

Digitization Deployment Challenges in Pharmaceutical Supply Chain

Ashish. A. Adhikari, DBA Scholar
Dr. A. Seetharaman, Dean Research

Abstract:- Digitalization and Digitization are related, however their meaning is different. Digitalization is made up of several different areas like Digital communications, while digitization is converting analogue information into data formats. Industry 4.0, another commonly used term is the digital network of people, machines and products.

Pharmaceuticals is a research intensive industry, which keeps on churning new products to save patients' lives. The safety and efficacy of products is stringently regulated, and rightly so. Pharmaceutical companies have started to explore Digitization for higher efficiencies, faster and better clinical trials and cost reductions. Digitization offers multiple opportunities, but there are also implementation challenges that need to be considered. The study result show the factors that affect Digitization in Pharmaceutical Operations and how mitigation can be done.

Keywords:- Digitization Application, Digitalization Impact, Pharmaceutical Operations.

I. INTRODUCTION

Industry 4.0 or digitization is the new buzzword across industries. It promises to bring in a revolution on how technologies can change the way work is done and managed. It provides a new perspective in making decisions between the priorities of cost, flexibility, speed and quality (Tava Lennon Olsen and Brian Tomlin 2020). When it comes to digitization, academic and industry leaders are in agreement that it will bring sweeping transformations across the value chain, right from R&D, supply chain, manufacturing and operations to commercial sales and service (Brian, William and Subu 2015).

With current progress in technology, the usage of data by people and organizations has seen a sea of change. Benefits of flexibility, analytics and artificial intelligence are providing greater insights from large amounts of data. Digital disruptions are creating advancements through Virtual and Augmented reality, future interfaces, advanced robotics and Additive manufacturing (Brian, William and Subu 2015).

There is greater synergy between the physical and digital worlds, which enables manufacturing companies to become digital (Linz et al. 2017). This is possible if technologies like the Internet of things industrial processes

and services can be integrated to generate value through managing data better. This integration can also serve as a future competitive advantage (Porter and Heppelmann 2015).

A. Research Questions

In the Pharmaceutical space both Industry and Product development are impacted by Digital technologies. Experts feel the Pharma Industry with its regulatory requirements as pre requisites to high quality products, can be one of the generators of digitization development in the world (Lisna A.G 2019).

There is a 90% failure rate in implementation of enterprise digital systems. Our understanding of how organizations implement digital tools is very limited (John, Sally, Vikas and Glenn 2018). The objective of this study is to understand the considerations to make Digitization successful by asking the following questions:

- How to choose the right Digital applications from the various choices?
- How to mitigate cybersecurity risks and reduce change resistance amongst stakeholders?
- What is the impact of leadership on Digitization deployments?
- How to consider high cost of Digitization implementation for success?
- Is there a role for Digital innovations in a Pharmaceutical regulatory environment?

B. Research Objectives

As a response to the above queries the study is aimed to meet the following research objectives. How to fit various Digital technology applications for maximizing benefits?

- How to minimize Digital fear and improve acceptance?
- How to incorporate proactive leader-led Digital strategy?
- How to develop a benefits calculation methodology to evaluate Digitization implementation?
- How to create a win-win synergistic relation with Regulatory to smoothen digitization?

C. Scope of the Study

The pharmaceutical Industry has already exceeded USD 1 trillion in revenues globally. However they have still not leveraged on the opportunities that Digitization offers. For example, in Germany, the Pharma/Healthcare industry is ranked at the bottom of a digital index scale in strategy, product, sales, customer experience, and processes (Alina, Eldar and Levent 2017). This article attempts to provide a

road map for a Digitization Applications deployment framework in the manufacturing operations area.

II. LITERATURE REVIEW

Pharmaceutical companies are facing a challenge on how to organize, utilize and predict future trends in supply chain. The big question is how to enhance performance in operations by using large quantities of data. (Shafique and Khurshid 2018)

The literature review is structured basis the factors considered for the research. The dependent factor is “Impact of Digitization applications in Pharmaceutical Operations” and the independent variables are i) Interactions between Digital technologies ii) Trust iii) Leadership iv) Costs and v) Regulatory policies. The article emphasizes on understanding their impact on Digitization in Pharmaceutical Operations.

A. Interactions Between Digital Technologies

Industry 4.0 has some main technologies like 1) Cyber Physical systems (CPS) 2) Internet of Things (IOT) and 3) Cloud computing. Other technologies include 1) Big Data 2) Virtual Reality 3) Augmented/Virtual Reality 4) Machine Learning 5) Artificial intelligence 6) 3D printing 7) Block Chain 8) Wearables 9) Advanced Robotics 10) Digital Twin etc. Industry 4.0 is utilization of all these technologies and their interactions, in the biological, physical and digital domains (Michael 2018). Data analytics are used to optimize factory operations. This helps in better equipment utilizations, improved product quality and lower energy consumptions. With several tools available, factory managers have a better understanding of raw material flow and conversion into finished products, which can help them cut costs and improve efficiencies (Brian, William and Subu 2015).

