

FILLING YOUR NEEDS



# THE FLECOTEC SYSTEM

THE CONTAINMENT SOLUTION  
FOR HIGHLY SENSITIVE SAMPLING,  
DISPENSING, DECANTING, AND  
FILLING PROCESSES.





WHEN PHARMACEUTICALS ARE MADE IN POWDER OR TABLET FORM, THE TRICKY STAGES OF THE PROCESS USUALLY BEGIN WITH A VERY MANAGEABLE DRUM. IT'S IN SUCH DRUMS THAT THE RAW MATERIALS ARRIVE AT THE ACTIVE INGREDIENT PRODUCTION POINT AND LATER ALSO THE PHARMACEUTICAL COMPANY. THESE DRUMS GENERALLY CONTAIN TOXIC OR HIGHLY SENSITIVE SOLIDS IN DOSES THAT CAN PUT PEOPLE'S LIVES DIRECTLY AT RISK. STRICT SAFETY STANDARDS THEREFORE APPLY TO ALL THE STAGES OF THE PROCESS IN WHICH PEOPLE MIGHT COME INTO DIRECT CONTACT WITH THESE ACTIVE INGREDIENTS. CROSS-CONTAMINATION WITH OTHER RAW MATERIALS AND ACTIVE INGREDIENTS LIKEWISE HAS TO BE RULED OUT AT ALL TIMES.

With **Flecotec**, Rommelag has developed an ingenious system that reliably protects workers and bulk materials from contamination, while also allowing protective clothing to be done away with in many work areas. We simply package your processes.

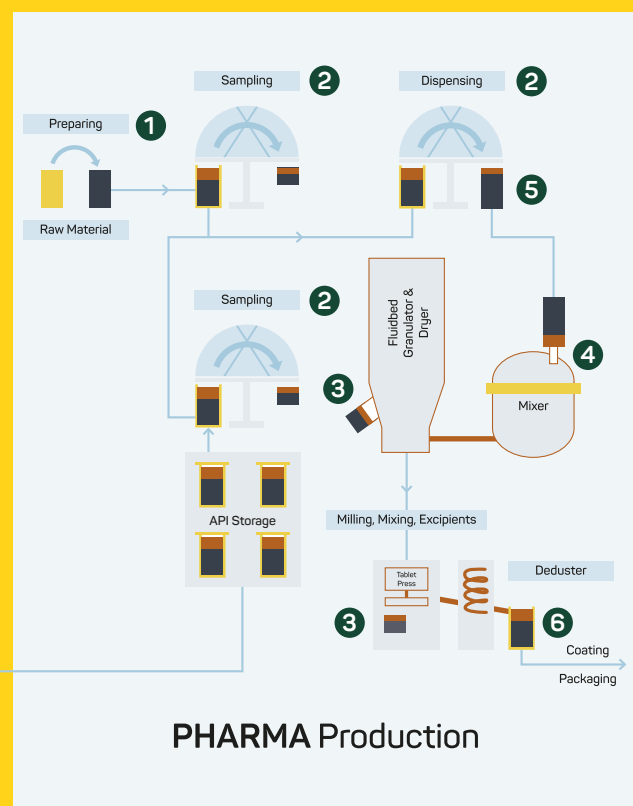
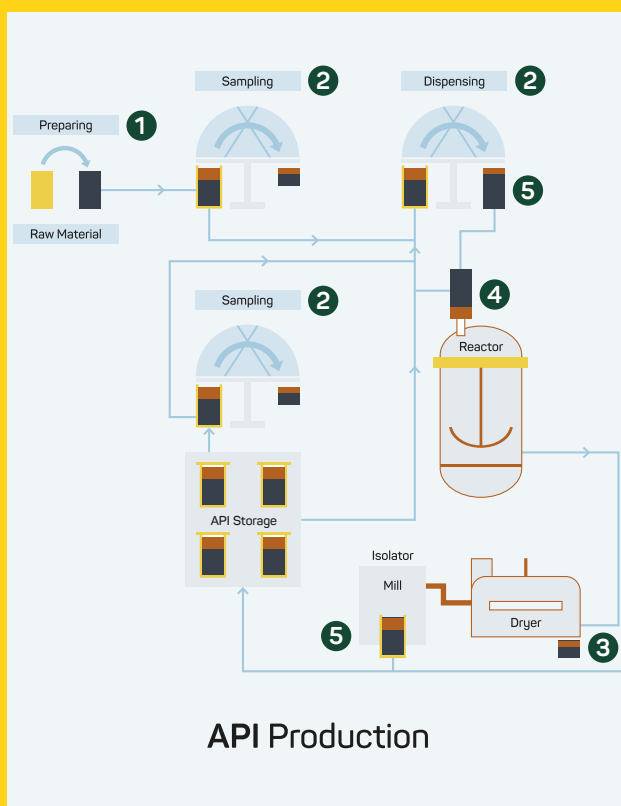
**The fundamental advantage for you: as all the sampling, dispensing, filling, and decanting processes are simply packaged when the Flecotec system is used, all your facility and process certification remains fully intact. There are absolutely no costs or expenses incurred for new or additional inspections.**

