

Accélérateur de Biotechnologies - ARD

Biotechnology accelerator - ARD



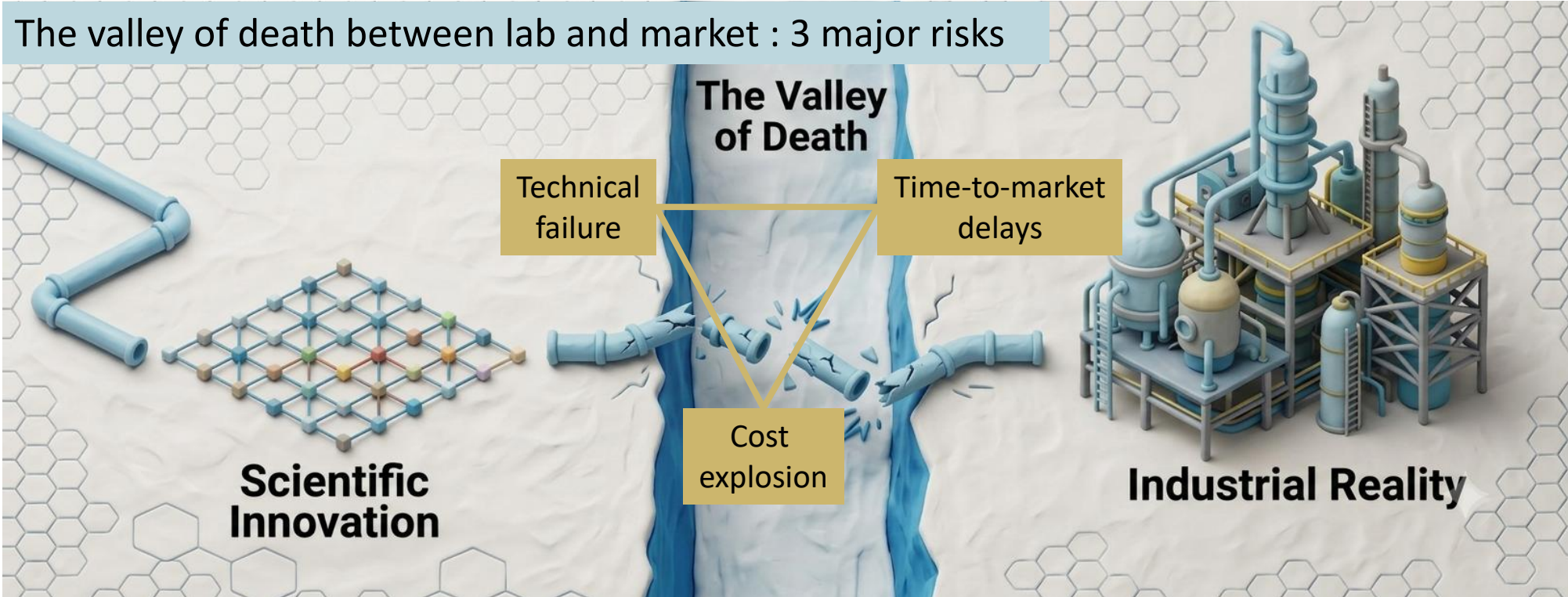
From innovation to production: mastering the art of industrial scale-up to secure your path to market

From innovation to production: mastering the art of industrial scale-up to secure your path to market



- 1 / Why scale-up matters ?
- 2 / What drives a successful bioprocess ?
- 3 / The scale-up challenges
- 4 / The scale-up methodology at ARD
- 5 / Time-to-Market & Business Outcome

1 / Why scale-up matters ?