With multiple choices available, organizations spend substantial amount of time deciding on specific technology applications and their interdependencies to maximize benefits. Further, the lack of subject matter expertise of technology applications complicates the matter.

B. Trust

Having an Operational standard is a pre requisite for success in a digital world. Without this data access and transparency will get hampered (Sebastian, Jeanne, Cynthia, Martin, Kate and Nils 2017). Introducing digital technologies in pharmaceutical setting is complex. We need to resolve a number of organizational, technological, legal, social and economic tasks. Looking for an optimal solution is difficult. Having trust in the technology application is vital (Vladimir and Valentina (2018). Data is increasingly being used to make decisions. Trust in data based decisions is a key factor for supply chain collaborations. (Gregor, Jannick and Gred (2019). Organizations are interested in using data processes which are more transparent, reliable and trustworthy (Ketevani 2019).

Today cyber-physical systems are connecting people, machines, and resources. We need to prioritize ownership, privacy, data security and transparency (Rohan, Laya and Nimita 2018). Cloud systems increase risks for data security. The difference between cloud and on-site systems is who controls security. Cloud-based security depends on the vendor while on-site security is in the hands of the organization (Francisca Maria Sousa e Silva 2019).

The use of cybernetics in digital applications can impact data security and online integrations between entities. This can lead to data leaks and security breaches resulting in high costs to manufacturing companies. Security is a serious issue which should be dealt with effectively (Francisca Maria Sousa e Silva 2019).

C. Leadership

Only 44% of managers and executives believe their companies are prepared for digitization. Worse, 50% of employees believe their leaders are lagging behind in digital innovation (Von Kutzschenbach, 2017). Leadership buy-in and support is required to create a digital vision. In most company's digitization is at an infancy stage. In these organizations, revenues come from products and services which are traditional. Successful digitization is limited to identifying ways of applying these technologies and data access to add value to customer relations, products and services (Sebastian, Martin, Jeanne, Cynthia, Kate and Nils 2017). In the pharma context, most of the thought leaders agree that the old organizational and business model must change and new ways need to be used. (David, Amy and Olivier 2015).

CEO's entrust digital topics to executives other than the CIO, creating a new role like the Chief Digital Officer. Research shows that CEO's and CIO's need to have a mutual understanding of common goals to promote successful business IT partnerships. This can create potential non collaborations within the organization. Alignment is necessary and this is usually the missing piece (Ingmar Hafke 2017). Organizations have to holistically think of integrating IT/Digital technology with Business strategy (A.B Kazim 2019)

Some research indicate leadership as the reason behind Digital failures, while others blame management practices, governance, culture and other transformational programs which are running in parallel. There are problems with getting new competencies to align with Digital practices. Studies from successful firms suggest that Digitization is less dependent on technology adoption than on leadership mindset and strategy (A.B Kazim 2019).

D. Costs

The pharmaceutical Industry is highly regulated, resulting in its inertia to adopt innovation. Rising costs and focus on patient centric products and services has pushed Pharma to embrace Innovation (Rohan, Laya and Nimita 2018). Digitization applications promises to reduce

Pharmaceutical manufacturing cost base provided enough scrutiny is done on the right Digital investments.

Customer demand helps organizations improve their processes and systems. Companies invest in innovative technologies to streamline their capability to provide customers what they need and anticipate future need. Process improvement using digitization should be a big priority for any organization (Francisca Maria Sousa e Silva 2019)

Once the decision to digitize Manufacturing is taken, next steps are to identify actions, feasibility and prioritization. Digitization costs would include technology costs, training and support costs and data maintenance costs. Also considering that Digitization will enable change, the costs involving ways of working will apply (Anne-Maarit, Linnea and Ville 2016). However it is hard to identify and prioritize the most viable actions with respect to manageable costs. This is because of restricted know-how in most cases (Andreas, Welf, Anders and Orjan (2017).

The concept of Smart factory, which incorporates most of the digital technologies to bring Manufacturing costs down in the long run is taking shape. Such an elaborate project requires significant implementation costs. It provides an area of uncertainty between potential benefits and the costs involved. Some investments need to be made upfront so that other beneficial systems can be implemented later. High early costs of smart factory implementations exacerbates the uncertainty, as benefits of these investments accrue in an uncertain time in the future (David, Vinit, Markus and Aleksander 2018).