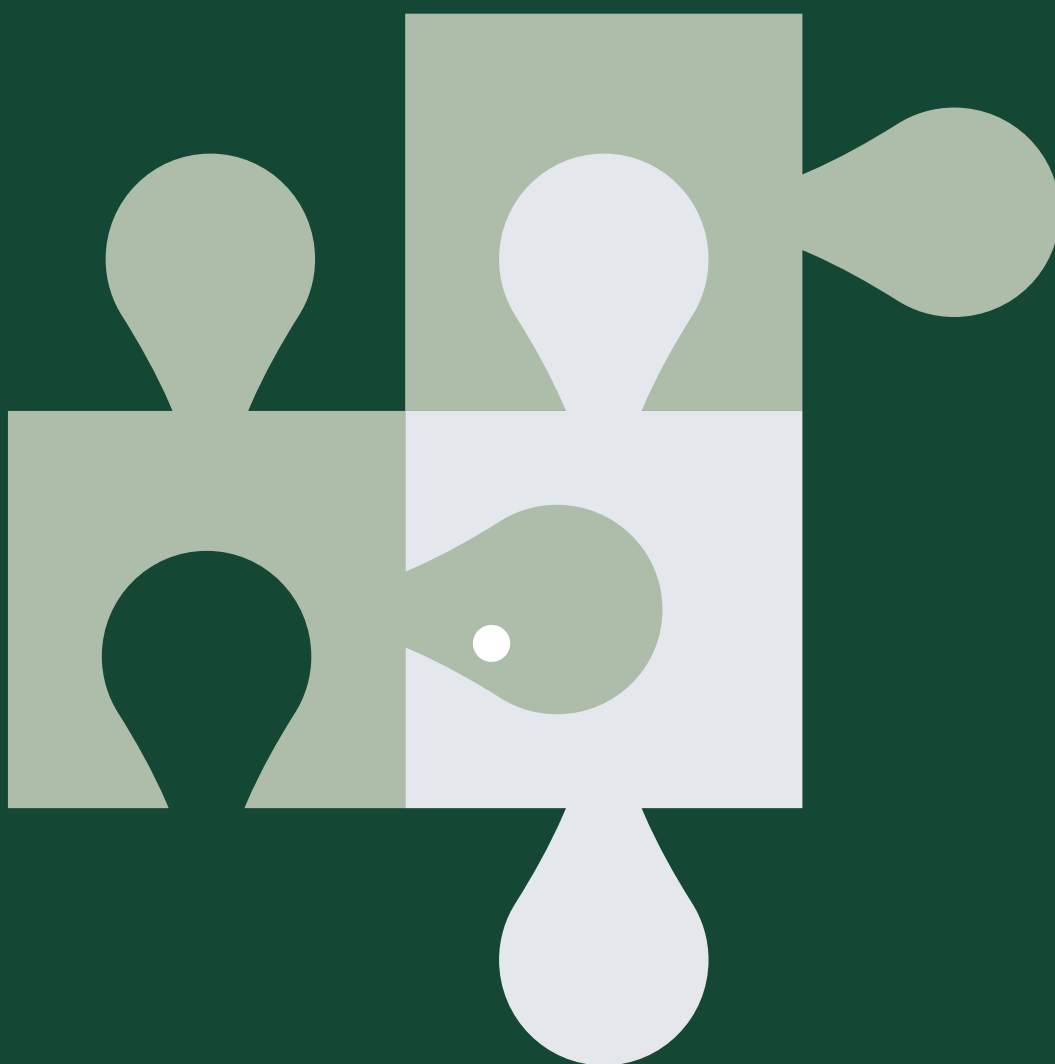
In addition, the Flecotec system is all about single-use containment – once a process step has been completed, the entire system is simply disposed of. This keeps cleaning and validation work that takes time and costs a lot down to a minimum.

