



***Workshop Hünstetten***  
*25<sup>th</sup> April 2023*



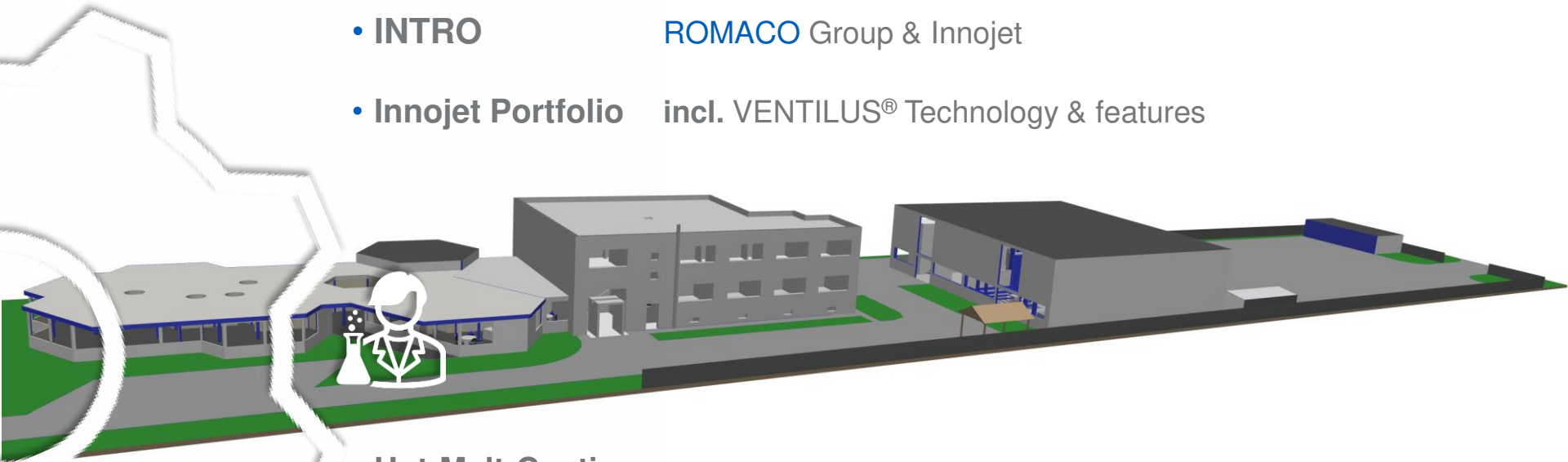
**Josef Brändlin**  
Product Sales Manager

***VENTILUS® Series***  
*Air Flow Bed Technology*  
*& Hot-Melt-Coating of Particles*

APR 2023

## Content

- **INTRO** ROMACO Group & Innojet
- **Innojet Portfolio** incl. VENTILUS® Technology & features

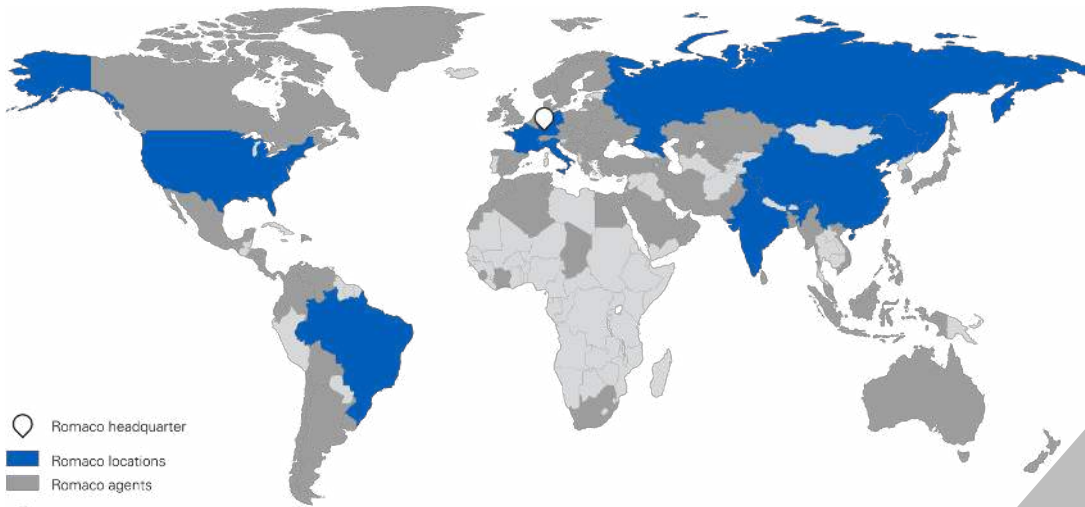


- **Hot-Melt-Coating**
  - Basics / Materials / Functions / Efficiency & Sustainability / Cases & Examples / Option Hot-Melt-Device
- **Trials**
  - @ BIOGRUND (tomorrow & in the future)
  - @ InnoTech (any time)



# Headquartered in Germany

– Delivering value locally, worldwide



**GERMANY  
KARLSRUHE (HQ)**  
180 Employees

- MANUFACTURING:
- Blister Packaging Lines
  - Strip Packaging & Tube Filling Lines for Effervescent Tablets



**GERMANY  
STEINEN**  
30 Employees

- MANUFACTURING:
- Granulation, Coating and Drying Systems



**ITALY  
BOLOGNA**  
155 Employees

- MANUFACTURING:
- Liquid & Powder Filling Lines
  - Cartoning & End-of-Line Equipment



**GERMANY  
COLOGNE**  
172 Employees

- MANUFACTURING:
- Tablet Presses



Ownership  
 **CHINA  
CHANGSHA,  
HUNAN**



Grand Total  
2500  
Employees

**TRUKING incl. ROMACO**  
biggest machine producer worldwide  
for pharma machinery

**ROMACO**  
Total  
800 employees



# one stop solids solutions

**INNOJET**  
Herbert Hoeslin

**KILIAN**

**TECPHARM**

**NOACK**

**SIEBLER**

**PROMATIC**

**MACOFAR**



Drying & Coating,  
Granulating Systems

Tablet Presses

Tablet Coating  
Equipment

Blister  
Machines

Heat Sealing &  
Tube Filling Machines

Secondary Packaging

Powder Filler & Liquid Filler





# 30 years leading in Fluid Bed technology



Dr. h.c.  
Herbert Hüttlin

# VENTILUS and IGL

## Complete solution machines

Development of high efficient  
Fluid Bed system named VENTILUS

- Controlled product movement  
**Orbiter<sup>®</sup>**
- Bottomspray one nozzle technology  
**Rotojet<sup>®</sup>**
- Particle retention system  
**Sepajet<sup>®</sup>**







# High degree of Standardisation

Standardisation of the modules

Drying  
Granulation  
Coating

## Innojet History – Globally Technology Leader

**1997**

- **Founded by Dr. h.c. Herbert Hüttlin**
- R&D of the innovative Air Flow Bed Technology (int.pat.)
- Design and construction of advanced functional
- Components for Fluid Bed Systems



**2008**

- Purchase of the **new company headquarter** and production site in **Steinen**



**2017**

- Member of **Truking Group**



**1997**

**2003**

**2008**

**2015**

**2017**

**2003**

- Establishment of the **VENTILUS®** System



**2015**

- Member of:

**ROMACO**  **Group**  
*beyond technology*



**2018**

- VENTILUS® - LE  
concept standardisation  
in modules
- &
- V 5 (Lab) face-lift (new series)



**2020**

- VENTILUS® P  
go to market



**2019**

- Innojet Granulation Line  
**IGL**  
go to market



**2021**

- Start of ISO  
Certification process



# Product portfolio

Our entire product range is scalable

Laboratory Scale

Pilot Scale

Production Scale (brim vol.)

**VENTILUS® Lab**



IHD 5

**VENTILUS® Pilot**



V 75



V 150, V 300,  
V 450, V 600,  
V 900, V 1200,  
V 1500

LE-D, -G, -C  
and PR = Premium

**VENTILUS®**

- ▶ Invented by Dr. h.c. Herbert Hüttlin who spent a lifetime for optimisation of the fluid bed technology
- ▶ Patented technology
- ▶ The Innotech lab in Steinen, Germany serves to optimize your production process in order to obtain the maximum efficiency