E. Regulatory Policies

In the pharmaceutical industry digital technologies can affect the development of both Industry and products. There

is high level of regulation to ensure quality products and compliance (Lisna 2017). The biggest barrier for Pharmaceutical Digitization are regulatory concerns. Sufficient data quality and tracking is needed to ensure regulatory compliance. Regulatory's biggest issue is ascertaining data quality, security and availability. Considering the value placed on end patient safety, this concern is valid (Alina, Eldar and Levent 2017).

Regulation of medical products is a basic and important part of any healthcare system to ensure Patient safety. While the simplified creation of digital products accelerates innovation, regulatory requirements remain the same yet seem to be necessary to provide a safe market entry. Because the risks of medical products cannot be assessed by the users it is the duty of regulatory procedures to reduce those risks. Regulatory processes must evolve to changing cycles of innovation and keep pace with digitization applications (Andreas and Simone (2017).

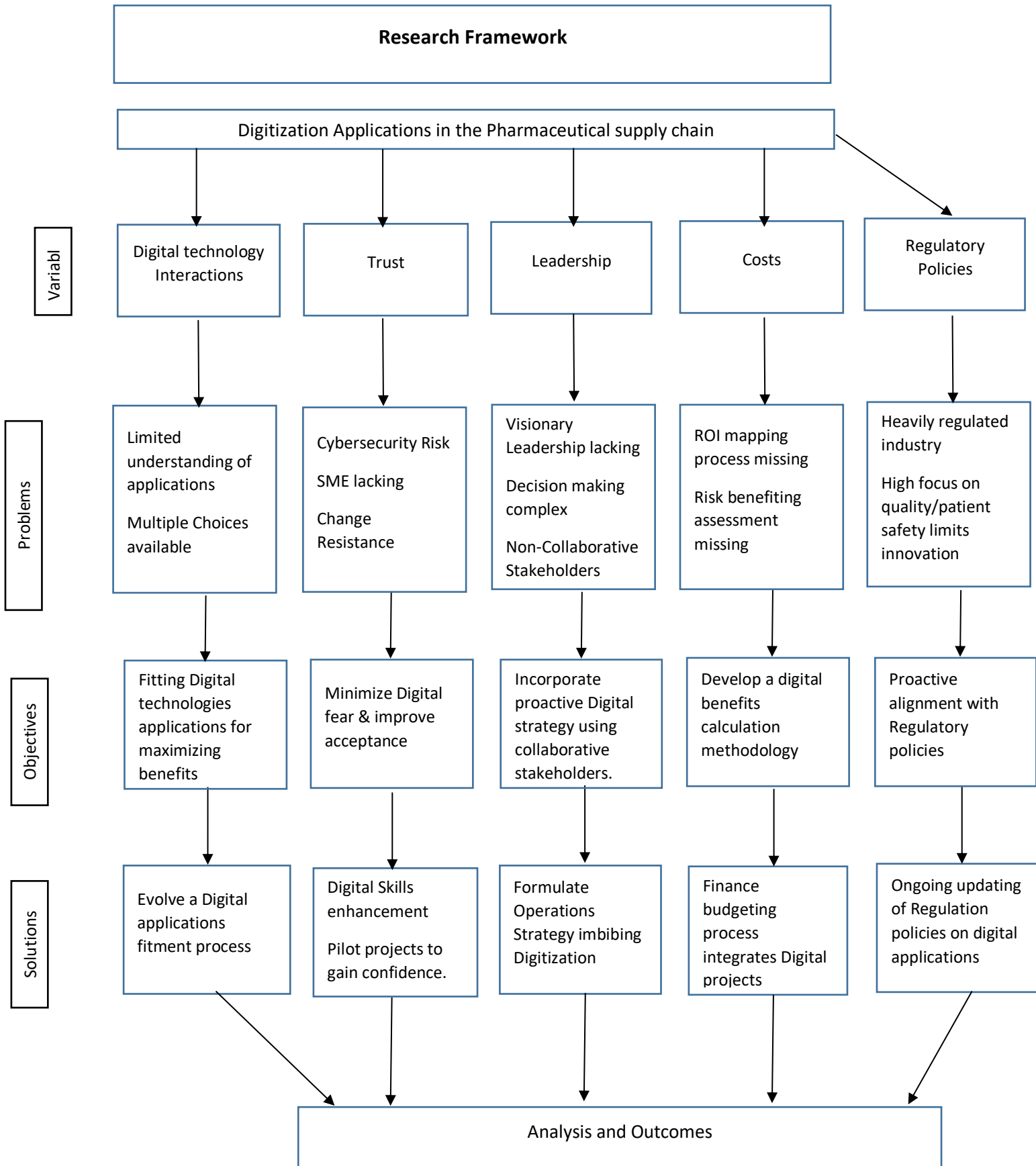
III. RESEARCH METHODOLOGY

Research Methodology is the process by which a researcher describe, explain and predict a process. Research methods are tools that researchers use when they inquire or investigate. It provides the focus and approach for the study and is the process through which methods will be used to address specific questions (Sami 2016).