On the following pages, you will learn how the Flecotec system can be used simply yet ingeniously at various process stages and how it makes your highly sensitive processes safer and occupational safety significantly easier.

# PROTECTION FOR MAN AND MATERIALS IN ALL SENSITIVE PROCESSES

1. Preparation
2. Sampling/Dispensing
3. Inline sampling
4. Emptying a bag
5. Filling a bag
6. Filling tablet bags





## OFF TO A GOOD START

### 1 Preparation

INCOMING DRUMS OF RAW MATERIALS ARE PREPARED FOR SAFE AND CONTAMINATION-FREE FURTHER PROCESSING OR STORAGE IN NEXT TO NO TIME THANKS TO FLECOZIP ADAPTERS AND EXPANDERS.

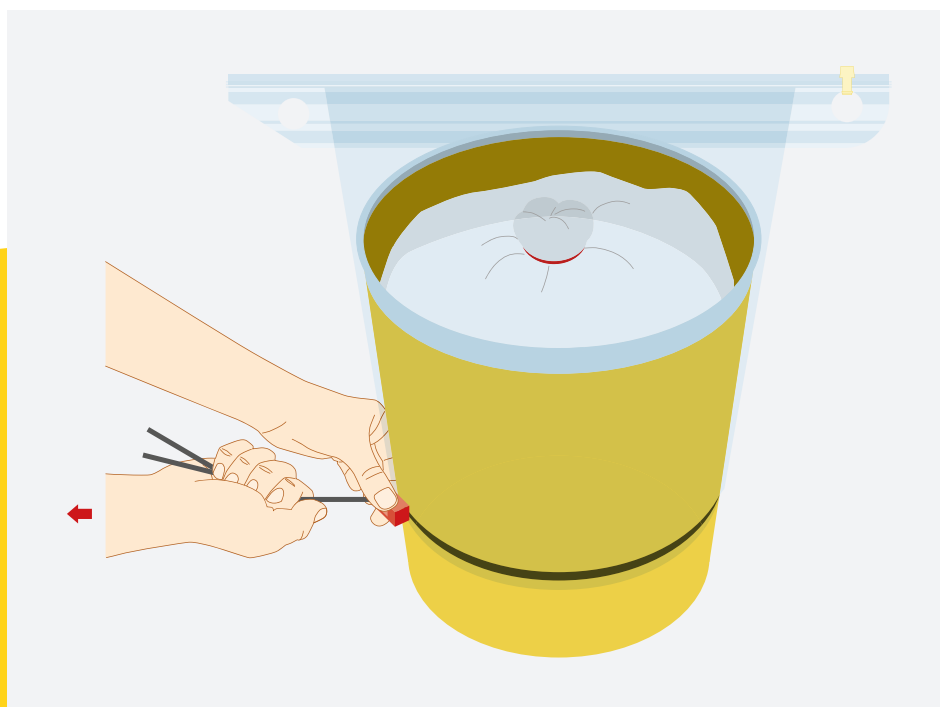
#### How it works

When the lid of the drum has been removed but the primary packaging has not yet been opened, a Flecozip adapter is pulled over the drum and is made to fit the barrel's outer diameter tightly with an expander.

Preparing a drum with an adapter in this way allows it to be attached to and detached from the Flecobox contamination-free, thus making it easier to perform enclosed sampling and

partial extraction in the area of dispensing, for example. The Flecozip adapter simply remains on the drum until it is entirely empty and ready to be disposed of.

