



## IIA INDIA QUARTERLY

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### Editorial

The last few months was a busy period for internal auditors with yearend activities and subsequently preparing for audit committee meetings. Now with schools closing for their summer, this issue has a few but useful articles to read during your vacation break, viz. *Internal Audit of Pharma Industry, Auditing Big Data & Auditing ERM in Non Profits*. The authors are IIA India members who have spent decades in the area on which they have written

The IIA International Conference was held in Dubai from May 7th to 9th 2018 with a record 3500 + delegates (mainly internal auditors from over 115 countries). The conference theme was- *Connecting the world through innovation*, with over 70 sessions, 100+ speakers and the popular topics were *cyber security, artificial intelligence, fraud and forensics and data analytics*. May 2018 saw the new IIA Global Chairman, Naohiro

Mouri taking office. This year's Chairman message is *"Emphasize the Basics. Elevate the Standards"* aimed to underscore how important conformance to the Standards is in ensuring that internal audit remains relevant.

*The next issue of the IIA India Quarterly is scheduled for August 14, 2018.*

### Happy Holidays

**Deepak Wadhawan FCA, CPA, CIA**

*Editor, IIA India Quarterly*

*[dwadhawan@iiaindia.org](mailto:dwadhawan@iiaindia.org)*



**Dear Professional Colleagues,**

**Greetings from IIA (India)**

*Since the time I wrote last in February, 2018 some of the significant happenings are enumerated below:*

#### **Seminar/Conferences**

The Annual Conference organised by the Madras Chapter in the month of March was very well attended. The discussions were thought provoking & the subjects selected were topical. The Bangalore Chapter also organised a very successful conference thereafter. The Delhi chapter is proposing to host a Conference shortly. The Calcutta Chapter is hosting an Audit Conclave in the month of June. Regular Seminars/Workshops are being organised by the various chapters. Dissemination of knowledge continues to be one of the pillars of the Institute.

#### **Training**

A Memorandum of Understanding has already been entered into with the National institute of Rural Development for training purposes. We are hopeful that this will provide immense training opportunities to our members. The Government of Bhutan has approached us for training its officials. The Institute continues to be in touch with CGA to train its officials.

#### **Membership**

The Growth in Membership continues to be a thrust area. CGA has evinced keen inter-

est in attaining Membership of the Institute for its officials. Every effort is being made to reach out to Internal Audit Professionals to become Members of this august body. I would like to take this opportunity to request all of you to help the Institute in enhancing the membership.

#### **Strategic plan**

A formal strategic plan is proposed to be presented in the forthcoming Council Meeting to be held in July. It has been the endeavour of the Council to take all necessary steps to professionalise its operations.

#### **IIA Global**

The Institute continues to operate in close association with its parent body-IIA Global. I would like to take this opportunity to acknowledge the constant support & guidance provided by our parent body.

*I look forward to your suggestions to further improve the functioning of the Institute.*

**Wishing all of you great professional success.**

**With kind Regards,**

*Yours Sincerely,*  
**Debashis Mitra**  
President, IIA India  
Place: Kolkata  
Dated: 30-05-2018



## Non-profits

We all know what “non-profit (organization)” (NPO) means; hence I would not venture into defining the term. The non-profit landscape is highly varied, although many associate NPOs with charitable organisations. An NPO need not necessarily be a charitable organization – it could be an association of persons/body with a stated objective (flying to Mars, promote veganism).

Auditing in NPOs essentially involves principles that are not much different from those relating to commercial, for-profit organizations. For NPOs, the basic purpose is something other than making profits. However, in order to sustain itself, it is essential for an NPO to manage its expenditure within the income generated. The macro-risks both categories (For Profit/ Non-Profits) are exposed to are essentially similar: strategic, operational, reporting and compliance.

## Enterprise Risk Management (ERM)

## ENTERPRISE RISK MANAGEMENT

### Role of Internal Auditing in non-profits

Risk management is now accepted as one of the cornerstones of good governance. All entities face uncertainties and the challenge for management is to determine how much uncertainty to accept as it strives to maximise stakeholder value. According to the IIA, Enterprise risk management (ERM) describes what happens when organisations put in place a structured, continuous process to identify, manage and respond to risk. ERM is defined by COSO as: “a process, effected by an entity’s board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risks to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.”

