

Process Design Strategy: The Advantages of Continuous Filtration for Pharmaceutical Manufacturing

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BHS-Sonthofen Inc.

presented at:



-
- BHS company profile
 - Batch vs. Continuous
 - Filtration Processes
 - Continuous Indexing Vacuum Belt Filter
 - Case Studies

1607 First reference as smelter- and hammerworks

1888 Production of first twin-shaft batch mixer

1953 Production of first BHS Rotary Pressure Filter

•  more than 50 years experience in Filtration Technology



1991 Sale of shares of BHS AG to SKW Trostberg AG

1996 BHS-Sonthofen Management Buy-Out

1996 Foundation of BHS-Filtration Inc. in USA/Charlotte



2001 Foundation of BHS-Sonthofen in China/Tianjin



2007 Foundation of BHS-Sonthofen in India/Hyderabad



2011 Foundation of BHS-Sonthofen in France



Location



- BHS-SF
 - Engineering, Manufacturing, Sales, Service
 - 225 employees
- BHS India
 - Sales, Service
 - 10 employees
- BHS China
 - Manufacturing (mixers), Sales
 - 45 employees
- BHS-SF Inc.

- Charlotte NC
 - Moved to new facility May 2013
 - Office
 - Storage
 - Lab and Pilot Facility
- Filtration Division
- Mixing Division
- Recycling Division

Areas of Competence

Mixing Technology



Recycling Technology



Crushing Technology



Filtration Technology



Filtration Technology Portfolio

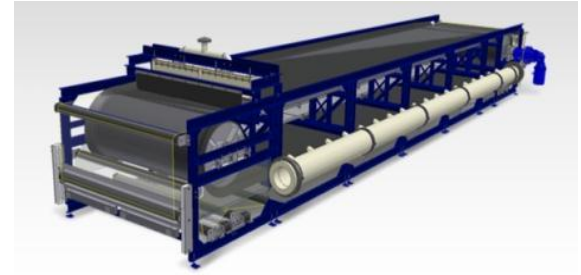
Rotary Pressure Filter



Indexing Belt Filter



Rubber Belt Filter



Candle Filter



Plate Filter



Autopress



Applications

- Chemical industry
- Petrochemicals
- Cellulose derivatives
- Pharmaceutical industry
- Food industry
- Environmental
- Power generation plants
- Further applications



- References
- More than 2000 filters sold worldwide!

Advantages of Continuous Manufacturing



- Lower Costs
- Shorter time to market
- Reduced Variability
- High Yield
- Increased Profitability

- Regulatory Requirements
 - <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM341197.pdf>
 - “Batch” or “lot” applicable to continuous process
- Quality Control Concerns
 - Relate process conditions to specific product quality results
 - Continuous monitoring
- Lack of Experience