Scale-up = risk management + value creation

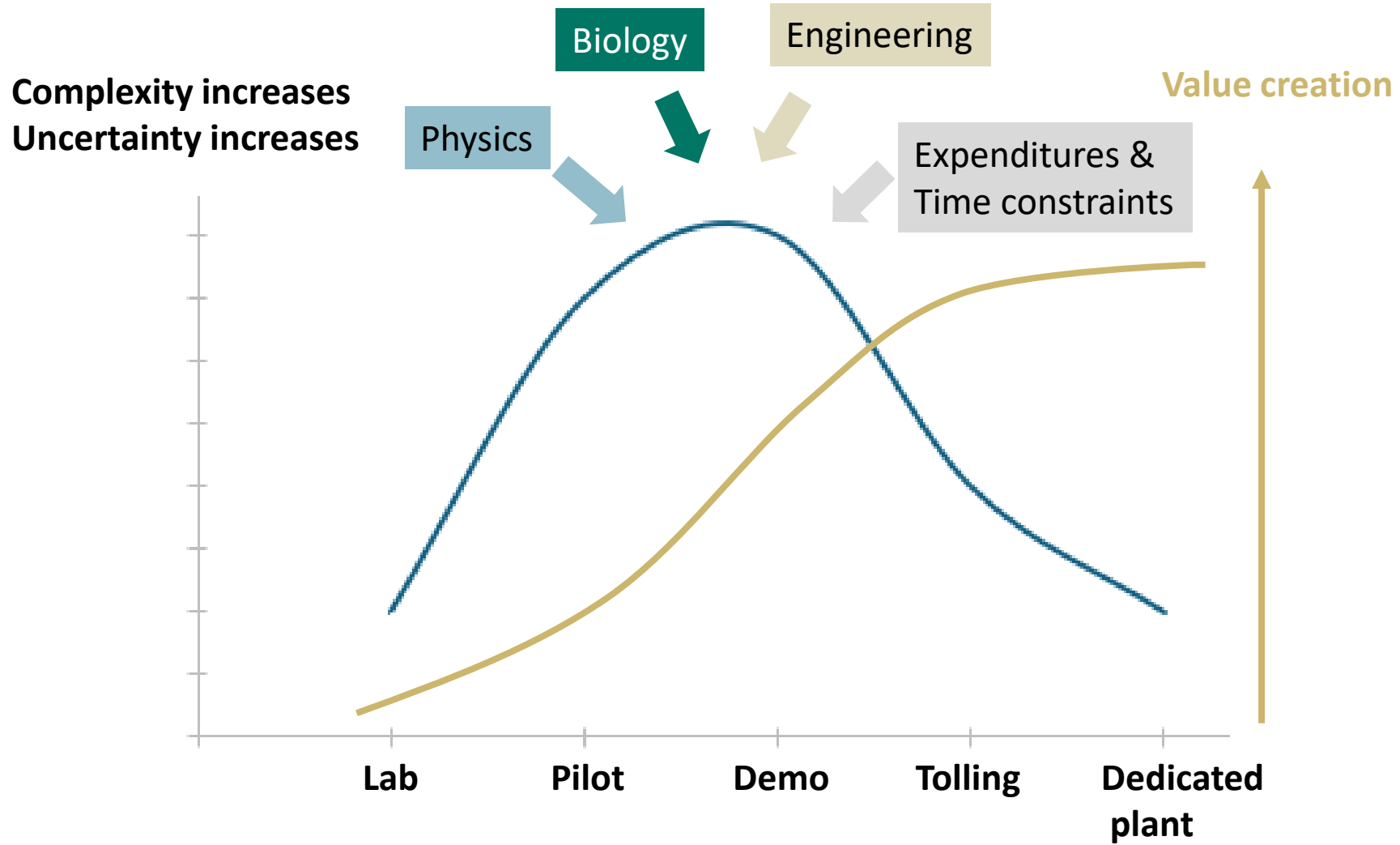
RISK MANAGEMENT

- Technical Risk
- Economic Risk
- Investment Risk
- Market Risk

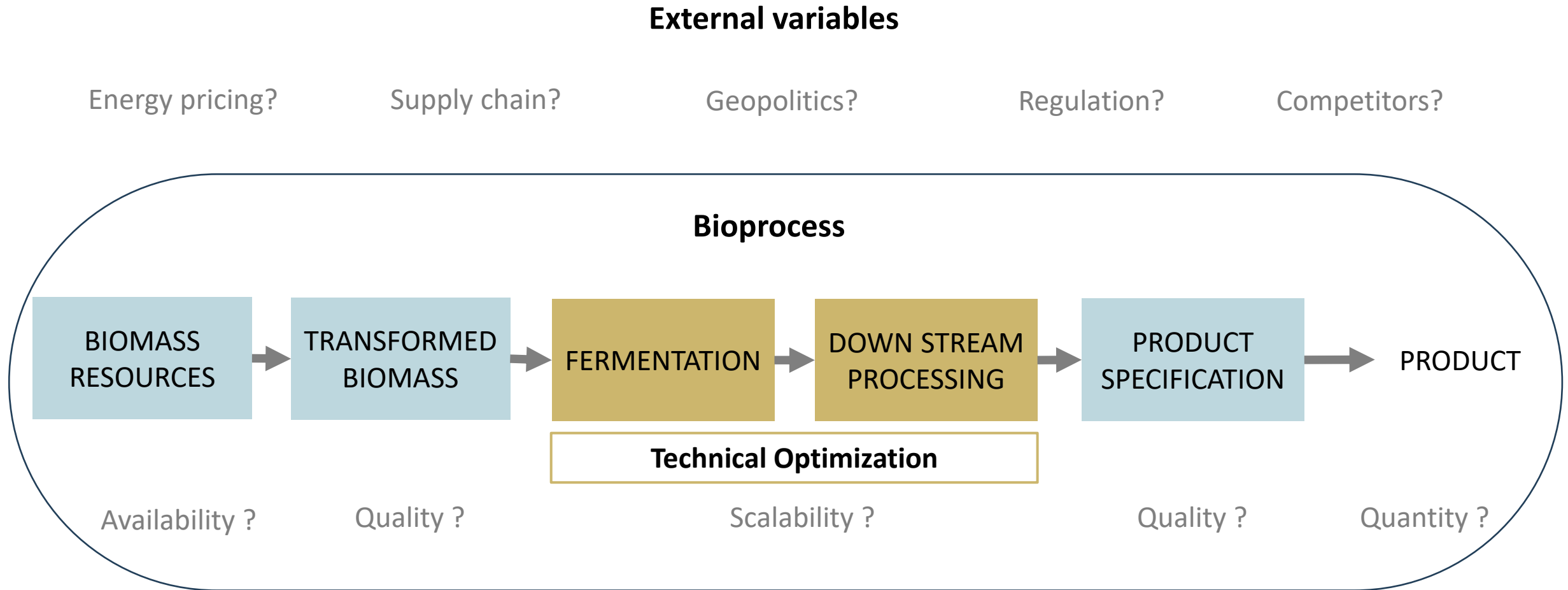
VALUE CREATION

- Lower Cost
- Faster Time-to-Market
- Higher Probability of Success
- Stronger Business Case

Why scale-up matters ?



What drives a successful bioprocess ?



What drives a successful bioprocess ?

A great process starts with a great strain

First key driver : the strain

- High Titer
- High Yield
- High Productivity



V0 STRAIN