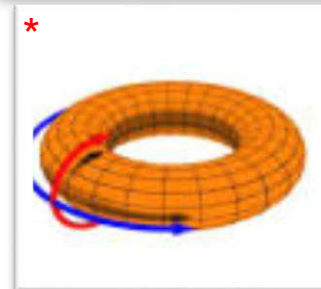
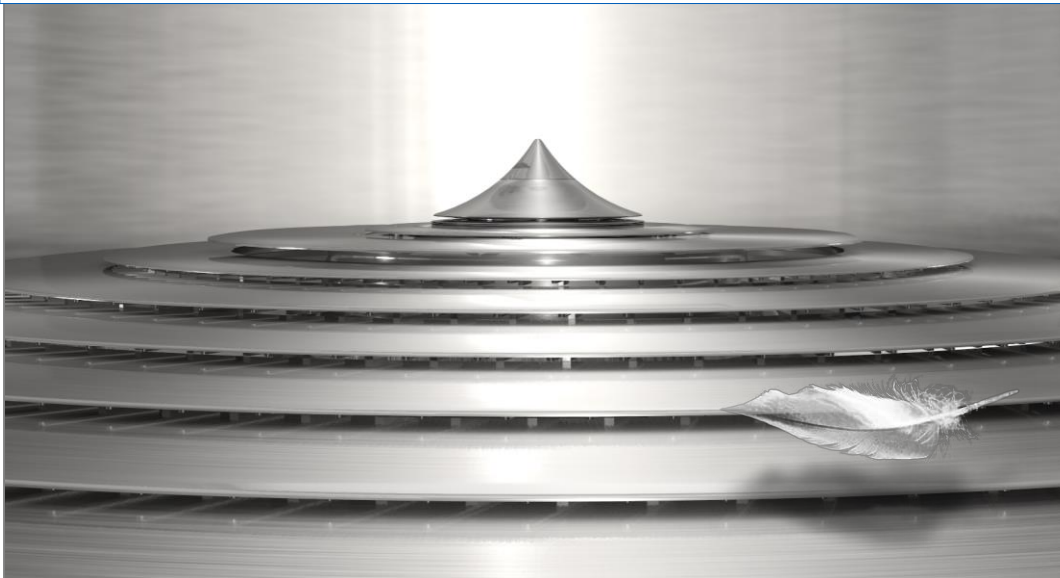
**Optimized  
core  
components  
work  
together  
in  
perfect  
harmony**

## Technology overview - ORBITER

The Air Flow Bed technology optimizes the fluidization of solid particles

### **ORBITER air distributor plate** optimizes the fluidization of solid particles

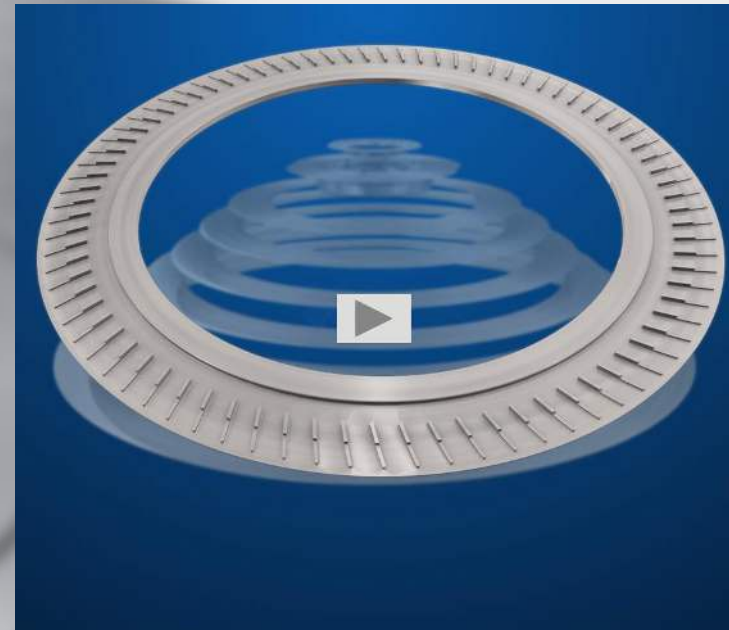
- Gentle product flow (orbital and controlled flow of process air → toroidal\* product movement)
- Particles float freely without any friction because the product hovers → rapid and even coating
- Shorter processing times as well as excellent and reproducible product quality





# Air distribution plate named **ORBITER®**

- ▶ **Overlapping plates fixed to the machine only in the middle**
  - Easy disassembly
- ▶ **Gap size adjustable depending on your product**
  - Customisation if needed
- ▶ **The only air distribution plate in a fluid bed system that is CIP compatible**
  - Reduced washing times



• 100% compatible

• Reduced washing times

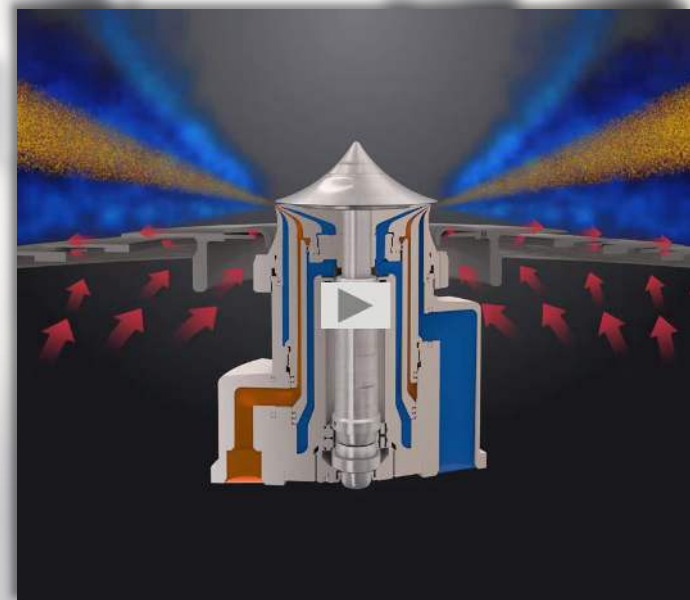
# ORBITER<sup>®</sup> driven controlled product movement

- ▶ **Highest exchange time between air and particle**
  - Reduced process time
- ▶ **Guarantee, that each particle is for the same time at the same place**
  - Each particle collects the same quantity of liquid
- ▶ **No product settlement in the product bowl**
  - Highest yield

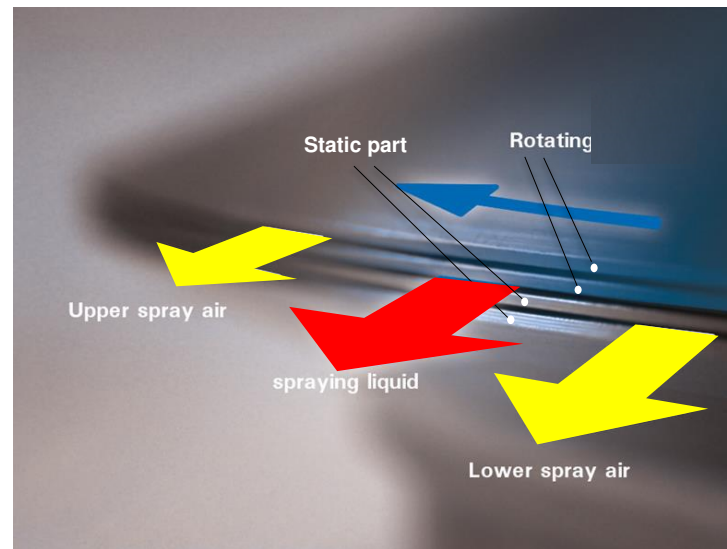


# ROTOJET® single nozzle system

- ▶ **One nozzle system**
  - Easy handling – easy scale up
- ▶ **Upper part of the nozzle rotates**
  - No blocking
- ▶ **Spray direction with the product flow**
  - Highest yield – and best quality



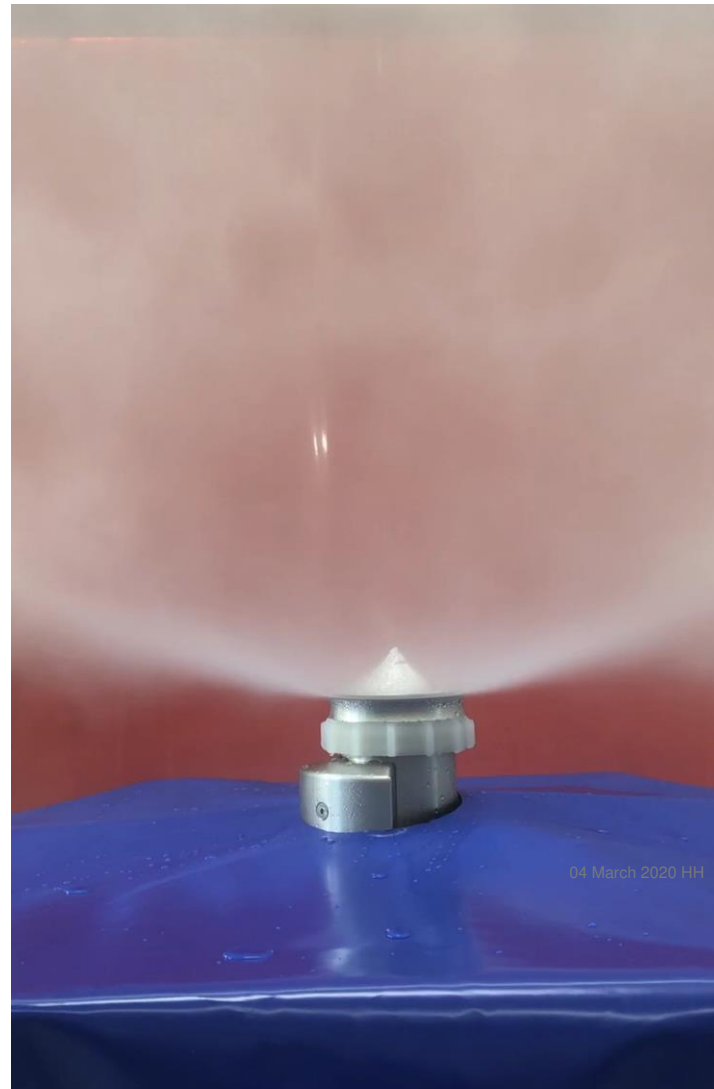
*Dynamic spray nozzle 'ROTOJET' - the new philosophy for a save scale-up*





