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Grace, Kung, Alfa Laval Taiwan Eric Li, Alfa Laval Taiwan Xiaoguang Li, Alfa Laval Sweden

Separation for Life

Biotech separation seminar in Taiwan

Content

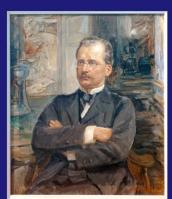


Seminar for separation challenge in biotech applications

- Alfa Laval company brief
- Alfa Laval involvement and perspective for Biotech market trend
- General separator applications
- Separation challenges in Biotech application
- Alfa Laval solutions and products
- Q/A

Who are we? What can we do?

Gustaf de Laval (1845-1913) Founder of Alfa Laval company



"The man of high speed"

- 200 projects and inventions
- 92 patents, including the milk separator (1878) and the steam turbine (1883)













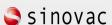




























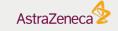














Market we are working for

Biotech market

Biopharma & pharma

- Antibiotic
- Insulin, GLP-1
- Human vaccine
- Animal vaccine
- Interferons
- Growth factor
- Therapeutic enzymes
- Antisera

Starter and probiotics

- Starter culture
- Probiotic for human
- Probiotic for animal

Cultivated meat and cosmetic

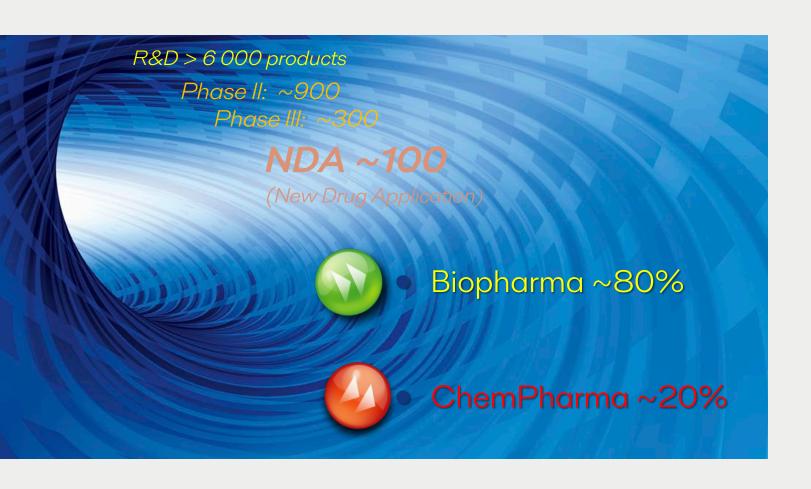
- Beef
- Chicken
- Fish
- Collagen







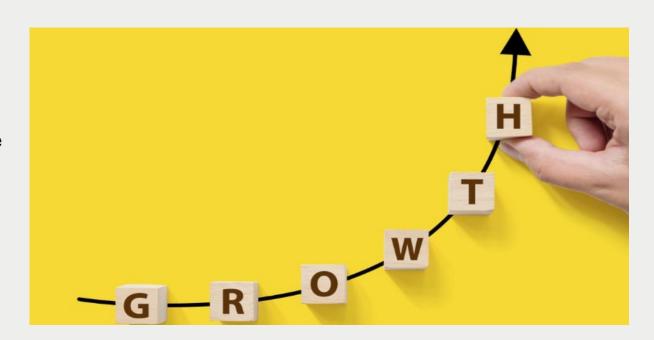
Our view of Technical trend



Our view of Market driver

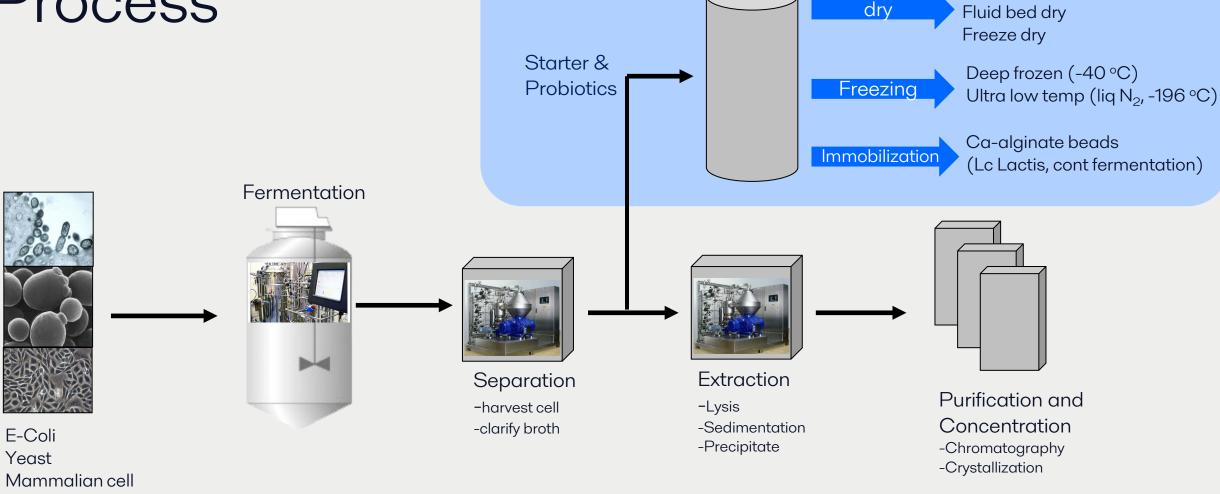
A very essential, fast and profitable market

- Market driver by improving of awareness of healthcare and people become rich to improve the healthcare awareness.
- Higher demands to the animal product (egg, milk and meats)
- Food safety
- Aging population
- Higher profits
- Compound Annual Grow Rate (CAGR) >10% during 2025-2030.



Spray dry

General biotech Process

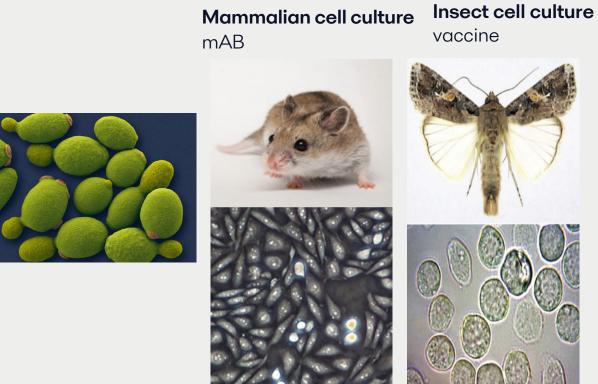


Expression system



 Virus
 Bacteria
 Yeast

 vaccine
 Vaccine, growth factor
 insulin



Alfa Laval

Expression ways

Extra cellular

Product is in outside of cell

Intra cellular

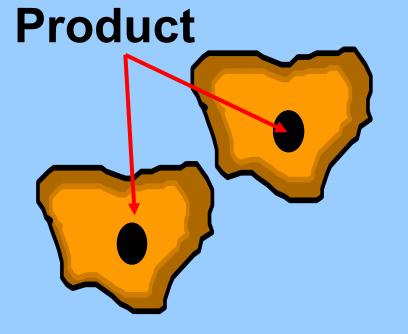
Product is inside of cell

Inclusion body

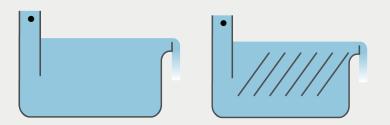
Product is inside of cell but it's particle

