Minimising Contamination in Pharma Cleanrooms

***PMPS* sat down with Paul Harencak at LPS Industries to understand the inner workings of cleanrooms, and the various considerations needed to produce and run a safe and clean facility**

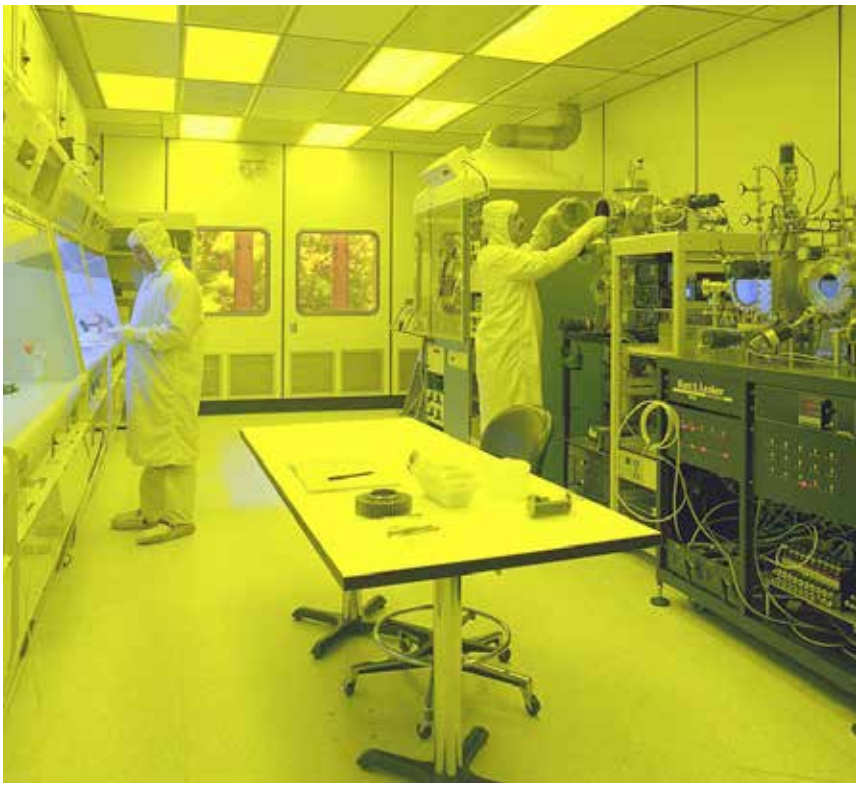
***PMPS:* What does a cleanroom team need to know in order to successfully carry out their duties in pharma?**

Paul Harencak: The cleanroom operators, quality inspectors, and production supervision must be trained in GMP and efficient recordkeeping to ensure compliance to the codes. Examples include handwashing, tool cleaning, test equipment, proper PPE, material handling in the cleanroom to guard against dirt and debris, proper equipment maintenance, and safety protocols when operating cleanroom equipment. It is important that cleanrooms are equipped with their own in-room heating, ventilation, and air conditioning (HVAC) equipment to keep the facility at ambient conditions, double sinks for dedicated washing of hands in one sink and tools and cleaning supplies in the other, its own hot water system maintained at the proper code temperature, as well as lockers for employees' PPE. A dedicated quality team can monitor and record all activities to ensure code compliance, while production teams prepare the necessary paperwork to detail their work.

Cleanrooms are notoriously tricky to manage. What difficulties do companies face when dealing with pharma products?

The challenge in operating a cleanroom is to ensure all employees are aware of the restrictions needed to maintain a safe cleanroom environment. To that end, it is imperative that access to the cleanroom is restricted to authorised personnel only. Should an outside contractor have to work inside the cleanroom, detailed protocols are in place to make sure the contractor observes all the rules and regulations. Once again, the production and quality managers are responsible to escort the 'outsider' into the room and maintain strict adherence to code. A senior management objective is established at the very beginning of any cleanroom project to designate a 'Cleanroom Safety Steering' committee, comprising members from each of the operating groups in the company. This committee acts as the overseer of communications, training, and implementation of all systems pertinent to the cleanroom.