*ERM can make a major contribution towards helping an organization manage the risks to achieving its objectives. The benefits include:*

- Greater likelihood of achieving those objectives;
- Consolidated reporting of disparate risks at board level;
- Improved understanding of the key risks and their wider implications;
- Identification and sharing of cross business risks;
- Greater management focus on the issues that really matter;
- Fewer surprises or crises;
- More focus internally on doing the right things in the right way

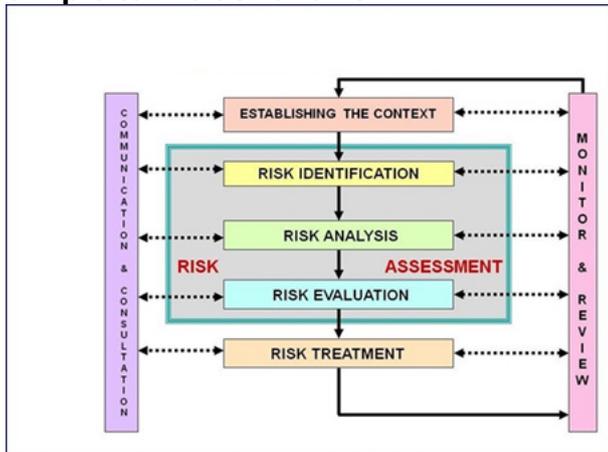
*Following are the key elements of ERM:*

- **Establishing the context** – defines the scope within the context of the organisational objectives, promotes through policies and procedures an appropriate internal environment
- **Identifying risks** – comprehensive identification and inventorying of all relevant risks
- **Analysing/assessing risks** – How the identified risks can impact the achievement of organisational objectives. This normally involves a two-dimensional evaluation – like-

likelihood of occurrence of the risk and the severity of impact

- **Treating risks** – Identifying various options for mitigating the risk, evaluating the options, formulating risk treatment strategy and plans and implementing the plans
- **Monitoring and review** – Risks are not static since the environment keeps constantly changing. Monitoring and review on an ongoing basis helps the ERM process to respond in time to the changes.

The ERM process<sup>2</sup> can be illustrated in simple terms as follows:



### Role of Internal Audit in ERM

The basic role expected of internal audit in ERM would generally be providing assurance to the management and board on:

- risk management processes
- evaluation of risks
- risk mitigation strategy
- reporting of risks
- operation of the ERM framework

### ERM in NPOs

It is widely recognized that in NPOs, ERM has not attained the same level of maturity as it has in their corporate counterparts. Therefore, internal audit may have to don the consultant's hat often while dealing with the topic in non-profits. This could be by way of working with the management with a degree of initial handholding as necessary to get the ERM framework established. Conducting seminars, workshops and awareness building activities may be necessary to get the concept of ERM imbibed

at the organization's grass root levels. Internal auditors need to exercise care not to cross the line between consulting and implementing (e.g., designing ERM framework, assessing risks and determining risk responses on behalf of management).

### Auditing ERM

**How do we audit ERM in NPOs?** The overall audit approach would be more or less similar, but finer details may vary. The objectives of an ERM audit would vary depending on the type of organization and the way ERM operates. An indicative list of objectives would be:

- Examine the adequacy and effectiveness of the organization's ERM Framework including policies/guidelines and the system and processes in place to assess and manage various identified risks;
- Evaluate compliance with the organization's ERM policy and conformance with good business practices;
- Evaluate the latest risk assessment carried out by organization.

The planning phase would include preliminary survey in which information on the ERM framework such as relevant policies/guidelines, particulars of oversight bodies relating to risk management, their constitution, terms of reference (ToR), meeting minutes, copies of reports to the board, and risk register. Based on evaluation of the preliminary survey results, the risk assessment is carried out which should bring out the risks that could impede ERM framework achieving its objectives. This would feed into the audit ToR and audit program. The field work would include interviewing the management, risk owners, and other key players in the ERM framework, in addition to testing a sample of risk mitigating steps and re-evaluating a sample from the risk inventory.

