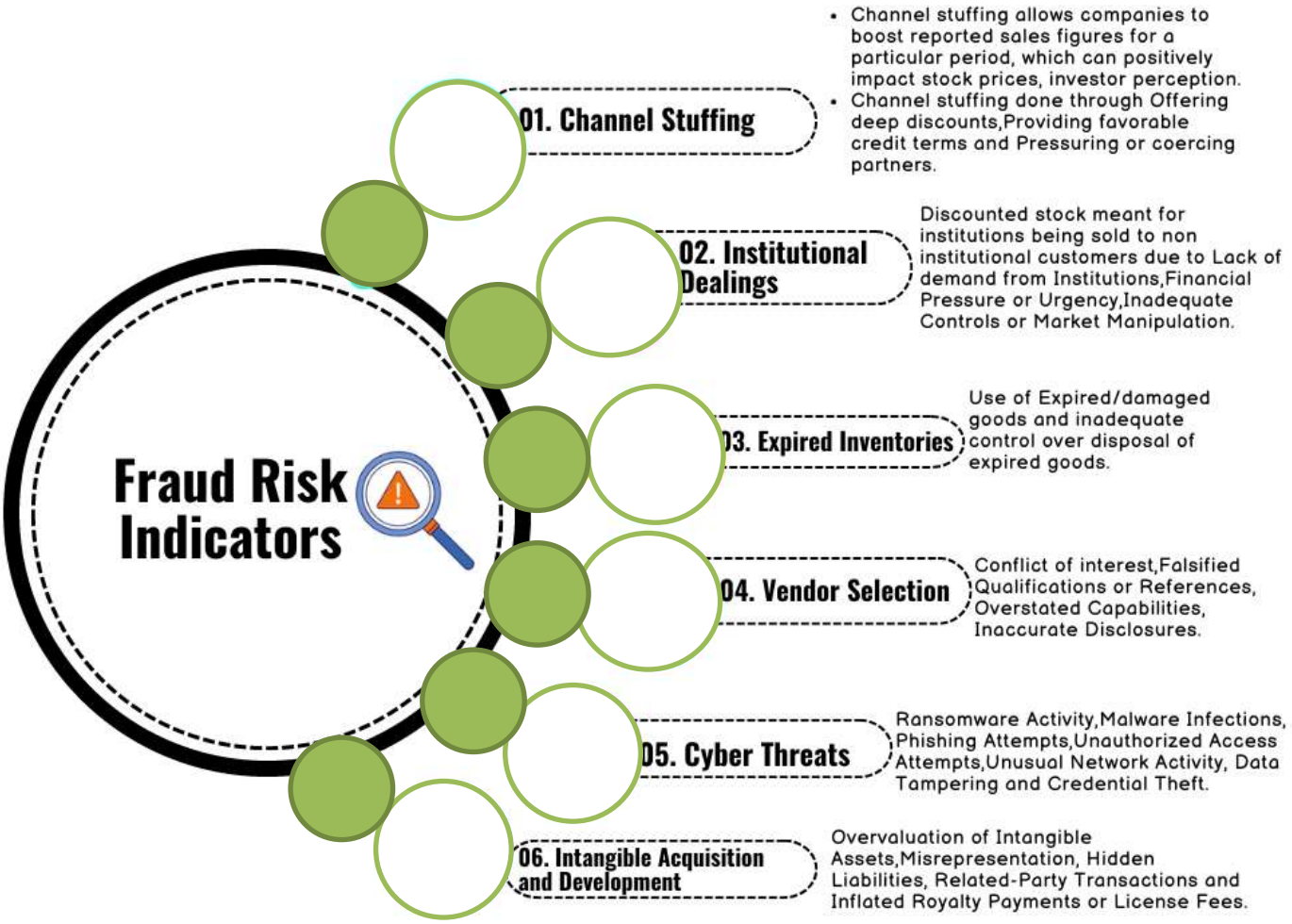
Ensures that the installed system is achieving the operational parameters specified

Validates the installed system is performing at the desired threshold



Key Accounting and Auditing Considerations

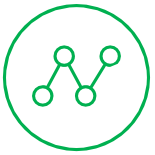
Fraud risk Indicators



Key risks in Pharmaceutical Industry

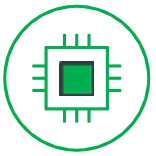
Common Risk

- People development and management
- Geopolitical/Economic changes
- Financial reporting
- Compliance to code of conduct
- Business Interruption
- Technology/Cyber security
- Product Management and Planning
- Price, cost and margin pressure



Pharma Specific Risk

- Trust of regulators
- Adverse event Management
- IP, Trademarks and Confidential information
- Compliance to NDPS and other Pharma regulations



Sub Risk

- Laboratory errors
- Manufacturing records are not clearly written
- Chances of human error/manual process
- Inadequately maintained Facility
- Compliance processes not harmonized globally
- Incomplete understanding of cGMP guidelines
- Inadequate vendor Compliances
- Delays in response to quality exceptions
- Inconsistency in data submitted to regulatory agencies
- Integrity issues in Quality System
- Database

Mitigation Plans: Use multiple levels to address risk

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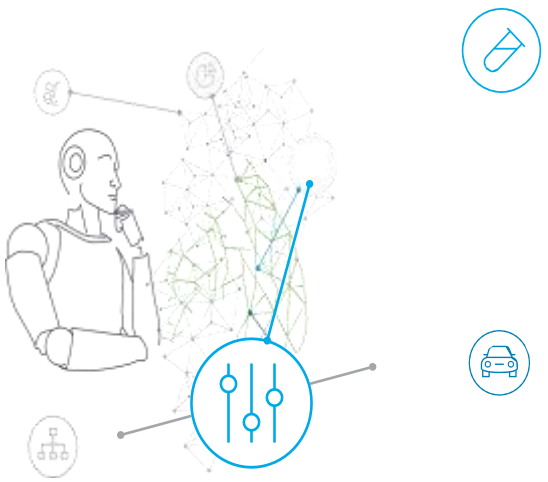
Risk Mitigation Steps

- Decentralized decision making
- Software & automation modules
- Training towards data integrity

Risk Mitigation Steps

- Develop, deploy cGMP training modules
- Develop minimum cGMP knowledge levels
- Standardized Job Descriptions & role based circular
- Training Assessments



Conclusion

In conclusion, the internal audit of the pharmaceutical industry reveals critical insights into the operational efficiency, regulatory compliance, and risk management practices within the sector. This audit underscores the importance of maintaining stringent quality control measures, adhering to regulatory requirements, and continuously improving processes to ensure the safety and efficacy of pharmaceutical products. The findings and recommendations provided should serve as a roadmap for enhancing organizational performance and sustaining long-term growth.

As Peter Drucker said, "What gets measured gets managed." This quote encapsulates the essence of the audit process, highlighting the importance of continuous monitoring and evaluation to achieve excellence in the pharmaceutical industry.