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ASSESSING AND MODELLING DIGITAL RISKS IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Companies across all sectors, including Pharmaceutical, are progressively making a shift to a more technology-based work. Work from Home had challenges but the businesses have been able to cope with this shift, with some companies like TCS claiming that by 2025, 75% of the workforce would be working from home. While businesses are adapting to this new work style, the need for managing risk that is associated with it is also growing. Digital and technology transformation have various risks attached to it and managing them is crucial. Digital risk is any risk that is caused when a business goes Digital. Each industry faces potential risks and identifying these risks and working towards securing it, is important. Businesses can face data loss, theft of critical data, privacy breaches due to digital shifts in the business. Businesses can face risks related to automation of businesses, and compliance. This study focuses on a detailed qualitative analysis of perspectives and experiences of the subject matter experts working in the pharmaceutical industry and coding the data to generate detailed inferences and conclusions from the codes

1. Objective:

To complete qualitative research on various Digital risks businesses face due to technology and digital shift in the industry. Also, understand the approach, risk

points, and perspective of the people working in the Pharmaceutical industry on the digital transformation.

2. Introduction

In 2018, 45% of devices in the Indian pharmaceutical industry were detected with malicious attempts. Businesses have digitized and emerged themselves as more powerful and efficient. Digitization has proved to be a new yet critical way of life. Various industries have shifted digitally to extract and use the data generated and the Pharma industry is not behind. Digitalization has allowed the industry to develop business model mechanisms, faster research, and development of the drug as well as drug testing using artificial intelligence and contactless distribution. The data generated by the pharma industries is huge and is used by the companies to streamline new information and activities. Pharmaceuticals have to abide by various stringent regulatory standards set by the industry, state as well as the central government. While Pharmaceuticals move digital, they carry the risks across cyber-security, data and privacy breaches, insider threats, etc. Studying these risks and modeling them in a way to minimize the losses is something pharma companies should focus on to safeguard their future. We also need to understand the relationship between the risks faced by the company and the risk-taking ability of that company.

While COVID-19 forced the pharmaceutical businesses to shift and change their business models and become more technology-driven/contact-less, this shift had led a way to a new set of risks that lie ahead for the industry. While managing this shift, companies should consider the impact on various business sectors and be ready for crisis management.

3. Literature Review:

One of the very essential and basic feature to measure industrial strength (Adis, 2007) is how the industry manages the internal and external complexities and to check the ‘best practices’ used by the industry. The Pharma industry should understand the risk attached to digitalization and handing business models. According to Warren Adis, risk estimation can be probability (P) of any similar event identified by its consequence (C) [1]

R= {P, C}

The major role of creating a link and having control of the system is performed by information technology. Pharmaceuticals should study and perform trials with various frameworks and maintain a risk repository and take corrective and preventive actions (CAPA)

CAPA will help businesses to reduce/mitigate the risk and losses and can limit the frequency of any risk/attack. The formula for this statement can be inferred as

R= {P, C, CAPA}

The paper, (Landwehr, Konstantin, 2015) talks about the significance and the role of digitalization in the Pharmaceutical industry. The pharmaceutical industry business model is product-centric and the developments in the

surrounding can help pharmaceuticals build a patient-centric model. Collaboration with ICT businesses can prove to be a milestone for the Pharma business in the digital age and can revolutionize the industry process. This can introduce 'connective-health' [2]

The paper (Mahaveer Prasad Kabra*, Dileep Kabra, Gourav Somani) talks about the role robotics can play in the pharmaceutical industry. Processes like Research and development, production, weighing, and packing can get easier and more efficient with the help of robots. These Digital revolutionary change opportunities can be seen for the pharma industry. However, using robots for industrial purposes can have its challenges but it can emerge as a safer and sophisticated option considering the rise in demand. [3]

The paper (Department of Health and Human Services U.S Food and Drug Administration, 2004) talks about the implementation of internal quality control systems for the pharmaceutical industry. The criterion for a better and developed organization is how fast and well it adapts to the new technology, ensure compilation to all the governance and regulations, the employees and the staff play an important role in understanding the shift in the model of business and should be kept well informed. It talks about the integrated and collaborated functioning of various components in the pharmaceutical industry. [4]

