

PHARMA



HECHT – We care.

As your reliable partner for safe bulk material handling our family business stands for tailor-made and efficient solutions.



Pharmaceutical Industry

In the pharmaceutical industry requirements concerning the entire process equipment are the most challenging to manage. On the one hand, the substances used are partly highly concentrated and valuable, on the other hand they are dangerous for the operator. To ensure adequate user-protection in the long term, most of these substances need to stick to the limit of OEB 5. Full compliance with FDA regulations, the qualification of the system as well as the validation of cleaning procedures are further requirements of the sector. These requirements are reflected in the used materials. For over 40 years we develop and supply qualified solutions. Here we maintain close contact with our customers and realize process requirements. The objective is to represent and realize process requirements. Our experienced engineers and bulk material experts advise you individually and provide support for the whole process – from conception to construction up to installation and commissioning. **We care.**

Containment: Classification of Containment Systems

Seite 04

Bio Pharmaceutical Process

Seite 06

Protection and Security for the pharmaceutical industry

Seite 07

Individual Containment Solution for the pharmaceutical industry

Seite 08

Typical Installation – best practice

Seite 10

Further HECHT Industries Food and Chemicals

Seite 12

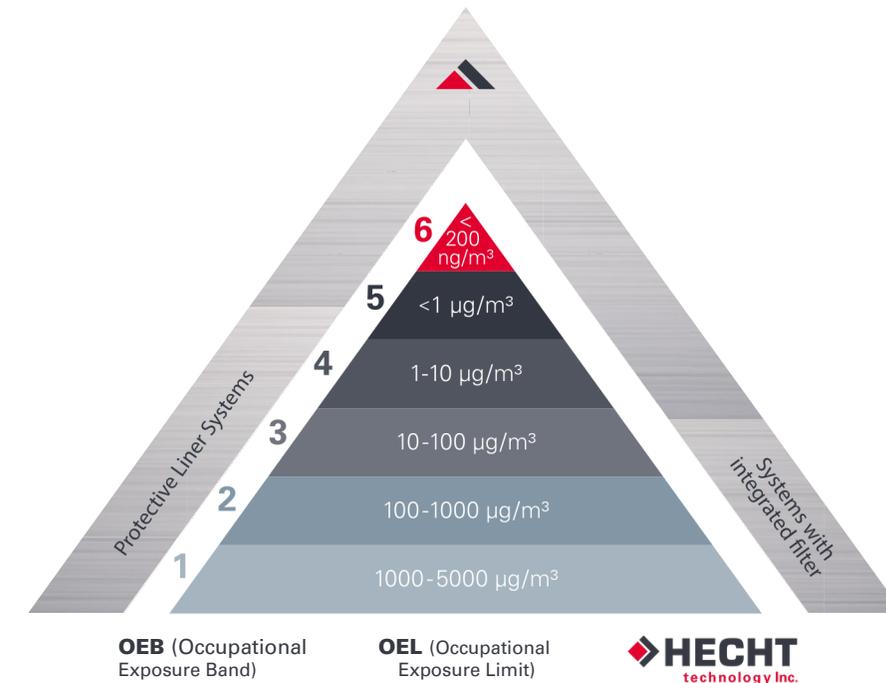
Containment: Classification of Containment Systems

Not all bulk solids are dangerous or sensitive in the same way, therefore, Containment systems are divided into different "categories" according to their application and field of use. Considering that, customer and / or legislative authority determine product specific limit values. The aim of this classification is to select the suitable production facility, respectively the "right" working process for the used product. In practice, a distinction is made between the following classifications or limit values:

OEL (Occupational Exposure Limit) is the average load of concentration of a substance in the air at the workstation measured over a defined time period so that no acute or chronic harms to the health of the employee are expected. It is calculated out of the **ADE (Acceptable Daily Exposure)** and some other values. If not all values for the calculation are known for the calculation you normally use a classification.