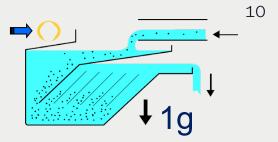






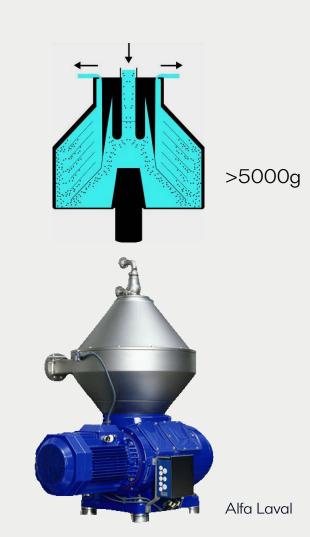
Separation in biotech





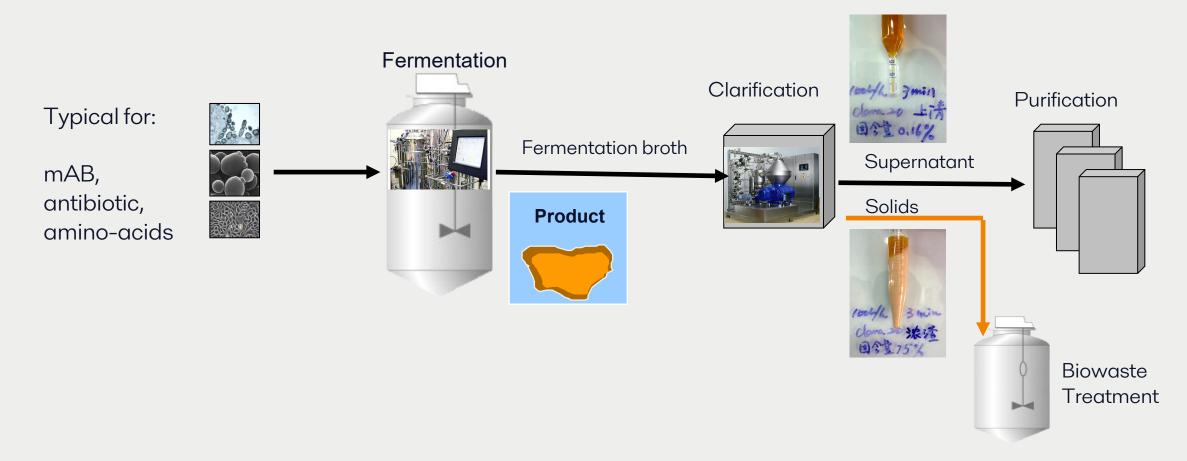
Classic and sustainable

- Disc stack separator is efficient separation technology, big in capacity, and low in operation cost
- High speed disc stack separator is a centrifuge for liquid-solid, liquid-liquid, liquid-liquid-solid mechanical separation
- It's a unique separation equipment based on settlement theory. It's often to see other technologies in biotech factories -
 - Filtration. Like hollow fiber filter, membrane filter
 - Tubular centrifuge
 - Chromatography

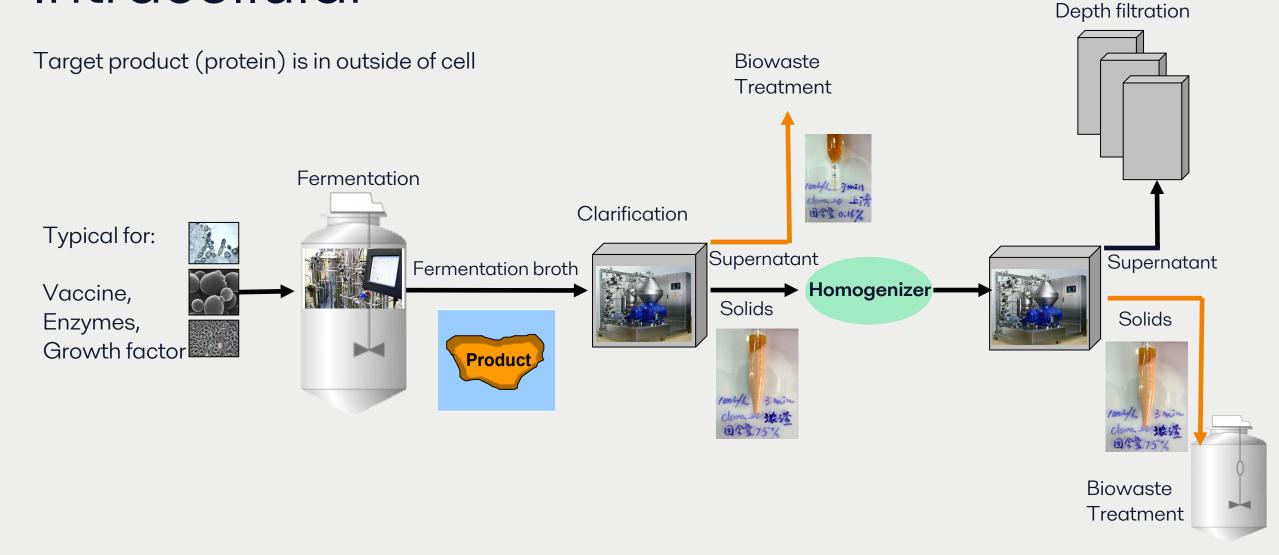


Extracellular

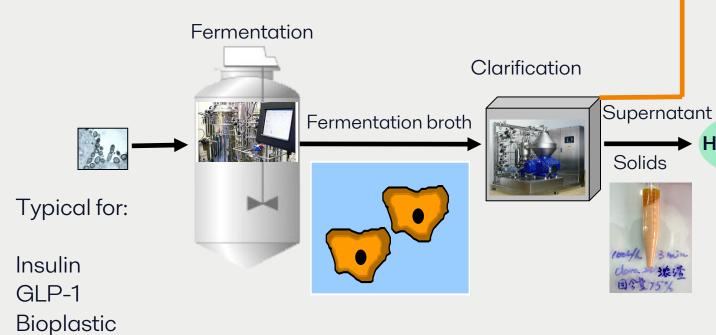
Target product (protein) is in outside of cell

