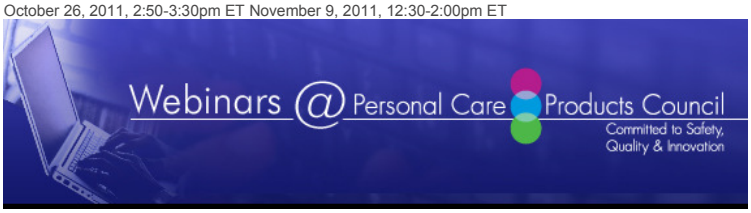
Current Good Manufacturing Practices

Date :
October 26, 2011, 2:50-3:30pm ET November 9, 2011, 12:30-2:00pm ET



Current Good Manufacturing Practices
Equipment Designs and Operations that Optimize -- Process Equipment Cleaning and Sanitizing
A Two Part Series

The personal care industry manufactures everything from soaps to over-the-counter drugs. These products are regulated by the US Food and Drug Administration under the Food, Drug and Cosmetic Act (FD&C Act, or "the Act") . The quality and safety of the manufacturer's products are assured, according to the standards enacted by the FDA, if the they are produced using Good Manufacturing Practices (GMPs). While OTC drugs must meet the GMP requirements codified in 21 CFR Parts 210 and 211, cosmetic products are not regulated by mandatory GMPs but may be deemed adulterated if produced under unsanitary conditions, thereby subjecting the product and producers to enforcement action. The industry is therefore tasked with preventing adulteration before it occurs through the use of GMPs. A critical element of GMPs relates to how the equipment is cleaned. Preventing product contamination, and selecting and investing in equipment that can be effectively cleaned of product require:

1) focusing on those cleaning efforts that most immediately impact product quality and safety, and
2) the methods for measuring and monitoring those efforts for repeated cleaning performance.

This two-part presentation will educate the attendee about two major areas or groups of GMPs related to process equipment cleaning. The first group of practices consists of those that can be designed into a new process, retrofitted into existing equipment or process, or purchased with new equipment designed for use to meet GMP performance standards. The second group of practices are those that address process cleanliness conditions through operating practices, SOPs, or other programs or devices that can be superimposed onto existing process equipment, whether designed for GMP operations or not. Attendees will acquire the background and simple skills to properly identify, prioritize, assess, and remediate potential sources of product adulteration associated with improper, incomplete, or inadequate cleaning operations.

Part I will be presented at the Council's Science Symposium Quality Assurance Workshop on October 26 and focus on background and characterization of any given cleaning problem and Part 2, presented as a webinar on November 9, will address implementation, prioritization and planning of corrective actions or process upgrades.

Major issues and conditions addressed in this series include:

- Selecting, using, monitoring, and modifying cleanliness performance indicators,
- Cleaning vs. sanitizing vs. sterilizing and some common effective cleaning and sterilizing practices,
- Selecting a cleaning target, identifying potential problems, and prioritizing cleaning practice goals,
- Adapting GMPs to batch and continuous processes (batching vs. filling), to age of equipment, size and type of batch/lots,
- Quality by design vs. quality as a consequence; the role of quality assurance resources in corrective and preventative actions,
- Designing for Clean-In-Place as GMP and the use of chemicals or mechanical agents,
- Are GMPs a sustainable program?

Join the Council and expert speaker David Coker (http://www.personalcarecouncil.org/sites/default/files/CokerBio.pdf) for this informational webinar series. David Coker is the Engineering Manager in the Alfa Laval Sanitary Equipment Division. He is responsible for project management and business activities related to the sales of sanitary capital equipment and operations, environmental engineering, process design, and regulatory compliance issues.

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