Glatt TwinPro®

The fusion of two batch processes, Glatt GmbH

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8. Consistent fluid bed components
9. Control system GlattView Batch

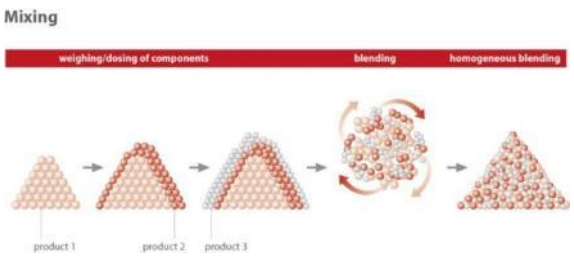
Typical granulation processors

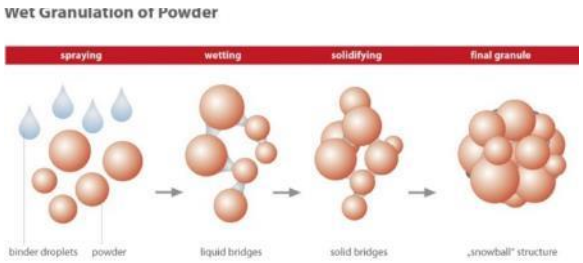
Fluid Bed Granulator

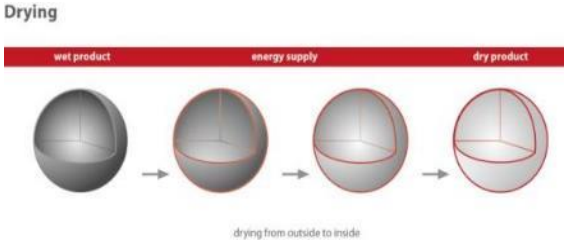
Granulation Line

High Shear Granulator

+Fluid Bed dryer







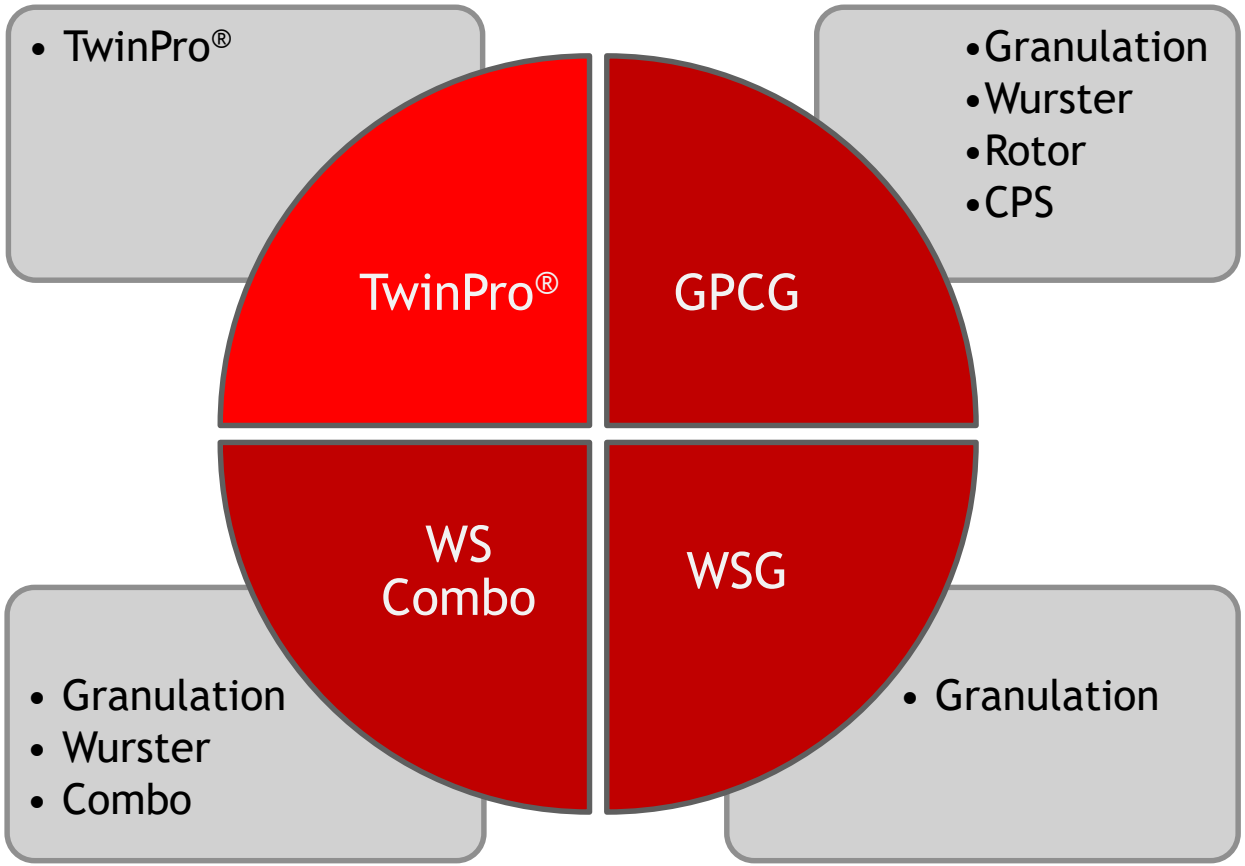
The new TwinPro® – fusion of two batch processes

standalone equipment

granulation line

1988	2014	2016	2018
first idea	initial decision	prototype	TwinPro®

TwinPro® -one out of 4 processors



Sizes and scale-up

	Lab	Pilot	Production	Production	Production
TwinPro®	10	65	200	400	600
VG	10	65	200	400	600

