A Plant Hygienist Ensures Manufacturing Quality & Product Integrity[i]

Manufacturing Quality: part one of a three-part series

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The mid to late-20th Century found substantial compromises in microbiological quality of personal care products.[1] Testing of marketed products in the US and Europe found concerning numbers of contaminated products. The personal care industry's very effective response through the 70's and 80's included development of more effective preservatives and improved manufacturing quality. The success of this effort was recognized by the FDA as the 20th Century closed.[2] Unfortunately, this 20th Century combination of preservation and manufacturing quality has not been maintained. Although effective and considered safe-in-use by relevant health authorities, traditional preservatives have fallen into marketing disfavor leading many to formulate with alternative preservative systems. Preservation is primarily intended to protect consumers in use. Manufacturing hygiene has not been optimized to its potential. It was not considered as a critical parameter by management. Preservatives were heavily relied on to protect the end-use products and in some ways to mitigate poor practices in the manufacturing process.

Significant microbiological issues have resurfaced in the 21st Century in context of alternative systems. Due to consumer pressure and a desire for non-traditional preservatives, the explosion of alternative preservative systems such as multifunctional ingredients and organic acids, saw increased use in the personal care market. The problem is especially impacting mid- to smaller-sized manufacturers. Regulatory publication and enforcement reports find a significant number of incidents of microbiological contamination of cosmetics associated with alternative systems.[3] Reasonably, these reports find alternative systems in their secondary role inadequate to support relevant non-sterile manufacturing systems. Labels indicate major manufacturers have largely maintained traditional preservations and are not included in contamination reports. However, they too are under marketing pressure.

Microbiological Quality with Alternative Systems

Evolution of preservative choice may have unbalanced the critical combination of manufacturing hygiene and preservative efficacy. If so, it is highly unlikely that traditional preservative systems will find a renaissance or that new chemicals of similar efficacy will be developed. However, manufacturing clearly has the tools and technology that should ensure microbiological quality with alternative systems.[4] Current manufacturing quality knowledge and applied technology is substantial and includes facility and systems design and maintenance, process and product design and risk assessment, quality control of raw materials and products, metallurgy and construction of sanitary manufacturing systems, process design and risk assessment, cleaning and sanitization, HACCP and environmental management, out-of-specification investigation, contamination recovery and, most critically, capable individuals to execute these technologies. In concert, their effective application will produce quality products. What is often lacking, is

[ii]knowledgeable execution and organization. This need is met by the functional role of the manufacturing plant hygienist. Rather than another layer of management, the manufacturing plant hygienist is a conductor of expertise.

The Role of the Plant Hygienist

As with an orchestra conductor, this capability ensures expertise and execution of critical and diverse sections and capabilities. Intimate with functional performance of experts on the manufacturing floor as the conductor is in the orchestra pit, the plant hygienist is specifically trained and knowledgeable of metallurgy, chemistry, sanitary design, microbiology etc. but not expert in all. The plant hygienist must recognize and address deficiencies and stay abreast of relevant technical advancements, obtain personal and technologists' training and requests for capital acquisition as needed. This does not bring a new layer of management but a technologist independent of specialist sections or organizations possessing the ability to create and manage multiple relationships within the facility as well as with development experts whose risk assessments the plant accepts.

In part two, we shall discuss establishment of the plant hygienist capability and detail the many areas of expertise which a plant hygienist needs to develop to be truly successful. In a final part three we will lay out the benefits of addressing the challenges described in this first part by investing in plant hygiene capabilities for businesses to be successful in developing, manufacturing and supplying personal care products in the 21st Century.

References:

1. Curry, J.C., Brannan, D.K. and Geis, P.A., 2006. History of cosmetic microbiology. In Cosmetic Microbiology (pp. 3-18). CRC Press.
2. Guide To Inspections of Cosmetic Product Manufacturers. 1998. "Microbial contamination of cosmetics during manufacture was a major issue during the 1960's and early 1970's. Since then, significant progress has been made by the cosmetic industry..." http://academy.gmp-compliance.org/guidemgr/files/1-2-22.PDF
3. Periz, G., Misock, J., Huang, M.C.J., Dewan, K. and Sadrieh, N., 2018. FDA 2014 survey of eye area cosmetics for microbiological safety. Letters in applied microbiology, 67(1), pp.32-38.
4. English, D.J., 2020. Prevention of Microbial Contamination during Manufacturing. In Cosmetic Microbiology (pp. 113-142). CRC Press.

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[i] Originally published in Happi on March 2, 2022