### Risk profile in NPOs

Though the risks inventoried in the risk register would by and large be similar for non-profits as well as for profits, the risk profile (likelihood of occurrence and severity of impact) may differ. Following are a few illustrative examples:

**Reputational:** As in the case of for-profits, many critical risks in non-profits would revolve around revenue generation. In the case of non-profits,

<sup>2</sup> ISO 31000:2009

revenues are primarily dependent on funds raised from donors. Factors such as credibility, goodwill and transparency play a major role in influencing donor decision, elevating the reputational risk profile.

**Strategic:** Non-profits being heavily mission-driven, the risks of mission drift to respond to donor preferences in order to secure funding could be higher. The ever transforming socio-demographic scenario places the continuing relevance of the mission at greater risk.

**People:** Non-profits are much more dependent on its people's commitment to the mission. Hiring strategies need to factor in this feature.

**Conclusion :** *The risk profile in NPOs include reputational, strategic, people, partner, political risk. ERM can contribute significantly towards helping NPOs achieving their objectives. Auditing an ERM requires testing the design & operating effectiveness and out by evaluating the latest risk assessment carried out by the management. In an NGO, The role of the internal auditor often includes consultancy to introduce & advise on ERM implementation.*

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The difference between data and information is normally understood. Data represents raw, unorganized facts that requires processing. Data can be simple, seemingly random till the time it is organized. Once the data gets processed, organized, structured or is presented in a format that is decipherable and helps in decision making, the same is called information. Information is normally effective only if it meets the needs of the information consumer (termed a stakeholder).

The terminology Big data refers to large, complex data sets (could even be unstructured data such as tweets, videos, commercial transactions, website hits etc..)

that go beyond the capabilities of traditional data processing applications. The origin of such data could be people, applications, market research information, social media and smart machines. Capturing unstructured data, traditionally documents and email messages, has been the territory of Enterprise Content Management. Volume, Variety and Velocity are the three fundamental dimensions or characteristics of big data.

The proliferation of structured and unstructured data, combined with technical advances in storage, processing power, and analytic tools, has enabled big data to become a competitive advantage for leading organizations that use it to understand emerging business trends, shifts in customer demands, gain insights into business

opportunities and to drive business strategies. Opportunities and risks are two sides of the same coin. As much as the opportunities provided by the analytics and the benefits that accrue through big data, risks and concerns also exist in the form of privacy, security, data integrity, quality and complexities.

Auditing big data is the new challenge that Internal Auditors face in the current era. Traditional auditing principles such as looking at completeness and accuracy of data still holds good, however traditional auditing methodologies might look irrelevant to address the audit objectives while auditing big data.

*An internal auditor can approach the audit of big data using simple basic steps of risk assessment and customizing the audit approach to evaluate the controls that addresses the risks associated.*

Typical risks that exist in a big data environment

- Source Data Reliability / Integrity
- Storage and related risks
- Data intervention / compromise of the quality of the data
- Processing risks
- Availability and performance
- Governance concerns

*Internal Auditor's approach and role in evaluating the effectiveness of controls in a big data environment should be to evaluate the risks, to map the controls and to assess the same from the perspective of design and operating effectiveness.*

**A typical audit program for big data review would be:**

**Governance :**

- is the data managed in-house or through a service provider ?

**Conclusion:**

*Well defined policies and procedures are important to handle any business process. The same holds good for big data management as well. From an auditor standpoint, identification of risks in the current environment as well as a good understanding of risks that are emerging due to changing business and data management models would be key, in customizing the audit program. The auditor should be in a position to up-skill, adapt and be flexible in his audit approach to ensure that the audit objectives of providing assurance to the key stakeholders are met.*

- if managed through a service provider, does the client have a strongly worded contract detailing the roles, obligations and responsibilities of the service provider ?
- is data ownership clearly defined ?
- does a strategy exist on how and where the data would be stored – own server, cloud or in a data center ?
- is the process for handling big data documented in a process document ?
- how is business continuity and disaster recovery aspects addressed as regards big data ?

**Input / Source data validation**

- are the sources of information / data identified ?
- are validation checks done to evaluate the sanctity and reliability of such data ?
- are the table structures well defined ? are all relevant aspects of data captured ?
- how is completeness and accuracy of data ensured ?
- Analytics / Data Processing
- how is data integrity ensured during the processing stage ?
- are the information processing objectives met by the big data analytics program ?
- is the analytics program presenting reliable and consistent results ?
- how are the results presented ? are the reports / output of the data processing tested for validity and reasonableness ?
- is the data secure from interference – intentional or otherwise ?