Scale-up of the machine

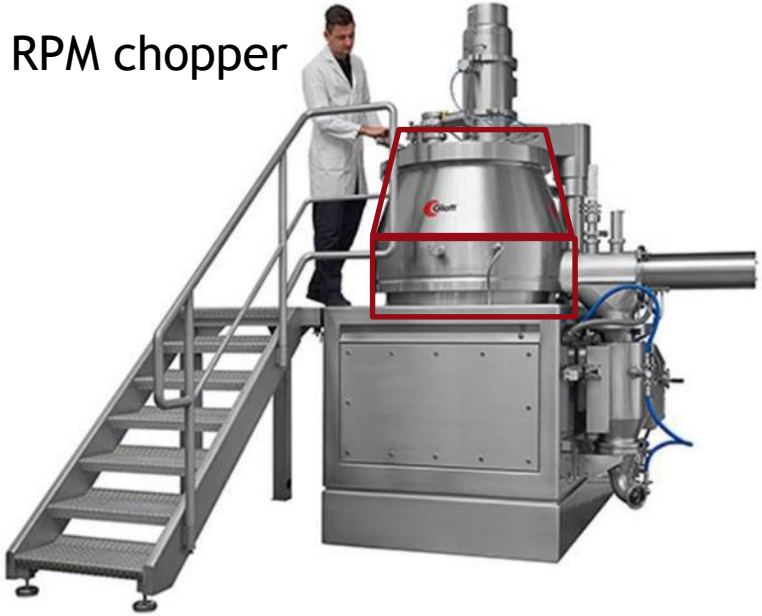
Tip speed

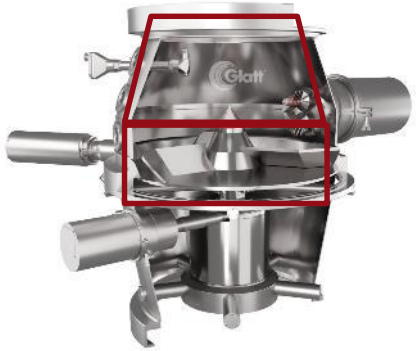
Dimensions of bowl > constant filling volume

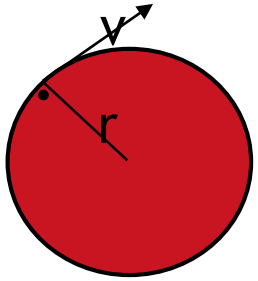
Dimension of Impeller > Swept volume

Liquid addition = Time or rpm > wet massing time

RPM chopper







$$P = 2\pi\, M\, n$$

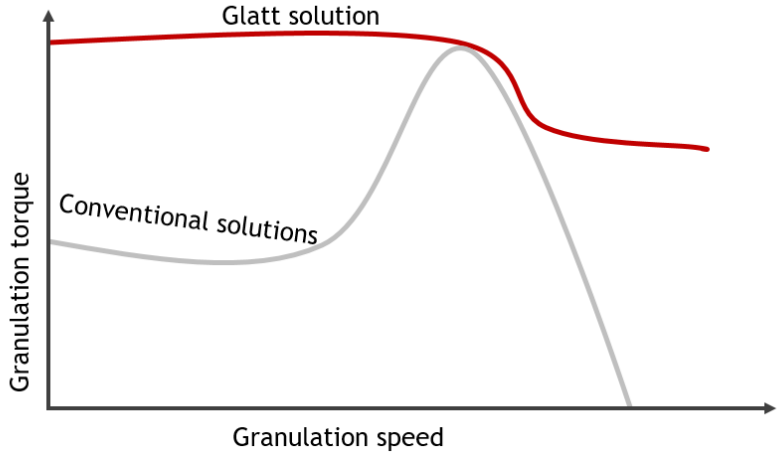
P = Power
M = Torque
n = Impeller Speed

Technical details - The innovative process insert

- **Granulation**
  - same Z-Rotor
  - same vessel shape
  - same volume
  - same nozzles
- **No milling**
  - as innovative chopper
- **No product transfer**
  - both processes in one container
- **Drying**
  - adjustable bottom plate

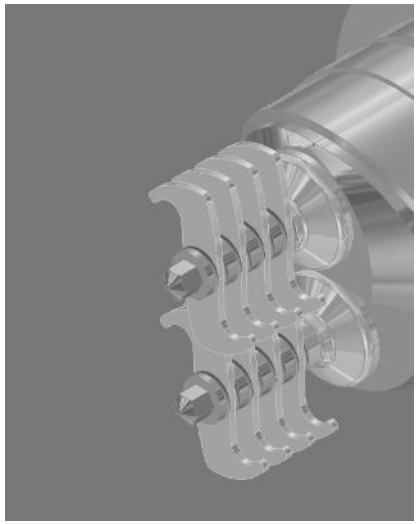
Technical details - Glatt Quantum “Q” Drive

- Immediate power by torque motor
- Direct drive, no gear and coupling
- Precise speed and torque measurement



Technical details – new chopper concept

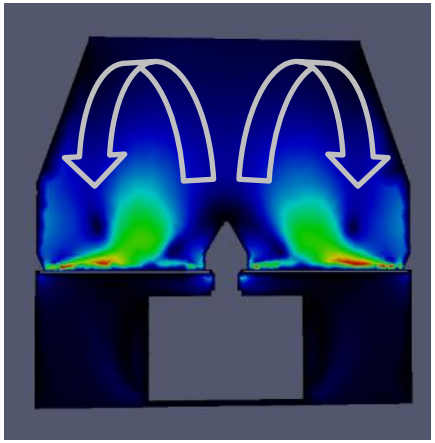
- 2 shafts + 10 blades
- No wet milling required