**Romaco Innojet VENTILUS®**  
*Homogeneous Spraying*

**with**  
Dynamic spray nozzle 'ROTOJET'



04 March 2020 HH

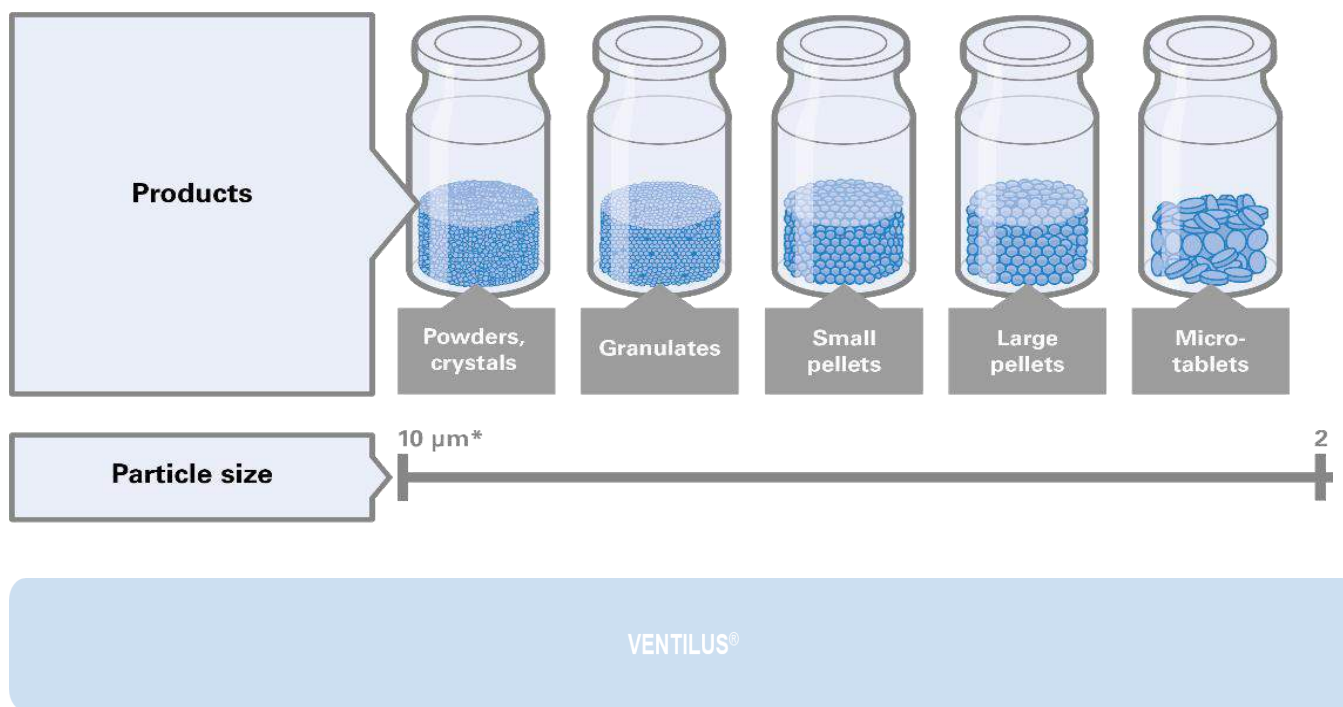
# SEPAJET<sup>®</sup> in process particle retention

- ▶ **Filter cleaning with process air**
  - No compressed air consumption
- ▶ **Filters flushed from inside out**
  - Increased standing time
- ▶ **Singular filter bags**
  - Easy replacement



# Application overview

Solutions available for a broad range of products





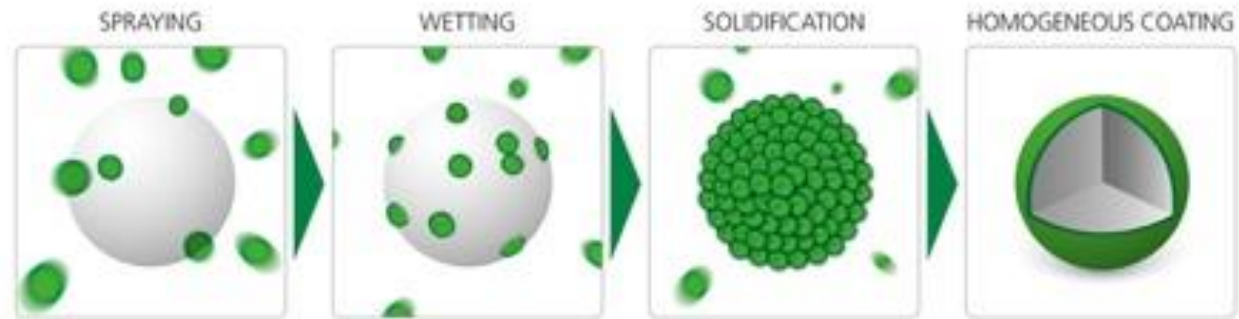
*Hot-Melt-Coating ..... What exactly does it mean ?*





# VENTILUS® and hot melt coating

## General Remarks & Definition



- Hot melt coating (HMC)

= spraying with melted materials

in a granulation (of powder or pellets)

and/or coating process



### **Definition**

- Hot melt coating (HMC) = spraying with melted materials in a granulation and/or coating process
- Highly profitable solution for production, mainly in the food and pharma industries

### **Advantages**

- Better control of taste (masking) and release (effectiveness) parameters
- Process speeded up significantly (no evaporation)
- Much better energy efficiency because there is no need to heat the process air
- No liquid / moisture in the system

### **Progress**

- Increasing availability of ready-to-use materials
- More and more materials are registered for pharma and food applications

The processing of different products and their encapsulation require a great **know-how** on:

- ✓ active ingredients
- ✓ raw materials
- ✓ R&D & PRODUCTION PROCESSES

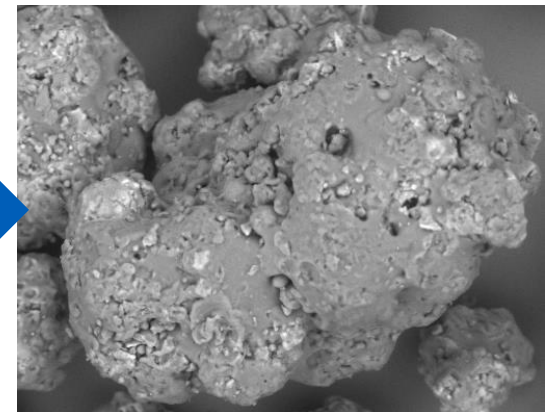
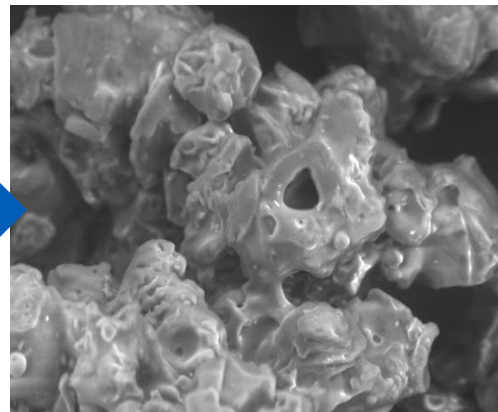
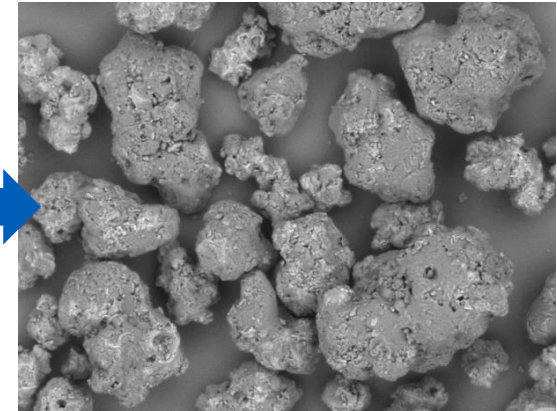
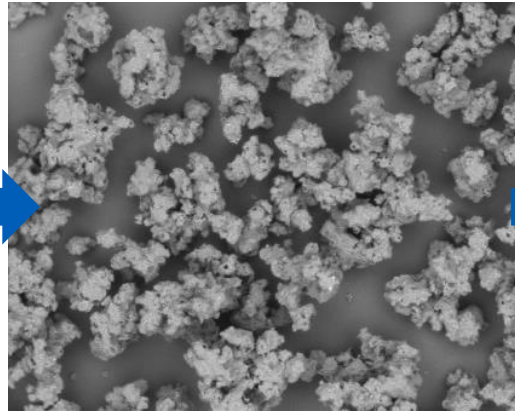
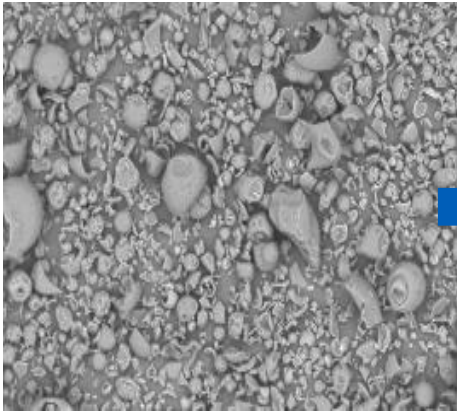
By a clever combining of active ingredients and various raw materials with the respective production processes, encapsulation of particles with very specific properties can be achieved.

