

Digitalization in the pharmaceutical industry: forms of digitalization with emphasis on Pharma 4.0

Grozdana Leshevska, Bojan Papadinov

Replek, Kozle 188, 1000, Skopje, Macedonia

Introduction

Digitalization of any manufacture industry is a key step in any progress of the production process. The process of digitalization includes both increased use of robotics, automatization solutions and computerization, thereby allowing to reduce costs, to improve efficiency and productivity, and to be flexible to changes (Hole et al., 2021).

Materials and methods

In this paper, we reviewed the literature on the subject of Digitalization in the Pharmaceutical Industry (PI) with emphasis on Pharma 4.0 model. Through search for relevant literature, evaluating the sources, identifying the themes and with outlining the structure of our article we conducted the meta- analysis of all the literature and got our final result.

Results and discussion

Digitalization in Pharmaceutical Industry

In the wake of Covid-19, digitalized technology is more important than ever allowing companies to improve performance through better manufacturing productivity, more accurate planning and forecasting, and financial sustainability (Faraj et al., 2021).

Digitalization in the PI can help organizations have better control on their manufacturing processes with greater product monitoring, visualization and remote data access, allowing them to identify and improve the processes.

In the PI, digitalization can be extremely beneficial to both small and large firms (Lakshmi and Patel, 2020). For

example, using digitalization to develop counterfeit-proof pharmaceuticals with traceable serial numbers through the supply chain should ensure quality while satisfying forthcoming serialization regulations (Anderson, 2018) (Rosenbaum et al., 2017). Pharmaceutical firms can also embrace digitalization to fulfill the predicted rise in demand from global markets. They may use digitalization to comply with regulations, uncover manufacturing efficiencies to reduce costs, and interact with suppliers and distributors more swiftly using cloud-based information exchanges (Kumar and Panigrahi, 2014).

In order to achieve full digital maturity manufacturers must take a methodical approach in the development of digitalization with stages complementing one another starting with computerization, connectivity, visibility, transparency, predictability and ending with adaptability (Hole et al., 2021).

PI needs to implement digitalization tools. Digitalization is necessary to continue to deliver medical products in accordance with the growing demand of a constantly changing world and population (Hole et al., 2021).

Industry 4.0 – Pharma 4.0 concept

Pharma 4.0 is the upgradation of the pharmaceutical industry to incorporate advanced technologies and digital strategies. Adoption of ideas of Industry 4.0 in the pharmaceutical sector could resolve hurdles faced by the pharmaceutical sector. The role of Industry 4.0 in the pharmaceutical sector is to design and manufacture innovational and customized products as per the varying customer taste and demands within no time, economically, and efficiently (Devansh et al., 2023).

Industry 4.0 promises advancements of entire manufacturing systems and infrastructures. In such an

environment, performance data can be analyzed by algorithms and used for critical real-time business and operational decisions that directly impact production outputs (Fuhr et al., 2014). The journey from simple data collection to digital maturity is one in which data transforms from raw data captured from a manufacturing process, to information gained by analysis of these data, to knowledge formed through the addition of contextual meaning perhaps by artificial intelligence, and finally to actionable wisdom to inform decision-making by the contribution of insight. This “wisdom” is what fuels autonomous systems and cyber-physical machines capable of self-optimizing, judgment/decision making, remote movement, and adaptive control (Guilfoyle, 2018).

Forms of Digitalization in Pharmaceutical Industry

Electronic logbooks automatically document relevant production information improving data integrity. These logbooks can compile and integrate information from machines and operators, expanding process visibility. Further, electronic logs can integrate notes, device history records — providing a more holistic record of production than paper-based forms, ensuring that information is attributable, legible, contemporaneous, original, and accurate.

In line clearance processes allows full implementation of digital, Internet of Things (IoT) - enabled work instructions to guide users through SOPs resulting with increased efficiency while ensuring that work is performed correctly and validated automatically

With the electronic batch records, manufacturers can spend more time ensuring the quality of a product and less time correcting transcription errors.

Through process visibility, with IoT devices and human-centric manufacturing applications, manufacturers can break complex processes into their constituent steps, creating a granular picture of how workers perform on the line.

IoT makes it possible to respond to changes in environmental conditions as they develop. This is called Clean room monitoring capability and it saves a significant amount of time in monitoring clean rooms, that normally require a technician onsite who undergoes a gowning and sanitization process, records the information on paper, and documents the data in a computer (Bringing Industry 4.0 to Pharma, 2023).

Conclusion

Digitalization in PI can bring several advantages like reduced production costs, improved quality reduced capacity restrictions.

The use of a digital platform can improve processes in a variety of ways, including data collection, real-time sharing of trial results, and the capacity to track various aspects of productions.

Achieving Industry 4.0 will require adopting advanced manufacturing technologies and overcoming regulatory, technical, and logistical challenges. Each step-change on the path to an Industry 4.0 manufacturing environment should lead to more autonomous manufacturing systems with enhanced process controls and more mature quality management. These changes should reduce variability across lots and produce consistently available products.

References

- Anderson, S., 2018. The digitization of the Pharmaceutical Historian archive. *Pharm. Hist*, 48:2
- Arden, N.S., Fisher, A.C., Tyner, K., Lawrence, X.Y., Lee, S.L., Kopcha, M., 2021. Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future, *Int. J. Pharm.* 602, 120554. <https://doi.org/10.1016/j.ijpharm.2021.120554>
- Sharma, D., Patel, P., Shah, M., 2023. A comprehensive study on Industry 4.0 in the pharmaceutical industry for sustainable development, *Environ. Sci. Pollut. Res.* 1–11. <https://doi.org/10.1007/s11356-023-26856-y>
- Faraj, S., Renno, W., Bhardwaj, A., 2021. Unto the breach: what the COVID-19 pandemic exposes about digitalization, *Inf. Organ.* 31(1), 100337. <https://doi.org/10.1016/j.infoandorg.2021.100337>
- Fuhr, T., Gonce A., Positano, L., Rutten, P., Tepis, V., 2014. Flawless—From Measuring Failure to Building Quality Robustness in Pharma. In: McKinsey & Company Chicago, IL.
- Guilfoyle P, 2018. Pharma 4.0: Industry 4.0 Applied to Pharmaceutical Manufacturing, *Pharmaceut. Process. World*
- Hole, G., Hole, A.S., McFalone-Shaw, I., 2021. Digitalization in pharmaceutical industry: What to focus on under the digital implementation process?, *Int. J. Pharm.* X. 3, 100095. <https://doi.org/10.1016/j.ijpx.2021.100095>
- Kumar, L., Panigrahi, C.M.A., 2014. Communication with doctors: empowering Pharma field force with modern marketing techniques. *Asian J. Manag.* 5(2), 191-201.
- Lakshmi B., Patel S., 2020. Digital Marketing in Pharmaceutical Industry—An Overview and Assessment, *International Journal of Pharmaceutical Science & Innovation* 1(1)
- Rosenbaum, M.S., Ramirez, G.C., Edwards, K., Kim, J., Campbell, J.M., Bickle, M.C., 2017. The digitization of health care retailing, *J. Res. Interact. Mark.* 11(4), 432-446. <https://doi.org/10.1108/JRIM-07-2017-0058>
- Tulip, 2023. Bringing Industry 4.0 to Pharma: A Breakdown of How to Drive Digital Manufacturing in Regulated Industries, <https://tulip.co/ebooks/pharma-4-0/>. Accessed 30 May 2023