Filtration Equipment

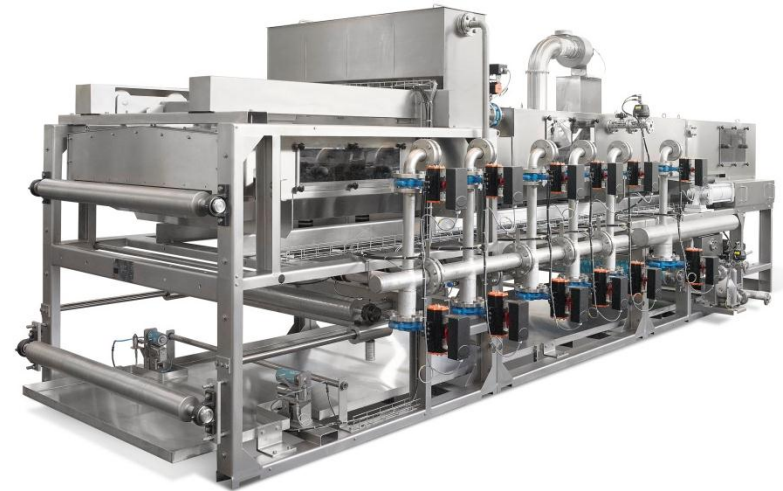


Nutsche Filter Dryer



Inverting Filter Centrifuge

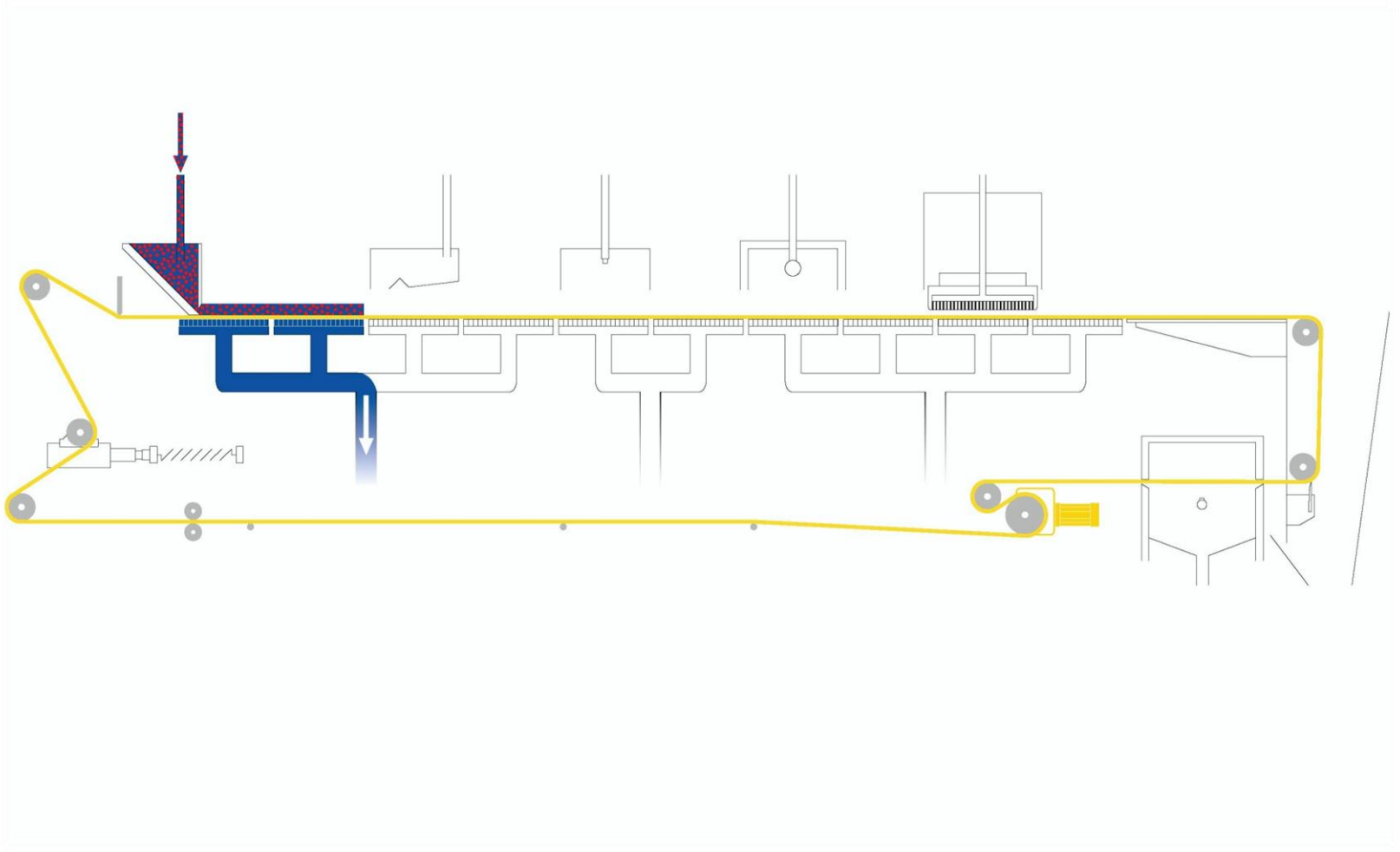
Filtration Equipment



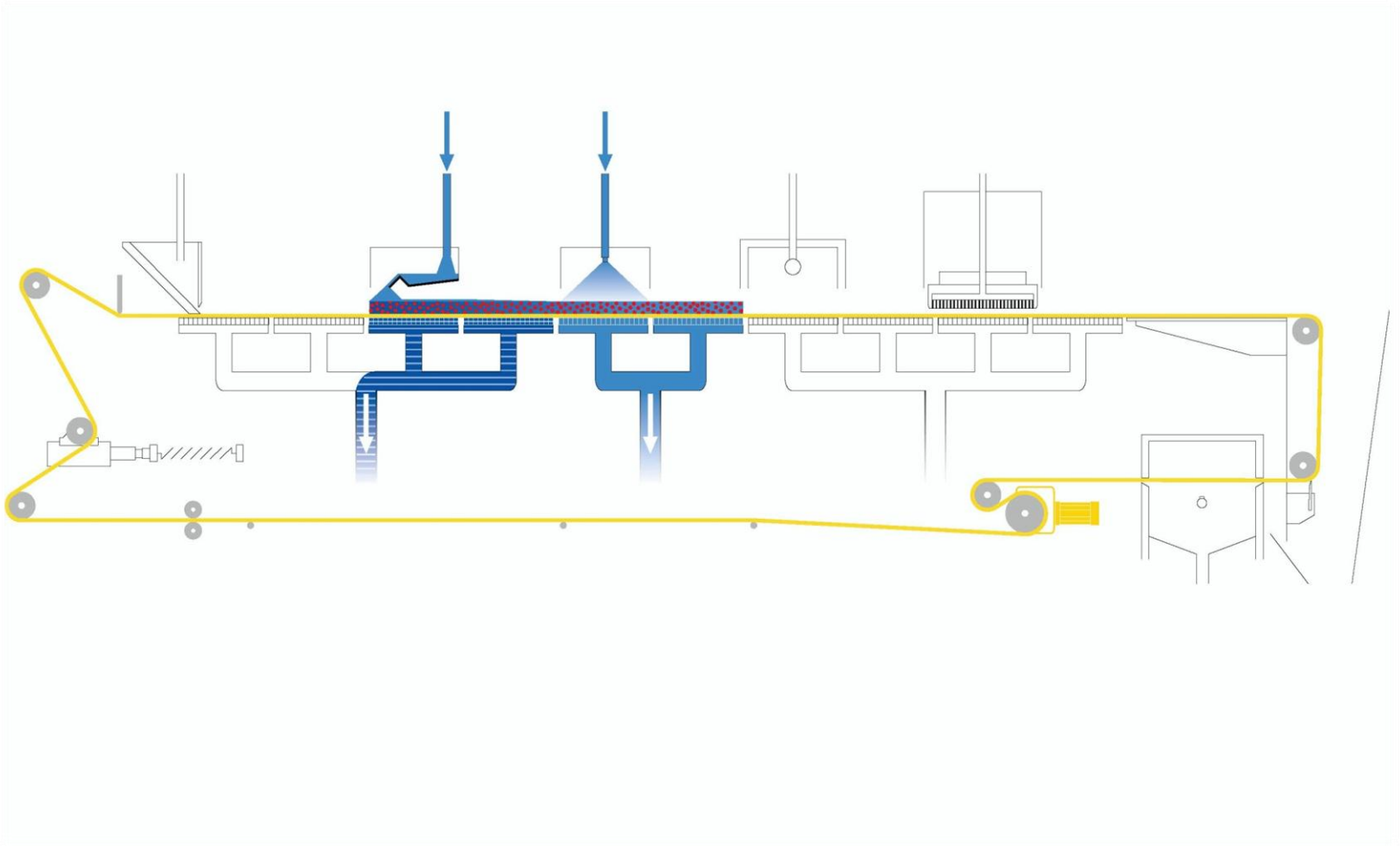
Continuous Indexing Vacuum Belt Filter