We treat pharmaceutical products, medical devices, and food all in the same manner. No matter what the industry, our cleanroom protocols and employees work within the confines of the Safe Quality Food codes to



ensure materials produced in the cleanroom are free from any type of contamination, which is even more critical for pharma as it can involve human consumption and contact.

What considerations are needed when implementing a cleanroom into a manufacturing/packaging setting and how can these be counteracted?

Commitment from senior management for all resources are needed to separate and isolate the cleanroom footprint. In addition, the proper design of a high filtration particulate air filtration system, working in conjunction with HVAC needs to create a constant positive air flow within the cleanroom to ensure only clean air will be inside, while temperature and humidity controls remain consistent and ambient. GMP training must be considered for all involved employees to provide control and maintenance of the cleanroom systems.

What is involved in certification of cleanrooms for pharmaceuticals, and what challenges are faced?

The biggest challenge is to locate a footprint within the manufacturing facility that allows the cleanroom to operate as a standalone facility – almost a 'facility within a facility'. It is imperative to dedicate the proper equipment to transport materials in and out of the cleanroom and to a proper storage area for either inbound inventory or outbound orders without the concern for contamination.

Everyone in the cleanroom and in the rest of the facility needs to be aware of the delicate nature of handling cleanroom materials.

What difference does a cleanroom have in securing new clients and ensuring safety in pharmaceuticals?

To have a certified cleanroom tells a prospective or an existing customer that the company operates in compliance to international standards in its operation of a cleanroom, from the equipment, maintenance requirements, to the employees, and their PPE. A certified cleanroom facility benefits the manufacturer and the customer. It tells the consumer that packaging materials were produced within the protocols that meet or exceed the safety code. Our company has designated a quality management team to be the facility leaders in coordinating the training and implementation of the standard operating procedures of the required co-educational institutions that pertain to packaging materials. By investing heavily in the design, building, and implementation of the safety codes, buying new, dedicated equipment for the new structure, and allocating all the necessary resources to bring the cleanroom into compliance and GMP standards for certification, the standards can support company growth.

How does a cleanroom help when working with hazardous products/ packaging COVID-19 tests?

Since many of the packages use materials that protect the product until the point of use, and many are uni-dose and not reusable, it is critical for the package to be as clean as possible to prevent any contamination from reaching the product, medical device, or pharmaceuticals that could be compromised if the package was not produced to cleanroom standards. Implementing a certified cleanroom gives extra benefits for customers to know that their packaging was produced in a controlled environment.

Why is a cleanroom needed for optimum performance?

Many of the applications using cleanroom-produced materials need the upgraded performance of using materials that are free of ingredients identified as hazardous to the final product. Keeping the materials within the regulatory standards ensures the final product will insulate the packaged product from its environment and will be free from any surface contamination within the package.

Do you have anything to add about future developments in cleanroom and sterilisation during the packaging process?

Given the COVID-19 pandemic, our society has had to work with new challenges as we carefully begin the process of returning to a 'new normal'. This being said, we believe more and more companies will want to protect their products in packaging that can be marketed as cleanroom certified.

As the world continues to work towards a cleaner planet with less pollution, it is important that we continue to investigate and evaluate materials and processes that could provide alternatives to conventional non-reusable packaging, such as recyclable or compostable materials. This, of course, will mean that any alternative would have to perform with the equivalent properties of today's products.

Paul Harencak is Vice President at **LPS Industries**, headquartered in Moonachie, New Jersey, US.

Paul's responsibilities include marketing, purchasing, and all technical services. Paul has an extensive background in coating and laminating for aerospace and electronics, owned a laminating manufacturing company, and consulted for small to large manufacturers in the chemical coatings industry, prior to LPS.

He is a graduate of Rutgers University, US, and qualified in Biochemistry Sciences. Paul is active in various business and civic organisations sitting on a number of boards in the science, business, and academic fields.