Digital Transformation in the healthcare sector (DIGITAL RISK IN HEALTHCARE TODAY: RSA, 2019) is changing rapidly. These new shifts are helping businesses to effectively manage the costs, protect the patient data, as well as abide by the various regulations put on the healthcare industry. However, these digital shifts come with a risk of compromising the health and patient records, all these risks are connected and it is the responsibility of the owner to secure and protect the data and interest of the organization. [5]

Pharmaceutical companies have started to invest in Digital transformation (CISCO) and trying to extract and use the data available to build a better and predictive analysis. The industry is now focusing on the personalization of healthcare and introducing new formats to tools to study the operations. This can create risks like data safety, workforce risk, and privacy. [6]

Digitalization in the Pharma sector, (Digital Transformation in the Pharmaceutical Industry: BearingPoint, 2015) has paved a way for a new business model and a more collaborative workforce. This has led to a customer and supplier centric chain and now they have the power. The paper talks about the changes because of transformation and the possibility of disrupting an entire supply chain as well as the business model currently functioning. It also talks about the effect of industry 4.0 on the pharma industry and various digital strategies. [7]

The paper (Judy E. Scott and Iris Vessey, 2002) assesses various risk factor models. The paper concludes that the system or enterprise failure is not just because of a single risk but integrated threats. A firm should understand and assess each risk and put down the effects and consequences of risks and how to tackle them. [8]

The paper (VARUN GROVER AND THOMAS H. DAVENPORT, 2001) studies the relation and interdependence between industry knowledge and the power of Information technology. It assesses frameworks on knowledge management and discusses the research. The businesses can gain strategic information and data from the digital shift in the business model. [9]

This article (2012) provides an overview of typical API/DP PAT toolboxes and discusses case studies in which PAT has been utilized during the development of pharmaceutical candidates. Although PAT tools are similar, the reasons for implementing PAT in development differ according to the nature of business and other factors. [10]

The paper (Parekh, Dhara & Kapupara, Dr. Pankaj & Shah, Ketan; 2016) talks about the use of digital marketing processes that are currently being implemented by organizations and tells us as to why they are not utilizing it efficiently. The Pharma industry has not been able to adapt digital marketing quickly. The reasons for this failure are strict regulations, poorly maintained websites, use of outdated technologies, etc. The author also provides strategies that can solve the problems currently being faced by the Pharma industry. [11]

The paper, (Pinto, M. 2003) explains how digital transformation can change the structure form and content of the documentation process. It proposes three trends: theoretical, methodological, and programmatic. It offers the conclusion that reengineering networking and visualizing would be the key areas for better abstracting in the new era. [12]

The book,(Stephen Goundrey-Smith, 2012) explains basic building blocks of IT systems in the Pharma industry such as medical coding, drug databases, etc. The book concludes with an overall study of some issues inherent in integrating diverse clinical systems and medical devices. It discusses the pros and cons, risks, and challenges faced while adapting to the new technology. [13]

The paper, (Topol, Eric. 2010) talks about two major areas essential for the digitalization of the Pharma industry: wireless technologies and genomics. The author predicts that future devices have huge potential to change the future of medicine because of their ability to produce exquisitely detailed individual biological and physiological data. [14]

The paper talks about gathering qualitative data and introduce the craft of coding the qualitative data (Linneberg, Mai & Korsgaard, Steffe; 2019). The paper explains a thorough and practical overview regarding the qualitative data and coding. It explains the ways and coding techniques while gathering qualitative data from interview transcripts, notes, audios, videos, etc. it also explains types of coding manually and with the help of software. [15]

4. Research Methodology:

The study of this paper is based on the analysis and study of various research papers on similar topics. The focus is on understanding the Digital risks faced by the pharmaceutical industry. After thorough research and understanding, the research was directed towards understanding the comparison between the digital adoptions in the pharmaceutical industry over the period.

Qualitative data was gathered by conducting various virtual as well as face-to-face interviews with industry experts. The Pharma industry is divided into various departments, like, Production, research and development, advisory, sales, marketing, operations, finance, distribution, analysis, testing, and human resource. The qualitative data gathered has included subject matter experts from various departments within the Pharmaceutical industry. The interviews were focused on understanding the Opinions of subject matter experts on pain points of the Pharmaceutical Industry, the adoption of digital technologies in the industry, and risks involved in the digital transformation.