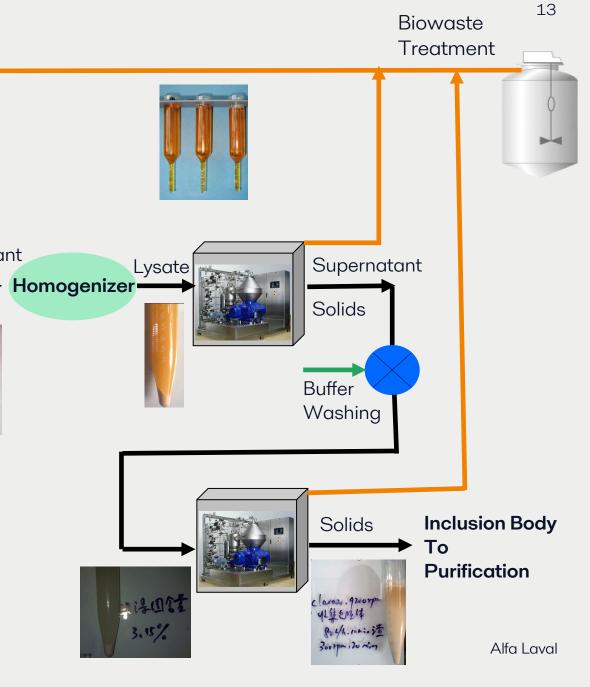


Intracellular

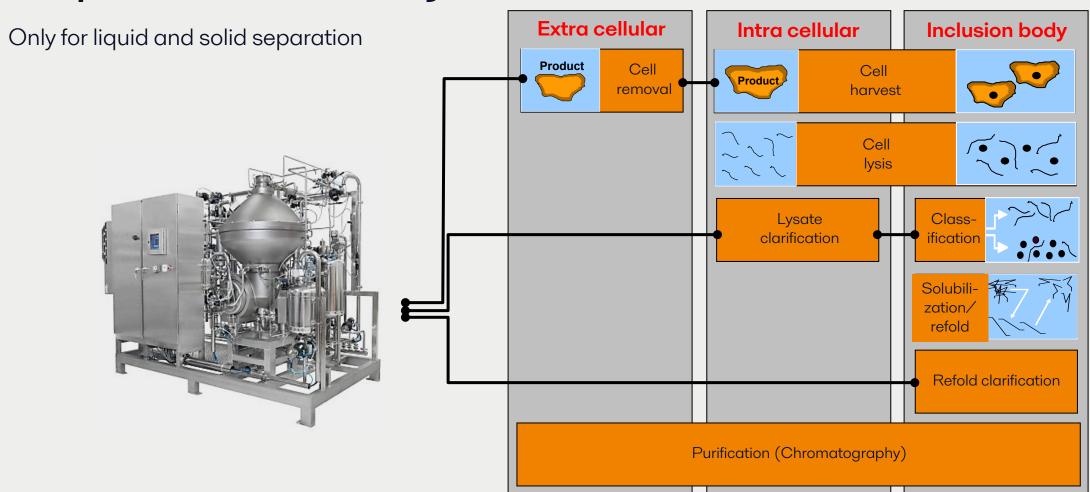


Target product (protein) is in outside of cell





Summary of separation duty









Challenges

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Challenges to disc stack separation

- 1. Separation efficiency
- 2. Shearing force sensitive separation
- 3. Keeping viability
- 4. Multi-products share one equipment
- 5. High fermentation density tender
- 6. Clean and validation to separation system





Alfa Laval contribution

Alfa Laval contribution

Alfa Laval can provide unique solution to help customer to optimize the performance.

