GRANTEK

Aseptic Processing & Packaging:

Pharmaceutical and Food & Beverage Manufacturing Solutions from Grantek

Aseptic processing is a technique wherein a product is packaged in a sterile container in the absence of pathogens or contaminants of any kind. Certain food packaged aseptically has a very long shelf life, even without refrigeration. This is convenient for the consumer and reduces shipping and storage costs for the manufacturer and the retailer.

Aseptic processing and packaging is incredibly useful in the manufacture of certain products in the life sciences industry, particularly where the absence of pathogens and their toxic byproducts is required to ensure the product is safe.

Grantek is an automation integration leader in the implementation of automated manufacturing solutions, specifically in the food & beverage and life sciences industries. We are a leading systems integrator with 40 years of broad experience in automation in these highly regulated industries, and have delivered many solutions that have incorporated aseptic processing and packaging techniques.

Process Overview

There are two methods to produce products completely or relatively free from microscopic organisms:

- In terminal sterilization, the product is packaged, and then sterilized by heat or radiation exposure. There are circumstances, such as product fragility or route of administration, in which terminal sterilization is not possible.
- In such cases, aseptic processing and packaging should be used. This technique involves the product and packaging components being sterilized independently, then brought together and packaged in a sterile environment.

In the life sciences industry, aseptic processing and packaging is used in the production of biological products, due to their inability to withstand the high heat or irradiation of terminal sterilization. Some examples of sterile technique include producing the product in sterile equipment, passing the product through a sterile filter (pore size 0.2 µm or smaller) prior to filling, sterilizing the packaging vials and removing pyrogens via depyrogenation ovens, sterilizing the rubber vial stoppers using an autoclave or steam sterilizer, filling and sealing the vials with sterile product in an isolator, and then packaging the vials in a foil overwrap to maintain sterility during shipment and storage.

Sterilization of processing equipment may include sterilization in place (SIP) in which a stainless steel vessel or stainless steel piping to be used for an aseptic process is flooded with saturated steam at a temperature in excess of 121° C and maintained at that temperature for a predetermined length of time. The temperature is monitored to ensure that it remains high enough for the duration of the sterilization period. Steam traps are used to prevent unwanted condensation at the drains to maintain temperature. The vessel is then vented and may be cooled using sterile compressed air.

After vessel sterilization, the product ingredients are then added. Chemicals may be added to kill pathogens in bioreactive ingredients such as blood plasma. Chromatography may be used to disinfect cultured product and then a final sterile filter is used at process completion to filter the final product

one last time prior to packaging. The processes are varied and may be different for each product. For example, vaccines are produced on dedicated production lines.

The filling and finishing processes of capping and closing the vials takes place in a clean room that typically must meet the stringent ISO-5/Class 100 standard (maintenance of fewer than 100 particles larger than 0.5 microns per cubic foot of air space). Smaller production capacity may be achieved using an isolator for filling and capping instead of an entire clean room. Vials may be filled by hand or by means of an automated filler in the isolator, equipped with alarms and sensors to stop the process if conditions go out of range. Human actions within the isolator are performed through the attached gloves.

To sterilize the isolator, one method is to spray vaporized hydrogen peroxide (VHP) onto all interior surfaces. This process can be automated. The VHP system is designed with spray nozzles positioned to cover all surfaces inside the isolator with VHP.

Lyophilization (freeze-drying) may be performed after vials a filled but before they are stoppered, which removes water, leaving a dry cake of product in the bottom of the vial. Freeze-dried product requires a separately-supplied diluent for rehydration. The diluent may require cooling to avoid thermal shock when adding it to the vaccine. Biological products are freeze-dried for shelf stability.

Product vials are generally packaged with a foil overwrap to keep the stopper in place and to maintain sterility. From that point, the packaging process is the same as for most other products.

Aseptic processing is also vital the food and beverage industry. The process of aseptic filling and packaging can greatly increase the shelf-life of many consumer food and beverage products without the addition of additives. As food and beverage trends continue to lean towards more natural products, aseptic processing is becoming more common in the space.

After non-aseptic packaged food leaves the production line, manufacturers often require a refrigerated or climate-controlled environment to store and transport the product. The use of aseptic processing allows for storage in a wider range of temperatures and warehouse types. This flexibility can reduce costs and remove logistical limitations across the supply chain.

The overall quality of the food and beverage product can also be improved through aseptic filling and packaging. Typically, aseptic packaging allows for processing to be down at a temperature that is lower than more traditional processing, while also taking less time. The result can be a finished product that maintains a taste and appearance closer to the original ingredients because of a gentler process. The cost reductions and quality improvements that aseptic processing provides have been very beneficial to food and beverage manufactures.

Grantek's Role

Grantek works with our pharmaceutical and food and beverage customers, the process designers, and the specialty equipment manufacturers to ensure that the customer's process requirements are met when developing and implementing automation and process monitoring specifications. Our broad experience in process automation and equipment integration means we have the capability to implement effective process error monitoring for aseptic lines and tie it into facility monitoring and data reporting. We ensure that new equipment is properly integrated with existing systems as well as with enterprise reporting systems and building monitoring systems.