OEB (Occupational Exposure Band) considers only the toxicology of the pure substance. The more toxic the product the higher the OEB will be.

If you have further questions about classification HECHT consults you at any time as a reliable partner.



Generally, Containment systems are designed in order to avoid contamination of the environment by dust and other critical substances. The systems requirements depend on the products and have to be repeatedly defined for each new project. Containment levels can be classified with our HECHT pyramid. It shows several classification levels: OEB (Occupational Exposure Band) and OEL (Occupational Exposure Limit). The classification refers to the toxicity of the products and permits to determine the amount of particles per air quantity.

Having classified your product, HECHT offers the appropriate solution (depending on your requirements). Cleanliness, safety and avoidance of cross-contamination play a major role. Therefore, it is crucial to consider the whole process and not merely isolated solutions. **Holistic Containment includes user- and product-protection.** User-protection stands for protection of the operator against hazardous substances. Product-protection prevents contamination and cross-contamination.



**USER-
PROTECTION**



**PRODUCT-
PROTECTION**

Bio Pharmaceutical Process



1: CFE-K

Low-contamination emptying of drums with inliner. Easy docking due to a tipping device.

2: PCC

Connection of value-creating steps through pneumatic conveying.

3: SE-H-EF

Used in hygienic applications with integrated dedusting filter and integrated vibrating sieve.

4: Big Bag Crusher

For breaking monoblocs and lumps.

5: Big Bag discharging station with walk function

Low-dust discharging of big bags.

6: PCC 700

Gentle transportation of large quantities.

7: Big Bag discharging station with LAS-EC with walk function

For dustfree discharging of big bags.

Protection and Security for the pharmaceutical industry



Cleaning

Validated cleaning through efficient WIP-, CIP- or SIP systems is integrated in the planning process.



Documentation

Gapless quality monitoring due to documentation during all process steps.



Product protection

Prevention of cross-contamination and contamination by impurities.



Best fit

Connection of cross-process steps by individual adaptations, that fit your requirements.



Ergonomics

The holistic system allows an ergonomic operation.



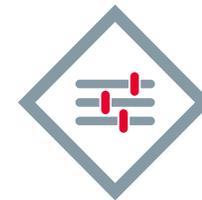
Certified

FDA conform technology guarantees Containment.



User- and environment-protection

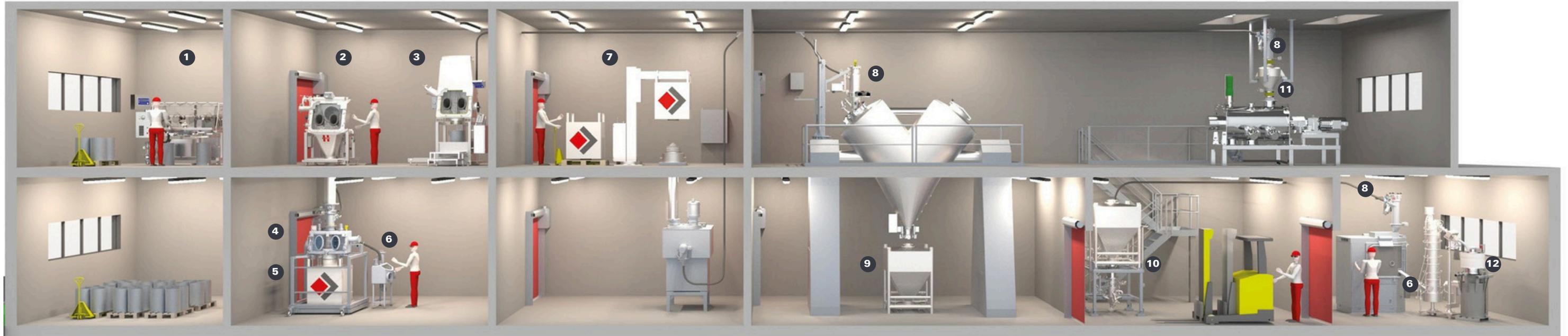
Hazardous substances cannot leak. Protection of user and environment.