- Improved milling by new blade design

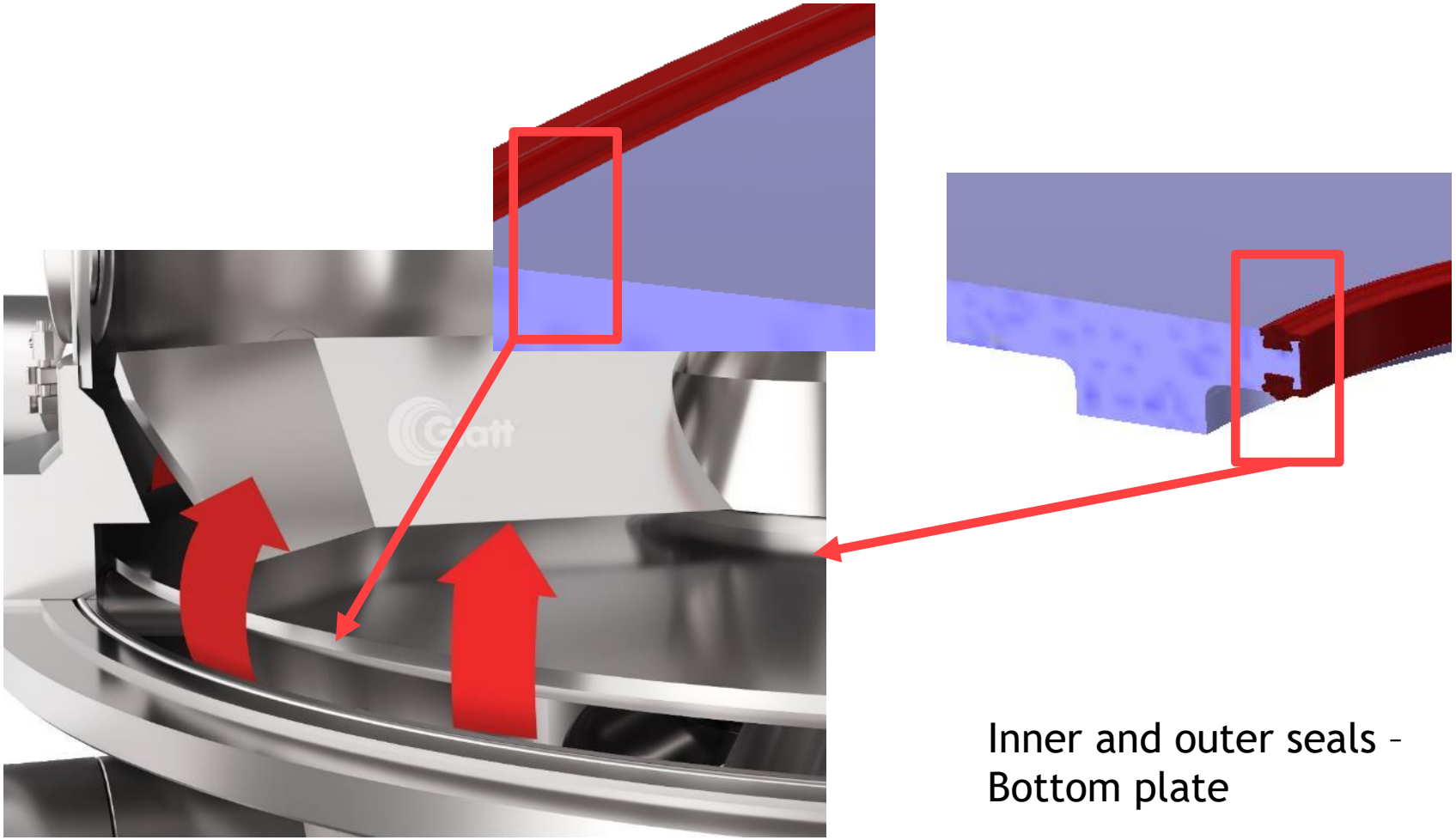
Technical details – Innovative drying concept

- Fully controlled bottom plate adjustment
- Shiftable bottom plate enables air gap between 0 and 8 mm
- Inner and outer air gap free area until 5%