Alternatively, at a repackaging station, the sealed primary packaging can be transferred to a drum fitted with a Flecozip liner bag. This liner bag then allows for contamination-free attachment to and detachment from the Flecobox.



## DOWN TO WORK – SAFE AND SOUND

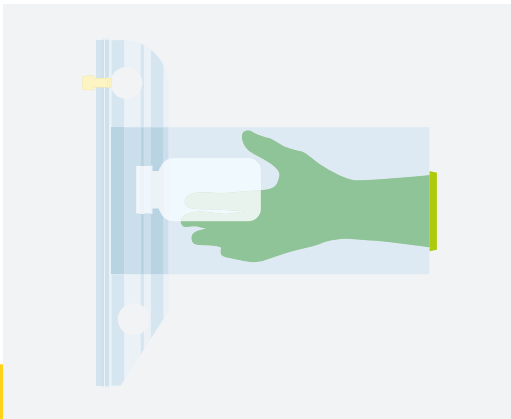
### ② Sampling and dispensing

THE PREPARED DRUMS ARE DOCKED TO THE FLECOBOX USING A FLECOZIP CLOSURE. THE PRIMARY PACKAGING CAN BE SAFELY OPENED USING THE GLOVE PORTS. THE DRUM CONTENT CAN NOW BE SAMPLED OR PARTIALLY EXTRACTED FOR DISPENSING INSIDE THE FLECOBOX.

#### How it works

The sample container, which is ready in a Flecozip bag with a glove port, is transferred to the Fleco-box through the second Flecozip closure, a sample is taken, and the container is then transferred back and detached. The tightly sealed bag can then be taken to the laboratory.

Material to be dispensed is put into Flecozip bags via an opening at the bottom of the Flecobox featuring a Flecozip closure. When material collection has been completed, these bags can likewise be easily detached from the Flecobox and taken to the processing units waiting to be filled.



*Need other utensils in the enclosure? Not a problem with the versatile Flecozip bags.*



## KEEPS PRODUCTION UP AND RUNNING

### 3 Inline sampling

TO TAKE A SAMPLE DIRECTLY FROM A PROCESSING UNIT, A FLECOZIP ADAPTER IS ATTACHED TO THE OUTLET FLANGE. THIS ADAPTER REMAINS ATTACHED AT THE SAMPLING POINT FOR THE ENTIRE CAMPAIGN.

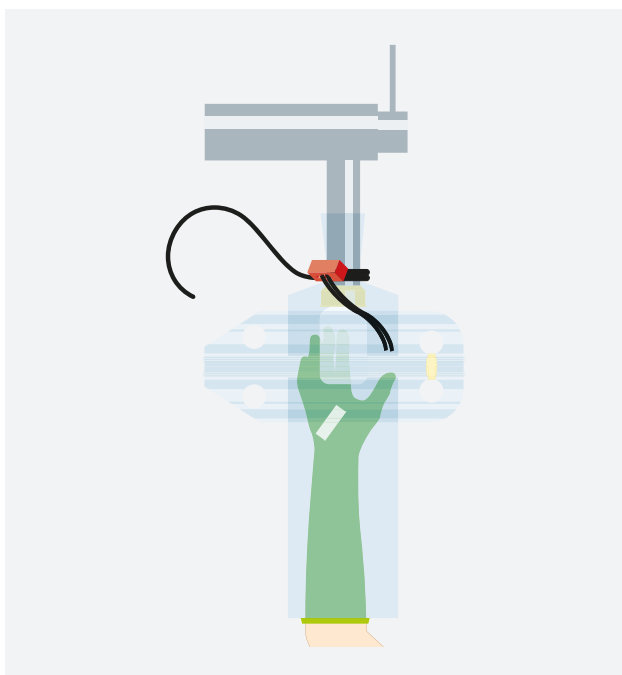
#### How it works

A Flecozip bag with a glove port and containing the sample container is attached to the Flecozip adapter by means of a slider and the closures are opened.

The sample container is then opened through the glove port, is passed through the opened Flecozip closures, and is attached to the sampling point. A sample can then be taken.

Once a sample has been taken, the sample container is unscrewed from the sampling point, placed back in the Flecozip bag, and sealed.