Different sources of information was used for the Research methodology. This included secondary data from an online search of journals, reports etc. The research model suggests a direct relation of five factors - a) Digital technology Interactions b) Trust c) Leadership d) Costs and e) Regulatory Policies on Digitization applications in Manufacturing Operations.

IV. RESEARCH FRAMEWORK

Based on the literature review a framework is developed as shown below.



V. ANALYSIS AND OUTCOME

A. Digital Technology Interactions – Analysis And Outcome

There is no doubt that pharmaceutical organizations should have sufficient software and hardware resource capabilities to maximize their operational improvements (Shafique and Khurshid 2018).

Key questions that organizations need to ask are

- Where do I Digitize? Which technologies do I use specifically?
- What comes first? What are the Interdependencies required?

Companies need to develop skills in Digital technologies to make an informed decision around the right prioritization and application. For example the analysis tools used in “Big Data” are complex and require skill in evaluation and visualization of results. Complexity of the results of digitization comes from complexity of the data sets (Fitzerald, Bonnet and Welch 2013). Organizations need to start thinking of ways of creating a process of understanding, evaluating all relevant and available technologies and fitting them together as part of the Implementation strategy.

The “Impact to Value Framework” (Hammer, M., & Mangurian, G. E. (1987). SMR FORUM the Changing Value of Communications Technology. *Sloan Management Review (1986-1998)*, 28(2), 65.) can be applied as a decision evaluation matrix to identify the right fitment of technologies. Based on the framework, companies can identify which technologies can offer the optimized value in terms of efficiency improvements, effectiveness and degree of innovation. This can be correlated to the time of implementation, geography or scope of application in multiple areas or locations and relationships.

B. Trust – Analysis And Outcome

The healthcare industry has reported a 10% increase in the number of industrial espionage cases since 2010. In 2017 this industry contributed to 18% increase in data breaches out of which 63% cases were attributed to malicious activities. (Donovan, Shannon, Jacqueline and Stacy (2019). In 2017, Merck & Co. a biopharmaceutical company, was affected by a worm Petya. This malware infected manufacturing processes connected computer systems, resulting in non-availability of Gardasil and Hepatitis B vaccine (Donovan, Shannon, Jacqueline and Stacy (2019).

Cybersecurity can affect suppliers of Pharmaceutical companies. This is when sensitive data, like customer data, security is compromised (Francisca Maria Sousa e Silva 2019). Digital attacks are a reality and it is a negative influence on digitization implementation (Saheed 2019). Trust in Digitization can be compromised if security threats are not mitigated. This can lead to organizational change resistance due to “Digital fear”.

Organizations need to embark on a skill enhancement drive to ensure people have complete understanding of Digitization technologies, applications and security concerns. It is advisable to start with the implementation of pilot projects (Vladimir and Valentina (2018). This can be used to gain confidence in technology applications, risks and benefits. Companies need to develop a time based implementation strategy.

Organizations need to adopt a Risk management model revolving around the FMEA (Failure Mode and Effect Analysis, *US Armed Forces Military Procedures document MIL-P-1629 1949*) Matrix to identify the impact of utilizing various technologies. The matrix can help quantify the risks which can be mitigated through brainstorming with internal/external subject matter experts and stakeholders.

C. Leadership – Analysis And Outcome

Culture and Leadership skills deficiencies are one of the top barriers to implement Digitization in Pharmaceutical Operations (Alina, Eldar and Levent 2017). Also Digitization in companies do not succeed because of fixed mindsets, cultures and processes that negate change. Lack of a Digitization strategy and competing priorities were typical obstacles in digitalization (Clara and Susan 2017) Research indicates that effective leadership ensure successful digital transformation, a focus on change management and organizational communication (John, Sally, Vikas and Glenn 2018).

Pharma companies that want to move ahead in Digitization need to be optimistic to act now and develop an innovative culture by investing in people and process capabilities (David, Amy and Olivier 2015). Digitization is not dependent on technology alone, and has a component of leadership. Leadership by influence is the need of the hour. For Digitization to be a success excessive force and power will not do. A leader need to understand when to lead, support, coach, facilitate and influence others. The traditional traits of charisma, all knowledgeable etc. are not going to be enough. Digitization requires a top driven visionary mindset, implemented through independent teams (A.B Kazim 2019).

The way forward is to formulate a long term business strategy with Digitization as one of the Key enablers. The top leaders need to communicate, practice and deliver on the change by using the power and influence of key stakeholders including internal/external change leaders and experts. Development of internal teams and restructuring/creation of roles might be needed, for example hiring of a Chief Digital officer.