The wide range of production technology enables extraordinary variability, both in terms of the active ingredients and raw materials used, as well as the properties of the end products.

# VENTILUS® and hot melt coating

Raw Material → Granulation

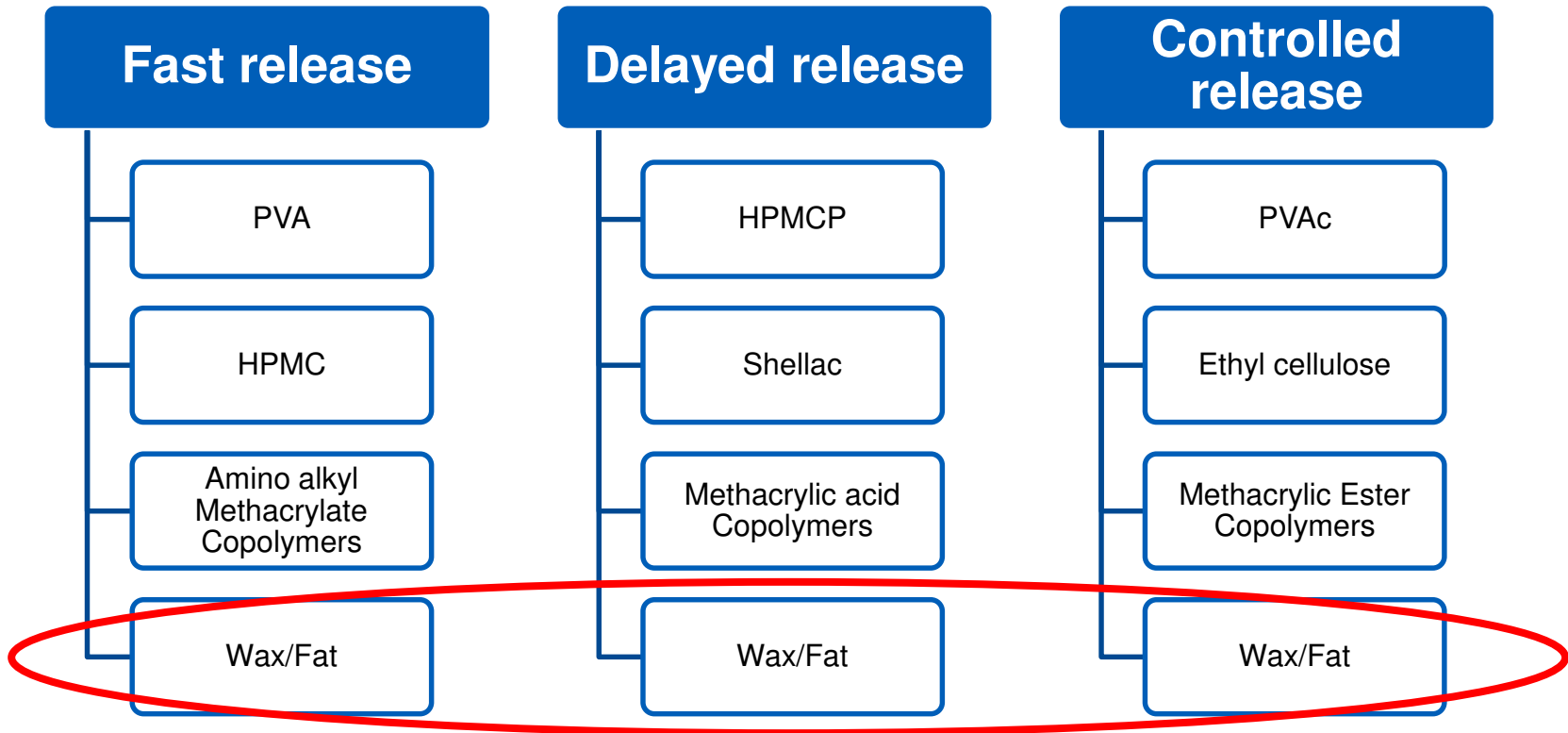
→ Hot melt coating



**Original raw material**

**Granulated material**

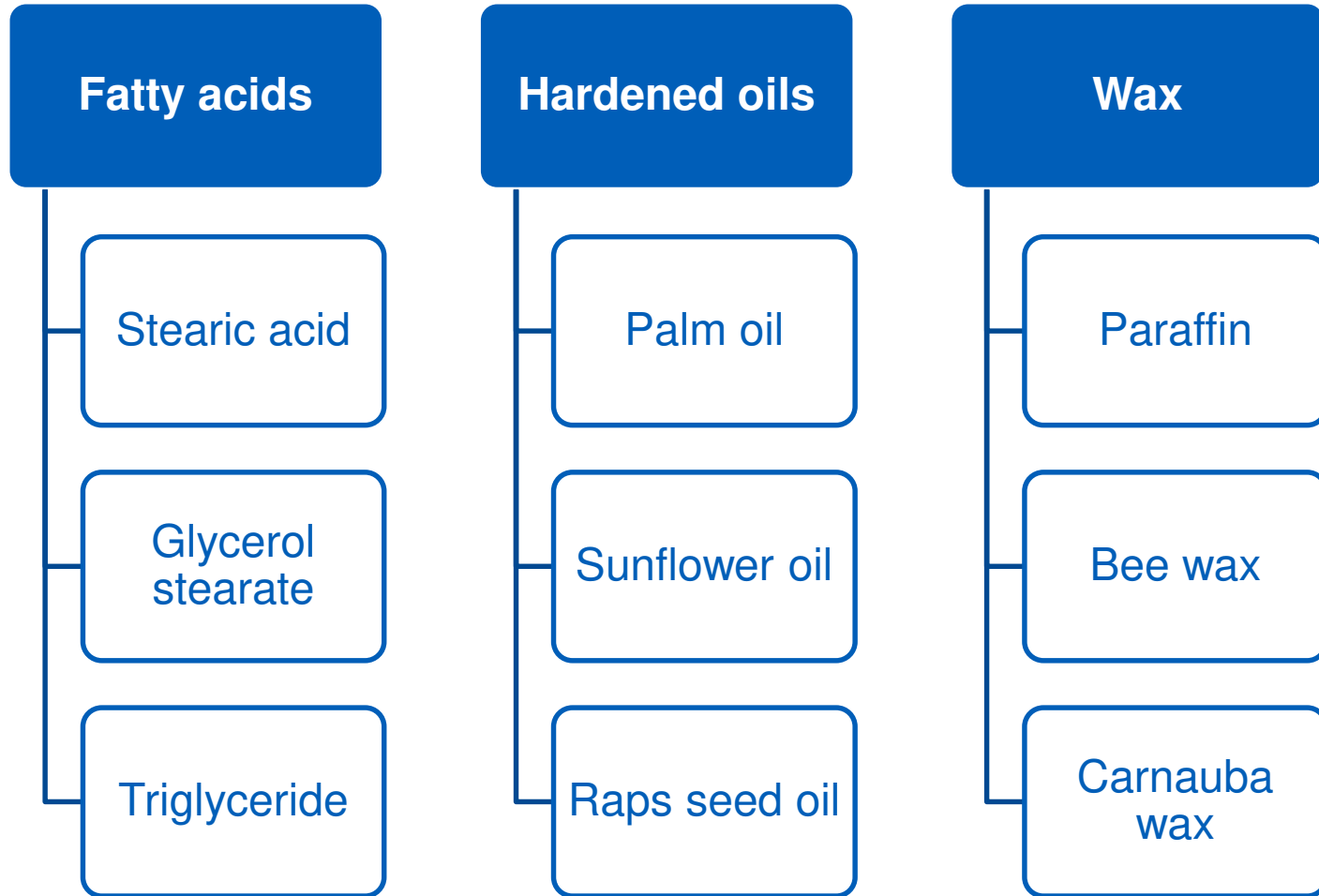
**Hot melt coated material**





# VENTILUS® and hot melt coating

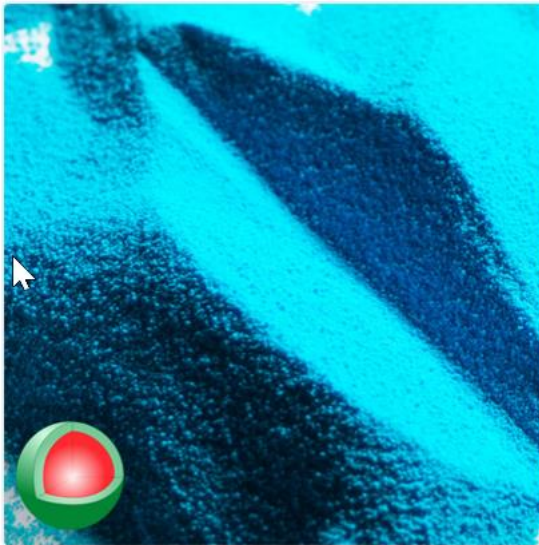
## HMC material examples



*...or combination of ...*

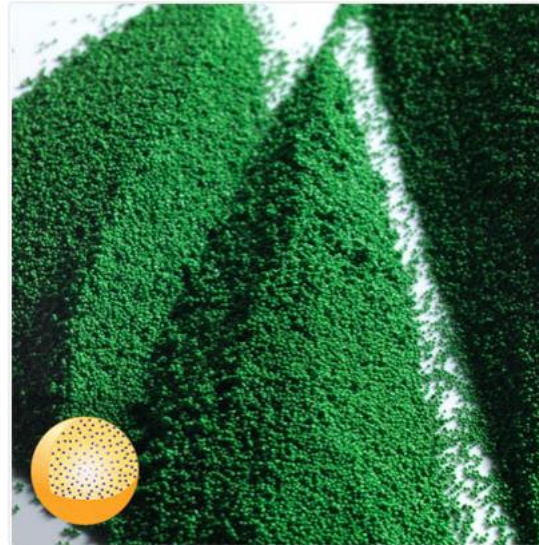
# VENTILUS® and hot melt coating

## Selection of possible product properties



### Protection

against physical, chemical and mechanical influences



### Release

controlled and targeted release of active ingredients

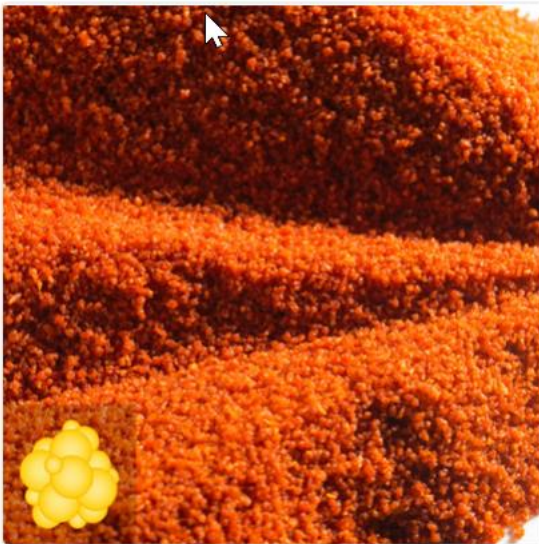


### Solubility

Improvement of the solubility

# VENTILUS® and hot melt coating

## Selection of possible product properties



### Dosing

Improvement of flowability and dosing properties



### Hygroscopicity

Reduction of hygroscopicity



### Masking

Taste and/or bad smell

## Applications



Granules  
Taste Masking

Seeds  
Protection

Pellets  
Moisture Barrier

Tablets  
Swallowing Help

Crystals  
Thermo Stabilization

Powder  
Coating

and many others...



## Advantages of the Hot Melt Coating Process

### Case study:

#### Taste masking of granules

**85% shorter processing time** with hot melt coating compared to coating with a polymer solution

→ Particularly suited for moisture barriers and taste masks (e.g. for ready-to-use granules or in MUPS tablets)

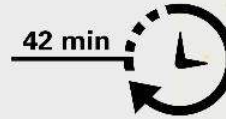
#### Hot melt coating



Granulate 1000g

Wax  
500g

42 min



Granulate with coating 1500g

Application: 50%  
Spray rate: 12g/min

#### Coating with polymer solution



Granulate 1000g

H<sub>2</sub>O  
2833g

Polymer  
500g

278 min



Granulate with coating 1500g

Must be evaporated  
▶ Time + Energy!

#### Hot Melt Coating Advantages:

- Significant process time reduction
- Less energy consumption
- No solvents required



# VENTILUS® and hot melt coating

Significantly lower energy consumption (ex.: V 600')

Example: crystal + EUDRAGIT-E vs hydrogenated palm oil

Process data	Standard process	Hot melt process
Heating up the inlet air	5 h x 125 kW = 625 kWh	1 h x 45 kW = 45 kWh