- Vacuum Filtration
Cake Thickness: 5 – 150 mm
- Cake Washing
Co-current and Counter-Current
- Drying
Vacuum, Convection, Pressing and Steaming

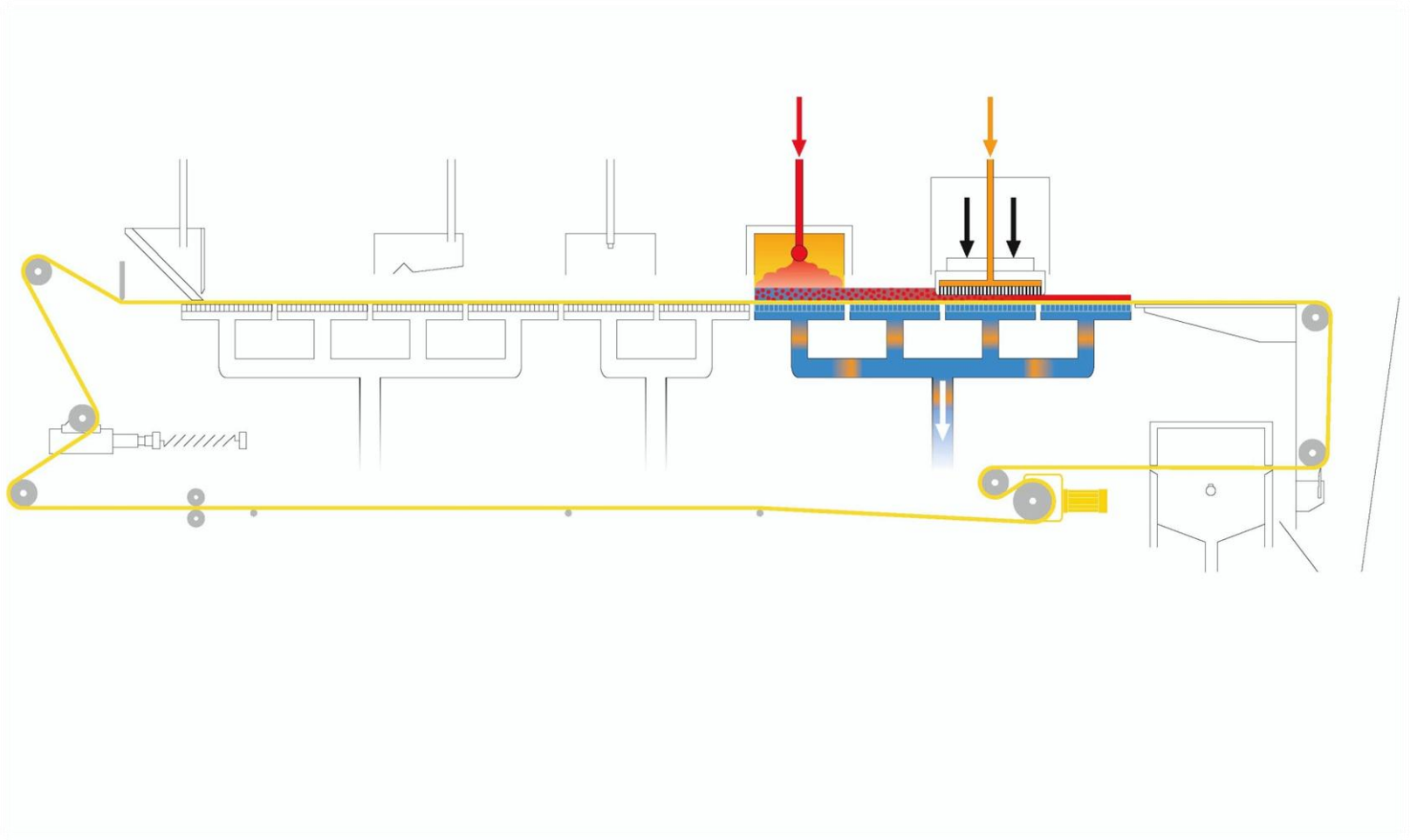
Phase 1: Suspension Feed and Cake Formation