To align business strategy to Innovation and IT Strategy we could use the “Strategic Alignment model” (Venkatraman, N., Henderson, J. C., & Oldach, S. (1993). Continuous strategic alignment: Exploiting information technology capabilities for competitive success. *European Management Journal*, 11(2), 139-149.). This will ensure that there is a creation of a dynamic administrative process to align Business and Digital strategy. This model results can

be integrated to the “Strategy Map” (Kaplan, R. S., Kaplan, R. E., Norton, D. P., Davenport, T. H., & Norton, D. P. (2004). *Strategy maps: Converting intangible assets into tangible outcomes*. Harvard Business Press) as created by Kaplan and Norton. This can be the basis of a top driven Digital action plan.

D. Costs – Analysis And Outcome

If we are planning a Cloud based platform, the initial costs are usually lower and is charged based on number of users. This is easier to predict and organizations can estimate the additional hardware and costs involved. However what is difficult is the amount of money required over a period of years. If the organization decides for an onsite solution, the initial investment is much higher. The organization will also have to pay for regular maintenance. However the onsite platform also offers much more predictability for costs over a period of time which is advantageous from a budgeting point of view (Francisca Maria Sousa e Silva 2019).

When it comes to solution customizations, cloud based platforms have less flexibility. This is balanced by more stability and upgrades. On site platforms usually have more flexibility and customizations and lesser upgrades. If there are upgrades there are costs involved (Francisca Maria Sousa e Silva 2019).

The main aim of Digitization is to reduce costs, enhance performance, create internal efficiencies and adapt to new changes (Degryse 2016). So the decision to introduce digitization has to be based on the return on investment and the cost – benefit analysis model (Boardman, A. E., Greenberg, D. H., Vining, A. R., & Weimer, D. L. (2018). *Cost-benefit analysis*. Cambridge Books).

When Digitization actions are identified, a feasibility analysis needs to be done and actions and outcomes need to be prioritized. The feasibility analysis needs to revolve around a cost benefit analysis, risk analysis and constraint analysis. Feasibility analysis can involve costs of trials, prototypes etc. to gain better understanding. These actions needs to be brainstormed for their interdependencies.

E. Regulatory Policies – Discussions Analysis And Outcome

One of the biggest challenge for Pharmaceutical companies is the cost of launching new products. Regulatory requirements are hinged on ensuring safety of patient and product efficacy. This can result in the reduction of clinical success rates. Over the past 13 years, in the US alone the success rate was 4% out of the total products launched, while the cost to launch products was 1778 Million USD. The return on investment is declining so rapidly that the pharmaceutical model has to evolve (Fumio, Tomohiro, Yeongjoo, Shintara and Kota 2019). This naturally creates additional cost pressures. Regulatory agencies, being aware of these challenges are inclined to be over cautious in scrutinising compliance to prevent companies from cutting corners.

Health Regulatory agencies and Pharmaceutical industry are natural stakeholders, partners and suppliers to the entire Patient health system. The objective of both are same, which is to enhance health. There needs to be an environment of trust, honesty and respect if this relationship has to progress. There is a need to collaborate, communicate and coexist. Regulatory Agencies face several challenges owing to legal, technical and scientific domains. There needs to be a strategic level partnership and synergy between the two which includes 2-way communication flow to strengthen this relationship (Sandeep, Vikram and Harish 2017).

Companies must evolve a security policy to protect against data breaches. The most sophisticated privacy regulations must be used. These proactive and committed actions can help create an environment of trust between Pharmaceutical companies and Regulatory bodies.

Pharmaceutical Industries who are moving ahead on Digitization could form a strategic consortium or knowledge group to further enhance their skills, challenges and understanding of regulatory framework. The Discussions could be focused around having a working relationship with regulatory agencies in terms of current and future trends, risk-mitigation plans etc.

The Pharmaceutical organization needs to analyse its relationship with Regulatory agencies as an important stakeholder using the “Instrumental approach of Stakeholder theory” moderation model (Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T. M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management journal*, 42(5), 488-506.). By using this approach senior leaders within the Pharmaceutical firm can re look at their collaborative efforts on Digitization applications through the prism of honest and ongoing communications.

VI. RESEARCH IMPLICATIONS

The study is based on qualitative research articles and validated secondary data. A framework is provided as the most important factors that need to be considered by any Pharmaceutical company to go for Digitization applications within its Operations domain. Implementation risks can be largely mitigated if stakeholders use the framework as a guiding tool. Pharma leaders can make use of Kotter’s “Change Phases” model (Kotter, J. P. (1995). *Leading change: Why transformation efforts fail*, Harvard Business Review) and integrate the five factors within their Operations domain. These research findings should help Pharmaceutical operations to realize better efficiencies, remove non value added processes, increase transparency, cut costs and help improve human performance and learning capability.

