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Industry 4.0 Preparedness in Indian Pharmaceutical companies - A Review and Agenda for Future Research

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Abstract

This study is based on literature review, collected from secondary resources regarding preparedness of "Industry 4.0" in Indian Pharmaceutical companies and set an agenda for future research. There is no denying the fact that companies should view "Industry 4.0" with all seriousness as we move forward from traditional manufacturing business models and ensure integration of the same with emerging technologies such AI & ML, Big data, IOT and leading towards virtually connected workspace culture. Going forward we are likely to see an amalgamation of these mechanics in business applications. Business sustainability will be built on foundation of a strong ecosystem combining forces from all stakeholder viz. corporate, government and research enterprises with role clarity for each. Further, with the growth of Pharmaceutical industry in the global market plateauing over time, it is the emerging markets like China, Brazil, Russia and of course India, with spurt in need, owing to a burgeoning population, who need take centre stage in contributing to add growth continuity in pharmaceutical industry. The paper attempts to a detailed study of concept of "Industry 4.0" and challenges therein in transformation of pharmaceutical organizations to match "Industry 4.0" requirements in light of strategy and policies being pursued. It further intends to reconnoiter the preparedness of pharmaceutical companies in India to execute the "Industry 4.0" propositions. Foremost a systematic literature review was conducted using quality journal data base sources like Sage, Emerald, Elsevier etc. The paper posits to conclude that, whilst literature review brings out a vehement need to gear up towards "Industry 4.0" execution, situation at ground level is very unalike and challenging. More systematic approach needs to be put with engagement of all stakeholders including the government to ensure strategic change towards transformation of Pharmaceuticals in India.

Key words: "Industry 4.0", Pharmaceutical organizations, Artificial Intelligence, Innovation, Challenges**,** Technology, Automation, preparedness

INTRODUCTION

In today's age of disruption, ambiguity and complexness, the manufacturing sector has to adopt technology, digitization and intelligentization of processes related to customer service models, dynamic supply chain networks modularization and network

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collaboration. Currently manufacturing industries have switched to customized production from mass production. Due to advancement in manufacturing technologies productivity and qualitative engagement increased across product and services. "Industry 4.0" describe the new models of smart organization spread over the full value chain. Few concepts which form the core of "Industry 4.0" dream includes IOT, Industrial Internet, Artificial Intelligence etc. For a vision to translate into action and reality it is critical that we understand the concept, its requirements and also see the current level level of preparedness to convert the vision into reality. According to M. Rüßmann et al. (2015), fourth industrial revolution integrate the human to machine interface, this improve the value adding activities and also reduced the waste.

REVIEW OF LITERATURE:

The "Industry 4.0" concept, coined by the German Government in the year 2011, as part of the manufacturing strategy towards 2020. The different authors, researchers, corporate and policy makers across the globe had interpreted and explore the term in context of different industries and geographical location. The table 1 compile the literature as mentioned below:

Table 1: "Industry 4.0" and Focus areas

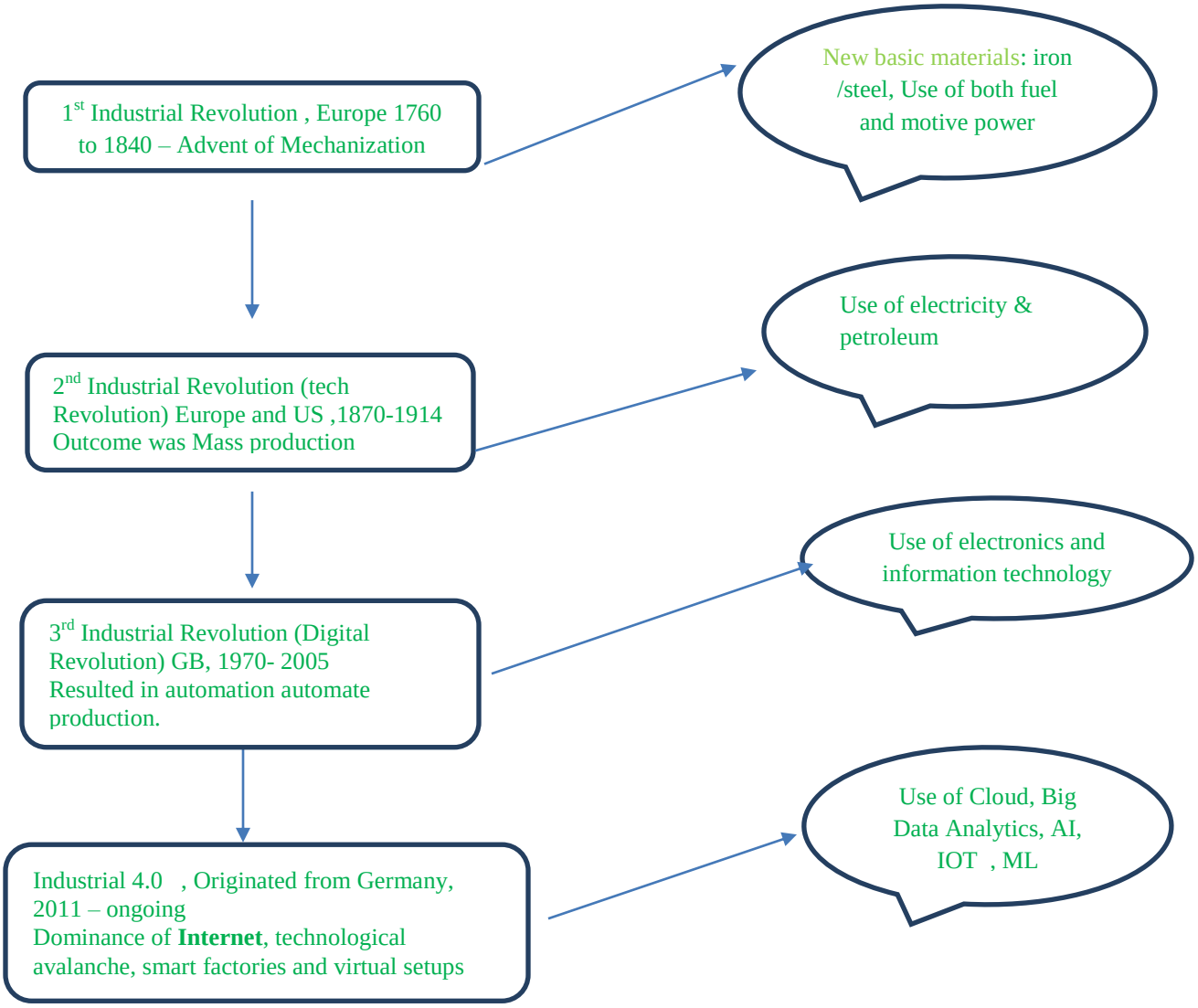
Author	**Focus areas**
Keliang Zhou et al. (2015)	Explore and define the term "Industry 4.0".
Ivanov et al, 2016; Lee et al. (2015)	Applying "Industry 4.0" using data analytics, cyber physical system.
Deloitte (2015)	Interpret "Industry 4.0" in context of IOT.
Lukac, (2015)	Machine interface, trouble shooting.
Hewitt (2002)	"Industry 4.0" required as elderly population increasing and short fall in working hands.
Qin et al,(2016)	"Industry 4.0" can help in addressing workforce challenges.

According to report by Frost and Sullivan (2016) there is a great opportunity in the manufacturing sector in India especially in the Automotive, Electronic and Semiconductors and Pharmaceutical & Chemical Industry and that the Make in India will enable fourth industrial revolution dream for India and develop the base for Advanced Manufacturing in India. The four focus areas are–

"**Industry Convergence:** IT-OT-Telecom – Crux of fourth industrial revolution will be formed by cross-pollination of ideas, technologies and processes between the worlds of Information Technology and Operational technology."
"Services 4.0 - This includes exploring newer avenues for service innovations, such as cloud-based service platforms and evaluating potential for new profit centres."
"Supply Chain Evolution - Existing supply chain networks will get realigned with advent of digitalization and increased connectivity."

"The "Industry 4.0" Business Ecosystem is likely to converge to unexpected business collaborations and interdependencies."

