

# How RFID Solutions Can Bring Increased Level of Product Safety

PROCESS ENGINEER?By John Stover

Chemical companies and industries that deal with high purity products such as pharmaceuticals and food are adopting process equipment tracking programs to minimize risk, reduce costs, and consolidate documents. Accurate records on equipment cleaning and maintenance are important parts of compliance and product safety, and automation can help to ensure the reliability and consistency of record keeping. RFID (radio frequency identification) tags are emerging as a technology to meet this need.

If you toured five different processing facilities, there is a good chance you would find five different methods for tracking events that are critical to equipment degradation. Process equipment includes hose and hose assemblies, tubing, pumps, vessels, single-use/disposable components, bags, valves, filters, and other critical items. Precise, detailed records must be kept regarding the usage of these components to minimize contamination risks and assure product safety. Log books and hand-written charts requiring human entry are not uncommon, though they are prone to errors such as transposed numbers, incorrect dates, illegible handwriting, misread data, and misfiled documents. Other companies establish equipment replacement dates based upon a calendar method, opening themselves to operating inefficiencies and increased costs. These companies may be replacing process equipment before it is necessary.

Timely access to a complete biographical history of any processing equipment in a production facility provides a comprehensive tool for equipment management and the required information for reordering. Such information can include the manufacture date, batch number, lot number, material specifications, material lot number, certificates of compliance, size specifications, and equipment description. What happens to a particular piece of equipment from the time it is installed to the time it needs replacement will have a direct impact on its life expectancy. These wear-related events include the date and number of cleaning cycles and the actual number of batches processed. By switching to a replacement method based upon actual usage, replacement decisions are based solely on the actual wear and condition of each individual part, thus providing a higher return on investment.

The automation of process equipment tracking has been requested — and in some cases demanded — in order to provide concrete evidence of the standard operating procedures (SOPs) used to determine equipment replacement schedules. Benefits of such automated systems include the substantial risk reduction of contaminating

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a batch of product, equipment failure, and the costly repercussions associated with waste and production stoppages. This results in an increased degree of safety for the final product.

A common challenge for manufacturers is the implementation of an automated system. Accurate identification is crucial, and this is where RFID comes in. RFID tags are now being used for process equipment identification and tracking. Assigning a hose assembly or another process equipment part with a unique serial number through an RFID tag attached to that item allows it to be identified, logged, and tracked with ongoing wear-related events and updated with the event information when completed. Updated information can then be downloaded to a tracking database and used to analyze the equipment's lifecycle, calculate its life expectancy, and even generate a reorder based upon its biographical data. When implemented as part of an overall maintenance program, the use of RFID tags can simplify record keeping and improve accuracy.

Other advantages of RFID tags include the following:

- The reduction of equipment failure due to overuse
- More accurate life expectancy using actual event data
- The elimination of an inefficient calendar method for replacing used parts, resulting in a reduction of wasted production life and underutilized equipment
- The ability to safely use with various cleaning and sterilization methods (SIP, CIP, autoclave, gamma radiation)
- The allowance of embedded production protocols such as disassembly and reassembly instructions and photographs, training aids, and damaged part examples
- Predictive maintenance systems use
- Space-saving record storage — computerized data is stored much more easily than file cabinets full of traditional paper records
- Reliability
- External attachment for cleanliness — no contact with material flow

RFID tags are available in an assortment of shapes and sizes and come in a gamma-irradiatable style for sterilization purposes. Tags may be attached to equipment by various methods, depending on which one best suits a particular application. They are used in conjunction with a portable, handheld reader/writer that recognizes each tag by its globally unique identifier (GUID). The reader/writer can record and access the complete biographical history of a part, which may include its date of manufacture or installation, cleaning cycle information, number of batches processed, or other user-defined events.

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Other identification methods such as bar code labels are currently in use but present a number of drawbacks. Labels are fragile yet are subject to rough handling and harsh environments. They can become damaged and unreadable or fall off. They require a clear line of sight for reading; RFID tags do not. No updated information can be written to a bar code. Their data storage is limited.

Identification and tracking systems that ensure the dedication of equipment for specific applications, processes, and products are important. Maintaining records on process equipment's age and consistency of application provides assurances against substance contamination and cross-contamination of product lines. RFID solutions greatly help to simplify record keeping, improve accuracy, and most importantly increase product safety.

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### **Case in Point: FDA Audit Preparation**

Gathering the data necessary for an FDA audit for pharmaceutical processes can be time- and labor-intensive as well as stressful. The appropriate log books must be located and the relevant information retrieved. Using an automated system, such as one involving RFID tags, to store data can save hours and headaches. Automated tracking systems allow process equipment usage information (e.g. cleaning dates or the number of batches processed) involving a particular piece of equipment to be easily found, sorted, and presented for inspection. RFID technology provides a secure, tamper-proof record to track time, date, and operator data.

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