The Flecozip bag then simply needs to be detached from the adapter and the bag and its contents can be sent to the laboratory for analysis.





## UNITING WHAT BELONGS TOGETHER

### 4 Emptying a bag

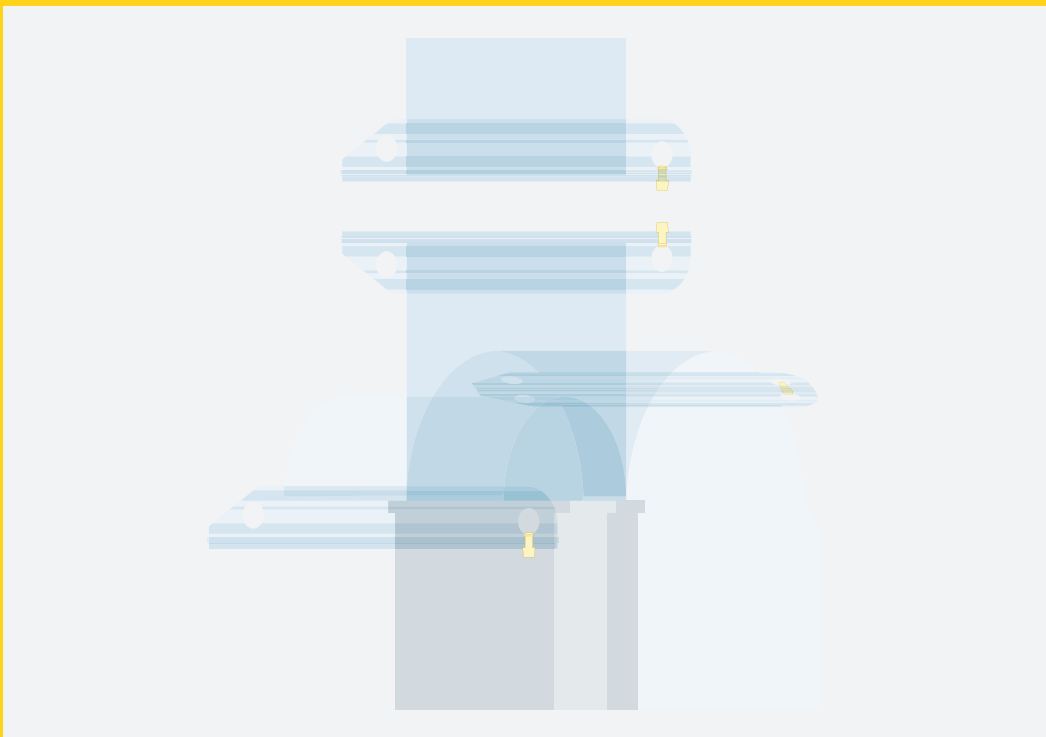
AN ELEMENT OF THE FLECOTEC SYSTEM IS A CLEVER MULTI-CARTRIDGE SETUP THAT ALLOWS YOU TO INTRODUCE UP TO FIVE SOLIDS INTO THE PROCESSING UNIT, EACH VIA THEIR OWN BAG, WITH JUST ONE FLANGE MOUNTING. CROSS-CONTAMINATION IS THEN COMPLETELY RULED OUT!

#### How it works

The Flecozip multi-cartridge is attached to the processing unit to be filled. The Flecozip bags to be emptied are then docked to one of the Flecozip closures on the multi-cartridge, one after the other, the closures are opened, and the bags are emptied via the cartridge.

Rather than being detached, the empty bags then simply remain there on the cartridge. Once the processing unit has been filled with the specified number of bags, the cartridge is rinsed by a spray lance where it connects with the process and can then be removed from the processing unit.

Alternatively, there is an innovative emptying process in which the Flecotec closures serve as a secondary interface, as is the case during bag filling.