Alfa Laval solution focus on:

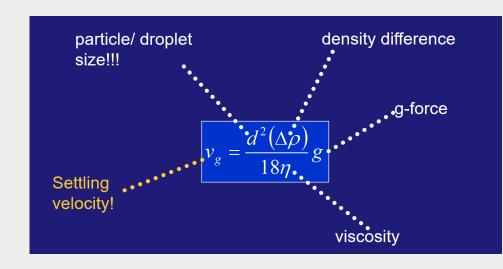
- improve the separation efficiency
- reduce shearing force to keep whole cell separation
- Less power consumption and friendly to use
- more aseptic operation



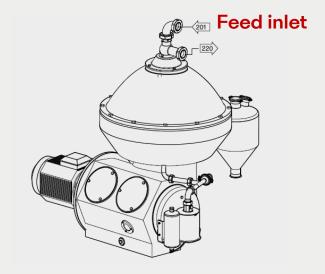


Different product (1)

Different feed structure higher separation efficiency in bottom feed machine due to lower shearing force to keep intact cell separation.



Top feed

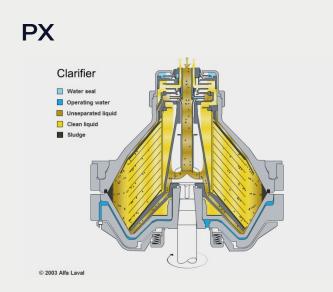


Bottom feed



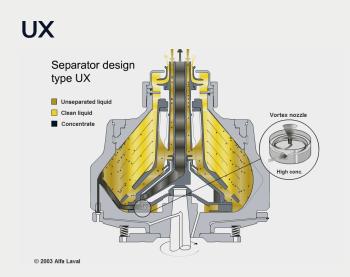
Different product (2)

Different of solid discharge system



Intermittent solid discharge

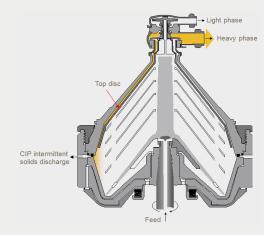
Typical apply for low fermentation bacteria separation



Continuous solid discharge

Typical apply for Pichia yeast, probiotics separation and high feed PCV duty

Bactofuge



Continuous solid discharge

Typical for mammalian cell culture, higher fermentation bacteria, probiotics separation

Different product (3)

The difference investment level

Clara series



CLARA 200 (VNPX 810)

Investment level x 1

MB series



MBPX 810

x 5

BT series, 121dC SIP-able



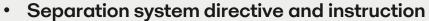
BTPX810H

× 10

Documentation/validation

Difference between Biopharma module and food module





- System manual
- Test report and validation

Certificate (GMP document package)

- Separator/Module/components
- Electric and pneumatic element
- Software
- Welding

Validation documents

- FAT
- SAT
- CIP validation
- IQ/OQ



- Installation and operation instruction
- Separator manual
- Module manual
- Electric drawing
- Test report and certificate

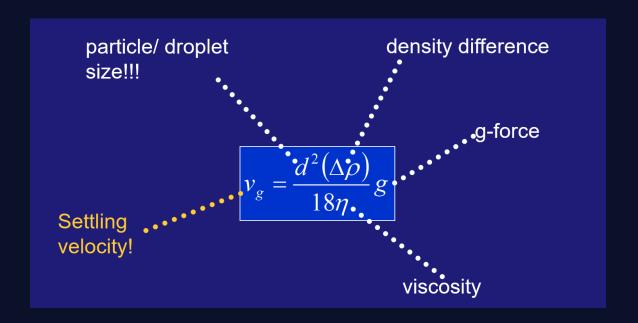
Higher cost for these documentation and validation protocols and longer lead time.

Challenges for intracellular

Separation efficiency and temperature

- Product is in liquid phase
- Cell debris is very small (<0.5um), it's very difficult for separation
- Low feed flow to generate high temperature up to denature the protein and clean issue





UniDiscTM

Traditional disc



Alfa Laval Unidisc

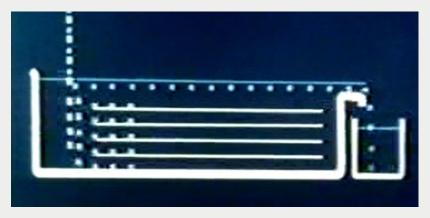


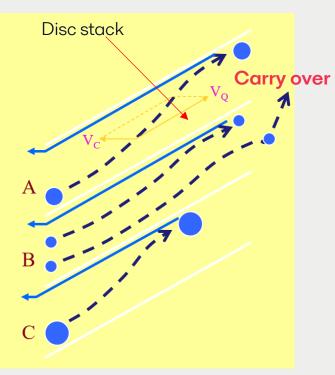


Total ~1400 spots on one disc surface



- New generation disc stack with patented integrated caulk design
- Enhance the small particles capture capability due to even short settlement distance
- Free gap between each disc become easier for CIP