Heating up the feed-block & transfer hose	-	5 kWh
Melting energy wax	-	200 kg wax = 10 kWh
Spray air heating	-	1 h x 15 kW = 15 kWh
<b>TOTAL</b>	<b>625 kWh</b>	<b>75 kWh</b>



## Hot Melt Coating

### Sustainability

- 85% shorter processing times
- No solvent emissions
- Coating agents made from renewable plant-based raw materials
- No chemical additives
- No need to heat the air in order to dry the product
- Optimised energy efficiency






... Hot Melt ... the green alternative to polymer coatings ...

## SUSTAINABILITY

- ❖ Process filter bags can be exchanged individually (per piece)
- ❖ Process filter cleaning w/o compressed air
- ❖ Low consumption of compressed air,  
based on only *-and always-* one (1) spray nozzle
- ❖ Additional reduced energy consumption based on short process times;  
especially when using hotmelt (option)

# VENTILUS® and hot melt coating

## Application examples of ROMACO Innojet (Food & Pharma)

Product	Function Coating	Industry	Application examples
Sugar	Humidity protection	Food	Decoration sugar 
Salt	Humidity protection	Food	Pretzel salt 
Acids (malic, citric, tartaric, acetic, sorbic etc.)	Sustained release, Humidity protection	Food	Sour candies 
API's	Taste masking	Pharma	Ibuprofen, Paracetamol, NAC
Excipients	Barrier coating	Pharma	Ascorbic acid 
Probiotics	Encapsulation	Nutraceuticals	Infant milk powder 



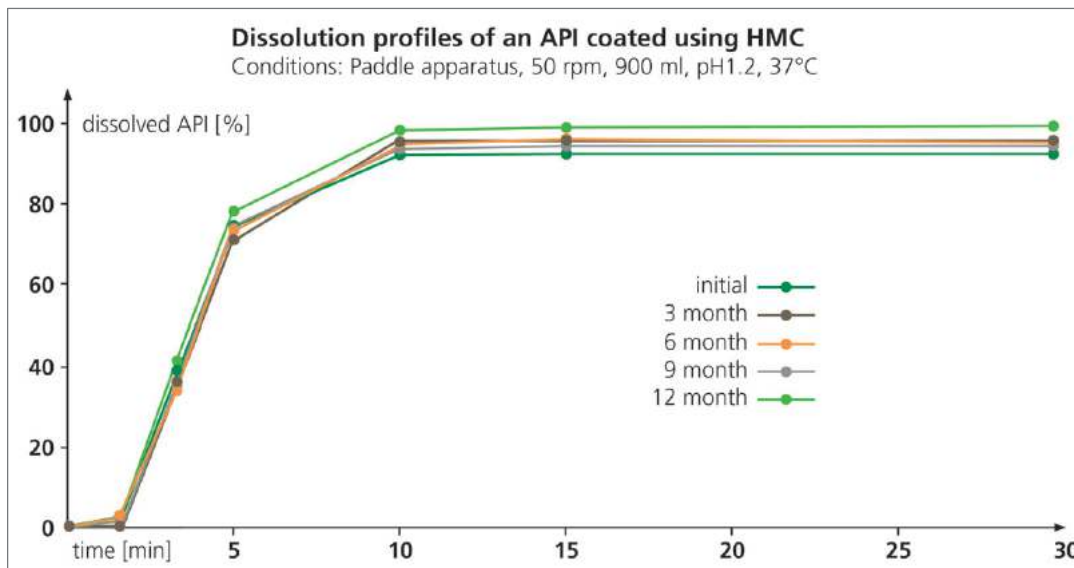
- | Advantages           |
|----------------------|
| Fast process         |
| Cheap raw materials  |
| Low production costs |
| Robust process       |
| Innovative           |



# VENTILUS® and hot melt coating

## Case Study: drug manufacturer\_GER & \_AT

- Dissolution profiles of a bitter tasting, fast acting API that has been HM-coated
- The profiles shows that the coated API is stable over a period of at least 12 months
- The intermediate was stored in bulk using polyethylene drums, in a warehouse under uncontrolled conditions

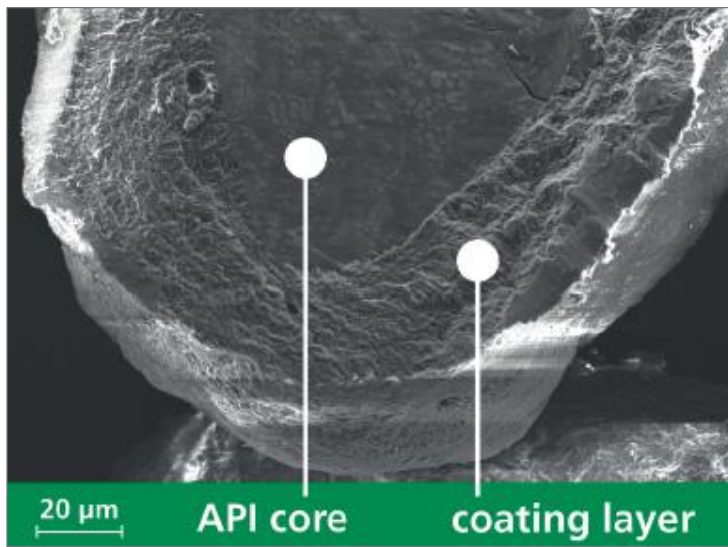




## VENTILUS® and hot melt coating

### Case Study: drug manufacturer\_GER & \_AT

- The image shows a cross section of the crystalline structure of the API core covered with a very homogeneous coating layer
- Used equipment: VENTILUS® 2.5 & IHD 1
- Production scale: VENTILUS® 150' & IHD 50
- planned soon: VENTILUS® 900' & IHD 300



