

Data for CAPA: *How RFID Technology supports corrective and preventive actions in pharmaceutical production*

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The Pharmaceutical Industry is lately undergoing massive changes in its production processes. Individualization of products, new markets with own preferences and research progress in personalized medication call for highly flexible production facilities. One common answer is the trend towards modularized machines, shorter production cycles and smaller batches in pharmaceutical plants and machines. These changes are currently accompanied by regulations that call for corrective and preventive action (CAPA) particularly the US American ICH guideline, Chapter Q10 concerning pharmaceutical quality systems and chapter three of the EU-GMP guideline. It seems that measures for corrective and preventive actions contradict a higher flexibility. The use of intelligent identification systems such as RFID can help to solve this opposition.

In the light of the above, Peter Ratermann presents in his lectures how RFID technology in pharmaceutical production helps to increase plant availability and productivity, product quality as well as safety of production and staff – especially in modularized and flexible plants with higher frequency of product changes. With reference to several running pharmaceutical applications, Peter Ratermann points out how RFID merges CAPA with flexibility.

Applications: Identifying Hose Connections

Hose connections in hose stations are a vulnerable point in pharmaceutical productions, ensuring the correct connections is crucial for product quality and plant safety. The demand for failsafe connections rises when plants increase product changes. Whether in ex zone 1, zone 2 or in safe areas; identification technology like RFID helps to establish an error-proof hose connection. RFID readers can be attached to connection panels. Data carriers can be attached to the hoses. When connected the reader reads the tag in front and checks via its network if the connection is valid and approved for resuming the process.

Besides their unique identification number the data carriers attached to the hose can store time stamps, cleaning information, the current and/or previous medium and other data needed. With clever integration of that technology, a more flexible production has no downside on safety, quality or productivity of a pharmaceutical plant.

Cryo Vessels and Mobile Containers

Wrong identification of mobile containers can cause serious risks for the pre-products or employees. RFID Technology in several flexibility grades as handheld solution, fixed mounted on machines or storage points guarantees that use of contaminated containers or use of wrong content is impossible. With cryo vessels identification technology can help to ensure and proof a closed cooling cycle even during transport and shipping. Combined temperature sensors with data storing on RFID tags guarantee that high value chemicals or living biological substance are kept in its needed environment.

Single Use Applications

Identifying single use accessories, tubes or bags can be an erroneous point in production. Before using the equipment, RFID readers match the ID with the dedicated use of the equipment. In this way the use of non-sterile, used or unfit equipment is prevented. As the tags are readable without physical or optical contact, sealing the tags for sterilization is no problem. The system can guarantee that single use equipment is definitely only used once.

Identification of Field Devices

Field devices such as sensors, pumps and meters have to be maintained in regular cycles. Within their network they identify themselves electronically, but the maintenance staff still has to identify and track devices by numbers and lists. With RFID tags attached to the field devices and mobile read/write devices for the staff, security and traceability of maintenance are enhanced. Furthermore RFID increases productivity as manual notation and other time-consuming work is replaced. Missed devices are easily to identify and manipulations of maintenance records are almost impossible.