**Storage and retrieval**

- how is continuous availability of data ensured ?
- does clear policies exist on data storage, restoration and retrieval ?
- is data retrievable at any time ? how is data backup and restoration done ?

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# INTERNAL AUDIT

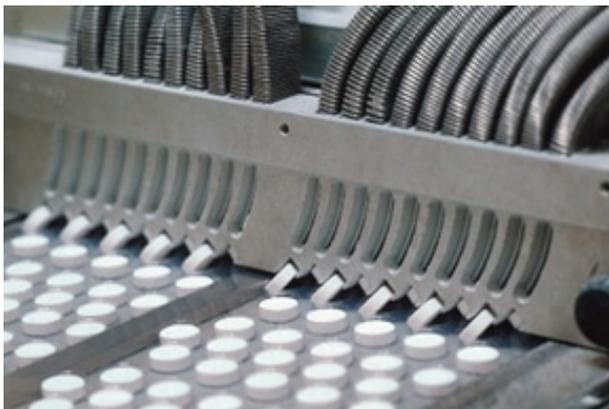
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## PHARMA INDUSTRY



### Background

The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as med-



ications. Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

Though the Indian pharmaceutical industry has grown at a high pace during the last few decades, it is going through a challenging phase during the last couple of years in view of the actions taken by regulators.

Some of the major challenges faced by the companies in the pharmaceutical industry are developing new products and services through research, shifting demographics, evolving governing regulations, transforming business models and increased expect-

tations from stakeholders. Another major challenge faced by pharmaceutical industry is in the area of generic drug exports which is a major source of their revenue.

Operational and strategic risks are central and inherent in pharmaceutical companies which are to great extent dependent on continuous research and development with long gestation periods, compliance issues with environmental laws, heavy capital investments as well as expenditures for environmental liabilities, management of their intellectual property rights, etc.

Strategic and Marketing risks on one side, compliance risks such as adherence to regulations, GMP, cGMP and other norms is again the most important and a whole different story where a small mistake or ignorance even at the minutest level of operation can cost a fortune to the businesses.

### The importance of quality in pharma industry

*The surge of substandard, fake and adulterated medicine is global threat. The pharmaceutical industry saw an increase in regulation after the 1957 thalidomide disaster. As a result, the various regulatory authorities have increased their monitoring. Some of the key regulatory authorities in pharma include:*

- **USA** – Food and Drug Administration (FDA)
- **UK** – Medicines and Healthcare Products Regulatory Agency (MHRA)
- **India** – Central Drug Standard Control Organization (CDSCO)
- **Australia** – Therapeutic Goods Administration (TGA)
- **Canada** – Health Canada
- **Brazil** – Agência Nacional de Vigilância Sanitária (National Sanitary Surveillance Agency)
- **Germany** – Federal Institute for Drugs and

## Medical Devices

The pharmaceutical industry is a vital segment of the Healthcare cycle conducting research and manufacturing products which are life-saving, life maintaining and life restoring. Quality directly affects the purity, safety, effectiveness and reliability of the drugs produced. The stringent, scientific, systematic and sustainable approach to commercial drug production ensures protection of patients health.

The system of specifications as well as practice control measures in the industry, which is also referred to as standard operating procedures (SOPs) that are designed by industry and scientific community and guidance is provided by regulatory authorities to ensure good manufacturing practice.

*The main functions of quality assurance systems in pharmaceutical companies are:*

- To be the caretaker of the Pharmaceutical Quality System
- Preparing the groundwork for certification by the qualified Person
- Quality on floor
- Product and safety liability

*Quality assurance exists to serve a number of objectives that include the following:*

- To offer a guarantee that the person who is administering medicine is confident that every unit will achieve the desired effect.
- To protect users for products from possible accidental defect in the manufacture, design, storage as well as usage instructions.
- To ensure the law is complied.
- To offer protection of the manufacturing organization.