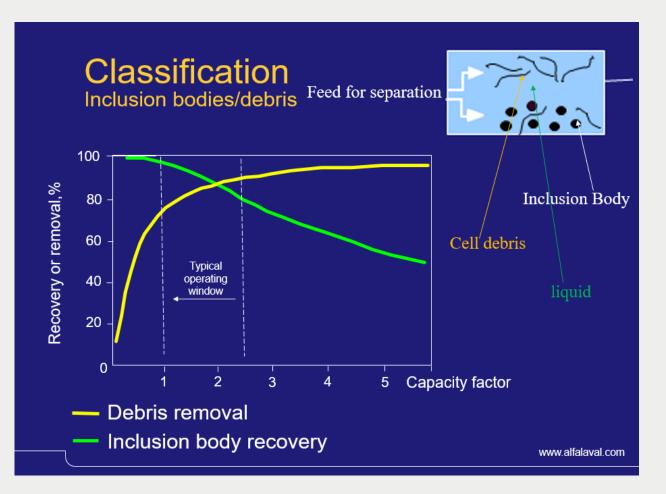
C-biggest size particle B-smallest size particle A-Cut size particle

Alfa Laval

Challenges for Inclusion body

Separation between two different particles

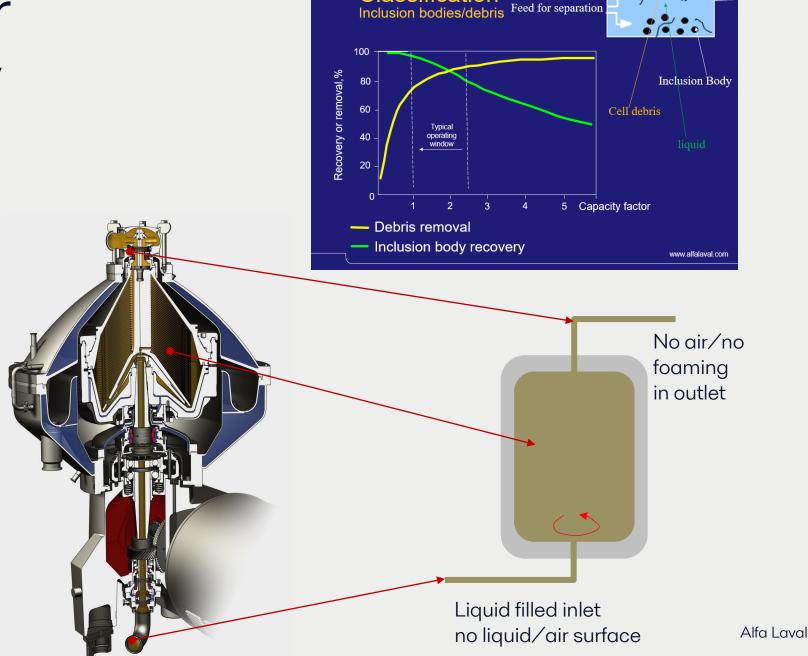
- Target particle is Inclusion body.
- Need high purity IB or need to less content of cell debris in harvested IB
- Don't expect the IB lose too much
- Narrow windows for operation



Challenges for Inclusion body

Alfa Laval full hermetic separator

- No foaming
- No need to adjust backpressure to control the operation window
- Max separator feed capacity