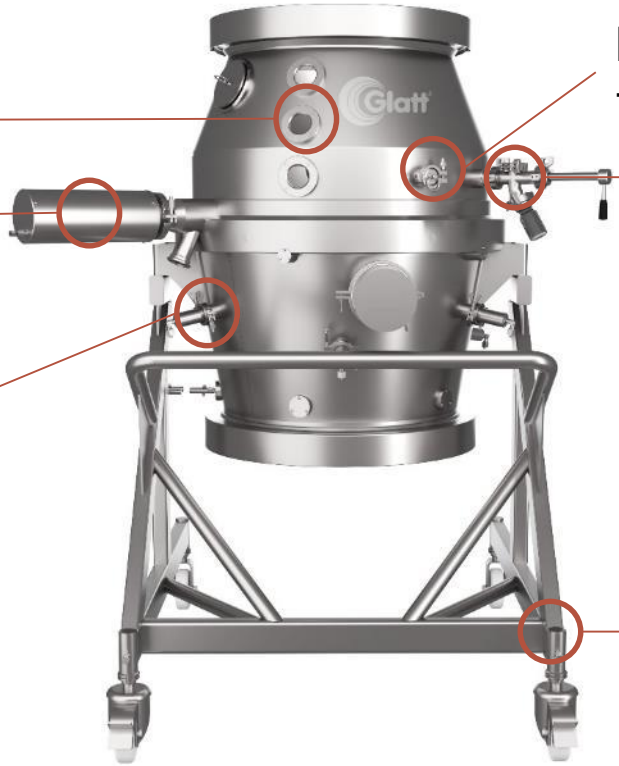
Simulation airflow velocity

Technical details – Innovative drying concept

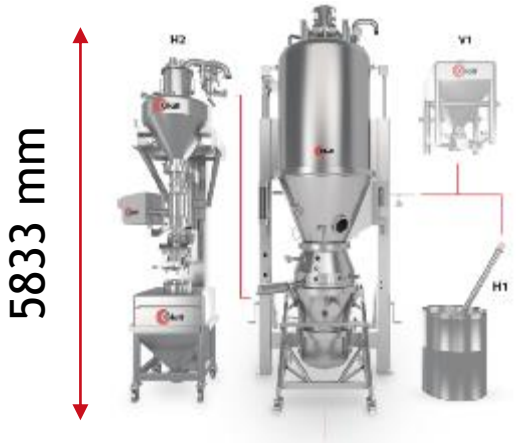


Inner and outer seals – Bottom plate

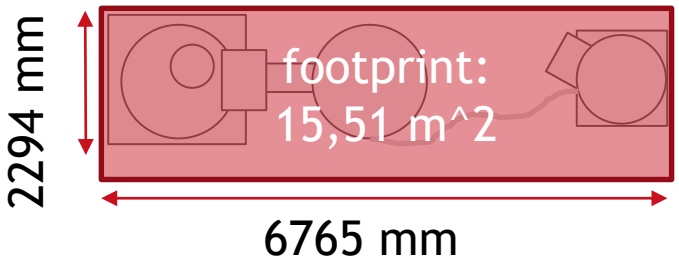
Technical details – Further components



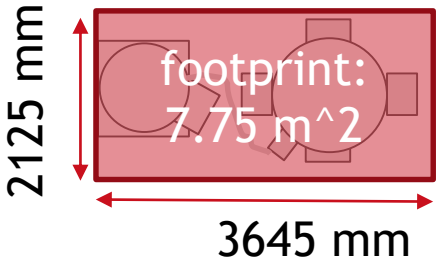
Comparison - Size



Granulation line



TwinPro®



Comparison – Process Time

½ - 1 hour

TwinPro®

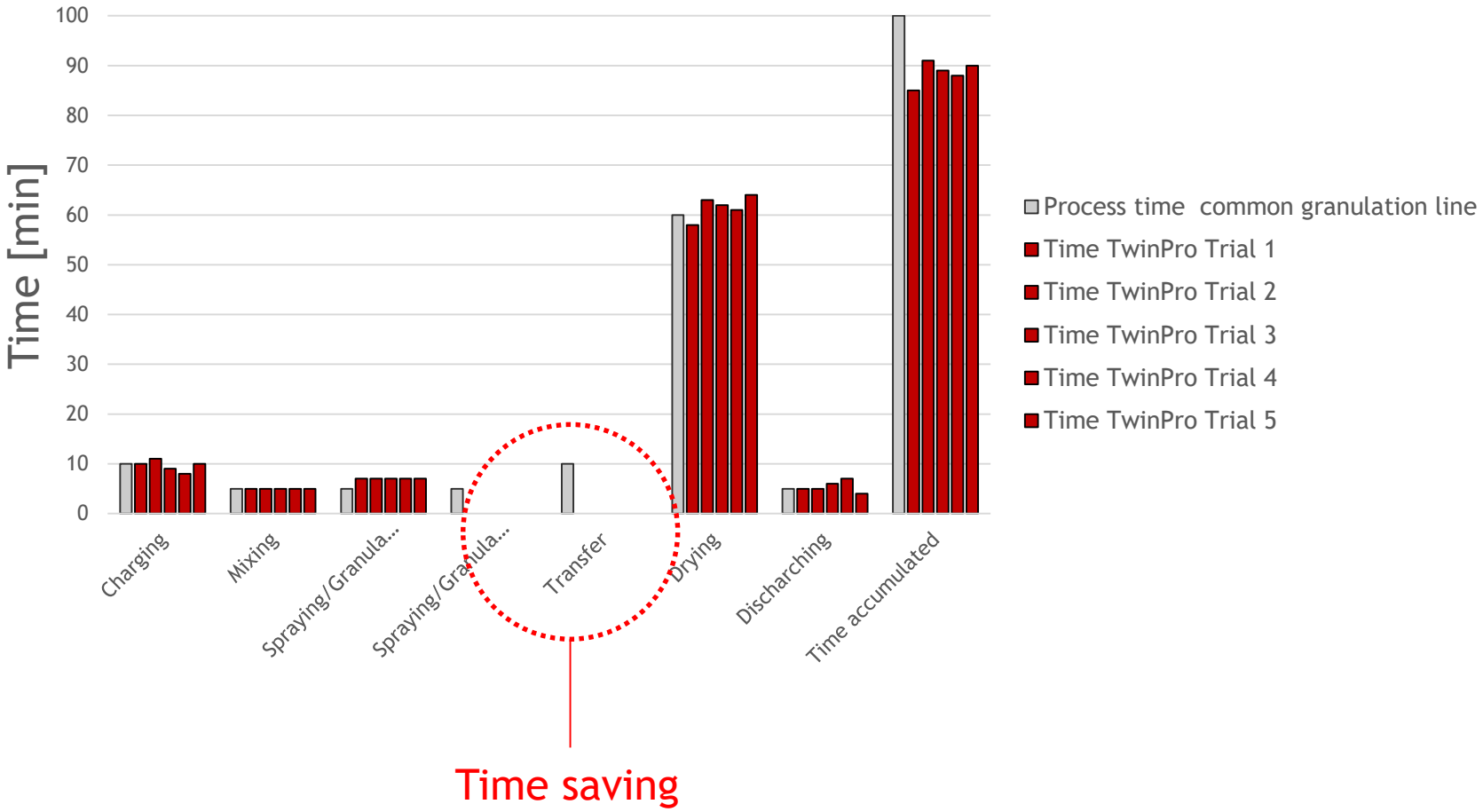
VG | **transfer** | **WSG**

2 - 4 hours

VG incl. drying = Single Pot

Process time [h]

Comparison - Time Granulation Line



Comparison - Yield

Granuline

Campaign	Charging	VG	Transfer	Dryer	Discharging	Accumulation
Accumulation						**95,03%**
Batch 1	99,90%	97%	97,00%	98%	99,70%	91,84%
Batch 2	99,90%	98%	99,00%	99%	99,90%	95,86%
Batch 3	99,90%	98%	98,00%	101%	100,50%	97,39%