Electron Microscope image of a bitter tasting, fast acting API (HM-coated)

# VENTILUS® and hot melt coating

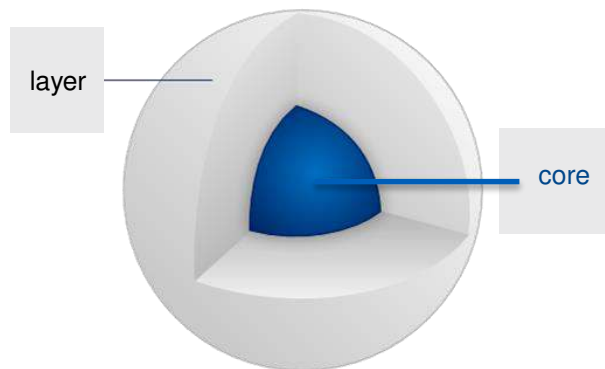
## Case Study: sugar producer\_GER

### Hot Melt Coating for Isomalt:

Moisture protection using ROMACO Innojet technology

#### OBJECTIVE:

A sugar pellet has to be coated with a solid barrier in order to **protect** it **against humidity** providing a water insoluble protection shield.



#### SOLUTION:

The **ROMACO Innojet VENTILUS® V 5** laboratory scale in combination with the **ROMACO Innojet hot melt device IHD 5** is particularly suitable for hot melt coating processes with waxes and hardened fats.



**Paul (9 months old)**  
Product Testing Manager

...his 1<sup>st</sup> test on **lemon!** ...



# VENTILUS® and hot melt coating

Application example: food producer\_ES

## Industry

- Food (sour drops)

## Process Example

- Hot melt coating of citric acid crystals (particle size 50 – 100 µm) with melted fat being heated up to 90°C

## Aim

- Protection against humidity, mechanical stress and controlled release of acid

## Used equipment

- V 900' / IHD 300



## Starter



## Final product





# VENTILUS® and hot melt coating Case\_GER

Product: Liposomes

Target: Enhanced bioavailability

## Challenges:

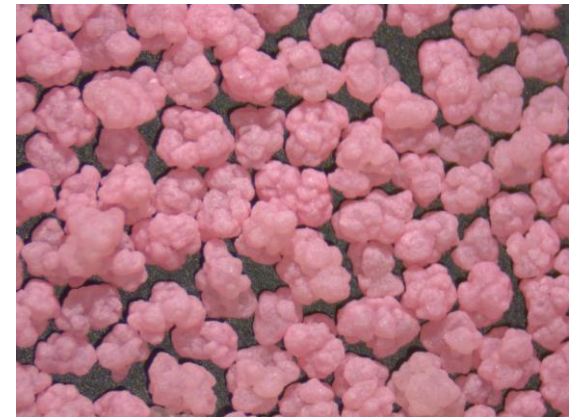
- change of Liposome form (from liquid to solid)
- protection against O<sub>2</sub>
- time to market

Success: HMC on sugar crystals

Highlight: clean w/o spots



**Starter** (sugar crystals)



**Final product**  
after 80 min. drug-layering  
+ 15 Min HMC\*  
(\*hardened palm oil)



# VENTILUS® and hot melt coating

## Case: University\_GER

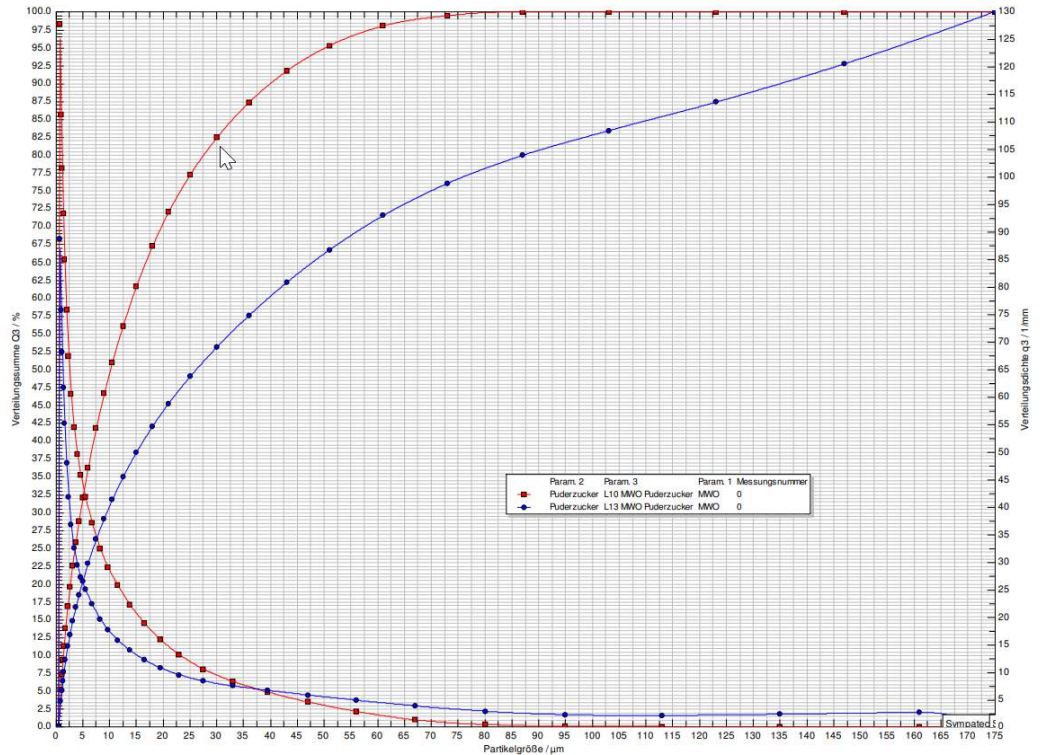
**Product:** Fine sugar powder

**Target:** Protection against air humidity  
(for the food industry)

**Challenge:** - very small particle size  
- bad flowability

**Success:** all targets reached

**Highlight:** short process time



# HMC products\_GER

## Case: Cosmetics\_GER

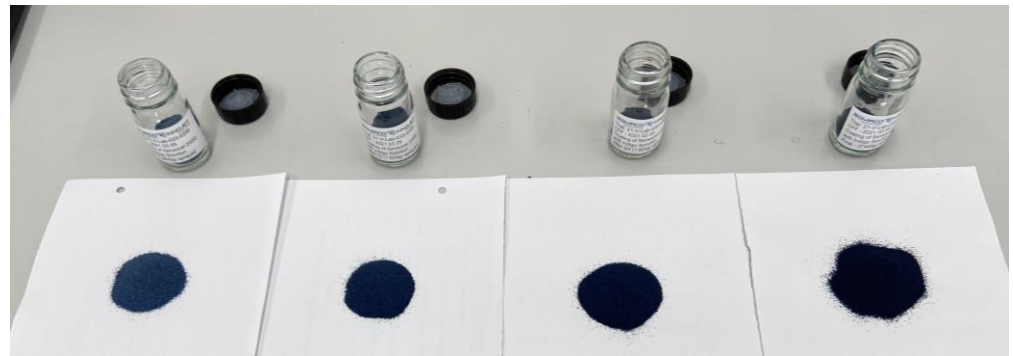
Product: Cellulose fibres  
HMC with rice brain wax

Target: haptic

Challenge: - very fine starter powder  
- bad flowability  
- low bulk density  
- closed coating  
- low amount of wax

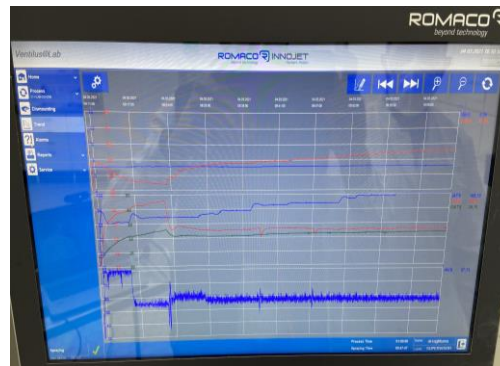
Success: multiple steps in one run  
w/o product discharging

Samples



Trends (on HMI)

Final product



*Product development still in progress!*

## HMC – Reference examples

(only extract, of those, which allow to name)

### Installed base

#### Lamirsa \_ES

Product:

Acid crystals (Sorbic, Malic, Citric, ...)