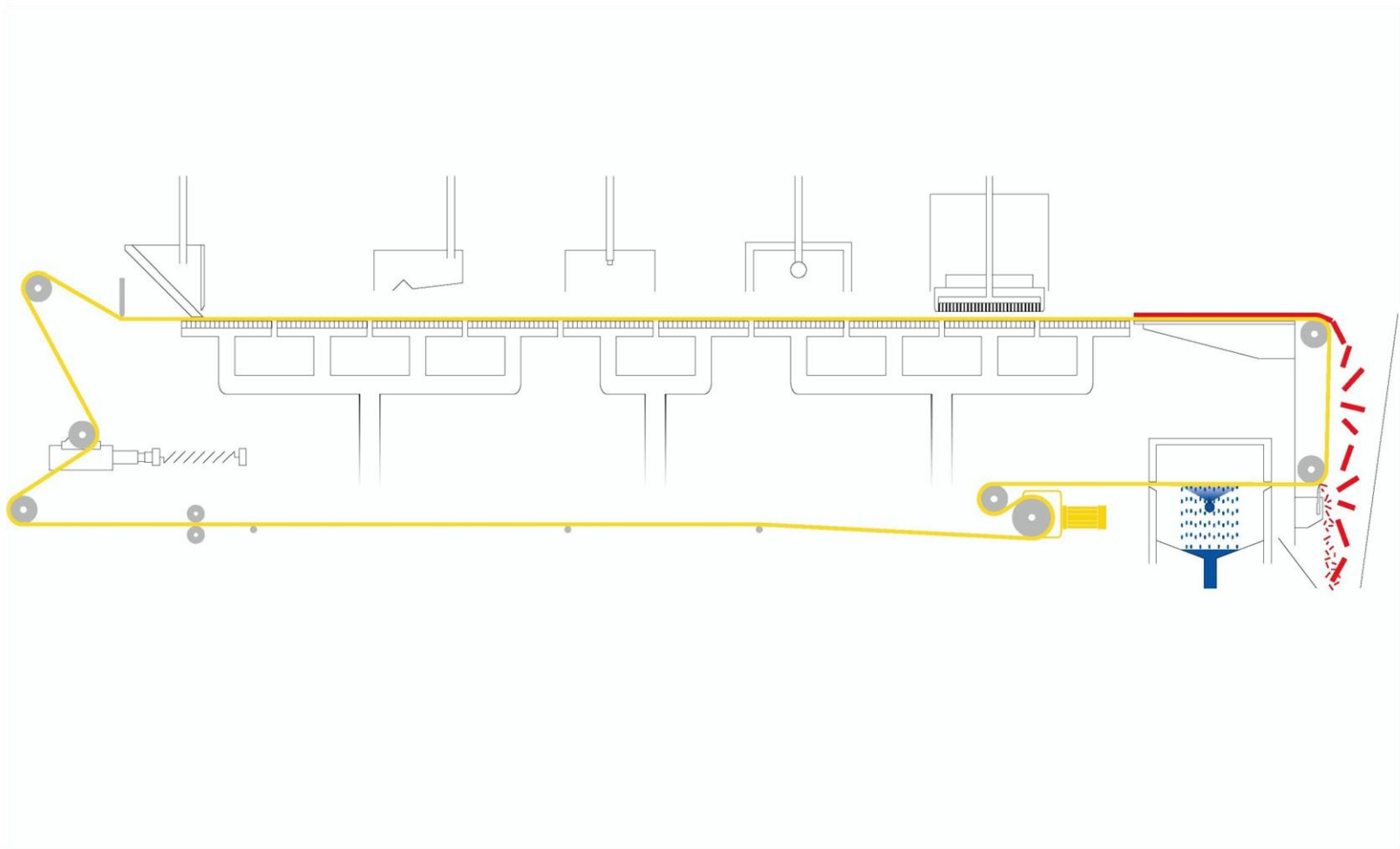
Phase 2: Cake Washing



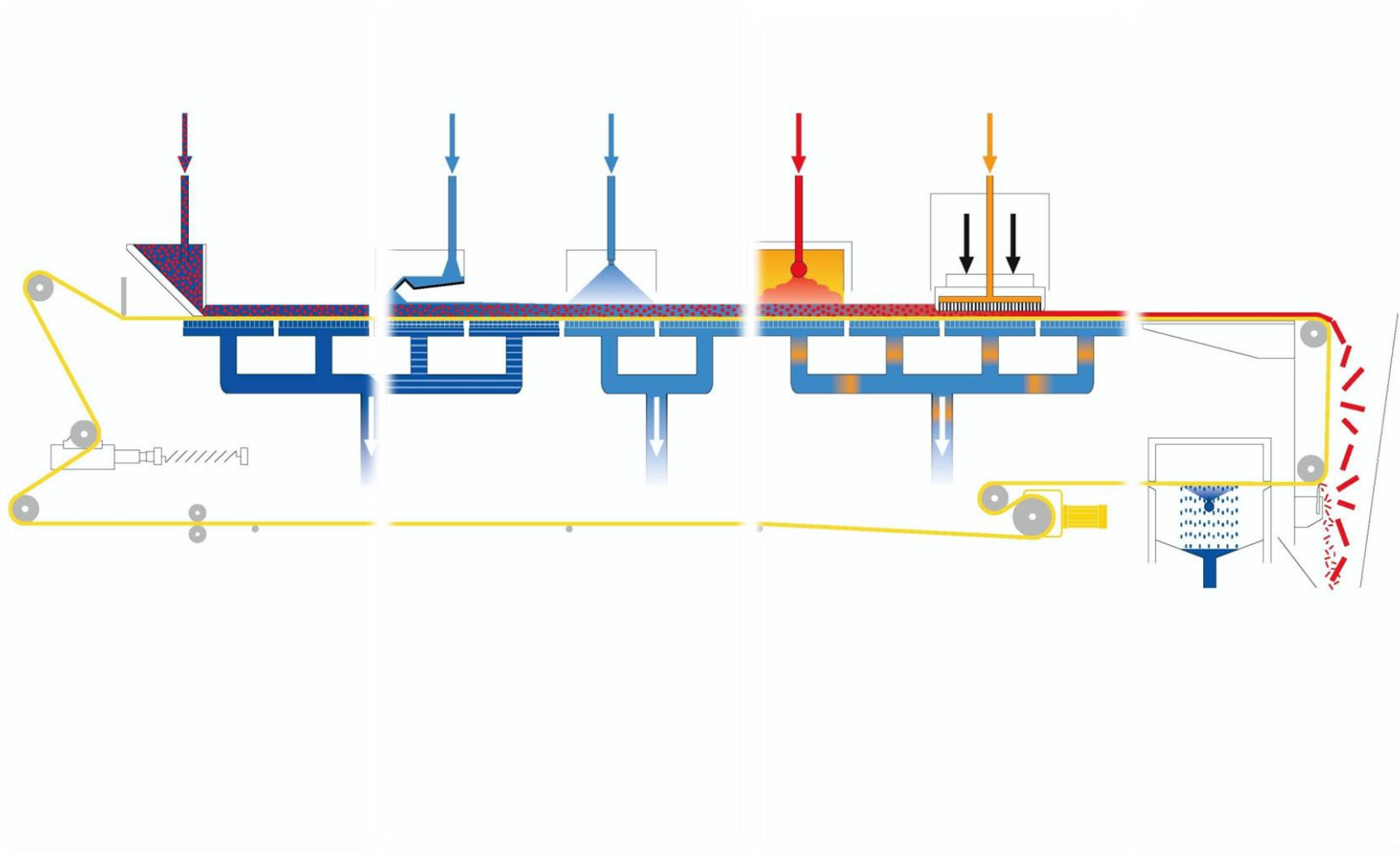