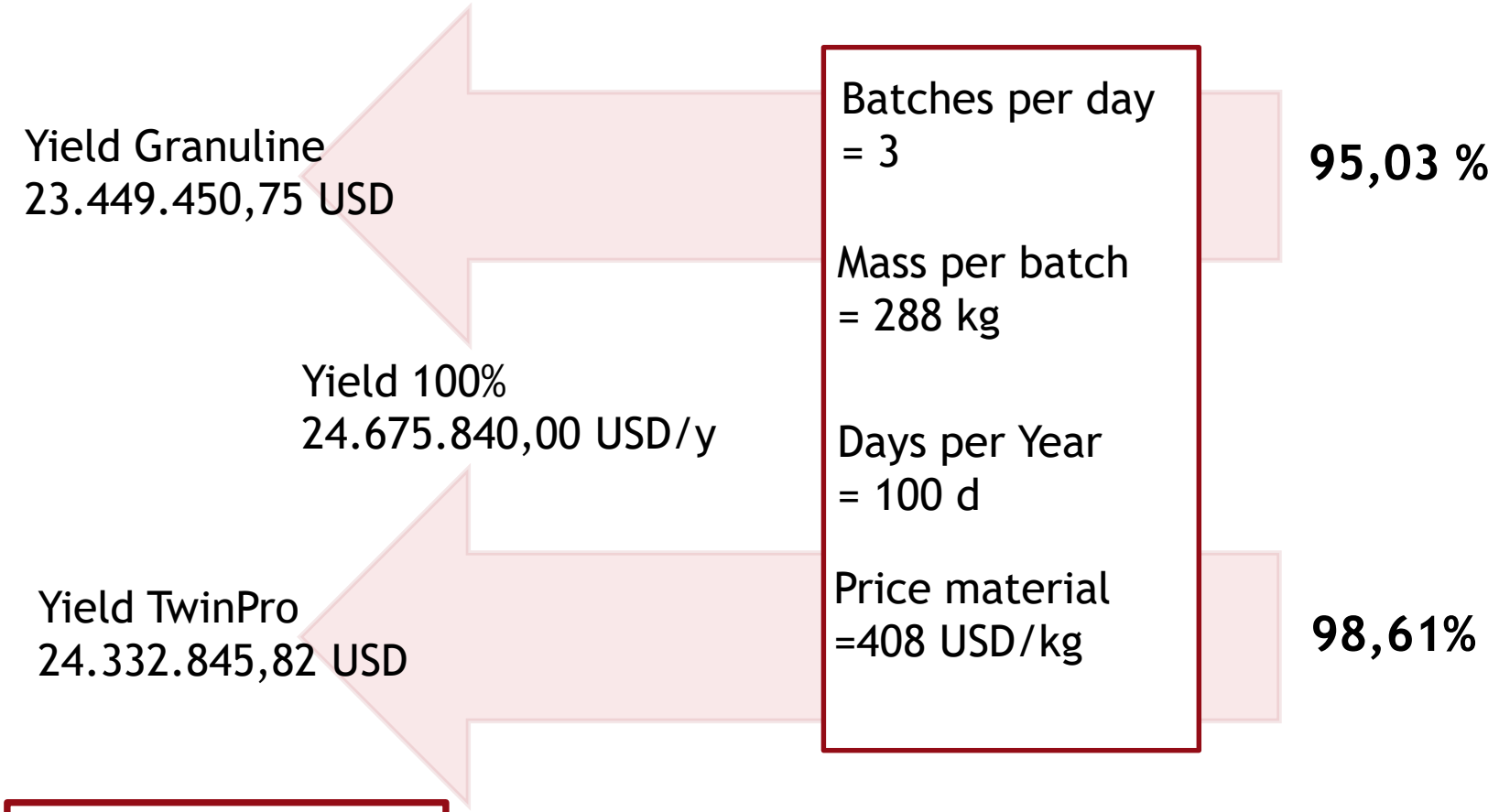
TwinPro

Campaign	Charging	TwinPro	Discharging	Accumulation
Accumulation				**98,61%**
Batch 1	99,90%	96,50%	99,70%	96,11%
Batch 2	99,90%	98,50%	99,90%	98,30%
Batch 3	99,90%	101,00%	100,50%	101,40%

Comparison - Profit

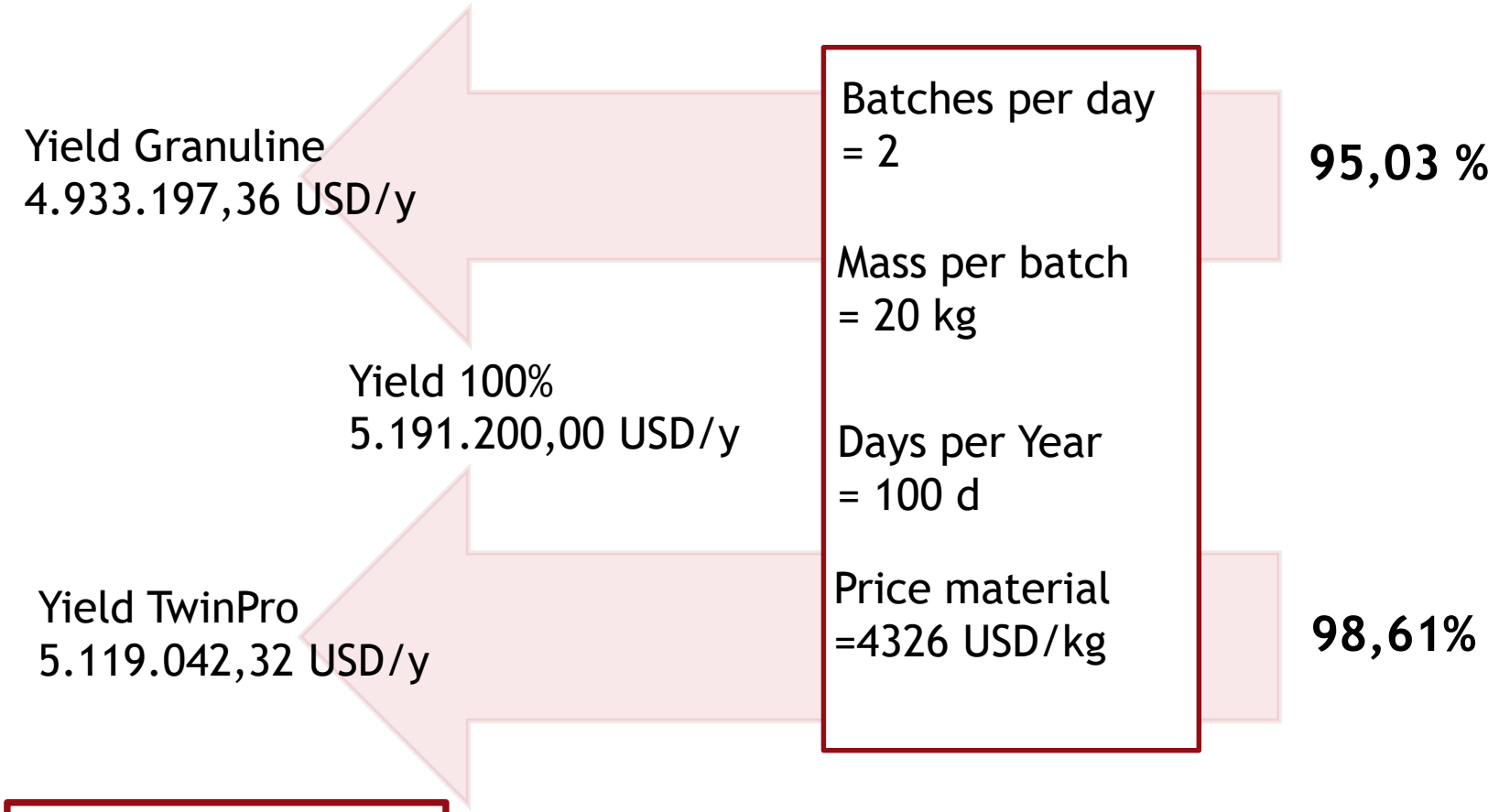
	Produkt 1	cheap								
	kg		d			kg	USD			
	Batch capacity	Batches per Day	Days per Year	Price/kg	API Conc	mass per year	theoretical Yield per year (100%)	Batch yield	practical Yield per year	lost
Granuline 600	288	3	100	84	90%	77760	6.531.840,00	95,03%	6.207.207,55 USD	324.632,45 USD
TwinPro 600								98,61%	6.441.047,42 USD	90.792,58 USD
Profit TwinPro										**233.839,87 USD**
	Produkt 2	expensive								
Granuline 600	288	3	100	408	70%	60480	24.675.840,00	95,03%	23.449.450,75 USD	1.226.389,25 USD
TwinPro 600								98,61%	24.332.845,82 USD	342.994,18 USD
Profit TwinPro										**883.395,07 USD**
	Produkt 3	Onco								
Granuline 65	20	2	100	4326	30%	1200	5.191.200,00	95,03%	4.933.197,36 USD	258.002,64 USD
TwinPro 65								98,61%	5.119.042,32 USD	72.157,68 USD
Profit TwinPro										**185.844,96 USD**