Machines:

VENTILUS® Lab; 4x V 900 PR



#### Hermes \_AT

Product:

Own development ACC direct, Vitamins

Machines:

VENTILUS® Lab; V 150 PR



#### RAPS \_GER

Product:

Acid crystals, others

Machines:

VENTILUS® V 25; V 1500 PR



## VENTILUS® and hot melt coating

### ROMACO Innojet hot melt coating devices – different development stages

Conventional Hot Melt Systems are:

- Optimized for continuous and automated production
- Clean surfaces to the production room
- Stainless steel covered insulation

BUT:

- No access inside the tubing
- Cleaning validation not possible
- For mono products only

Production scale: IHD 200 2-stage version– Food





# Hot Melt Coating

## New Technology for Pharma Production

Our solution for Pharma Applications

- GMP execution
- CIP cleaning function
- One common heating source
- Exact dosing function
- Compact unit – easy to handle
- Safety execution – fully covered and insulated
- Control system integration, data recording, GFR 21 Part 11 compliance

Melting vessel

Overhead stirrer (option)

Dosing piston

Diaphragm valves

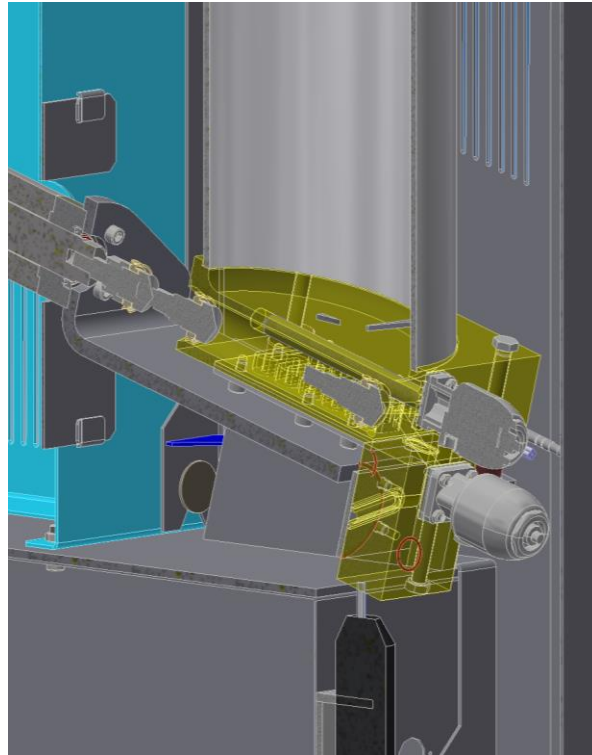
Heating block





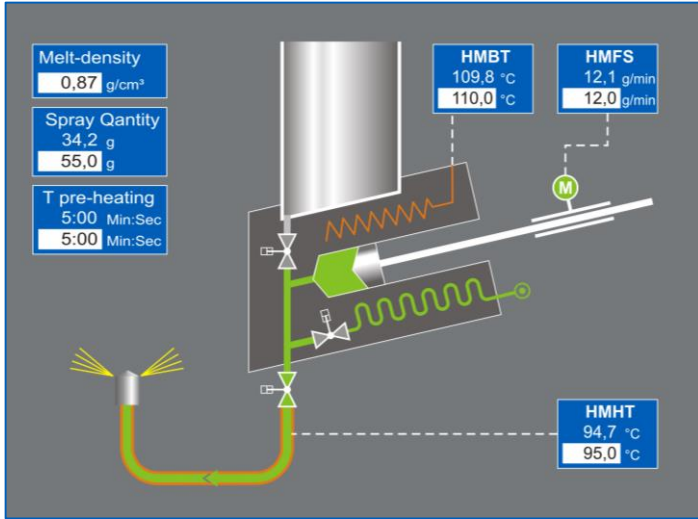
# Hot Melt Coating

## New Technology for Pharma Production



# VENTILUS® and hot melt coating

## Innojet Hotmelt coating Device IHD 5 (patented 2021)



- Strictly GMP compliant design
- Pulsation-free application of the melt
- Heating block with integral diaphragm valves guarantees a uniform temperature level
- Preheat function for the conveyor section to the spray nozzle
- Dosing piston with precision linear drive for optimal control of the dosing rate
- Heating block with CIP capable design and automatic cleaning function

Bundesrepublik Deutschland

## Urkunde

über die Erteilung des  
Patents Nr. 10 2017 109 235

Bezeichnung:  
Vorrichtung zum Dosieren einer Schmelze  
IPC:  
B01J 4/02  
Inhaber/Inhaberin:  
Romaco Innojet GmbH, 79585 Steinen, DE

Erfinder/Erfinderin:  
Koch, Kai, 79585 Steinen, DE  
Tag der Anmeldung:  
28.04.2017

Tag der Veröffentlichung der Patenterteilung:  
01.07.2021

Die Präsidentin des Deutschen Patent- und Markenamts

*Cornelia Rudloff-Schäffer*  
Cornelia Rudloff-Schäffer

München, 01.07.2021



Den aktuellen Rechtsstand und Schutzzumfang entnehmen Sie bitte dem DPMAregister unter [www.dpma.de](http://www.dpma.de).



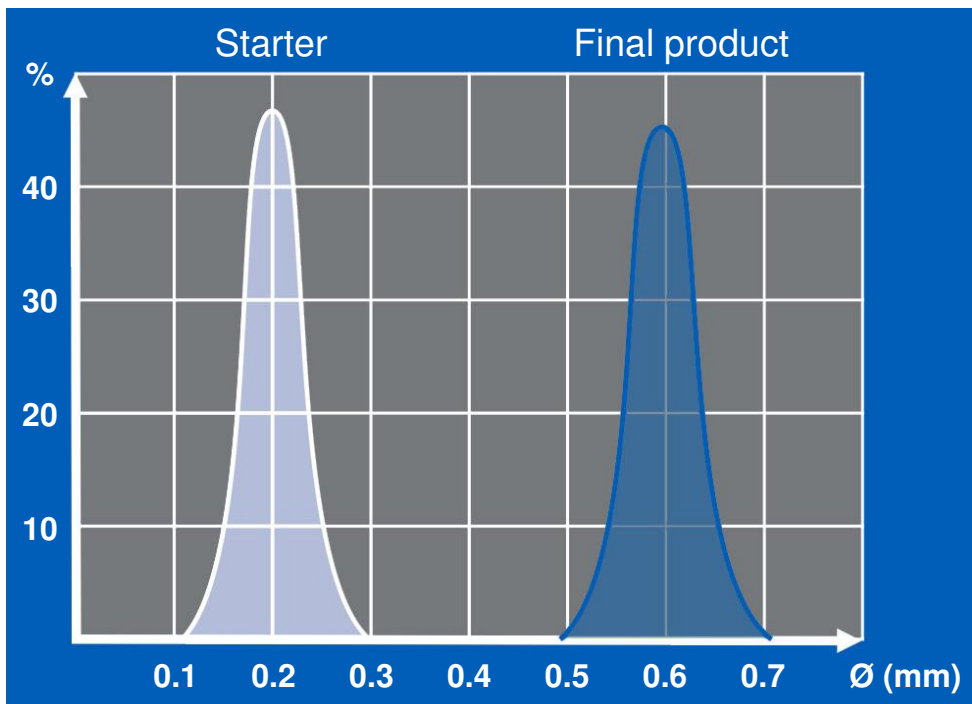
### GMP compliance

- Pharmaceutical grade cleaning validation
- Fully visible
- Suitable for swab testing
- Hygienic design with no dead spaces
- No risk of cross-contamination

## Scale-up

### Process example: Pellets layering and coating

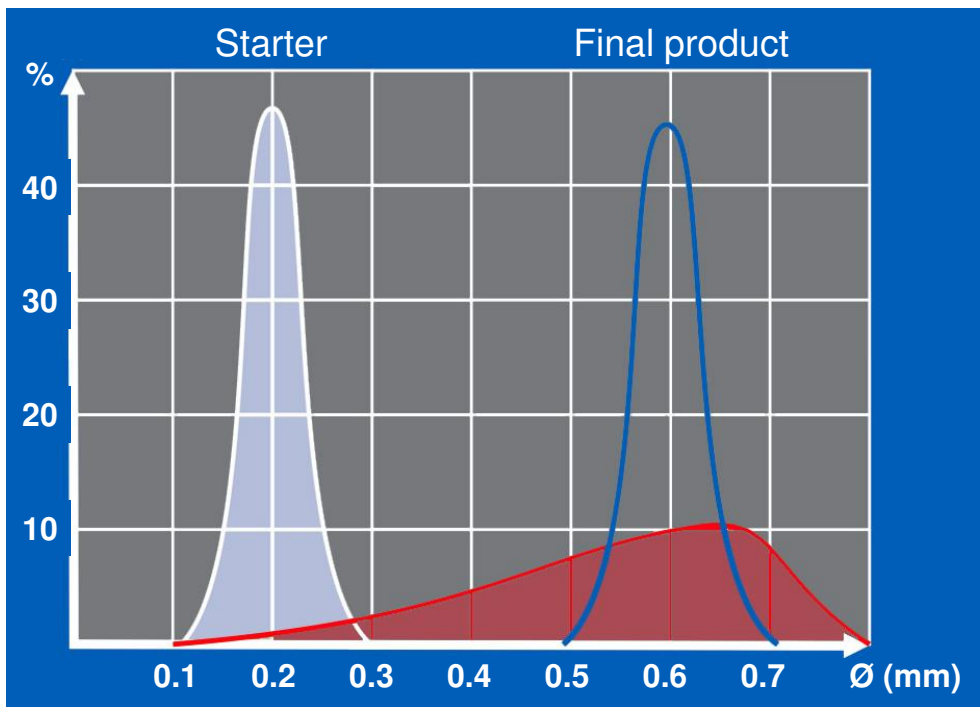
Final product results of ROMACO Innojet V 800 **yield** the same, as previous trials on laboratory (V 2.5) and Pilot (V 25) scale equipment.



