

Worthwhile Operational Guidelines & Suggestions

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MICROBIAL VALIDATION

According to the Food and Drug Administration (FDA) "Process validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product, meeting its determined specifications and quality characteristics". Microbial validation is an important verification step assuring that the HACCP plan is;

- Based on solid, scientific principles,
- Adequate to control microbial hazards with the product, and
- The process is effective and being followed.

Validations should be conducted at each critical control point (CCP) to show that all methods used are effective in controlling the hazards. Validations should be performed at least annually, when changes are made into the process and product, when deviations are found, when new hazards or control methods are identified. Validation data can be obtained from research data, product testing records, scientific literature, and official or regulatory guidelines. Microbial validation methods vary depending on the type of product, the CCP, and the microorganism(s) of interest. Whether qualitative (yes or no) or quantitative (enumeration), testing should be conducted with approved methods (BAM, FDA, USDA etc.). In addition to meeting HACCP requirements, microbial validation provides important information on cleaning and sanitation programs, and employee adherence to Sanitation Standard Operating Procedures (SSOP's) and accepted Good Manufacturing Practices (GMP's). Microbial validation reduces the dependence on more extensive (and expensive) in-process product testing. Microbiological safety must be designed and built into the process or CCP, since it can not be inspected or tested into the finished product.



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