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 innovation 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.

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