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

The plant hygienist needs a working knowledge of a wide range of functions to maintain harmonious systems and deliver quality products.

By Philip Geis, PhD., Geis Microbiological Quality affiliated with Advanced Testing Laboratory • Deepika Raina, L'Oréal • Geoff Waby, Advanced Testing Laboratory • Michael Loewenstein, Q Laboratories LLC • Pamela Wilger, Cargill Inc. • Ly Tran-Osowski, Troy – an Arxada Company Manufacturing Hygiene Task Force • PCPC Microbiology & Quality Committees

This is the second in a three-part series that describes and details the role and function of a central element of manufacturing quality—the manufacturing plant hygienist.

In Part I, we introduced the concept of the "plant hygienist." We presented the idea that, as a successful orchestra needs a conductor, so does a successful personal care products manufacturer need a plant hygienist to help direct various functions to overcome a growing list of challenges to producing quality products. Here in Part II, we expand on the analogy of plant hygienist as conductor and provide more detail around what a plant hygienist must know to be successful. In an orchestra, while individual musicians express separate sounds, a conductor visualizes how the individual lines work together to produce musical harmony. In manufacturing, individual departments such as operations, microbiology, engineering, quality and so on, work separately. The plant hygienist needs a working knowledge of this wide range of functions, to serve as the conductor in this manufacturing orchestra—maintaining harmonious systems and delivering quality products.

Microbiology

Historically, the person serving the function of what we discuss as the plant hygienist was a microbiologist by education or training. While this certainly is not a necessity for the successful plant hygienist, a strong foundation and understanding in fundamental industrial microbiology is critical to being effective in this role. The plant hygienist is not only be conversant in the major microorganism types of concern, including bacteria, yeast, and mold, but be familiar with typical sources, vectors, and growth patterns for each.

The most successful plant hygienists understand that finished product testing alone is not an effective check of the microbial health of a manufacturing environment. Particularly in the personal care products industry, the plant hygienist is aware that they are typically working in a non-sterile environment, and must be able to explain the implications of that to other team members. They are able to design and implement effective microbiological monitoring programs such as initial and ongoing testing of raw materials/pre-mixes, environmental monitoring, utilities monitoring (e.g., water system monitoring, compressed air monitoring etc.)

A plant hygienist understands that developing strategies to maintain, and programs to demonstrate, strong microbial control of the manufacturing environment, is critical to providing proper context to,

and confidence in, batch release test results, as well as expertly reviewing data holistically, to assess microbial risk.

Chemistry

In addition to microbiology, the plant hygienist must be at least conversant in several basic chemistry principles to be successful. First, a plant hygienist must understand how physicochemical parameters of a formulation can be expected to impact the microbial growth risk profile of the products and raw materials with which they work. The plant hygienist articulates how these parameters can be expected to impact the microbial robustness of products and raw materials. Furthermore, the plant hygienist understands the difference between attributes that can be expected to retard or prohibit microbial growth, versus those attributes that can reasonably be expected to provide some level of hostility. A plant hygienist must not only understand these scientific facts but be able to articulate their significance.

Likewise, a plant hygienist must understand that many common preservatives are dependent on pH. While assuring the formula itself is adequately preserved is often an R&D function, the plant hygienist must have a general idea of the principals involved, and how the manufacturing environment can have a deleterious effect. Take for example an acidic preservative system whose peak effectiveness is close to the target pH of the formula. The plant hygienist understands that any drift in pH of the formula observed during ongoing product testing is not simply a formulation concern but puts the product at risk of minimizing the efficacy of the preservative system as well and will be assertive in working cross-functionally to investigate and remedy the outage.

In addition to formulation chemistry, the plant hygienist understands different chemical parameters and how they can be expected to impact cleaning of manufacturing systems. The most efficient plant hygienist can reasonably predict material deposition patterns, hardest to clean ingredients from formulas, what cleaning agents will be required and more. Being fluent in cleaning requirements, and being able to quickly troubleshoot issues, is essential not only for initial cleaning validations, but for ongoing monitoring and excursion investigations.

