Are you confident that your cleaning process could pass a regulatory inspection?

By STEQ America. July 1, 2016

IWT's M-Line Mobile High Pressure Washer

The issue of manufactured medicines that don't meet quality standards is a leading cause of failure towards treating patients.

So where are things going wrong?

A primary root cause can be poor quality of active pharmaceutical ingredients (APIs), especially those that are being imported, along with deficient formulation of the finished pharmaceutical products (how the medicine is formulated using inactive ingredients). Add to that, contamination risk during drug production. It is essential that all of the visually accessible product contact surfaces of pharmaceutical manufacturing equipment are free from residue before manufacturing can commence.

Despite procedures and processes substandard medicines are still being produced as a result of inferior cleaning validation programs and residual contamination during the manufacturing process.

STEQ America is devoted to assisting manufacturing environments maintain high levels of cleanliness in order to comply with cGMP and helping manufacturers address the deficiencies that result in medicines that fall short of today's quality standards.

STEQ America is the US supplier of International Washer Technology [IWT] premium cleaning solutions. With products engineered and manufactured in Europe, IWT have specialized in the design of environmentally friendly and energy efficient washing systems for both the life sciences and pharmaceutical industries worldwide for more than 20 years. These superior washing systems are used by many of the largest life sciences and pharmaceutical companies around the world.

Addressing an industry need for a cost effective, mobile, high pressure washing solution, IWT developed the M-Line Mobile High Pressure Washer. Suitable for a extensive range of applications, including bins and process tanks, the M-Line is built using AISI316L stainless steel components and supplies water via a pump capable of generating up to 1,2000 PSI pressure at the cleaning nozzle. The system is designed to minimize the use of chemicals and water usage thus reducing the need for effluent treatment and detergent consumption. Created to comply with the most stringent requirements of the pharmaceutical industry, the M-Line is fully cGMP and FDA compliant.

The mobility of the M-Washer

Main features:

- Water flow rate as low as 9 gal/min for ultra-low water consumption
- Heavy duty non-marking wheels for ease of movement
- All surfaces made of best in class sanitary grade components
- System fully managed via a PLC for software compliancy and consistent operation
- Multiple levels of User ID and log-in, password protection
- On-board printer generates a comprehensive batch report following cleaning completion
- Multiple inlets allow the use of different grades of water within the same cleaning cycle, if required
- Piping can be automatically dried with filtered, compressed air to eliminate any residue or contamination after each cleaning cycle

Washing and drying unit options

Control console

Manual lance

Hydrokinetic head

The most sought-after application of the M-Line is the cleaning of internal surfaces of bins which are in direct contact with the products being manufactured.

A typical bin washing setup involves the washing machine with the hydrokinetic lance mounted on a special lid designed to prevent water splashes from the bin's upper opening, whilst performing thorough neck cleaning. The ergonomic design of this lid means an operator's work is minimized, therefore saving their time and reducing the potential for human error.

Clean in Place (CIP) of manufacturing and processing equipment requires a deep understanding of the engineering of a device to clean, an accurate and feasible study, preparation and the conduction of a cleaning procedure, and several tests to verify the effectiveness of the overall process. STEQ America takes pride in providing you with the information you need in order to reach your targets and be an industry leader. That's why we strive to offer you the highest quality, safest, most innovate and most durable cleaning solutions to improve your cleaning validation process. When GMPs are not properly followed, cross-contamination can occur among products manufactured at the same facility, leading to finished pharmaceutical products with dangerous levels of other ingredients not intended to be there. How can you prevent this? Avoid cross-contamination and microbial threats of this type by ensuring your manufacturing and processing equipment is properly cleaned before the changeover of products, and utilize cleaning equipment such as the M-Line with proper water and air handling systems to prevent the movement of particles and media from one medicine in production to the next.

Don't rely on a visual inspection or inadequate cleaning equipment to assess only the visually accessible product contact surfaces of your pharmaceutical manufacturing equipment. Because it is crucial to patient safety, medicine quality, standards and regulatory compliance, invest in an IWT cGMP washing system today.

*Contact **STEQ America**, your official IWT representative in North America, for your customized quote or additional technical information today*

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About STEQ America

STEQ America is dedicated to helping biotechnology and pharmaceutical companies find the right information and solutions to be leaders in their industry. We do this by providing premium products that feature the latest, most innovative technologies, with the highest standards that cone with reliable longevity.

What we can offer

German engineered and manufactured solutions for dissolution, disintegration, hardness, friability, blister density, granulate and powder flow testing for the pharmaceutical, veterinary, chemical, food and biotechnology industries, with a focus on laboratory needs and research and development. We also offer European designed and manufactured solutions for the storage of hazardous and flammable materials, cleaning and drying in pharmaceutical manufacturing environments, and bio-medical freezers and refrigerators. Ask us about our mobile, autonomous cleanroom containment options.