Comparison – Profit high volume product



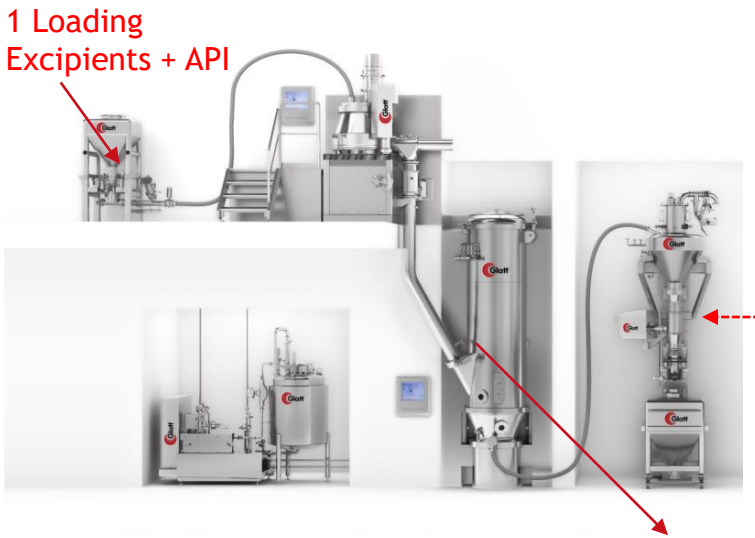
Profit with TwinPro
=883.395,07 USD/y

Comparison – Profit Onco product



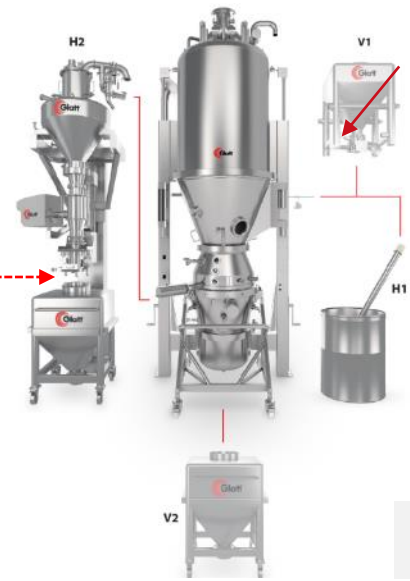
Profit with TwinPro
=185.844,96 USD/y

Ideal for Total Containment



Granulation Line

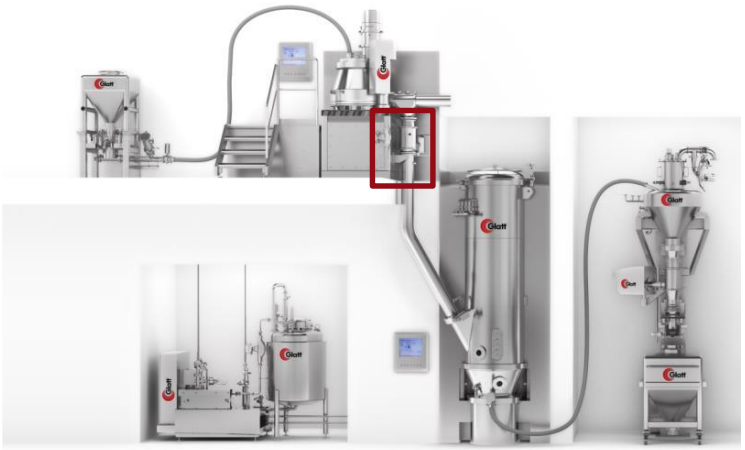
Discharge



TwinPro®

- No wet product transfer
- Loading and discharge with containment interface
- Less surfaces in product contact
  - → less cleaning
  - → higher yield
- Option: Multi purpose processor for Top spray & Pellet coating

SUPAC (Scale-up and post-approval changes)



Granulation Line

Dry Mixing in High Shear

↓

Wet Granulation

↓

Wet Milling

↓

Fluid Bed Drying

↓

Dry Milling

TwinPro®

Process results - Parameter

Agitator [rpm]	low/med	med	med	med/high	low/med	low/med	
Chopper [rpm]	off	off/low	low/med	high	med/high	off	
Inlet air [m^3/h]	1200	-	-	-	1500	1700 (30%)	
Air temp [°C]	-	-	-	-	60	-	
Duration [min]	5-10	2-5	3-10	0-3	20-30	5-10	Min 35min Max 68min