Physics

To round out the plant hygienists foundational scientific understanding, some basic principles of physics must be understood. An effective plant hygienist is familiar with the rheology and homogeneity of the products in their purview. Indeed, many personal care products are emulsions, so the plant hygienist must have a general understanding of how the phases are emulsified, and what may cause the emulsion to break. The plant hygienist must also understand the risks such a phase separation poses, particularly from a microbiological perspective. For example, if an organic preservative remains trapped in the “oil” layer of a broken emulsion, the “water” phase is at high risk for microbial proliferation.

A basic understanding of flow dynamics is needed to be able to predict efficacy of proposed cleaning protocols. A plant hygienist is conversant enough to be able to ask questions to the appropriate members of their team such as: Are we achieving turbulent flow in that area? Can you demonstrate it to me? It seems the flow rate is dropping in this section—how can we make sure we are adequately cleaning that section of the system?

A general understanding of heat transfer is necessary for adequately assessing heat-based sanitization protocols. A plant hygienist can reasonably identify and address the "coldest" areas of the system, to ensure and validate adequate temperature exposure during sanitization validation. Likewise, the impact of dry versus moist heat must be understood.

Metallurgy

Basic knowledge of metallurgy is important to plant hygienists in the context of assessing hygienic design. Choosing the optimal material of construction for various equipment such as tanks, pipes, storage, filling lines, unions and pumps, that balances material compatibility, cost, and ease of cleaning (particularly when cleaning in place), is a difficult task that the plant hygienist must navigate.

Having a keen understanding of different stainless-steel series, particularly 300 series SS grades (e.g., 304, 316, 316 L, etc.), risks from different welding processes, and metal upkeep requirements (e.g., passivation, etc.), allows the plant hygienist to help holistically assess risk, bringing immense value to the manufacturing team.

Engineering and Cleaning & Sanitization

As has been hinted at through our discussion of the basic sciences above, one of the unique functions of the plant hygienist is to use this scientific understanding to assess equipment for "clean" or "sanitary" design. This refers to the ease with which a manufacturing system or piece of equipment, can be cleaned. Ease of cleaning is critical to assess because only a clean surface can be sanitized. The successful plant hygienist is well versed in various types of commonly used equipment designs such as those of pumps, valves, tanks, agitators, piping, heat exchangers, filler heads, drains, overhead surfaces, HVAC systems and more.

In addition to expertly articulating the importance and benefit of the "ideal" design choices to the rest of the manufacturing team, the most valuable plant hygienists understand the reality that 100% "Clean Design" systems are almost never feasible. This is particularly true in the personal care products industry. Consequently, a plant hygienist must assess risk of both; proposed system designs, by reviewing and providing feedback on piping & installation diagrams, etc.; and existing systems as installed. These risk assessments should provide "ideal" equipment/design choices, but also ideas for procedural changes that can help minimize risk of less desirable designs.

Water

In addition to assessing equipment risk, the plant hygienist must assess risk of raw materials. Perhaps the most critical material of concern is water. Oftentimes, it's the source of microbial contamination. The plant hygienist must not only ensure a well-controlled water system "by design," but also through monitoring and risk assessment, guarantee microbiologically acceptable water all the way to the point of use. The contamination risk needs to be controlled through the hygienic design of storage and distribution, robust preventative maintenance, and oversight by someone like a plant hygienist who not only has a thorough understanding of water systems and waterborne organisms but is intimately familiar with routine procedures.

HVAC

Water is not the only utility of concern to the plant hygienist. A well-planned facility is the main line of defense against airborne contamination. Heating Ventilation and Air Conditioning (HVAC) systems in manufacturing environments are responsible for more than just delivering comfortable air temperature and humidity; they are also critical in stabilizing and controlling the indoor air quality. The plant hygienist must be aware of pressurization of the facility, air handling unit maintenance, MERV filter selection and placement, air turnover rate, sloped drain pans, cleaning of HVAC ducts and wet coils that are readily invaded by bacteria and fungi. Having a good understanding of the fundamentals, they will help provide solutions through thoughtful consideration keeping operational and capital costs down without compromising air quality and product quality.