# Scale-up

## Process example: Pellets layering and coating

**Comparison:**  
ROMACO Innojet VENTILUS® Lab (1 spray nozzle)  
*versus*  
Top-Spray Fluid Bed



■ Starter

■ **Final product:**  
VENTILUS® Lab, Pilot & Production Scale

■ **Final product:**  
Top spray (laboratory scale)

➔ **Results**  
Unacceptable!



# Hot Melt Coating

## Hotmelt device IHD 50 – pilot size

- Dosing piston drive
- Switch cabinet for dosing control
- Melting vessel
- Valve block
- Magnetic stirrer





# Hot Melt Coating

## Hotmelt device IHD 50 – pilot size

### Access to the dosing piston:

Piston moved backwards  
Drive is uncoupled



Piston is lifted manually  
Drive stays connected



Drive position on switch cabinet  
Piston moved out for cleaning



## Hot Melt Coating

### Hotmelt device IHD 50 – pilot size

*Access to valves and liquid channels:*

Valve block is opened and flapped down



Liquid channels open for cleaning and inspection



# VENTILUS® and hot melt coating

ROMACO Innojet hot melt coating devices – different development stages

Pilot scale: IHD 50 – Pharma, 2012



Production scale: IHD 300 – Food, 2015



# VENTILUS® hot melt coating

## Advantages & Conclusion

- ✓ Better control of taste (masking) and release (efficacy) parameters
- ✓ **Process speeded up significantly** (no evaporation)
- ✓ **Much better energy efficiency** because there is no need to heat the process air
- ✓ No liquid / moisture in the system
- ✓ **Highly profitable solution** for production, mainly in the food and pharma industries

## Progress

- ✓ Increasing availability of ready-to-use materials (see e.g. [www.Biogrund.com](http://www.Biogrund.com))
- ✓ More and more hot melt able materials are registered for pharma & food applications
- ✓ **VENTILUS®** is a very innovative technology to control this process by:
  - only one spray nozzle = ROTOJET in the center of the cylindric FB-body
  - + ideal product movement & fast crystallisation via air-booster = ORBITER

**ROMACO Innojet has >10 years experience in HMC !**

## BonuWax® P 200.10

**BonuWax®** is a fine, homogenous mixture which can be used for hot melt technology.

The recommended weight gain is between 15% up to 50%.

<b>Coating Equipment</b>		Ventilus® 2.5
<b>Spray procedure</b>		continuous
<b>Tablet load</b>	(kg)	0.5
<b>Product temperature</b>	(°C)	38 - 40
<b>Atomizing air pressure</b>	(bar)	1.5
<b>Temperature atomizing pressure</b>	(°C)	120
<b>Spray rate</b>	(g/min)	5
<b>Inlet air temperature</b>	(°C)	35
<b>Exhaust air temperature</b>	(°C)	40 - 43
<b>Drying air volume</b>	(m <sup>3</sup> /h)	35
<b>Weight gain</b>	(%)	15 - 50





### BonuWax®

ready-to-use excipient premix **BonuWax®**

for hot melt coating is a water and solvent free application and provides good moisture sealing, taste masking and stability for granules and particles.

**BonuWax®**, consisting of **carnauba and/or beeswax plus two additional lipids**, has a suitable melting temperature and is easy to apply on particles and granules by a fluid bed coating process. **BonuWax®** can be sprayed with a 100% solid content which leads to a high productivity.

# List of InnoTech Processing Equipment [extract only]



➤ **VENTILUS® V Lab\*** incl. cooling device ICD 5 & Hotmelt device IHD 5  
incl. smaller product containers: IPC 2.5 & IPC 1.0 lit.  
Incl. air-dehumidifier MUNTERS

➤ **VENTILUS® V Pilot\*** incl. Hotmelt device IHD 5  
incl. smaller product container: IPC 10 lit.

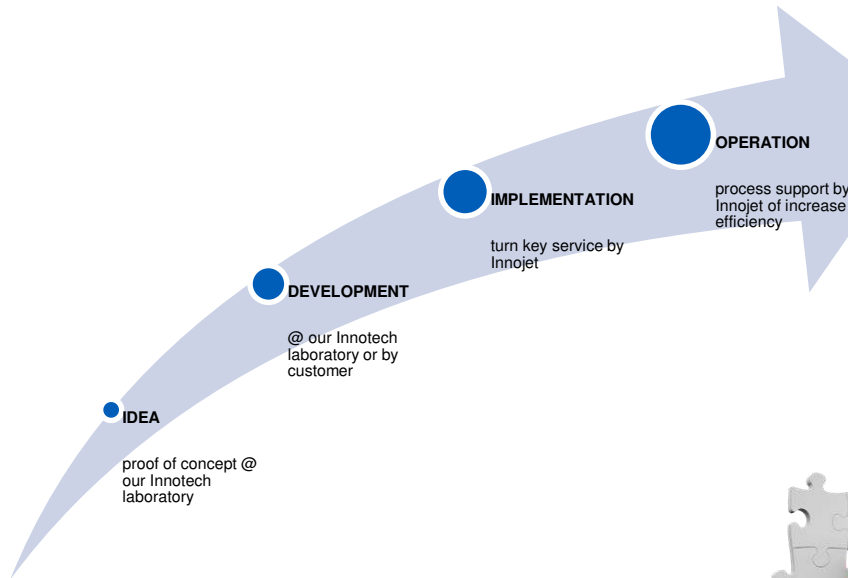
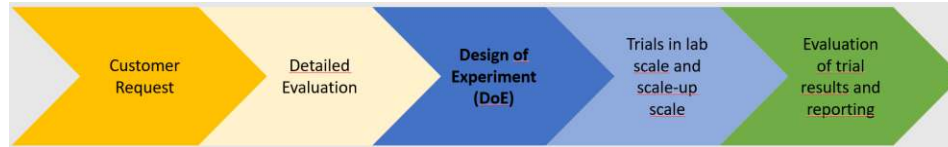
➤ **VENTILUS® V 150** incl. discharge container with air-filter-system\*

➤ **Retsch CAMSIZER X2** PSD measuring unit



# InnoTech

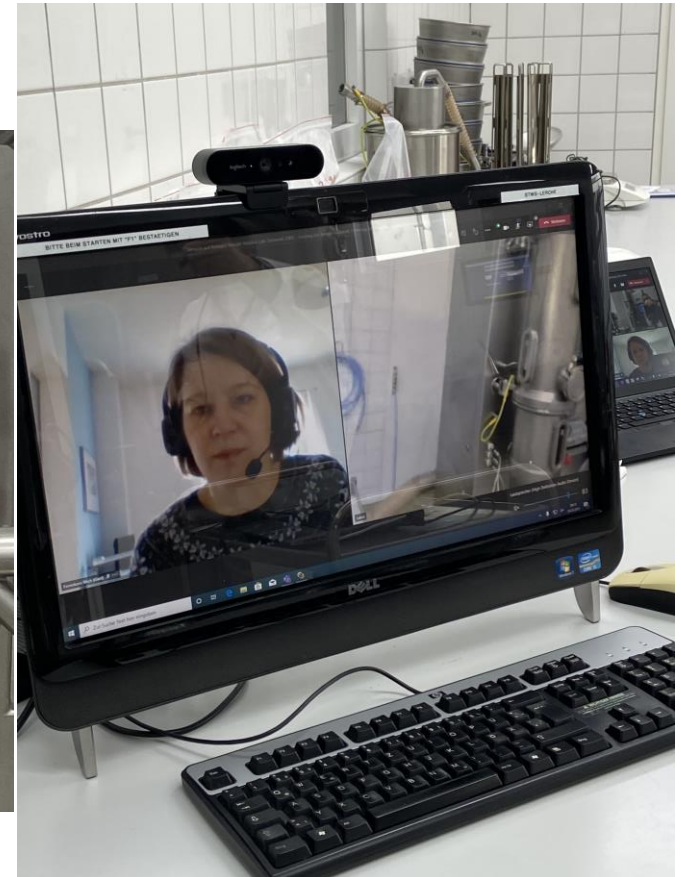
@ Innojet in Steinen





Several Trials:

- Via Live streaming (MS-Teams)



## Product trials worldwide

Laboratory equipment is at our customer's disposal locally



## VENTILUS®

**Rental – Concept**

**Decisions**

**made**

**easy:**

**Rent me ...**

**buy me... or**

**...return me!**



- VENTILUS® Lab scale is installed at our Sales and Service Centres in China, Russia, USA and also planned in Mexico, but **can also be rent (in Europe only!)**
- Our customers can thus gain an insight into the benefits of the VENTILUS® technology "on their doorstep"



# Our Top Clients

– Working with the best



Our Customers appreciate Romaco's excellent service, reliability of equipment and added value through the variety of the Romaco Product Portfolio!

We look forward to meet you.

**BIOGRUND US**  
Production  
R&D // Sales  
Technical Support

**BIOGRUND CH**  
Sales  
Market development

**BIOGRUND DE**  
Production  
R&D // Sales  
Technical Support

**BIOGRUND RU**  
Sales  
Technical Support



*What's Your*  
**QUESTION?**  
ASK US NOW

*We thank you for your interest!*