Granulation can be implemented in drying step

Process results - TwinPro® 200 Metformin

Metformin 50000 g
Water 4500g
PVP 1500 g

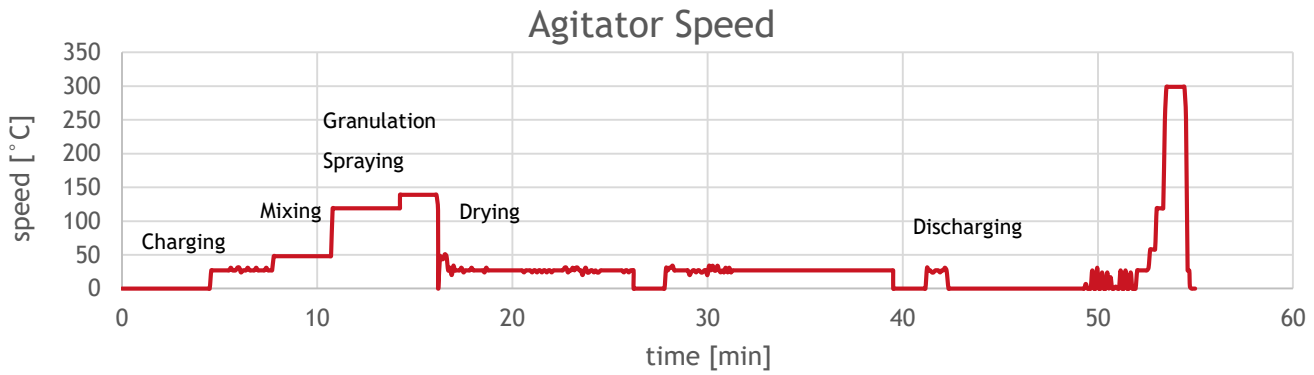
Yield: 98,3 %
Moisture Dry Product: 1,05 %