## What is internal audit?

According to the Definition of Internal Auditing in The IIA's International Professional Practices Framework (IPPF), internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, dis-

ciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes

Performed by professionals with an in-depth understanding of the business culture, systems, and processes, the internal audit activity provides assurance that internal controls in place are adequate to mitigate the risks, governance processes are effective and efficient, and orga-



nizational goals and objectives are met.

Emerging trends in internal audit leverage on machine learning, predictive analytics and other data science techniques are also capable of identifying potential future threats and non-compliances through trend and process analysis allowing the organizations to have adequate controls and precautions to be future ready.

## The Internal Audit Process

*As part of the providing assurance and value add, the entire process of internal audit revolves around the following key steps.*

- The audit process starts with the preparation of an audit universe which lists all the auditable units within an organization. Every year the first step that is undertaken is to update the audit universe and bring it in line with the organizational current state.
- Then the Chief Audit Executive (CAE) would prepare a detailed audit plan taking into consideration the key risks as per the Enterprise Risk Management (ERM); including any other emerging risks; periodicity of coverage of the auditable units; perceived sensitivity; change in people, process and technology; understanding the business strategy and goals of the organization, and finally taking

into account the inputs from the various stakeholders. These would include the various functional heads, business heads, CEO, CXOs and the second line of defense viz. financial controlling, security, risk management, quality, inspection and compliance. The final plan is then presented to the Board of Directors (BOD) for approval.

- *Then the various audits are performed as per the planned approach. These include:*

- ♦ Process Audits covering
  - ♦ Manufacturing locations (with focus on planning, production, quality control, quality assurance, safety, health and environment, facilities management). A well designed and appropriately implemented internal audit function provides valuable information that can be used to prevent issues before they become compliance concerns during a regulatory inspection. Having corrective actions in place will instill confidence that the quality system is under control and there is a process in place for continuous improvement. The information

obtained during the audits is useful to improve business processes.

- ♦ Sales and distribution offices (with focus on marketing strategies, planning, budgeting, sales process, marketing spend)
  - ♦ Key corporate processes (information technology, corporate communications, corporate social responsibility, corporate taxation, human resource)
  - ♦ Continuous Audits covering areas that include high voluminous data and controls
  - ♦ Specific Reviews centered towards frauds or confidential assignments
- The observations noted are reported to Audit Committee and the Board depending on the seriousness and risk category.
  - But the value add that internal audit is able to provide occurs only on the implementation of the various action plans that are agreed upon by process owners.

Internal audit plays a crucial role in helping pharmaceutical companies to address the said challenges presented by today's complex, competitive and risk driven environment by strategizing and channelizing the threats into opportunities and assist the management of the said companies in taking future course of action.

## **Conclusion**

*Internal audit provides an independent and unbiased view on the organizational processes and activities thereby adding value to the organization. It greatly contributes in improving operational efficiency by objectively reviewing the organization's policies and procedures, providing assurance that the organization is doing what the policies and procedures say they are doing, and that the processes are adequate in mitigating unique risks, continuously monitoring and reviewing the processes, identifying control recommendations to improve the efficiency and effectiveness of the processes in turn, allowing your organization to be dependent on process, rather than people.*

**Seema Grover, Head**  
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### Mark your Calendar

**June 30, 2018** – Last day of the extended period to pay annual subscription fee. Pay online at [www.iiaindia.org](http://www.iiaindia.org)

**August 24, 2018** – Annual conference IIA Delhi Chapter at the Grand Hotel, Vasant Kunj, New Delhi



### Video Watch

**2018 IIA Chairman's Message** <https://www.theiia.org/sites/auditchannel/Pages/player.aspx?v=prMjM2ZjE66akNDs12hGt-d3p2EZNqq-y>

**Lecture by Nawshir Mirza on Corporate Governance – Role of Internal Auditors organized by IIA Bombay & BCAS**  
<https://youtu.be/ceBzfWTiGkU>



### Suggested Readings

**Tailoring IPPF Implementation** - Internal Auditor, June 2018, Page 29 ( The online version of Internal Auditor is available free to IIA India members)



### Chapter News

**Pls volunteer at your local chapter.** For your Chapter News visit <https://www.iiaindia.org/chapter-club>



### Training Programs

**For IIA India held training programs visit** <https://www.iiaindia.org/training/training-programs>



### Letter to the Editor

We look forward to your letters, emails

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