Phase 3: Cake Drying



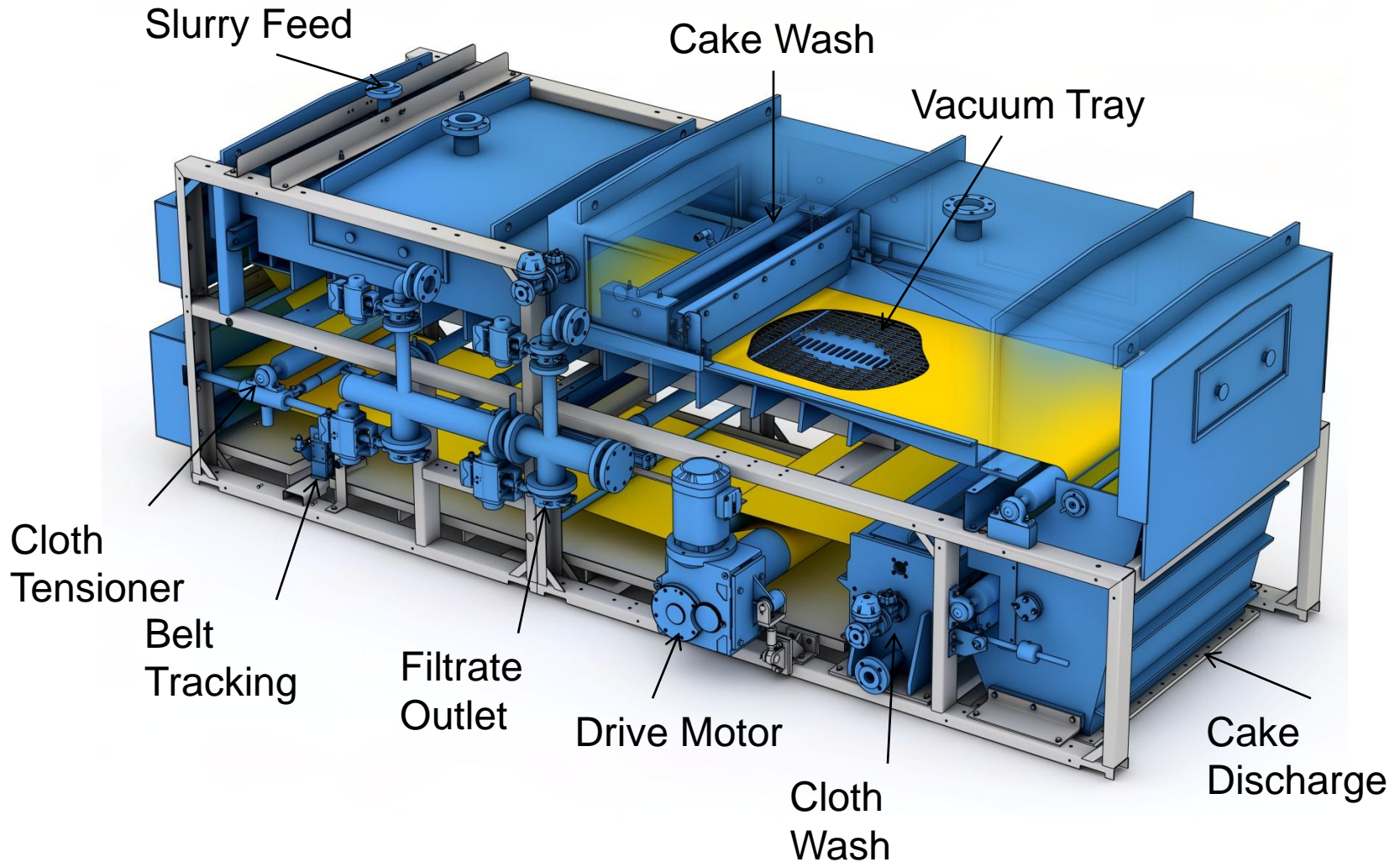
Phase 4: Cake Discharge and Cloth Cleaning