The Interviews helped in gaining a clear perspective about the understanding and approach of the ones working in the Pharma industry. Level 1 of coding includes the coding of interview transcripts into small words/phrases. After finalizing the level 1 of codes, the codes were arranged and segregated according to the relevance as well as the frequency of the occurrence of a particular code. Level 2 coding was based on the selection of the most frequent codes in terms of their occurrence and then representing them in a tabular and graphical format for better research and understanding. Once the graphical representation was ready, the analysis is based on the frequency of codes, interview transcripts, and various relevant research papers. The analysis was then quantified and summarized for deeper insights.

5. Analysis And Results:

The data presented include the interviewee's details like age, gender, designation, and the company they are working/worked with.

Interview No.	Gender	Age (Years)	Designation
1	Female	42	Marketing Manager, Sun Pharma
2	Male	53	General Manager, Sales & admin at Atlas Pharmaceutical
3	Male	53	Assistant General manager, Training- Mylan
4	Male	52	Regional Business Manager, Dr. Reddy's Laboratories
5	Male	49	Area Sales Manager, Dr. Reddy's Laboratories
6	Female	35	Group Product Manager, Dr. Reddy's Laboratories
7	Female	45	Brand Manager, Glenmark Pharmaceutical Ltd.
8	Male	52	CFA (Consigning Agent), United Chemicals of Belgium
9	Male	54	Zonal Manager, Alchem Pharmaceuticals
10	Male	46	Sales Manager, Mylan

Table 1: Interviewee details for Qualitative Data

First Level Coding:

First level codes were decided after studying and interviewing the professionals working in the pharmaceutical industry on various posts and departments. The interview transcripts were studied and then coded into words/phrases maintaining the meaning and intentions of the interviewer. The codes were finalized on the basis of their occurrence frequency.

The first level codes as sorted alphabetically are as under:

1. Analytics	2. Benefits	3. Change
4. Compliance risk	5. Confusion	6. Critical point
7. Data availability	8. Less delay	9. Digital transformation
10. Employee satisfaction	11. Faster feedback	12. High liability
13. Human error	14. Issue identified	15. Job threats
16. Lack of awareness.	17. Correction is hard	18. Limit to tech adoption
19. Limitation	20. Low staff satisfaction	21. Need of control
22. No Tech use	23. Not Tech-savvy	24. Perceived benefit
25. Perceived risk	26. Points to consider	27. Production control
28. Reimbursement	29. Risk factors	30. Risk perception
31. Saves money and time	32. Shift	33. Slow digitalisation
34. Auto-generated report	35. Task Redundancy	36. Tech & admin control
37. Tech development	38. Tech. shift	39. Third party risk

Second Level Coding:

After studying the first level codes, the most common/top occurring comments/codes came up as a result of level 2 coding. These codes were then segregated as per the categories. The Top 5 second level codes categories are as follows:

Category 1: Data Availability

Digital transformation has made the data related to sales, employee, market, demand, stocks easily available. Companies have their own software were the sellers, the distribution, and the sales team update. This helps companies understand the whole market

Category 2: Digital Transformation

Digital transformation for the pharmaceutical industry is how the pharma industry has shifted from traditional processes to more technologically, digitally developed processes. Digital transformation for the pharmaceutical industry can be seen in almost all the departments, finance, marketing, production, sales, and distribution, etc.

Category 3: Perceived Benefits

The advantages or the benefits of Digital Transformation perceived by the ones working in the pharmaceutical industry. These benefits include points like accuracy, better planning, speed, data availability, saves money, real-time knowledge check, less delay, data analysis, efficiency in drug testing and approval, developed research and development, etc.

Category 4: Perceived Risks

Perceived risks are the points that can be a threat or a risk because of adopting digital ways or digital transformation. Example: data security, privacy, job threats, reliance on software, employee satisfaction, compliance risks, third party risks, etc.

Category 5: Limited Digitalisation

The pharmaceutical industry has evolved in terms of digital transformation. Having a physical and manual reporting to a software-based reporting, having paper-based reimbursement to a digital one. The pharmaceutical industry is slowly adopting digitalization. According to subject matter experts, the Pharmaceutical industry cannot be completely digitalized.