Low titer e.g. 0.1%



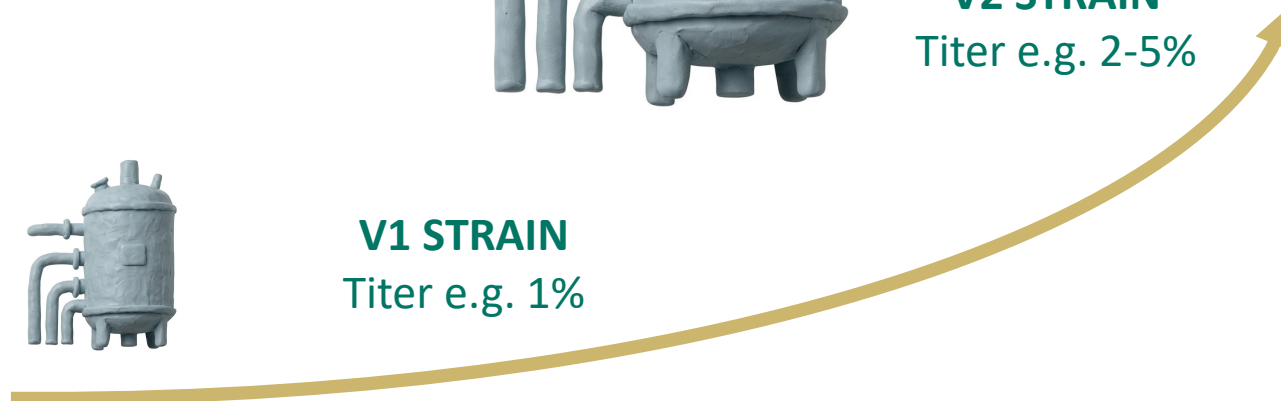
V1 STRAIN
Titer e.g. 1%



V2 STRAIN
Titer e.g. 2-5%



V3 STRAIN
High titer e.g. >10%



What drives a successful bioprocess ?

Second driver : the fermentation process

MEDIUM



Price of the recipe, availability & versatility of raw materials

TYPE OF FERMENTATION



Operability (easy or not), Productivity

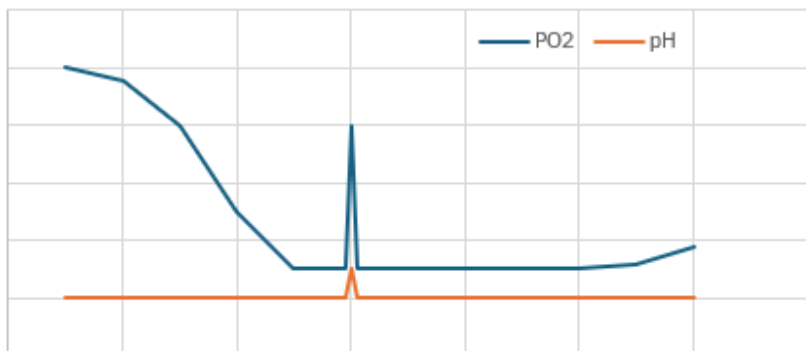
BIOREACTOR DESIGN



Vessel design
Stirring design/speed/power
Aeration rate
Overpressure
Inlet points
Sensor
Stainless steel quality
CIP design

