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Designed for Critical Aseptic Processing Applications ASEPCO close connects are for connecting flush-mounted probes,

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instruments, and valves to tanks. They are easier to install and clean than the alternatives, and have ASEPCO's patented aseptic seal, which is based on the same reliable seal that you find in our valves.

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Get the critical knowledge needed for these critical processes. From aseptic technique to cleanroom design and construction, we have the foremost experts in aseptic and sterile product manufacturing. We are actively involved in the regulatory bodies, and participating not only in the implementation of Annex 1, but also

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educating others on the ...

## **Aseptic + Sterile Products | CRB**

Aseptic filling systems have also been designed for HPDE and PET bottles (Ammann, 2001). Bottles made by blow molding are sterile and can be used directly for filling the product. For aseptic bulk packaging and storage,

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containers like tanks, totes, pouches,  
and bag-in-box systems are used.

## **Aseptic Processing - an overview | ScienceDirect Topics**

LIVE Aseptic BREATH Aseptic EDUCATE  
Aseptic REWARD Aseptic Form 483s The  
Aseptic Culture 61% 56% 50% 0% 10%  
20% 30% 40% 50% 60% 70% Proportion

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of DP observations out of overall observations Genentech, Genzyme, Gilead, Hospira Industry avg. is 10 obs 8

## **Aseptic Operations and Cleanroom Principals**

Sidel has received Food and Drug Administration (FDA) approval for its Aseptic Combi Predis FMa blow fill seal

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filler following tests run at a dairy customer in North America. This means that the Sidel Aseptic Combi Predis FMa PET filler is validated for low acid manufacturing and commercial distribution in the United States market. The [...]

## **FDA APPROVES OF ASEPTIC COMBI**

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## **PREDIS BLOW FILL SEAL FILLER ...**

Improvement is needed in aseptic processing, especially in older facilities that may have poorly designed or maintained equipment because these lead to increased manual interventions that in turn raise the risk for microbial contamination. These problems have led to both drug defects and critical drug

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supply shortages.

## **Aseptic Processing Next Steps Addressed at 2019 ISPE ...**

Your aseptic manufacturing process should be designed, and operations executed, to prevent contamination hazards to your sterile product. Flaws in the design of cleanrooms and aseptic

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## **Wintac Limited - 606700 - 08/13/2020 | FDA**

Aseptic processing and packaging consist of several operations that need to work safely concurrently, and any misstep can end in an unsafe product. Every part of the system—from the

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utilities, ingredient dosing, batching and mixing, to the control and data recorder—must be fit for purpose and perform as designed at all times.

## **Ensuring product safety in aseptic food processing | CRB**

Originated by Rowley in the late 1990s , the Aseptic Non Touch Technique (ANTT

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® ) Clinical Practice Framework was designed to help address variable and poor standards of practice and ambiguous theory by providing a rationalized, contemporary, evidence-based framework to standardize this critical competency and help improve standards of practice.

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## **Right Asepsis with ANTT® for Infection Prevention ...**

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ASEPCO close connects are for  
connecting flush-mounted probes,  
instruments, and valves to tanks. They  
are easier to install and clean than the  
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patented aseptic seal, which is based on the same reliable seal that you find in our valves. Page 6/28

## **Aseptic Designed For Critical Aseptic Processing**

Facilities for aseptic manufacturing and sterile fill-finish should be designed such that any transition from filling to

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Lyophilization takes place in a Critical Area with ISO 5 (Class 100) certification. Procedures for transferring product should also be designed to minimize movement of product and reduce risk of contamination.

## **Aseptic Manufacturing and Sterile Fill-Finish for Complex ...**

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Aseptic Processing and Packaging for the Food Industry ... This continuous flow relies on pumps, and as such, these pumps are critical in the design of the system. 21CFR 113.40 (g)(i)(f) states "A ...

**Aseptic Processing and Packaging  
for the Food Industry | FDA**

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The Sidel Aseptic Combi Predis contributes to production simplicity and reliability, because a line with a small sterile zone and minimum critical factors is managed and maintained more safely, easily and effectively. The dry preform sterilisation before the oven prevents re-contamination and avoids the need for blow moulder sterilisation.

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## **Leading in aseptic PET filling: Sidel celebrates three ...**

Aseptic materials and room design options help companies prepare to perform important medical or bio/pharmaceutical operations, as well as others requiring an easy-to-sterilize environment. You can get such a room

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in a few days and be ready for operation quickly, while meeting regulatory guidelines.

## **What Makes a Room Suitable for Aseptic Processes? - Terra ...**

A large Fortune 500 company required Critical Airflow Visualization testing (Smoke Studies) on a new aseptic filling

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line with active RABS barrier configuration. Additionally, modifications to two existing aseptic filling lines were completed in conjunction with the new filling line.

## **New Aseptic Filling Line - Critical Airflow Visualization ...**

Aseptic technique is a procedure used

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by medical staff to prevent the spread of infection. The goal is to reach asepsis, which means an environment that is free of harmful microorganisms.

## **Aseptic Technique: Uses, Benefits, and Complications**

Aseptic means something has been made contamination-free, that it will not

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reproduce or create any kind of harmful living microorganisms (bacteria, viruses and others). Sterile describes a product that is entirely free of all germs. Basically, one is the removal of anything that could contaminate an area, whereas the other doesn't discriminate ...

## **Difference Between Aseptic and**

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Vanrx's SA25 Aseptic Filling Workcell and Microcell Vial Filler have both been designed to reduce the risks of gene therapy filling. The advanced automation of these systems designs out sources of human interventions in conventional systems, allowing them to be completely closed with no glove

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