VII. LIMITATIONS AND SCOPE FOR FUTURE RESEARCH

Secondary data was used for the study. Depending on when the data was collected some of the facts could be outdated. Technology life cycle is short, hence considering that the topic of research was around Digitization, some of the parameters of the data set studied may have changed. The study was conducted considering Pharmaceutical Operations. How do these factors change or behave for other functions of the Industry like R&D, Commercial and Marketing, Upstream and Downstream Supply chain, Logistics have not been studied. What is the impact of these factors with respect to cultures, geographies, regions and countries, has not been studied in depth? Further, relative weightage of the five factors has not been arrived at.

VIII. CONCLUSION

The Pharmaceutical Industry remains one of the strongest pillar for global economies due to its impact on healthcare, patient safety, employment generation and Research focus. However years of traditional style of working coupled with high regulatory outlook has kept the industry lagging when it comes to emerging technologies. Nevertheless, many companies especially Big Pharma have realized what they are missing out and are investing in the future. This can create a wave of innovation and perhaps serve as a competitive advantage. Organizations need to make adjustments to ensure that the needs of the market and patient is continuously met. This can be supported by digitization. This should be a never ending action.

Data shows examples of the last 10 years, where big enterprises went bankrupt because they couldn't keep up with the pace of Digitization. Companies need to adapt and evolve to this change. This is no longer a choice but a matter of survival (Francisca Maria Sousa e Silva 2019).

REFERENCES

- [1]. Alagarsamy, S., Kandasamy, R., Subbiah, L., & Palanisamy, S. (2019). Applications of Internet of Things in Pharmaceutical Industry. *Anna University*
- [2]. Almalki, S. (2016). Integrating Quantitative and Qualitative Data in Mixed Methods Research-Challenges and Benefits. *Journal of education and learning*, 5(3), 288-296.
- [3]. Azoev, G., Sumarokova, E., & Butkovskaya, G. (2019, December). Marketing communications integration in healthcare industry: digitalization and omnichannel technologies. In *International Scientific and Practical Conference on Digital Economy (ISCDE 2019)*. Atlantis Press.
- [4]. Bellgran, M., Kurdve, M., & Hanna, R. (2019). Cost driven Green Kaizen in pharmaceutical production–Creating positive engagement for environmental improvements. *Procedia CIRP*, 81, 1219-1224.
- [5]. Berman, S. L., Wicks, A. C., Kotha, S., & Jones, T. M. (1999). Does stakeholder orientation matter? The relationship between stakeholder management models and firm financial performance. *Academy of Management journal*, 42(5), 488-506.
- [6]. Biggs, J., Hinish, S. R., Natale, M. A., & Patronick, M. (2017). *Blockchain: Revolutionizing the global supply chain by building trust and transparency*. Rutgers University.
- [7]. Blossey, G., Eisenhardt, J., & Hahn, G. (2019, January). Blockchain technology in supply chain management: An application perspective. In *Proceedings of the 52nd Hawaii International Conference on System Sciences*.
- [8]. Boardman, A. E., Laurin, C., Moore, M. A., & Vining, A. R. (2009). A cost-benefit analysis of the privatization of Canadian national railway. *Canadian Public Policy*, 35(1), 59-83.
- [9]. Carrus, P. P., Marras, F., Musso, M., & Pinna, R. (2016). The impact of digitalization in the drugs logistics and clinical process: an Italian case study. *Sinergie Annual Conference, Management in a Digital World. Decisions, Production, Communication. University of Udine (Italy)*.
- [10]. Champagne, D., Hung, A., & Leclerc, O. (2015). How pharma can win in a digital world. *Pharmaceuticals & Medical Products*. McKinsey & Company.
- [11]. Chilukuri, S., Rosenberg, R., & Van Kuiken, S. (2014). *A digital prescription for pharma companies*. McKinsey & Company, 1-6.
- [12]. Chircu, A. M., Sultanow, E., & Sözer, L. D. (2017). *A reference architecture for digitalization in the pharmaceutical industry*. Informatik 2017. DOI: 10.18420/in2017_205
- [13]. Cordeiro, P. M. A. (2016). *Evaluation of the cost-benefit of the implementation of PAT systems for the production of solid forms in a pharmaceutical company* (Doctoral dissertation, Universidade de Lisboa).
- [14]. Degryse, C. (2016). Digitalisation of the economy and its impact on labour markets. *European Trade Union Institute Research Paper-Working Paper*.
- [15]. Dhiman, S. K., Gummadi, V., & Dureja, H. (2019). Partnership Efforts–Their Potential to Reduce the Challenges that Confront Regulators and Pharmaceutical Industry. *Applied Clinical Research, Clinical Trials and Regulatory Affairs*, 6(1), 7-17.
- [16]. Drossos, D., Lekakos, G., Doukidis, G. I., Tsatsa, N., & Coursaris, C. K. (2018). Public-sector Digitization: An Analytical Cost-effective Framework. *Mediterranean Conference on Information systems (2018)*.
- [17]. Fitzgerald, M., Kruschwitz, N., Bonnet, D., & Welch, M. (2014). Embracing digital technology: A new strategic imperative. *MIT sloan management review*, 55(2), 1.
- [18]. Gbadegeshin, S. A. (2019). The Effect of Digitalization on the Commercialization Process of High-Technology Companies in the Life Sciences Industry. *Technology Innovation Management Review*, 9(1).