A chart and a graph showing the frequency of codes occurrence is shown:

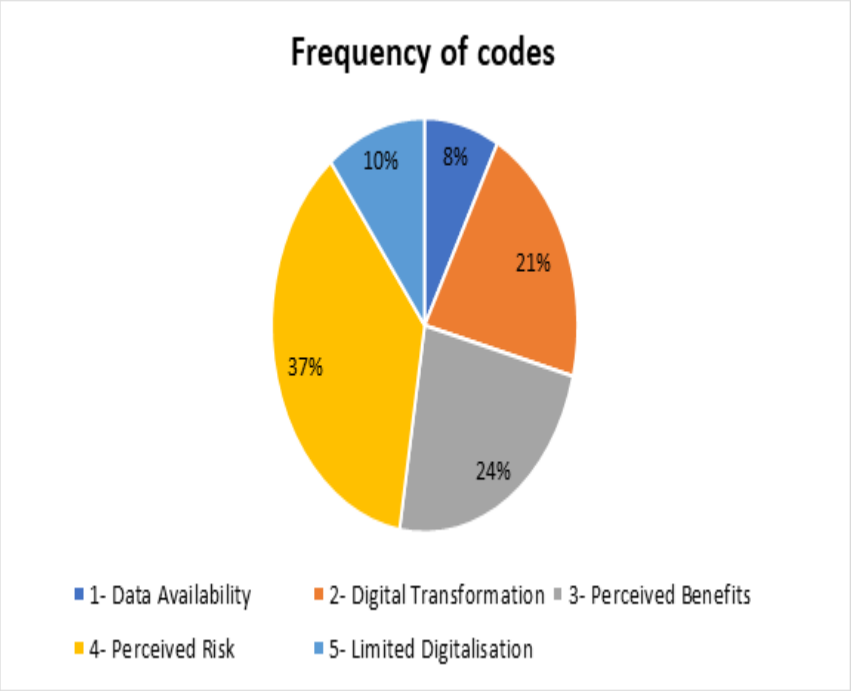


Figure 1: Percentage distribution of occurrence of First level codes

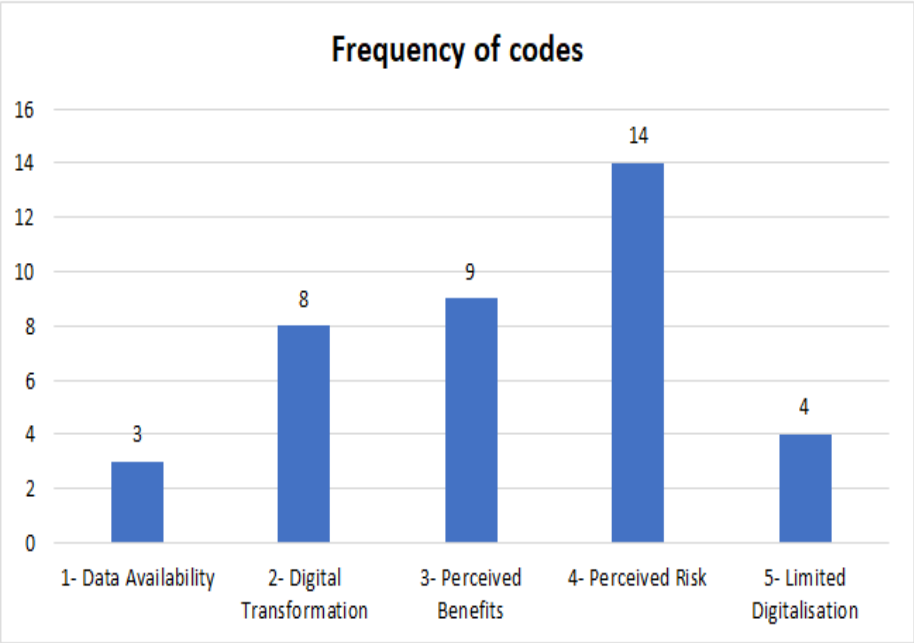
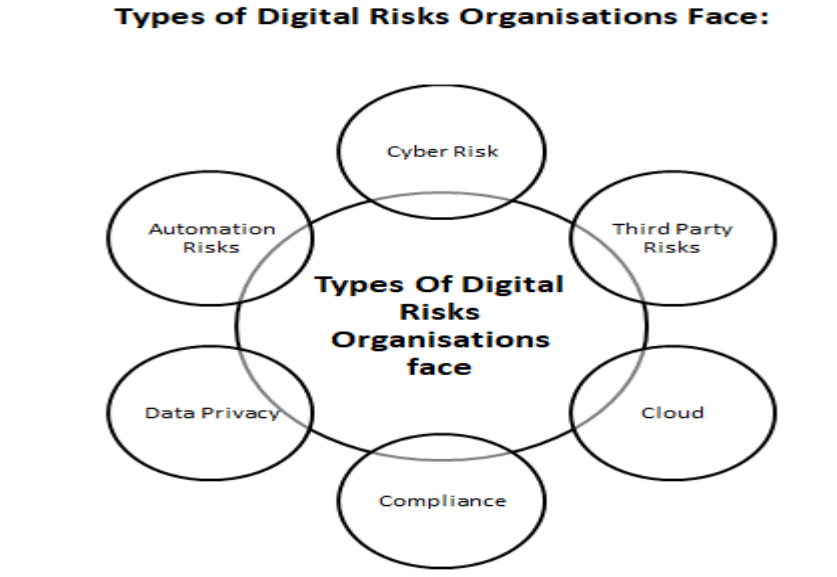


