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Digital Technologies are the Evolutionary Mandate for Medical Device Manufacturer

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Abstract

Digital Technologies including IoT, ML, AI and Block-chain are revolutionizing the conventional Manufacturing norms. In the pre-covid era Digital was confined to e-commerce and marketing avenues. But, now the focus lies on leveraging the new age technologies for automating processes and optimizing time in the core manufacturing industry. Medical Device Manufacturing being a highly regulated and people dependent industry has always been reluctant to invest in digital. But with fast paced dynamic requirements there has a been a major digital revolution in the Medical Device Manufacturing domain. Here we discuss the impact of Digital Technologies on different cascaded processes of Medical Device Manufacturing.

Keywords: Digital Technologies; Medical Device Manufacturing; Manufacturing Controls

Abbreviations: MOM: Manufacturing Operations Management; IQC: Initial Quality Check; IPQC: In Process Quality Check; FQC: Final Quality Check; AI: Artificial Intelligence; ML: Machine Learning.

Overview

Fourth Industrial Revolution, Industry 4.0 in MedTech stands for the active implementation of advanced technologies like AI, ML, Blockchain, Big Data and Robotics in Medical Device Manufacturing. In the beginning of 21st century most of the contract manufacturing facilities operated in a people-dependent manner. SMEs in Medical Device Contract Manufacturing business were reluctant to invest in digital technologies as they could not analyze relevant impact on their annual ROI.

FDA data reveals that between 2013 -2018, 52- 54% of products (Class I and Class II) recalls were due to errors related to manufacturing controls in the production process. Manufacturing controls are often a struggle in conventional setups due to limited accessibility, human errors & miscommunication.

During COVID-19 peak, SMEs in different parts of the world who weren't keen on digital, were forced to invest in digital technologies like AI, ML, Big Data, IoT and app-based communication and data sharing platforms. Digital empowerment helped them to cope up with supply chain disruptions, uncertain manufacturing demands, remote working and much more. As manufacturers see digital technologies being one of the most pressing requirements to sustain the fluctuating manufacturing environment, now, the focus lies on eliminating unnecessary dependencies and incorporating digital technologies at every level. Deploying automation, enabling cloud storage, promoting remote working environments and software-based documentation have made processes more efficient, time-bound, transparent, cost-optimized and hassle-free.

Let's analyze deeply how implementing digital at various levels can improve manufacturing controls in different

aspects of Medical Device Development & Manufacturing.

Ways Medtech 4.0 Impacts Medical Device Manufacturing

Regulatory compliance: The Medical Device industry is highly regulated and every new medical device has to go under multiple phases of evaluation to enter the market. Incorporating new-age technologies eliminates human error, improves efficiency and automates redundant processes across multiple levels. AI, ML & IoT based manufacturing processes and digital documentation makes regulatory compliance a natural byproduct [1].

Integrated MOM (Manufacturing operations Management) solutions set the product specific environment and processes. Digital platforms for IQC (Initial Quality Check), IPQC (In process quality check) and FQC (Final Quality Check) help in deriving rich, accurate and timely data to identify quality issues at every stage. eDHR improves the agility to identify & respond to compliance issues [2].

Production Floor: AI enabled production line eliminates the need to hire technicians for repetitive tasks. Smart tools with machine learning algorithms improve efficiency and reduce possible human errors.

Study conducted in 2021 by The Lancet found that 222 artificial intelligence (AI) and machine learning (ML)-based medical devices were approved by the FDA for use in the United States. It also reported that 240 such devices were approved for use within Europe*

Supply Chain Efficiency: The use of advanced software in the supply chain management helps in inventory management, tracking, communicating, and pre-planning. Unlike conventional excels and other mediums of data management in the supply chain, ERPs like SAP enable transparency and reduce possible errors in the development & manufacturing process [3].

Prior to technology indulgence, keeping tabs and communicating with supplier in a different geography at all times required long mail chains. Now, with real time tracking applications, communication is regular, transparent and easy. The real time tracking reduces equipment downtime, manufacturing delays, and material shortages. SAP (ERP) enabled inventory management improves efficiency & eliminates the unnecessary paperwork and critical data access concerns [4].

Benefits of Manufacturing Digitalization in Medical Devices

Medical Device Manufacturing is a cascaded process. In a rapidly evolving industry, digitalization of manufacturing operations is the wisest strategy to adapt. Investments in implementing digital technologies for different functions positively impacts ROI in numerous ways. Key benefits of implementing digitalization in Medical Device Manufacturing are:

1. **Reduced Paperwork,** since everything from purchase documents to BOMs and other in digital format. The SVN documentation promotes need based accessibility to relevant individuals within the organization.
2. **Improved Quality & Automated Compliance,** with ML based manufacturing modules. The chances of human error in testing, assembly, soldering and other similar tasks are reduced.
3. **Easy tracking & Visibility** with ERPs like SAP avoids discrepancies and ensures timely delivery of consignment.
4. **Closed-loop Manufacturing enables more control** as everyone holds equal accountability. KPIs are clear & evaluation is justified.
5. **Cost-optimized Manufacturing with** AI tools, Robotics and, smart machinery enables repetitive tasks automation. These may include soldering of components, repetitive inspections, data sharing & tracking applications.
6. **Insightful Medical Device Development** using data from real world. Using information gathered over a period of time, developers can come up with more user oriented medical devices. The data derived from patients, hospitals, clinics and different avenues can be useful in multiple ways to improve processes and quality of healthcare solutions.

Conclusion

Conclusively, digitalization is the fuel driving the Med-Tech industry ahead. It's an evolutionary mandate which no manufacturer or developer in Medical Device Industry can skip.

References

1. Ghai I (2021) How is Digitalization Transforming the Medical Device Industry: Top Reasons to Embrace AI. Industry Outlook.

2. Bellisario S (2020) TOP 5 Benefits of Manufacturing Digitalization in Medical Device and Diagnostics – Opcenter.

3. Joshi A, Zhen Zhu B, Xu L (2019) Trends in Medical Device Recalls. MedTech Intelligence.

4. Life Sciences & Health Care.