## FILLED AND PACKAGED – JOB DONE

### 5 Filling a bag

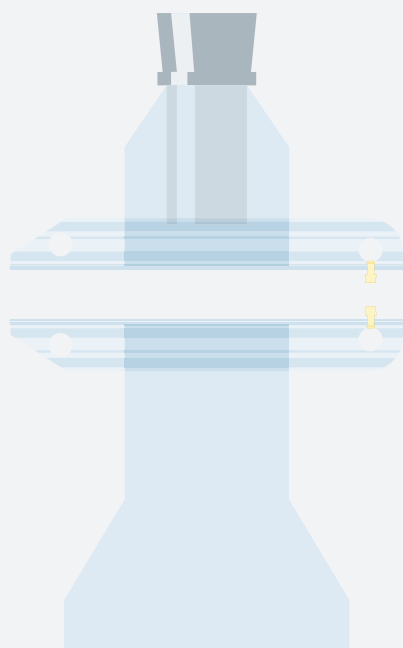
PERFECT FOR SWIFT AND SECURE CONNECTIONS – THE FLECOZIP BAGS WITH VARIOUS CONNECTION OPTIONS ALLOW FOR FAST MATERIAL TRANSFER.

#### How it works

A transfer tube fitted with a Flecozip adapter is attached to the outlet flange on the processing unit to be emptied. The Flecozip bag to be filled is docked to the Flecozip adapter and opened, and the opened closures are slid over the transfer tube. The bag is then sealed around the transfer

tube directly below the arranged closures. The material transfer can begin.

Once the bag has been filled, the seal is broken and the Flecozip closures are pulled off the transfer tube and detached from one another. Job done.



## TAKES THE PRESSURE OUT OF PRODUCTION

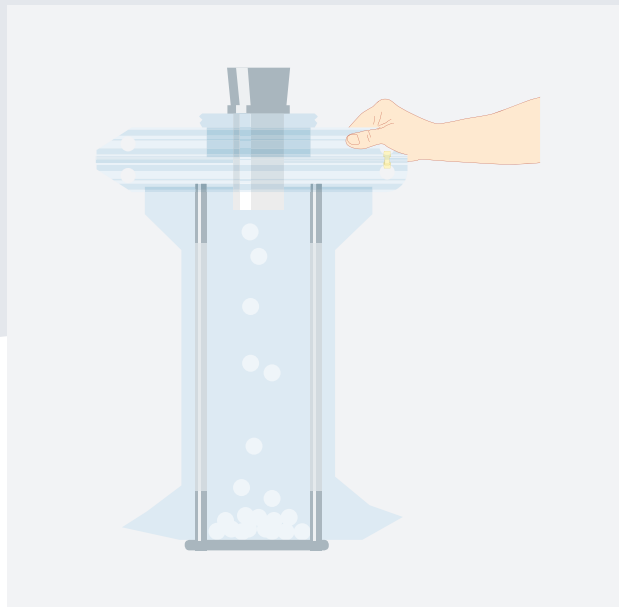
### ⑥ Filling tablet bags

THE FLECOTEC SYSTEM ALSO INCLUDES SPECIALLY DEVELOPED BAGS AND FASTENERS FOR THE FILLING OF READY-PRESSED TABLETS.

#### How it works

As the tablet presses and downstream deduster work with slightly negative pressure, the tablet bag is fitted with special straps that are simply

pulled over an opening device. This ensures that the bag remains open during the filling process in spite of the slightly negative pressure and doesn't fall in on itself.



# THE END OF THE BEGINNING

AS NOBODY EVER BELIEVES EVERYTHING THEY READ IN A BROCHURE, WE INVITE YOU TO EXPERIENCE THE MANY BENEFITS OF THE FLECOTEC SYSTEM FOR YOURSELF. TRY IT OUT YOURSELF AND ASK US QUESTIONS – IDEALLY CRITICAL ONES AND MOST DEFINITELY QUESTIONS REGARDING YOUR OWN, SPECIFIC CHALLENGES. OUR SPECIALISTS WILL BE HAPPY TO ANSWER ALL YOUR QUESTIONS, BE IT AT OUR PREMISES OR YOURS.

Talk to us and start to enjoy the benefits of Flecotec, the comprehensive single-use containment system, in all your highly sensitive processes.



Flecotec AG  
Schweighofstrasse 3  
79410 Badenweiler  
Germany  
T +49 7632 828553-0  
[mail.ft@rommelag.com](mailto:mail.ft@rommelag.com)  
[www.rommelag.com](http://www.rommelag.com)