Figure 2: Top 5 First-level Codes base on their occurrence in Level 1 coding

After a deeper study about the perceived risks of Digital Transformation on Pharmaceutical industry as collected from the interview transcripts, following types of risks were highlighted:



The effects of each risk mentioned above are assessed as follows:

Risk 1: Cyber Risks:

1. Organizations can face cyber breaches, which can lead to an attack on the system. It can be in the form of Ransomware or Malware.
2. Protecting Digital Environment can reduce Vulnerabilities.
3. According to Cyberdefense Magazine, Global cost for cyber-attacks may be up to $6 Trillion by 2021

Risk 2: Third-Party Risks:

1. Organizations can shift process/business to vendors/third-party operators. Any risk associating with violation of privacy due to inappropriate control can be called a third party risk.

Risk 3: Cloud Risks:

1. Risks related to the cloud can be typically due to change in the architecture of the services or deploying new software.
2. As the cloud computing market is growing, the risks are ever evolving and rapidly increasing.

Risk 4: Compliance Risks:

1. Compliance risks are caused when the business is unable to cope/adapt to the changing market scenarios concerning the law, technology.
2. Compliance risk exposure can impact businesses' reputation and can have a financial as well as legal impact

Risk 5: Data Privacy Risk:

1. Businesses store data and information of the customers. The businesses are responsible for maintaining the secrecy and privacy of this data. Businesses also generate a huge amount of data on their own and this information is very crucial and confidential.
2. Any risk related to data privacy can expose this information and can cause harm to the business.

Risk 6: Process Automation Risk:

1. When businesses shift the operations to automation, the risk of process automation may arise. These types of risks can be mitigated by managing and securing the process software.

6. Conclusion:

The points like Digital transformation, perceived benefits, and risks from digital transformation, limited digitalization, data availability together provide us with better insights while understanding digital transformation in the pharmaceutical industry.

As we can see in figure 1, 37% of the codes suggest perceived risk due to digital transformation in the Pharmaceutical industry. Which is the highest concern or observation in the qualitative data collected followed by Perceived benefits of Digital transformation with 24% occurrence frequency. Over 21%

codes i.e. 8 out of 38(figure 2) mentioned a shift from traditional processes to digitally transformed process. Four out of 38, i.e. 10% of the interview codes suggested that the Pharmaceutical industry has a limit to digital transformation and a bit rigid to accept the paradigm shift. 8% of codes suggested the important factor 'data'. Digital shift/ processes have eased the data available for businesses from across the departments and the deployment of customized software by the companies to gather the data from the market and study.

It will be safe to say that with increasing technological developments and companies adapting them, the healthcare and pharmaceutical industry will lead a way for safer and better facilities. Digital Transformation has more advantages and can bring a brighter future for the industry. The introduction of new technologies like Artificial intelligence and their appropriate use can lead to path-breaking success for the industry

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