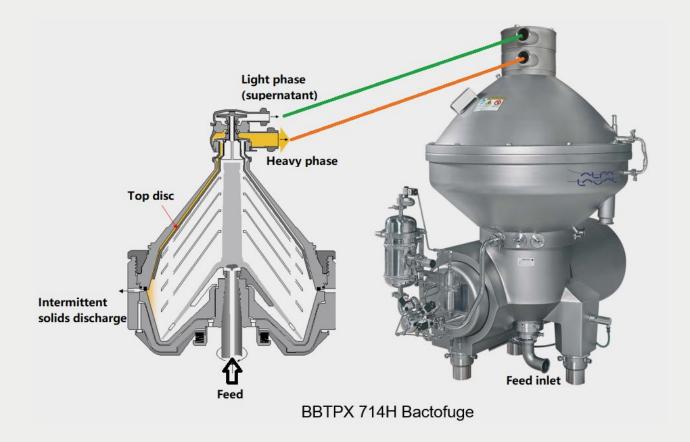


Classification

Bactofuge

Flexible operation for muti-production

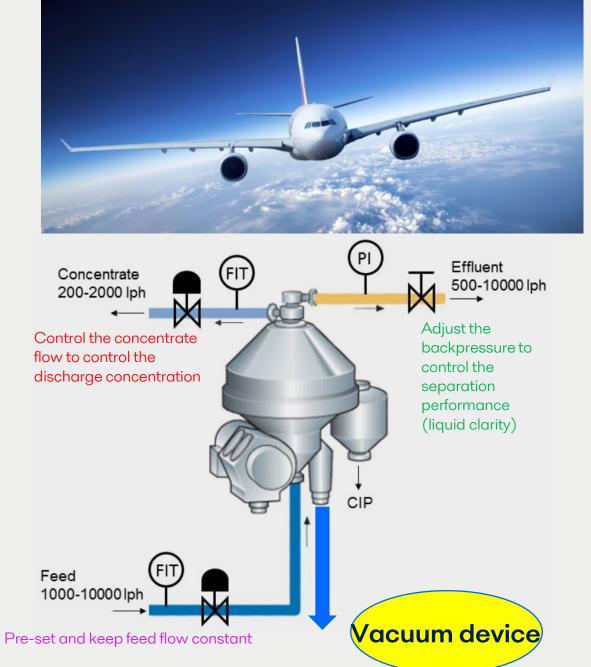
- Continuous solids output, over the top disc, through a second outlet on top – fully hermetic design. Fit for high density fermentation duty.
- Combined solid intermittent(traditional) and continuous discharge



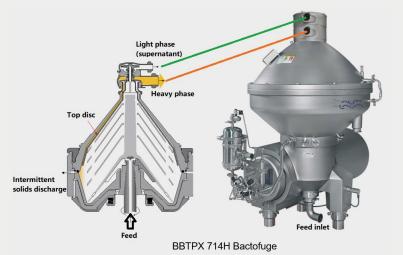
Bactofuge

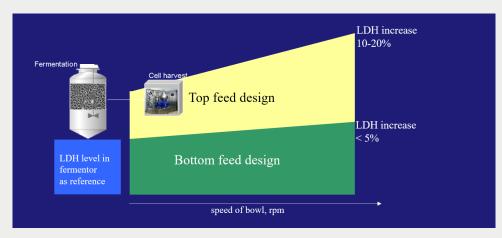
With eMotion

- Cooling water can be used to reduce the temperature
- eMotion function is under development to continue reduce the temperature pickup, reduce power consumption and ever lower noise

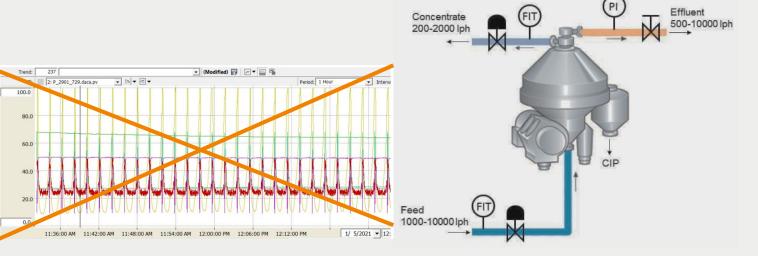


Bactofuge





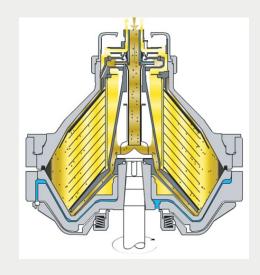
- Full hermetic design with very gentle feed, low extra lysis
- Constant supernatant quality, constant solid discharge
- Traditional intermitte solid discharge available
- Easy for operation



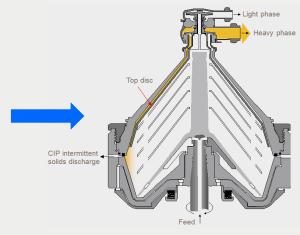
Importance to starter and probiotic

Keeping viability from continuous discharge

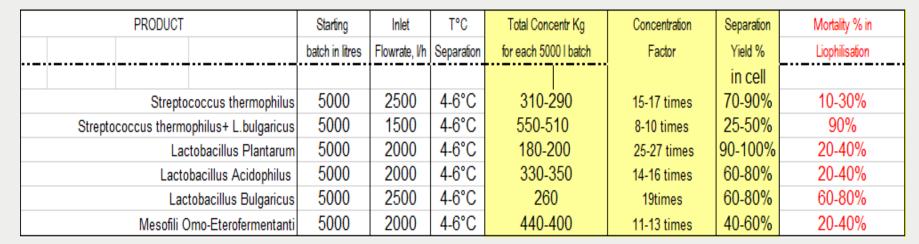
- Keep the micoorganism with viability after separation, To avoid to be hurted by temperature and high G-force
- Separator selection depends up acceptance of mortality and product value