Impact of the design on performances
Available equipment or new dedicated design

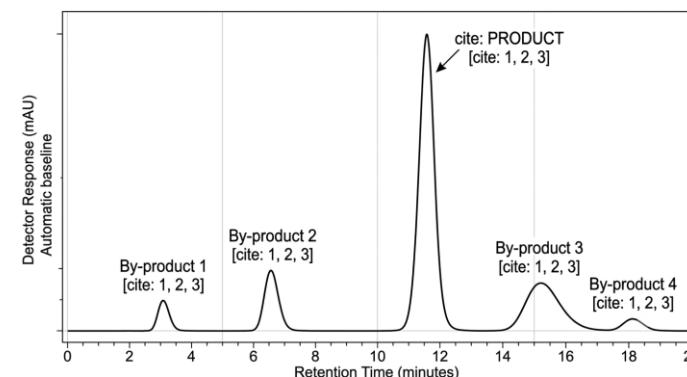
IN PROCESS CONTROL



Temperature
pH
DO probe
Off gas analyzer
Mass flow controller
New sensors technologies
Calculation

Leverage online data & real-time processing to improve process control and performances

ANALYTICS



HPLC
GC
Specific methods

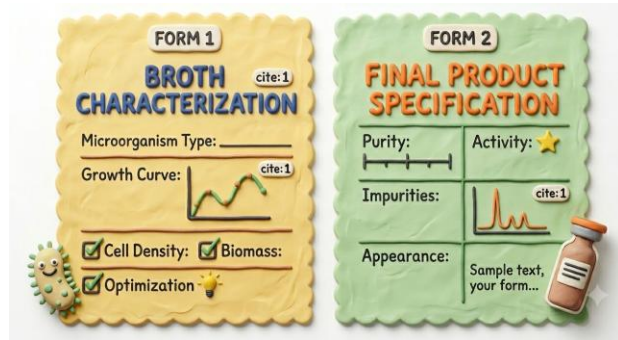
Product
Byproducts

Develop simple analytical methods and streamline the sampling plan

What drives a successful bioprocess ?

Third driver : the downstream processing

CHARACTERIZATION



FORM 1
BROTH CHARACTERIZATION cite:1

Microorganism Type: _____

Growth Curve:  cite:1

☒ Cell Density: ☒ Biomass:

☒ Optimization 

FORM 2
FINAL PRODUCT SPECIFICATION

Purity: _____ Activity: ★

Impurities:  cite:1

Appearance: _____

Sample text, your form... 

Constraints imposed by the fermented broth
Product purity target vs. complexity of the DSP

PROCESS CHOICES



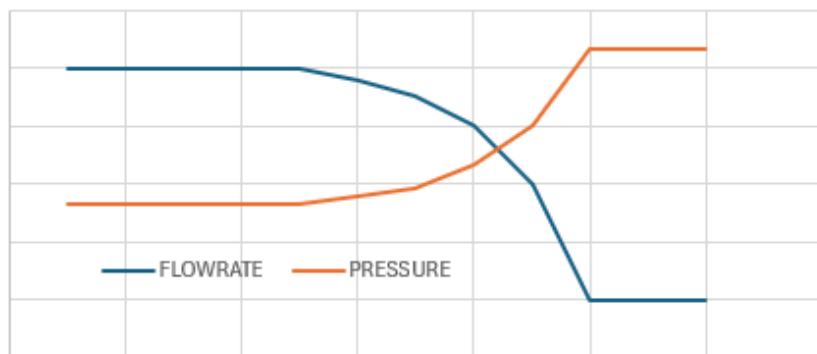
Pros / Cons of several technologies
Use representative volumes
End of process : often the most challenging part

SEQUENCING



Chosen sequence can be significant
(e.g. color removal before or after step #3 ?)