Settings

Automated settings e.g. for sampling guarantee consistent quality.

Individual Containment Solution for the pharmaceutical industry



Convince yourself of many advantages HECHT offers during the production process!

Systems protect user and product at the same time and prevent dusting of critical substances. Depending on the requirements, single process steps or holistic solutions for the production process can be delivered. Optimal Containment is guaranteed. The shown process illustrates possible process steps.

1: EWI - Isolator (Single-Use)

Safe and contamination-free dosing, sampling, filling or weighing small volumes of highly-active, toxic and hazardous substances.

2: Containment Drum Discharger CFE-K

Low-contamination discharging of drums with inner liner up to OEB5. By means of the tipping device drums can be easily connected to the station.

3: Containment Drum Discharger CFE-L

Contamination-free discharging of drums by using a suction lance.

4: Liner Filling Head LBK

Dust-free High Containment Filling of any kinds of bins with or without liners.

5: Filling Station BG Basic

A cost-efficient solution that can be integrated into an existing production environment.

6: Vacuum Sampler

Closed and automated inline-sampling of powders and granulated materials from a product column. The special design for flush-wall-installation was patented: Due to its dead-space-free structure cleaning is eased.

7: Double Cone Connecting System

Fully automatic, low-contamination and contained discharging and dosing.

8: ProClean Conveyor PCC

The pneumatic device is the ideal connection of different machinery.

9: Container Filling with Dosing Vale

Smooth discharging of bulk solids like powders or granulates. Product bridges and crystalline compounds can be loosened and a correct dosing is guaranteed.

10: Container Discharging

Containment-free discharging of IBCs, containers or bins.

11: Scale Compensators

Safe decoupling of scales with a high resolution. Due to its special shape with seamless and smooth compensator walls, it prevents any residues inside the compensator.

12: Endless-Liner Filling Head

Due to the folded continuous liner a frequent container- or bin exchange is not necessary. Filling of continuous- or endless liners as well as exchanging the foil packages is a completely closed process.

Typical Installation – best practice

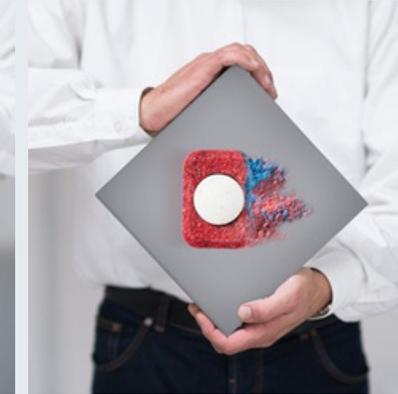


Further HECHT Industries Food and Chemicals



Food

Designing machinery in Hygienic Design combined with helpful ergonomics for the operator have become a matter of fact for us. Retraceability, allergen management, ATEX-compliance, plant availability and quality management are further topics that manufacturers of food and nutritional have to take care of 24 hours / 7 days a week. Therefore, an investment in HECHT systems is definitely paying off – among other things we have the daily proof: many satisfied customers.



Chemicals

In the chemical sector, the requirements for process equipment have considerably increased in the last years. To some extent, the applied substances are extremely valuable in their high concentration but may on the other hand be very hazardous for the operator. The REACH regulation as well as the increasing demands in terms of product- and operator protection are a decisive aspect for the growing needs of Containment equipment. In order to protect the operator from consequential damage, the threshold values of the substances in use need to be strictly adhered to.

Discover our large product range and HECHT systems at www.hecht.eu



WE CARE.



**NORTH AMERICAN PARTNER FOR
LEADING EUROPEAN SUPPLIERS**



CONTACT US

 +1.773.234.8003

 gqind.com

 4796 Colt Road
Rockford, IL 61103