PUREZERO*

Behind the Innovation

HALYARD

MANUFACTURING GLOVES DESTINED FOR **CLEANROOMS**

For the Cleanroom Environment
For Industrial Use Only

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Gloves are a type of personal protective equipment (PPE) that are used in many different environments, from hospital exam rooms to operating suites to semiconductor and pharmaceutical cleanrooms.

While cleanroom gloves may not look that different, the manufacturing process involves many different steps that are important for cleanroom customer applications.

The primary purpose of wearing cleanroom gloves during manufacturing is to minimize submicron particles from the operator's hands from contaminating the product or process being manufactured. Semi-conductor or any other electronic device manufacturing cleanrooms are designed to tightly control the level of particles. Pharmaceutical, biotechnology and medical device cleanrooms are designed to control microorganisms from contaminating these types of medical products and to ensure patient safety.

Below, SiewHow Tan, R&D Director, who has been involved in manufacturing gloves for HALYARD* for over 20 years at the **SAFESKIN Scientific & Medical Thailand Ltd.** facility, talks about the special considerations, requirements and advancements used in the manufacturing of HALYARD* **PURE**ZERO* Cleanroom Gloves.

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What factors are most important when manufacturing PPE that is destined for cleanrooms? And what manufacturing techniques contribute to the safe production of cleanroom PPE?

The process starts with having the right material and optimum formulation, which will create a product that can meet customer demands such as pliability level and class of cleanroom. Then, it is critical to maintain the cleanliness of the product throughout the entire manufacturing process.

While exam gloves are manufactured on automated lines, inspected and shipped, cleanroom gloves require additional processing and rigorous post-processing steps after they come off the production line. All gloves are washed with chlorine and de-ionized water on both sides of the glove to remove surface particles, powder-residues and extractables to very low levels.

Cleanroom gloves then undergo extensive testing for physical properties such as the presence of particles and extractable ion content as well as barrier integrity and tensile strength. Gloves are then vacuumed-packed in multiple layers of cleanroom-compatible polyethylene packaging inside a Class-100 or ISO Class 5-controlled cleanroom.

This cleanroom environment is designed to maintain certain levels of particulates and airflow standards to protect the product during the post-processing and packaging steps.

Another important element for cleanroom manufacturing customers is traceability of their cleanroom gloves. Tracking of gloves by lot and batch number from the glove manufacturer is critical to ensuring compliance with Good Manufacturing Practices per ISO Standards. The cleanroom glove packaging must have product lot and batch numbers as well as expiration dates on the packaging to ensure the product and its components or raw materials used to produce the gloves can be traced to their original supplier.

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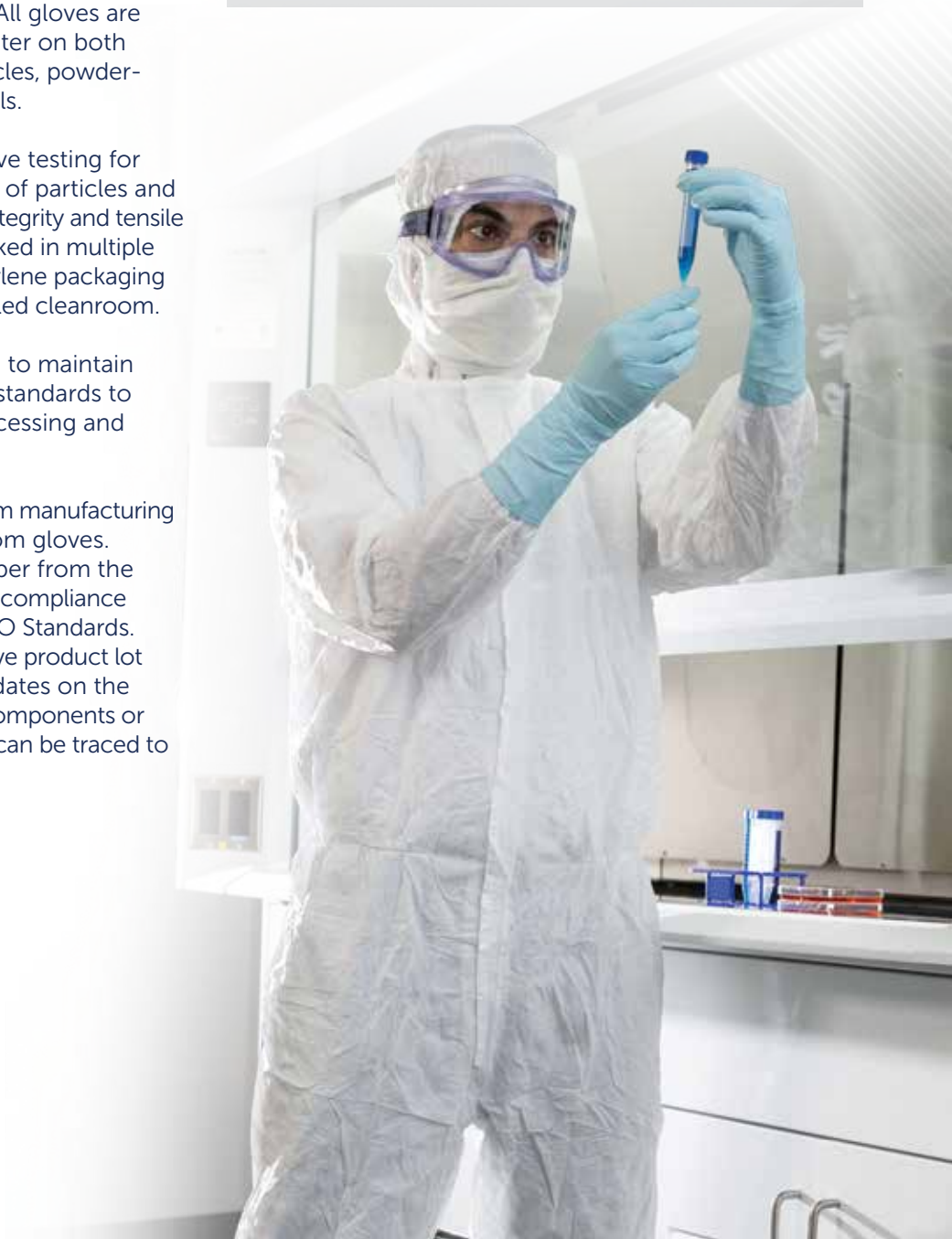

