Applying Industry 4.0 in Pharmaceutical Production: Pharma 4.0

Christian Wölbeling, Werum IT Solutions, Lüneburg, Germany

The introduction of advance automation and the increasing interconnectivity of Industry 4.0 is not only revolutionizing the Pharma industry but also introducing many new challenges and production roadblocks.

Shifting the paradigm to Pharma 4.0 and focusing on the issues specifically surrounding pharmaceutical priorities will lead to improvements in productivity, quality, and security of the supply chain.

Description:

Understand how the Holistic Manufacturing Control Strategy as the key element for production execution is created out of the Control Strategy in development. Pharma 4.0 is the Holistic approach in Manufacturing to make the ICH Control Strategy happen in production environments.

We need the interdisciplinary collaboration of the different departments (QA/QC, Process Development, Manufacturing Operations, Engineering, Automation and IT) to design a robust and flexible production execution environment.

Based on Best Practice case studies the enablers, elements and challenges of the Holistic Manufacturing Control Strategy implementation are discussed.

As this Holistic Manufacturing Control Strategy initiative is relatively new, the workshop will show the new opportunities in creating a best practice based methodology to create the Production Control Strategy.

A well designed Holistic Manufacturing Control Strategy is enabling Right First Time, Data Integrity by Design and high performance best practice based processes.

The Presentation will discuss how to approach a Holistic Manufacturing Control Strategy implementation and its benefits when it is designed in a cross divisional approach.

Background Information:

The ICH Guidelines define how to design the Control Strategy and to apply this for all products. The pharmaceutical design of the site and the manufacturing operations environment, as well as the production processes, is based on the ICH Control Strategy coming out of development.

The physical and operational design of the pharmaceutical equipment, facilities, logistics and operations concept incl. e.g. work instructions shall be based on

Process Maps and Process Data Maps and needs the early collaboration of all pharmaceutical departments: QA, QC, Process Development, Manufacturing Operations, Engineering, Automation and IT to design a facility which is operating with a high quality level, robust, flexible and right first time. This needs also a "Data Integrity by Design" implementation principle to enable Data Integrity by applying a risk based approach based on "Critical Thinking". Future facilities will have a high level of automation.

Current Regulatory Guidelines are in place to leverage these potentials but examples to put them into practice are still missing.

There is also an increasing strong demand by Regulatory Authorities and Inspectors to apply the current requirements of Risk Management and safe production for pharmaceutical products.

It is not just the next wave of hot topics but will lead to the biggest paradigm change ever for the pharmaceutical manufacturers and product owners.

One chance to overcome the burdens is to evolve from "Product Control" to "Holistic Manufacturing Control Strategy".

Keywords:

Control Strategy, Holistic Manufacturing Control Strategy, Data Integrity by Design, Critical Thinking, ICH Guidelines, Equipment & Facilities Design, Industry 4.0, Pharma 4.0