Each phase of processing happening simultaneously



Mechanical Design



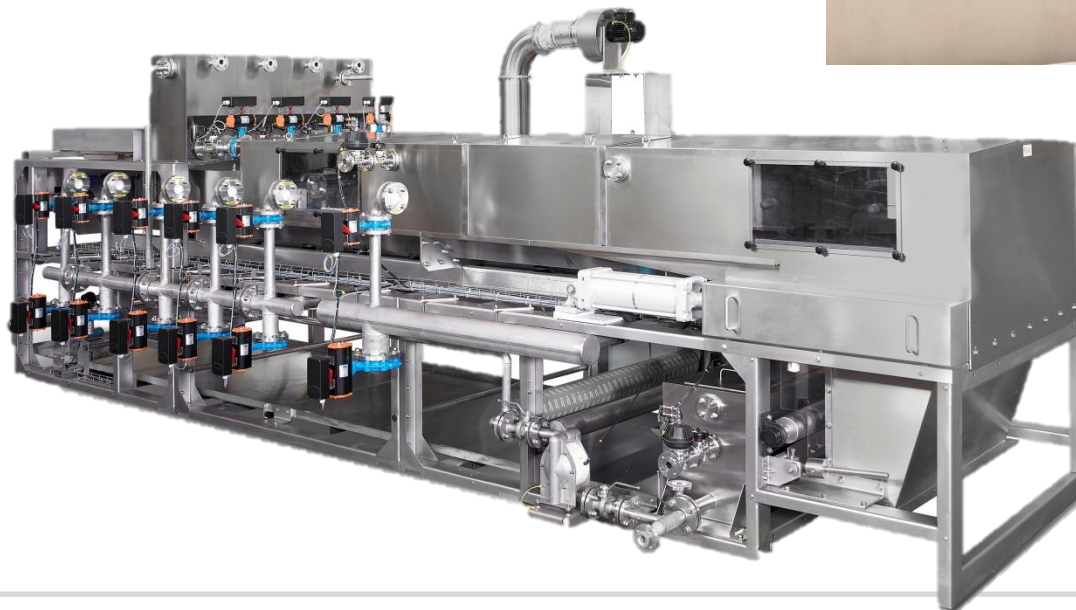
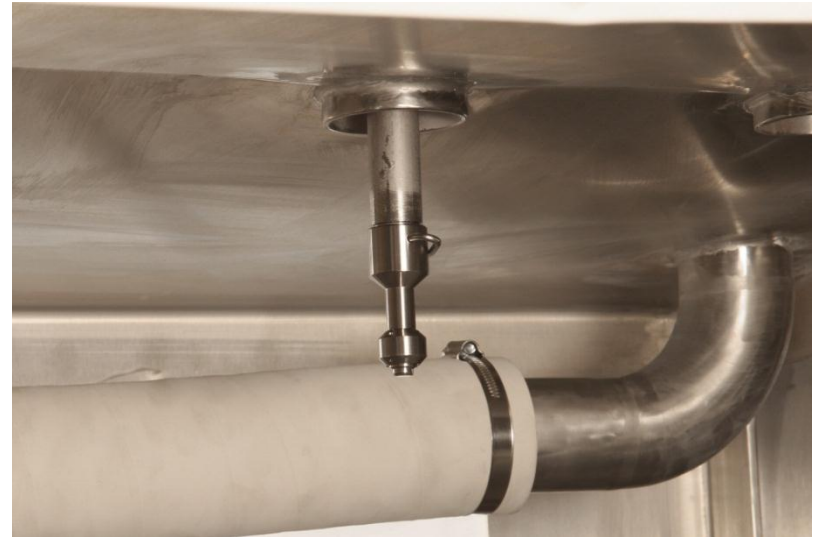
Mechanical Design: GMP options

- Polished Surfaces ($<0.76 \mu\text{m Ra}$)
- Welds ground smooth and flush
- Closed profile steel beams for frame



Mechanical Design: GMP options

- FDA approved components
- Tri-clamp connections
- CIP nozzles to clean tray, wash box
- CIP connections on piping
- Sloped (free draining) filtrate outlets
- Special designs for cleanability



Case 1: Organic Narcotic Filtration



Filtration Process – Separate solids and wash out ammonia and salts.

Solids:	organic narcotic crystals
Liquids:	water, ammonia, ethanol, dissolved salts
Design Capacity:	85 kg/hr DS
Cake Moisture Target:	45%
Filter Type:	BF 050-045
Filter Area:	2.25 m ²

200 l/hr cloth wash (recycled to filter cake)

350 l/hr fresh water cake wash

5 hp electric drive

20 hp vacuum pump (350 acfm)

Case 1: Process Challenges



Filter Sizing Strategy:

- Use required time for pressing and blowing as determining factor for zone area
- Decrease vacuum in filtration and washing zones to prevent cake cracking