Our extensive experience with pharmaceutical facilities and GAMP-5 allows us to understand customer requirements for large projects where a whole new line is being added, or small projects involving just one equipment skid. We are knowledgeable regarding U.S. Food and Drug Administration (FDA) and Health Canada requirements for aseptic processing and pharmaceutical manufacturing facilities.

The typical process for a facility upgrade involves Grantek working with process engineering personnel and the skid builder to determine the requirements for automating and/or integrating the new equipment. We work with the customer's engineering team and their equipment builders, and plan each project in accordance with the customer's schedule. Retrofits of existing lines obviously need to be planned carefully to minimize downtime. The addition of new production capabilities also requires careful planning and schedule management to ensure equipment is brought online in a timely manner that meets the customer's strategic marketing plans.

Grantek is knowledgeable on enterprise integration standard ISA-95 and the ISA-88 standard and recommended practices for the design and specification of batch control systems.

Grantek provides a computerized validation documentation set for each project. We typically provide a Functional Requirement Specification (FRS) designed to meet the customer's user requirement specification, along with all necessary software and hardware design specifications. We work with the customer to accomplish qualification testing. For retrofits, we assist with System Acceptance Testing (SAT) and provide support for installation qualification and operational qualification testing as required.

For sterile processing rooms, automation is desirable to minimize the number of personnel who must go through the stringent gowning process required to enter the cleanroom. The costs of an entire sterile room, requiring HEPA-filtered air at positive pressure to prevent intrusion, may be prohibitive depending on the quantity of product needed, and in those instances an isolator is an alternative for filling operations.

Grantek has successfully completed many projects in which all equipment must be sterilized before each use. We have the capabilities to accomplish special activities that may be needed for custom-built equipment and have worked with many of the specialized vendors who provide isolators, SIP, VHP, and water-for-injection (WFI) equipment. We can automate autoclaves and other equipment used for sterilization and sterile processes.

Our experienced technical staff can quickly get into the details needed to upgrade, automate, and monitor a wide variety of very specialized equipment. We have experience with the electrical and mechanical aspects of machine integration.

Some specific areas in which Grantek has assisted our customers with aseptic processes include:

- Setting up control systems and performing system integration for isolators, filling machines, freeze dryers, and other equipment used in aseptic packaging and production.
- Automating and retrofitting freeze dryers that required updates to their controls in order to meet current regulatory guidelines. We have also overhauled equipment for customers to enable them to get more use from older equipment instead of being forced to replace the device.
- Retrofitting existing equipment to add or update automation capabilities as required to conform to current regulatory requirements, reducing the cost by avoiding complete replacement of the equipment.
- Integrating older or non-standard equipment to use newer control and monitoring systems that allow the equipment to provide meaningful electronic batch records and data needed for the facility's MES and historian.
- Retrofitting for facility integration: new equipment with a built-in control system, but without integration capability, can be retrofitted for SCADA or other systems in order to monitor the process and provide control. The control system supplied may not match with the enterprise-level requirements of the facility. In these cases, Grantek does the custom work needed to get the data points collected from the machine or process to map to the requirements of the facility's MES.

Advantages of Working with Grantek

Our experience in the area of pharmaceutical production automation and integration, including pharmaceutical-grade water production systems, gives Grantek an advantage over other integrators who may not be as familiar with the stringent requirements of the pharmaceutical industry and aseptic packaging in particular.

Grantek has broad-based general knowledge and experience in the pharmaceutical industry. This allows us to work with pharmaceutical manufacturing equipment suppliers, who tend to be extremely specialized. Over the past 15 years, Grantek has worked with many specialized equipment manufacturers and skid builders in the pharmaceutical industry, and we have the knowledge to successfully integrate their equipment into the MES-enabled overall production environment. We have successfully automated and integrated clean steam, WFI, and clean-in-place systems (CIP) necessary for aseptic production and packaging.

Grantek's experience implementing MES systems also enables us to be able to capture pertinent data from the aseptic line for use in production reporting, planning, and traceability activities. Grantek's broad experience across the entire manufacturing automation environment, allows us to tie all the data in a facility together in the most effective way. From recipe management, process monitoring, water production, in-line cleaning systems, historian functions, to building and warehouse monitoring and up to the MES enterprise reporting level, Grantek has the capability to efficiently automate and integrate aseptic processing and packaging equipment into the pharmaceutical manufacturing site.

If your Operations, IT, or Engineering staff would like more information about Grantek's aseptic packaging automation and integration capabilities, please email info@grantek.com.

For 40 years, top manufacturers in Food & Beverage, CPG and Pharmaceuticals have called upon Grantek to solve their most complex business and manufacturing challenges. Grantek automates Pharmaceutical and Food & Beverage manufacturing operations, including integration with business systems for seamless solutions. Grantek helps customers meet the stringent requirements and challenges of the 4th Industrial Revolution. Grantek's team of professionals located in 17 offices across the globe deliver solutions to complex problems in Smart Manufacturing, Industrial Networking, Automation and Industrial Safety. Call 1.866.936.9509 or email info@grantek.com to learn more.