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TUBING, HOSE AND FITTINGS

When, Where and How

Hose labeling, tracking and replacement solutions for process facilities

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FDA HAS RECENTLY STEPPED UP INITIATIVES for the control and monitoring of all pharmaceutical product contact materials including flexible hose and tubing. Falling under the section FDA 21 CFR 211.67, many pharmaceutical companies are adopting hose tracking programs. These tracking programs require specific information about each hose used in the pharmaceutical manufacturing processes. A common challenge is the implementation of a simple program to evaluate frequency of use and how and where process hoses are used. Thus, proper hose identification becomes crucial.

Quick and Easy Identification

Emerging permanent hose labeling systems allow users to identify and trace all the components of the hose assembly back to original batch or lot control numbers of the raw materials used in their manufacture. These labeling systems also can include information for quick and easy identification of each product ensuring its proper use. Information recorded in a hose-labeling program would include the date of the assembly, pres-

sure and temperature limitations, part numbers, lot numbers and information indicating where specifically the hose is to be used in the manufacturing process. Also important would be recording the frequency of use of the hose to ensure aging would not be a cause for biological contamination of the product.

Hose labeling is not new. Though wired hose tags can provide the user with similar information, they are not ideal. Tags can fall off or be tampered with. They are also a source of dirt and contamination and cannot be easily cleaned.

More attractive methods of labeling a hose now provide a cleaner and more permanent record of each assembly. New vulcanized silicone labels, which become a permanent low profile part of the hose, are fully autoclavable, tamper-resistant and easy to clean. The label contains all the information a user needs to trace and specifically identify the hose, its pressure and temperature limits. The use of color stripes in the label allows for quick and easy identification of the hose and helps prevent its improper use. This system is also offered on silicone covered stainless steel overbraided fluoropolymer hose. Other innovative methods offering instant visual identification for a tubing or hose line include lengthwise color striping of clear silicone tubing, colored silicone tubing and color braiding of reinforced silicone tubing.

Another tracking system is a laser-etched stainless steel collar used to crimp the fitting end connections into the hose. The identification information is etched on each assembly providing a permanent,

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autoclavable and tamperproof record of the assembly. This method can be used on any hose that uses a stainless steel crimp collar.

Emerging Electronic Methods

If you walk into five different processing facilities, there's a good chance you will find five different methods for tracking "events" that are critical to hose degradation and, that ultimately, lead to its replacement. Handwritten charts requiring accurate and timely human entry are not uncommon. Requirements for automating this procedure have been requested for providing concrete evidence of having SOPs in place to accurately determine hose replacement schedules and create an audit trail for FDA in validation processes. The benefit of such automated systems to pharmaceutical companies is the substantial reduction in the risk of contaminating a batch of product, an actual hose failure, and the costly repercussions associated with waste and production stoppages.

Timely access to a complete biographical history of any and all hose assemblies in a production facility provides a comprehensive tool for hose management and the required information for reordering. Such information could include manufacture date, batch number, lot number, material specifications, material lot number, certificates of compliance, hose size and fitting specifications and hose description.

What happens to a particular hose, 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 date and number of cleaning cycles (clean-in-place, steam-in-place and autoclaving) and the actual number of pharmaceutical batches processed. Companies that presently establish replacement dates based on a uniform calendar projection method, open themselves to operating inefficiencies by replacing underutilized hoses and increasing costs. By switching to a replacement method based upon actual usage through life cycle analysis, hose replacement decisions are based solely on the actual wear and condition of each individual hose, thus providing a higher return on investment for that particular assembly.

The RFID Method

Providing such data in an organized and accurate accounting method enables thorough life cycle analysis and calculation of life expectancy for a particular hose in its unique application. Electronic databases help catalog hoses for a quick and easy lookup. For this process to work, a unique characteristic to reference an individual hose is needed.

The method of identification used must address a number of critical concerns. It must be able to resist the extreme temperatures introduced through the ster-

ilization and cleaning process and it must be easily accessible. One such form of identification that meets these criteria today is the radio frequency identification tag method (RFID) presently being implemented by the Federal government and major national retailers for tracking inventory.

Invented in 1969 and patented in 1973, RFID tags are essentially microchips that are now becoming commercially and technologically viable. These chips, some just a third of a millimeter across, act as transponders listening for radio signals sent by transceivers or RFID readers. When a transponder receives a certain radio query, it responds by transmitting its unique ID code, perhaps a 128-bit number, back to the transceiver.

Most RFID tags don't have batteries; instead, they are powered by the radio signal that 'wakes' them up and requests an answer. Most of these 'broadcasts' are designed to be read between a few inches and several feet away, depending on the size of the antenna and the power driving the RFID tag. The benefit of an RFID tag over a bar code is that the reader does not have to be perfectly aligned and unobstructed with the tag as with a bar code.

Assigning a hose assembly with a unique serial number through an RFID tag embedded into the hose allows that

hose to be identified, logged and tracked with ongoing wear-related events and reprogrammed with the event information when completed. Updated information can then be downloaded to a hose tracking database and used to analyze the hose's life cycle, estimate its life expectancy and even generate a re-order based upon its biographical data. Databases can be setup according to different departments within the processing facility or transmitted via Internet to remote locations where other hose information may exist.

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Systems currently under development and scheduled to be available to the market in the third quarter of 2004 offer users the ability to obtain information regarding their hose assemblies via the Internet. A user can access information pertaining to the manufacture date, lot traceability, certificate of compliance and other specific hose assembly component configuration information. RFID tags are embedded into the hose at assembly and portable handheld reader/writer devices and a database tracking software interface are optionally available to perform life cycle analysis.

Labeling systems that ensure the dedication of hose components for specific applications, processes and products are important to the compliance of FDA, 21 CFR 211.67. Maintaining records for a hose's age and consistency of application provides assurances against biological contamination and cross contamination of product lines or product matrix components.

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