What factors are most important when manufacturing PPE that is destined for semi-conductor or pharmaceutical cleanrooms? What manufacturing techniques contribute to the safe production of cleanroom PPE?

Employees at semiconductor facilities need to use PPE that allows them to work on delicate products such as electronics and mobile phones without the risk of introducing particulates into the work environment. PPE used in semiconductor cleanrooms must be manufactured in a strictly controlled environment ensuring the incorporation of additional in-house lab testing capabilities and packaging the PPE in a controlled environment to monitor and control the level of cleanliness.

Employees at pharmaceutical facilities need to use PPE that allows them to handle sensitive chemicals and drugs without the risk of introducing particulates or micro-organisms into the work environment or contamination into the drug itself. PPE must be produced with the right design, material and formulation, while maintaining the cleanliness of the product throughout the entire manu-facturing process including in-house testing to ensure the level of particle and endotoxin cleanliness.

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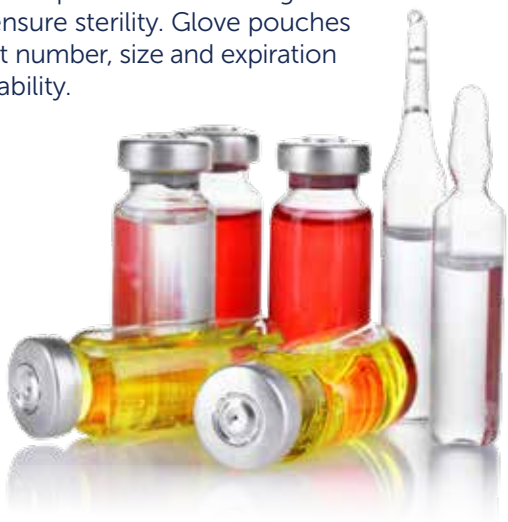
Are there differences in the packaging, shapes and sizes of cleanroom gloves?

Yes, cleanroom gloves do not come in dispensers and are usually packed in two layers of sealed polyethylene bags. Materials are technically specified for maintaining cleanliness. The double-bagging inside a lined carton is designed to maintain the product cleanliness as the packaging layers are removed to transport the gloves from the point of receipt into the cleanroom areas inside the end customer's manufacturing facility.

In terms of shapes and sizes, non-sterile gloves are ambidextrous, meaning they fit on either hand, and typically come in sizes XS, S, M, L and XL. Sterile gloves are traditionally hand-specific and sizes range from 5.5 to 10.0. Sterile cleanroom gloves are packaged in pairs in individual glove pouches and then gamma irradiated to ensure sterility. Glove pouches include the lot number, size and expiration date for traceability.



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Apart from the production process, what else is different when manufacturing gloves for cleanrooms vs. manufacturing PPE for healthcare settings such as hospitals?

Apart from the significant differences in product design, regulations are also quite different. While healthcare gloves are FDA-regulated as medical devices, cleanroom PPE is not. Cleanroom glove specifications and requirements are defined by the cleanroom manufacturing customer requirements.

For semiconductor and electronics manufacturing customers, low particle and extractable ionic content is extremely critical. Pharmaceutical and biotechnology manufacturing customers are also concerned with particles, but have the added requirement to minimize contamination from microorganisms, including endotoxin levels.

In this market, manufacturers face regulatory requirements enforced by the FDA and thus must follow Good Manufacturing Processes (GMP) in order to maintain compliance for their production, product efficacy and ultimate product safety. PPE manufacturers must therefore understand the customer requirements for cleanliness as well as the cleanroom application to provide the right product for the right level of protection.

How has manufacturing for cleanroom gloves evolved?

While the design of the glove has remained relatively consistent, there have been evolutions made to the formulation in cleanroom glove products. HALYARD* has recently developed an accelerator-free[1] cleanroom glove call HALYARD* **PURE**ZERO*. Unlike other gloves in the market, these have no accelerator residues that can cause skin allergies and irritation, such as Type IV allergic reactions.

What should customers ask a manufacturer about their process before deciding to use their product?

When searching for a manufacturing partner, customers should ask about the type of quality controls that are in place to ensure consistent, safe production, what is the recommended ISO level of the gloves as well as recommended applications, and what's the ability to provide technical documentation and support.

Customers should be clear about the intended use of the gloves (class of the cleanroom and product they will be handling) and ask about special offerings, such as accelerator-free, that can be a benefit to cleanroom employees using the gloves. Lastly, they should ask if the manufacturer can tailor their process to meet their specific needs. For example, can they control the grip properties of the gloves?

These questions will help customers find the right manufacturer with the right cleanroom glove products to meet their critical needs.

1 Not formulated with these commonly used vulcanizing chemicals: Sulfur, Thiurams, Thiaxoles, Guanidines and Carbamates.