- [19]. Grennan, M., & Town, R. J. (2020). Regulating innovation with uncertain quality: information, risk, and access in medical devices. *American Economic Review*, 110(1), 120-61.
- [20]. Grishikashvili, K. (2019). *Capabilities for Big Data: An Empirical Study in a Global Pharmaceutical Company*. Doctoral dissertation, The Open University.
- [21]. Gutteres, D., Stewart, S., Wolfrum, J., & Springs, S. (2019). Cyberbiosecurity in Advanced Manufacturing Models. *Frontiers in bioengineering and biotechnology, Massachusetts Institute of Technology*.
- [22]. Haffke, I. (2017). *The Implications of Digital Business Transformation for Corporate Leadership, the IT Function, and Business-IT Alignment*. Doctoral dissertation, Technische Universität Darmstadt.
- [23]. Hartmann, B., King, W. P., & Narayanan, S. (2015). *Digital manufacturing: The revolution will be virtualized*. McKinsey & Company.
- [24]. Heberle, A., Löwe, W., Gustafsson, A., & Vorrei, Ö. (2017). Digitalization Canvas-Towards Identifying Digitalization Use Cases and Projects. *J. UCS*, 23(11), 1070-1097.
- [25]. Hennelly, P. A., Srari, J. S., Graham, G., & Fosso Wamba, S. (2020). Rethinking supply chains in the age of digitalization. *Production Planning and Control*, 31(2-3), 93-95.
- [26]. Kaplan, R. S., Kaplan, R. E., Norton, D. P., Davenport, T. H., & Norton, D. P. (2004). *Strategy maps: Converting intangible assets into tangible outcomes*. Harvard Business Press.
- [27]. Klünder, T., Dörseln, J. N., & Steven, M. (2019). Procurement 4.0: How the digital disruption supports cost-reduction in Procurement. *Production, Ruhr-University Bochum, Germany*.
- [28]. Kotter, J. P. (1995). Leading change: Why transformation efforts fail. *Harvard Business review*
- [29]. Kumar, U. S. (2019). Case Study: Digitization and digitalization in pharmaceutical industry: opportunities and challenges in India. *Advances in Management*, 12(4), 23-29.
- [30]. Kusi, B., Li, C., Gyasi, R. S., & Afful, J. M. (2018). Concurrent Product Co-Creation through Collaborative Networks among Pharmaceutical Manufacturing Enterprises. *European Journal of Contemporary Research*.
- [31]. Kuusisto, M. (2017). Organizational effects of digitalization: A literature review. *International journal of organization theory and behavior*, 20(03), 341-362.
- [32]. Layard, P. R. G. (1994). *Cost-benefit analysis*. Cambridge University Press.
- [33]. Lee, M., Ly, H., Möller, C. C., & Ringel, M. S. (2019). Innovation in regulatory science is meeting evolution of clinical evidence generation. *Clinical Pharmacology & Therapeutics*, 105(4), 886-898
- [34]. Limaye, R., Kumar, L., & Limaye, N. (2018). Fourth generation technologies in pharmaceuticals-Revolutionizing healthcare. *Journal of Systems Biology & Proteome Research*.
- [35]. Lin, K. C., Shyu, J. Z., & Ding, K. (2017). A cross-strait comparison of innovation policy under industry 4.0 and sustainability development transition. *Sustainability*, 9(5), 786.
- [36]. Lisna, A. G., & Posilkina, O. V. (2019). Analysis of impact factors on the process of implementation modern digital technologies in domestic pharmacy. *National University of Pharmacy, Kharkiv, Ukraine*.
- [37]. Loonam, J., Eaves, S., Kumar, V., & Parry, G. (2018). Towards digital transformation: Lessons learned from traditional organisations. *Strategic Change*, 27(2), 101-109.
- [38]. Majanoja, A. M., Linko, L., & Leppänen, V. (2017). Developing offshore outsourcing practices in a global selective outsourcing environment—the IT supplier’s viewpoint. *Developing offshore outsourcing practices in a global selective outsourcing*.
- [39]. Olk, P., & West, J. (2020). The relationship of industry structure to open innovation: cooperative value creation in pharmaceutical consortia. *R&D Management*, 50(1), 116-135.
- [40]. Olsen, T. L., & Tomlin, B. (2020). Industry 4.0: Opportunities and Challenges for Operations Management. *Manufacturing & Service Operations Management*, 22(1), 113-122.
- [41]. Parrish, R. H., Gilak, L., Bohannon, D., Emrick, S. P., Serumaga, B., & Guharoy, R. (2019). Minimizing Medication Errors from Electronic Prescription Transmission—Digitizing Compounded Drug Preparations. *Pharmacy*, 7(4), 149.
- [42]. Parviainen, P., Tihinen, M., Kääriäinen, J., & Teppola, S. (2017). Tackling the digitalization challenge: how to benefit from digitalization in practice. *International journal of information systems and project management*, 5(1), 63-77.
- [43]. Patidar, A., Vinchurkar, K., & Balekar, N. (2018). Digitalisation in Pharmacy. *International Journal of Research in Pharmacy and Pharmaceutical Sciences*.
- [44]. Plotnikov, V., & Kuznetsova, V. (2018). The Prospects for the Use of Digital Technology “Blockchain” in the Pharmaceutical Market. *MATEC Web of Conferences*, 193, 02029
- [45]. Porter, M. E., & Heppelmann, J. E. (2015). How smart, connected products are transforming companies. *Harvard Business Review*, 93(10), 96-114.
- [46]. Rachinger, M., Rauter, R., Müller, C., Vorraber, W., & Schirgi, E. (2019). Digitalization and its influence on business model innovation. *Journal of Manufacturing Technology Management*.
- [47]. Reddy, A. V. J., & Rao, B. M. (2017). Opportunities and challenges for Indian Pharmaceutical companies in overseas markets and need of digital tools for sustainable success. *Indian Journal of Pharmaceutical Education and Research*, 51, 226-238.
- [48]. Schumacher, A., Erol, S., & Sihm, W. (2016). A maturity model for assessing Industry 4.0 readiness and maturity of manufacturing enterprises. *Procedia Cirp*, 52(1), 161-166.