Fig 1: **Evolution of "Industry 4.0"**



Benefits of "Industry 4.0" to the Pharmaceutical manufacturing units

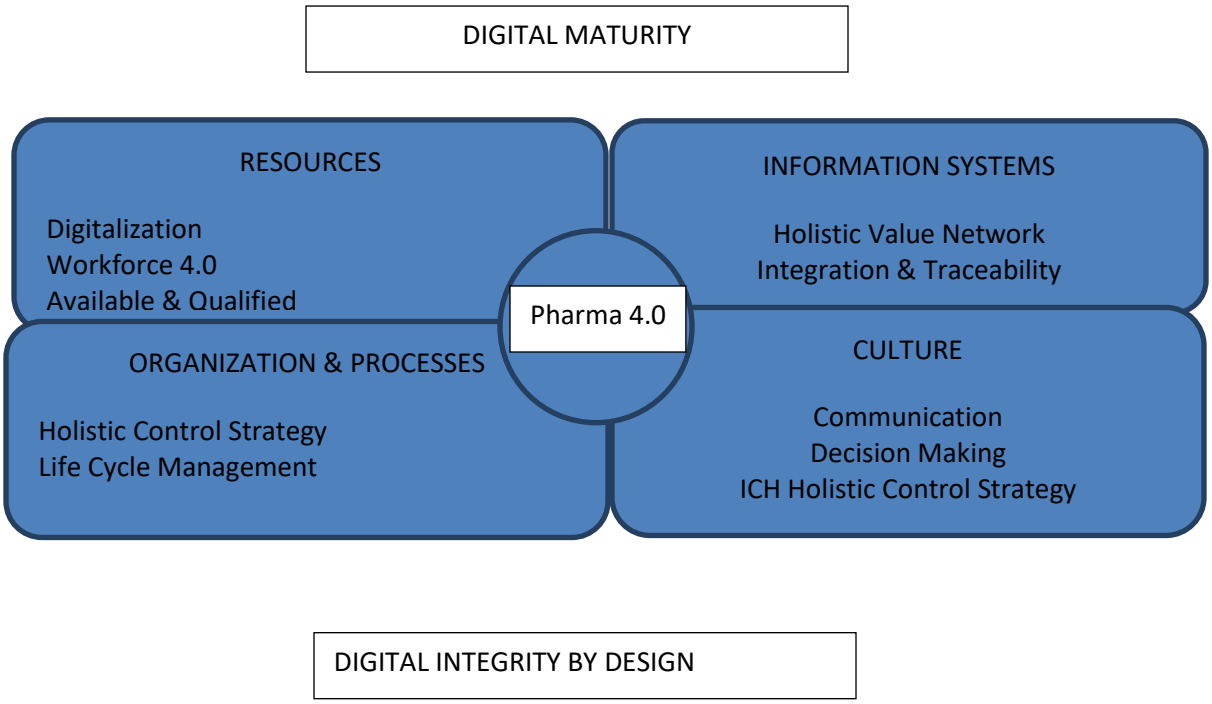
Xu and Duan (2018) explain the benefits of "Industry 4.0" such as IOT, CPS, SOA, Block Chain, and Cloud technologies. The application of "Industry 4.0" in Pharma is termed as Pharma 4.0 along the product life cycles through digitization and automation, (Xu et al. 2017 , Lu 2017a, b). It is important to develop understanding of readiness and maturity, starting with enablers and components defined in ICH Q10. This is a model for pharmaceutical quality system spread across different stages of a product lifecycle. The case based adaptation and

demonstration can showcase the automation and digitalization in Pharma sector but there are lot of challenges due to regulatory compliances in Pharma sector.

The "Industry 4.0" adaptation in Pharma will lead sector towards Pharma 4.0 that will enhance transparency level and speed in manufacturing plants. The decision making is going to be faster and will enhance the overall control and Security. Implementation requires integration of expectation, interpretations and definition alignment with pharmaceutical regulations.

The International Society for Pharmaceutical Engineering and its members have developed Pharma 4.0 Operating Model.

Fig 2 Operating Model " Pharma 4.0"



Goals to achieve "Industry 4.0"

The different authors suggested the roadmap for digital transformation across the Pharma Sector and its functional areas as mentioned in the table 2;

Table 2 "Industry 4.0" and Pharma Sector Goals

Author	**Goals towards "Industry 4.0"**
Drath and Horch, (2014)	Planning and outlining goals.
Dudek et al. (2015)	Reference architecture and system standardization.
Oesterreich & Teuteberg (2016)	Efficient management.
Hermann et al. (2016)	Comprehensive, reliable industrial broadband infrastructure.
Intel IOT Report (2016)	Safe and secure environment.
Ivanov et al. (2015)	Organizing and designing work.
Kagermann (2014), Kagermann et al. (2011), Kagermann et al. 2013	Personnel training, organizational framework, efficiency of resource utilization.
Oztemel and Tekez (2009a)	Self-behavior.
Gursev et al. (2018)	Product , process interaction.

Despite the broadness of the term, most agree that fourth industrial revolutions' impact on the pharmaceutical manufacturing industry will be significant. It has the impending to disrupt both processes and products. There could be a 360 degree change in the way the sector is operating now. However, during review of literature there seems to be limited awareness on the subject at ground level and empirical investigations are far and few. Hence, it will be appropriate to conduct an investigative study on the readiness to invest and adapt the "Industry 4.0" concept.

CONCLUSION:

This review paper based on concept of fourth "Industry 4.0", its evolution and integration with embedded systems to cyber-physical systems in context of the pharmaceutical manufacturing units. Industry 4.0" integration with production technologies and processes lead to a new technological age which will further result in a radical transformation of industry and production value chains and service model. The review supports in understanding that pharmaceutical manufacturing industry will be able to produce, efficient and customized production at reasonable cost. However, this needs a faster than usual attention and unless the preparedness level of leadership team, infrastructure and employees at large in pharmaceutical manufacturing units are not gauged, we are likely to miss the bus. It's largely written on the wall that implementation of the "Industry 4.0" needs focus on increased research on the areas and figure out the challenges in execution of the "Industry 4.0" vision. The journey towards execution of "Industry 4.0" is a long road and checking preparedness of Indian Pharmaceutical companies needs paramount attention. Further, investigation using focus group discussion and case study of leading pharmaceutical organization in the country is recommended. As we explore "Industry 4.0" preparedness, concept of Industry 5.0, which focuses on co-existence of machine and humans, takes seed!

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