Filter after full process

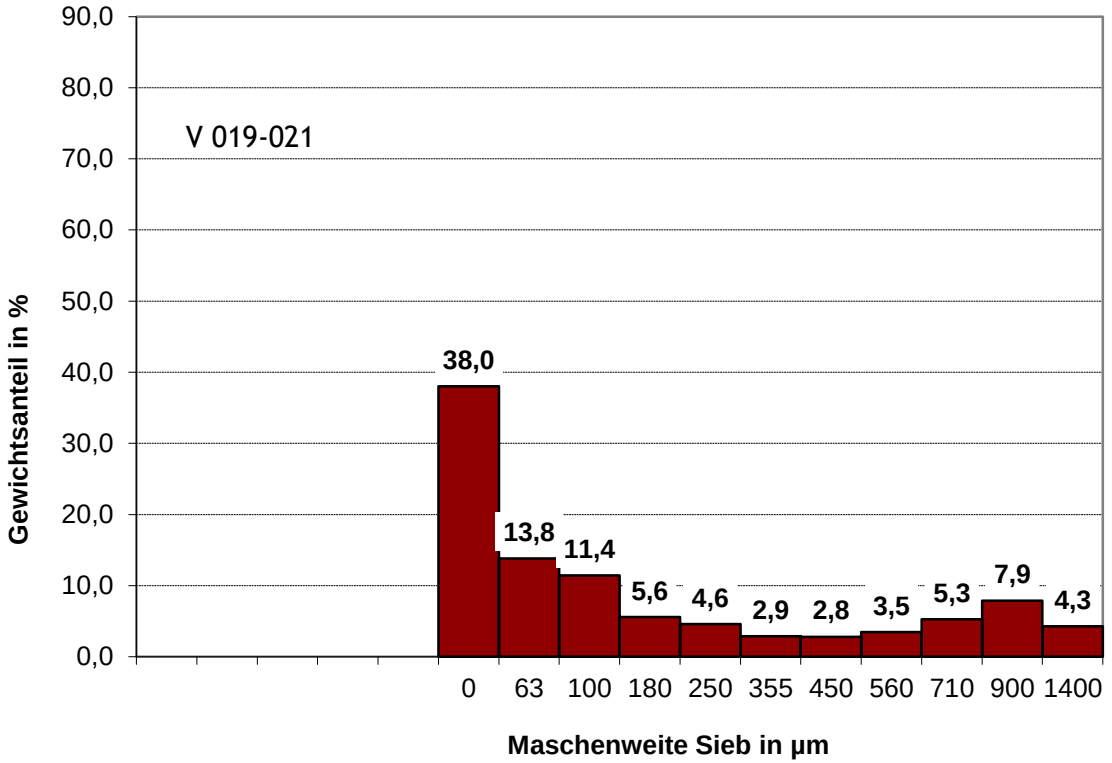
Product container after full process

Process results – TwinPro® 200 Metformin

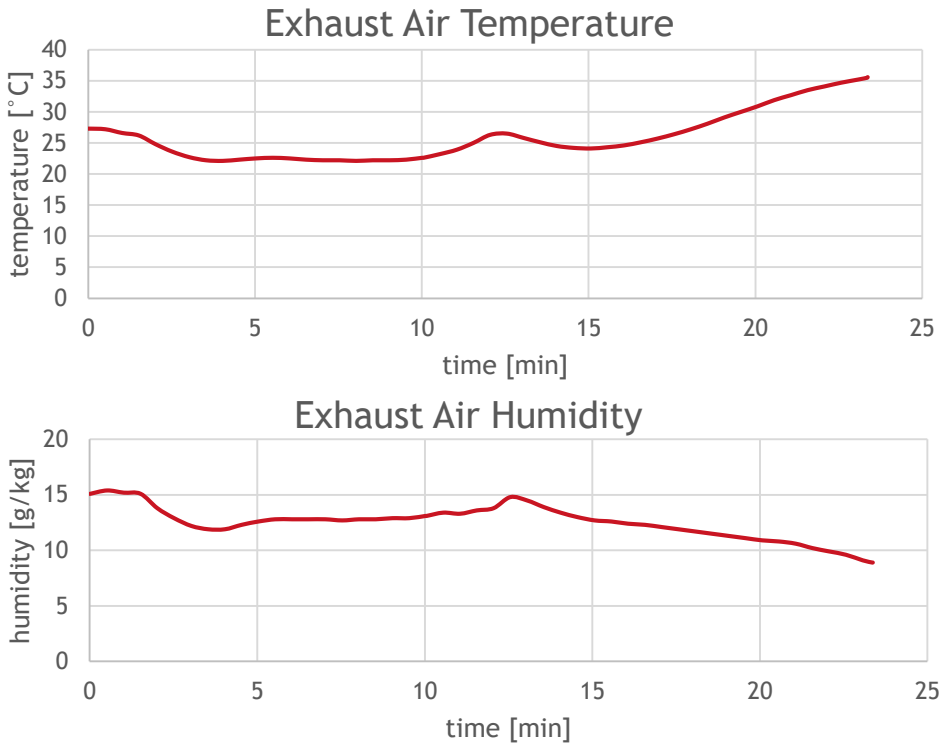
Process Step	Time [min]
Charging	8
Mixing	3
Spraying	6
Granulation	2
Drying	23
Discharging	15
Total Time for Trials (Summary + Discharging)	**56**



Process results – TwinPro® 200 Metformin



Process results –TwinPro® 200 Metformin

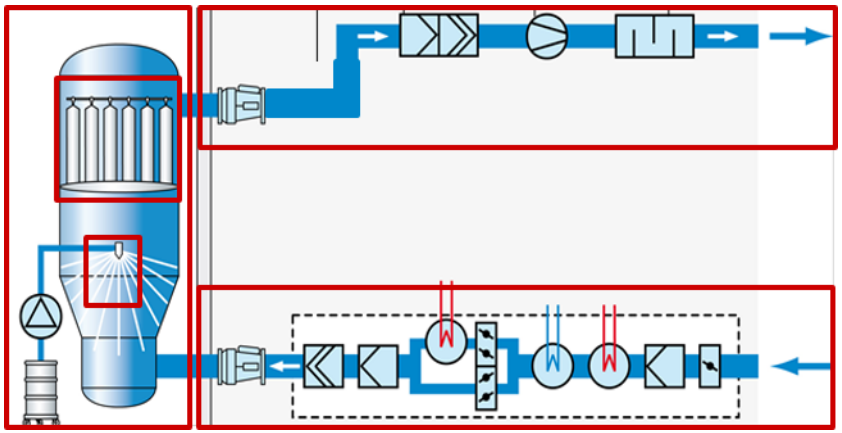


Wet mass
LOD 9.9 %

Drying

Dry granules
LOD 1,05 %

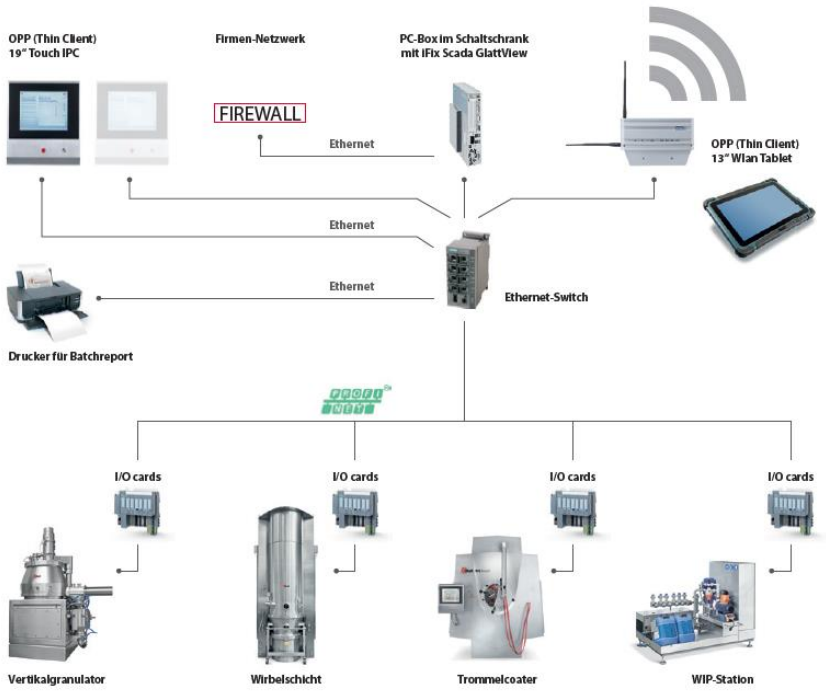
Consistent fluid bed components



1. air handling unit
2. product filter
3. cleaning options
4. Ex-concept
5. PAT-options
6. total containment options

Control system – *GlattView* Batch

GlattView | BATCH



GlattView Basis-Software

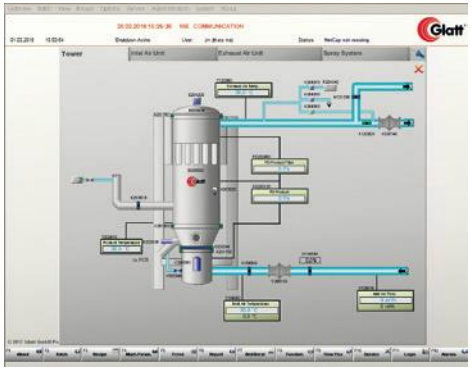
- Operating System Windows 7 / 10
- MS SQL server
- Office 2016
- SCADA Software iFix 5.5 from GE

GlattView Batch process control

- Phase control
- Unlimited number of recipes
- Recipe editing during ongoing batch processing
- Recipes with authorization functions
- Backup and restore functions (manual & automatic)
- Audit trail including viewer
- Other options on request

Control system – *GlattView* Batch

GlattView | BATCH



Intuitive graphical operating system

- Complete touch operation with optimized screen design
- Large 19” monitor (21” optional)
- Perfect ergonomics with freely positionable tilting panel
- Individual configuration
- High operating reliability

Advice trials in the Innovation Center to customers!