- [47]. Sebastian, I., Ross, J., Beath, C., Mocker, M., Moloney, K., & Fonstad, N. (2017). How big old companies navigate digital transformation. *MIS Quarterly Executive*.
- [48]. Shafique, M. N., Khurshid, M. M., Rahman, H., Khanna, A., & Gupta, D. (2019). The Role of Big Data Predictive Analytics and Radio Frequency Identification in the Pharmaceutical Industry. *IEEE Access*, 7, 9013-9021.
- [49]. Shawosh, M. (2018). INFORMATION SYSTEMS STRATEGIC LEADERSHIP IN THE LAST DECADE: NEW ADVANCEMENTS AND BLUE OCEAN OPPORTUNITIES. *Information Systems*.
- [50]. Sjödin, D. R., Parida, V., Leksell, M., & Petrovic, A. (2018). Smart Factory Implementation and Process Innovation: A Preliminary Maturity Model for Leveraging Digitalization in Manufacturing Moving to smart factories presents specific challenges that can be addressed through a structured approach focused on people, processes, and technologies. *Research-Technology Management*, 61(5), 22-31.
- [51]. Sony, M. (2018). Industry 4.0 and lean management: a proposed integration model and research propositions. *& Manufacturing Research*, 6(1), 416-432.
- [52]. Sousa, F. M. (2019). How to Improve Procurement on a Digitalization Age? *UNIVERSIDADE DO PORT*
- [53]. Tehrani, N., & Jin, Y. (2018). How Advances in the Internet of Things (IoT) Devices and Wearable Technology Will Impact the Pharmaceutical Industry. *RA Journal of Applied research* 4, 1530-1533.
- [54]. Teramae, F., Makino, T., Lim, Y., Sengoku, S., & Kodama, K. (2020). International Strategy for Sustainable Growth in Multinational Pharmaceutical Companies. *Sustainability*, 12(3), 867.
- [55]. Uhlemann, T. H. J., Schock, C., Lehmann, C., Freiberger, S., & Steinhilper, R. (2017). The digital twin: Demonstrating the potential of real time data acquisition in production systems. *Procedia Manufacturing*, 9, 113-120.
- [56]. Venkatraman, N., Henderson, J. C., & Oldach, S. (1993). Continuous strategic alignment: Exploiting information technology capabilities for competitive success. *European Management Journal*, 11(2), 139-149.
- [57]. Von Kutzschenbach, M., & Brønn, C. (2017). Education for managing digital transformation: a feedback systems approach. *Systemic, Cybernetics and Informatics*, 15(2), 14-19.
- [58]. Zachman, J. A. (2003). The zachman framework for enterprise. *Zachman International*, 38.