Top feed PX separator



Bottom feed Bactofuge







MB 20 MB 20B



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MB 20 / MB 20 Bactofuge

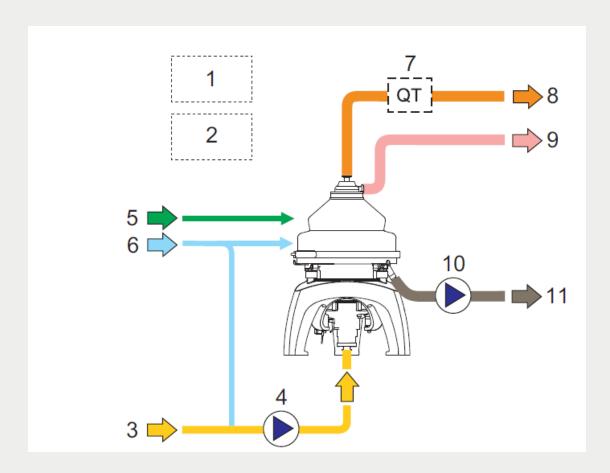
The first small fully hermetic disc stack centrifuge

The first small fully hermetic disc stack centrifuge with **continuous solid discharge**



Flow Chart

MB20



- Control cabinet
- Main motor starter cabinet and VFD
- Feed inlet
- Feed pump (optional)
- Utilities
- Standby water
- Turbidity meter for solids discharge (optional)
- Light phase outlet
- Heavy phase outlet
- Solids receiving unit (optional)
- Discharged solids outlet

MB 20 / MB 20 Bactofuge

| Separator | |
|---------------|----------|
| Bowl speed | 9500rpm |
| Motor | 5KW |
| Free steaming | 90-100°C |

| Feed type | Max feed capacity [I/h] |
|---------------------|-------------------------|
| Ecoli | 120-180 |
| Cell debris | 40-80 |
| Lactobacillus | 200 |
| Saccharomyces yeast | 600 |
| Pichia yeast | 350-450 |
| CHO | 200-250 |



Application and Scalability

From smallest to largest

- MB 20 offers the same bowl design as larger models from Alfa Laval
- Capacity can be scaled up with high reliability
- Cell return in continuous fermentation if free steaming is avaible



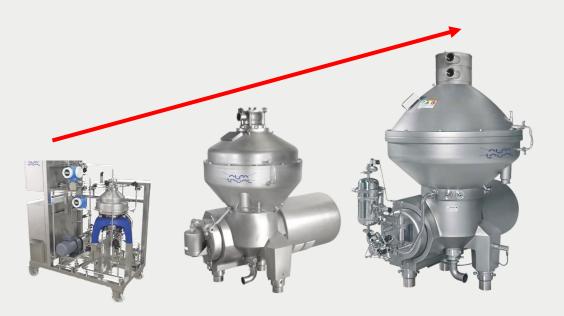
TopStreamTM





Hermetic Design[™]

UniDiscTM



User benefits with MB 20 systems

Flexible in flow rate

- Hermetic design allows for 50-600 I/h without modifications

Handles feeds with low and high solids, above 30%

- Easy for customer to convert between clarifier with PX discharge and Bactofuge

High separation efficiency

- Hermetic inlet avoids cell disruption

No foaming

- No air present in outlet



Customer benefits







Hermetic DesignTM



UniDisc[™]





To optimize the performance of our customers' processes Time and time again.

- High awareness of Biopharma processes, problems and difficulties.
- Focus on the separation solution rather than a mechanical equipment
- Good adaptation with customer process, and high bio-safe design
- Local resource, competence and experience even if the lessons

Your contact

Taiwan





Grace Kung

Location: Taiwan

Division Manager, Tel: +886 988 733 316

E-mail: grace.kung@alfalaval.com



Eric Li

Location: Taiwan

Sales Manager, Tel: +886 988 737 552

E-mail: eric.li@alfalaval.com

Sweden





Xiaoguang Li

Location: Tumba, Sweden

Global Sales, Tel: +46 70293 7964

E-mail: xiaoguang.li@alfalaval.com



Your question?



Thanks for your time!