Case 1: Mechanical Design Features

Isolation Valves at each zone outlet



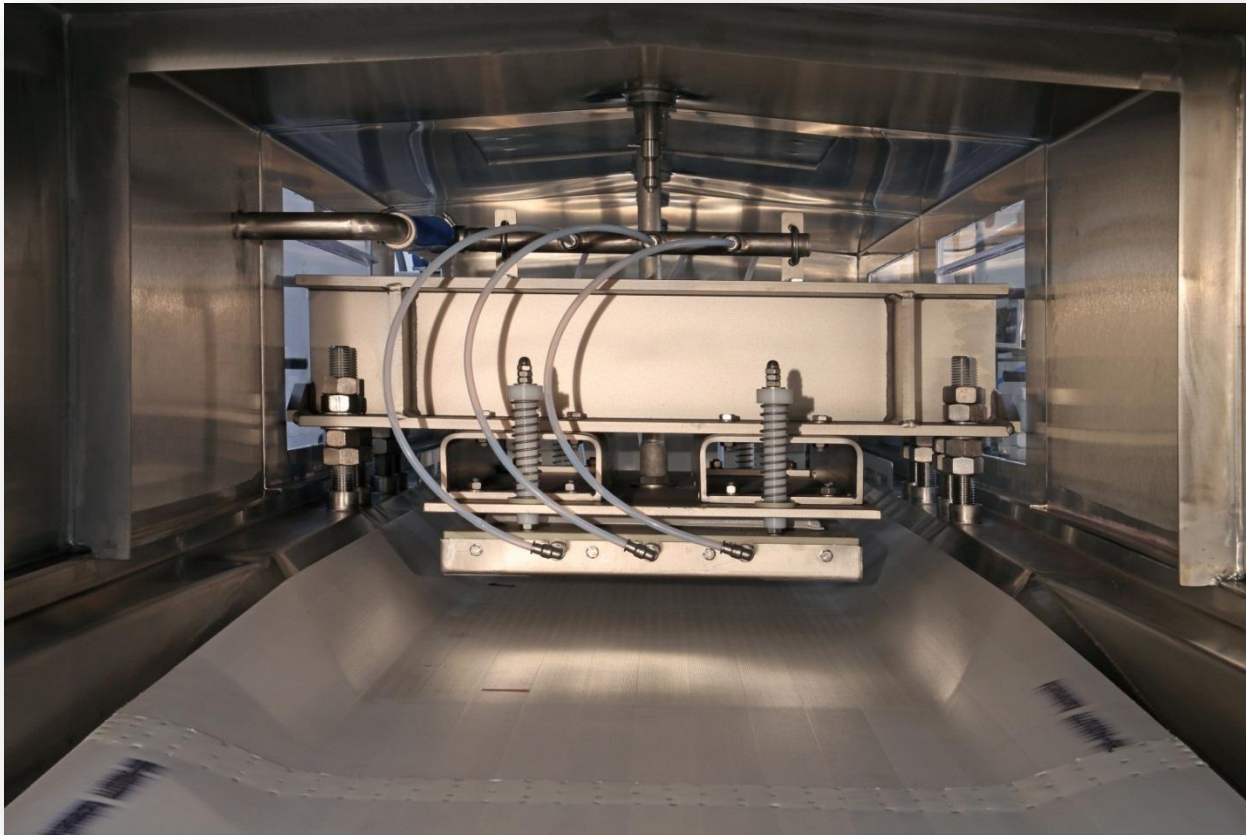
Case 1: Mechanical Design Features

Three individual filtrate receivers to allow for different vacuum levels for each stage



Case 1: Mechanical Design Features

Cake pressing required to minimize cracking during drying



Case 2: Metal Hydroxide Slurry



Filtration Process – intermediate step to remove chlorides

Design Capacity: 10 kg/hr solids (250 kg slurry)