Compressed Air

One of the most expensive, indispensable utilities is also the one that gets overlooked the most: compressed air. It is important for both product contact and service compressed air, to filter out particulates, oil, water and microorganisms at each point of use. Like all utilities, a well-trained plant hygienist armed with multiple disciplinary knowledge is better positioned to assess and mitigate risks associated with existing systems, and they will be indispensable when evaluating proposals for new system investments.

Quality Control

To this point we have discussed the role of the plant hygienist in assessing design and risks associated with facilities and materials, but the plant hygienist needs to understand the interrogation of the efficacy of these programs and procedures through quality control (QC) testing. The plant hygienist must be able to understand the results from various QC testing including microbiological, chemical, and physical testing, and be able to interpret the data through the lens of manufacturing to assess risk and make recommendations.

Quality Assurance

In addition to their role in QC, the plant hygienist will play a key role in quality assurance (QA). This team is focused on the systems which prevent issues and ensure that problems are thoroughly investigated to prevent a recurrence. Either as a formal member of the QA unit, or in consultation, the plant hygienist works at prevention, execution, and investigation, and as a result, needs to be aligned with all the relevant quality systems.

Investigations & Problem-Solving Tools

Like different instrument sections of an orchestra, so far we've discussed the various functions the plant hygienist must work across to be successful. During a product recall, the true value of the plant hygienist as the "conductor" is essential, to facilitate and establish a line of communications with other disciplines to determine the root cause of the microbial excursion and to minimize the risk to public health. Indeed, the product may already be on the market, in which case not only is efficient communication within the company essential but coordination with regulatory agencies may also be required. It also means working with the supply chain and commercial organizations to execute the retrieval. This is a time of high stress, and fast but accurate decision-making is critical. The plant hygienist can play a crucial role in conducting such cross functional projects.

Behavioral Science

So far, we have focused on the variety of individual subjects a plant hygienist must be fluent in—like a conductor must be familiar with the different instrument sections of an orchestra. But a successful conductor is not simply an expert in reading musical notes, and understanding different instruments. The best conductors read their musicians, feel the music they are making, and influence changes in tempo, dynamics and more, in real time, to ensure the different sections blend and work together harmoniously to deliver the most musical experience for the audience. So too must the plant hygienist work diplomatically, to facilitate working within a dynamic structure of their organization and deliver quality products. The ability to balance arts and sciences is crucial. It requires emotional intelligence, and an appreciation of the reality that the human decision-making process is often driven by emotion rather than cold facts. A plant hygienist must have a conceptual framework for understanding people's emotional needs and a passion for meeting them.

Understanding Business

The world we are living in is rapidly changing. Reacting slowly to the new challenges and sticking to business as usual, particularly how we view a manufacturing plant hygiene program, may not be in the best interest of companies that want to protect their brands and win customer loyalty. Adopting the role of a plant hygienist in your operation is an opportunity to harvest this new knowledge to elevate your brands and reputation. The need for the role is increasing, and a specialist from one of

the scientific areas outlined above, who wants to broaden their knowledge and contribution, is a good candidate to expand into the plant hygienist role.

In the third part of this article, we will expand on the benefits from the company's point of view and demonstrate the need to invest in training good people to become plant hygienists as part of their career development. In Part III, we will also discuss the clear return on investment that such a role delivers, and offer advice on introducing the role of a plant hygienist to your organization.

The Hygienist Must Have a Basic Understanding of:

- Microbiology
- Chemistry
- Physics
- Metallurgy
- Plant Engineering
- Cleaning & Sanitation
- Water Systems
- HVAC
- Compressed Air
- Quality Control
- Quality Assurance
- Investigations & Problem-Solving Tools
- Behavioral Science
- Business

[i] Originally published in Happi on April 1, 2022