Filter Type: BF 100-075

Filter Area: 7.5 m²

Chloride Target: 94% reduction

Cake Thickness: 7 mm

150 l/hr cake wash

50 l/hr cloth wash, recycled to cake

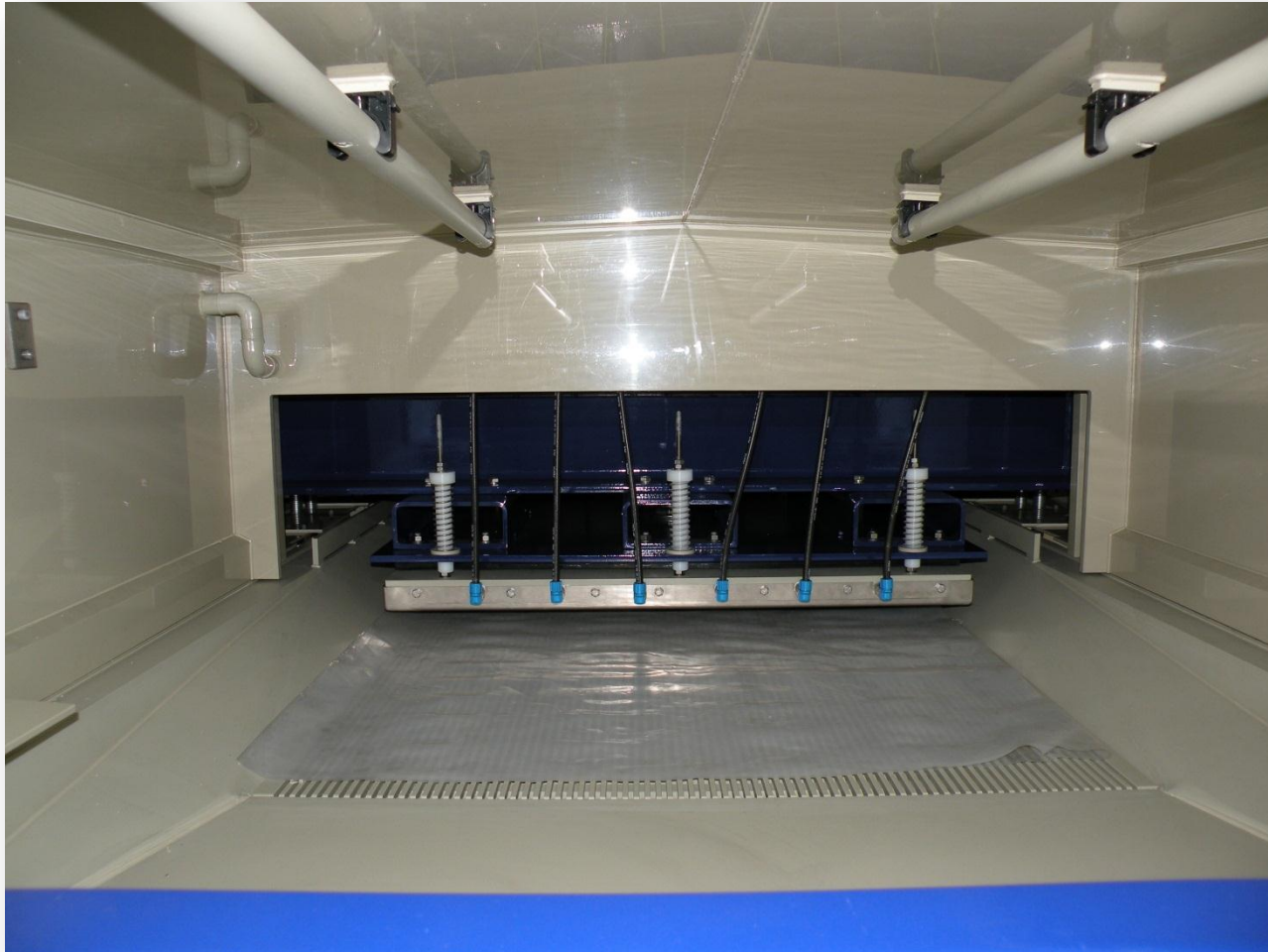
Case 2: Process Challenges

- Slow Filtration
 - Lab testing
 - Pilot testing (0.1 m², 0.6 m²)
- Thin cake
- Flooded wash

Case 2: Mechanical Design Features



Case 2: Mechanical Design Features



Case 3: Phospholipid Extraction

Filtration Process – extraction from solvent exchange

Slurry: egg yolk powder (25%) and ethanol

Design Capacity: 330 kg/h dry solids

Filter Type: BF 150-075B

Filter Area: 11.25 m²

Case 3: Phospholipid Extraction

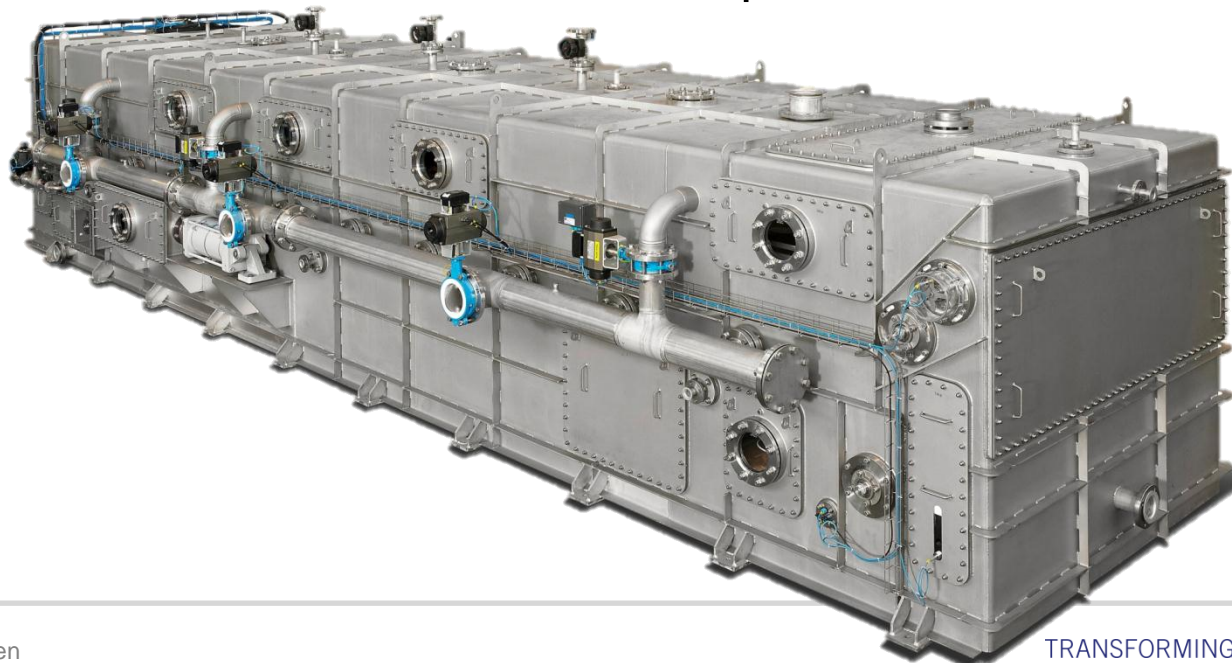
- Previous Process
 - Several mixing tanks with filtering bottom
 - Re-slurry with fresh ethanol x 2
 - Long cycle times
 - Did not fulfill FDA requirements
- CIVBF Process
 - Ethanol applied to filter cake by spray wash
 - Ethanol consumption reduced, yield improved
 - FDA validated for food grade and pharma grade material

Case 3: Installation



Case 3: Mechanical Design Features

- Enclosed (Box) Design
- Polished Surfaces – Product Contact
- Polished Welds on inner surfaces of filter housing
- Free Draining
- Non-metallic parts, FDA approved
- Tri-clamp connections on product contact parts
- Nitrogen Atmosphere
- CIP in housing (caustic solution) once per week



- Continuous processes offer significant advantages
- Continuous filtration possible for pharmaceutical manufacturing with indexing vacuum belt filter
- Many options exist for customizing equipment to specific process needs

Thank You



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