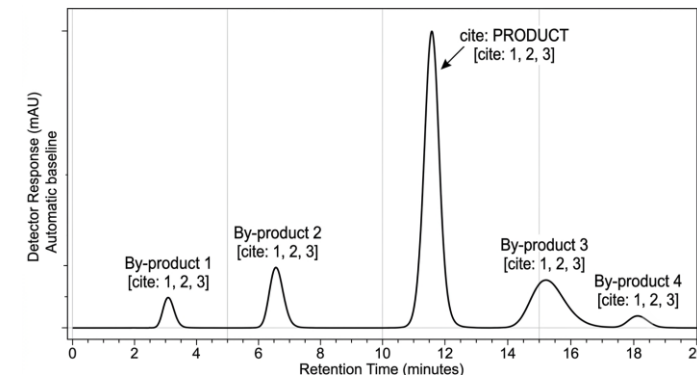
IN PROCESS CONTROL



Temperature
pH
Pressure
Conductivity
Density
Turbidity
Mass flow controller
New sensors technologies
Calculation

Leverage online data & real-time processing
to improve process control and performances

ANALYTICS



HPLC
GC
Specific methods
Product
Byproducts
Impurities

Develop simple analytical methods and
streamline the sampling plan

What drives a successful bioprocess ?

Three Key Parameters : Titer (fermentation), Yield and Productivity (fermentation & DSP)

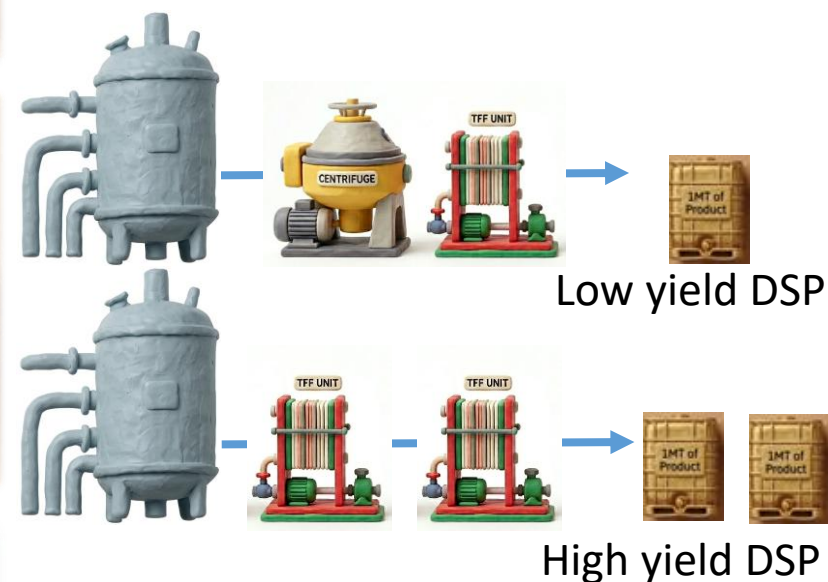
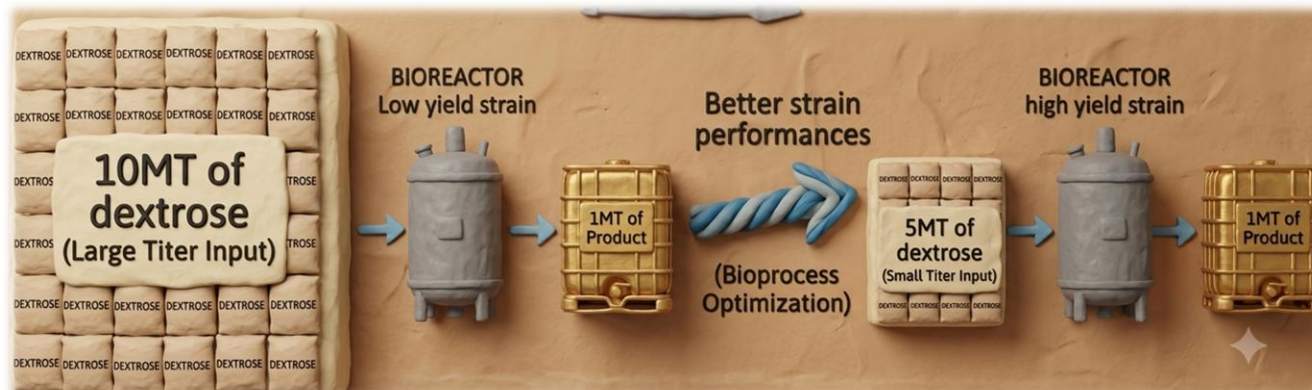
TITER

High titer makes the DSP easier



YIELD

High yield decreases the costs/kg



PRODUCTIVITY

High productivity decreases CAPEX



What drives a successful bioprocess ?

The purity dilemma

LOW PURITY PROCESS



Direct Impacts

YIELD

PURITY

COST

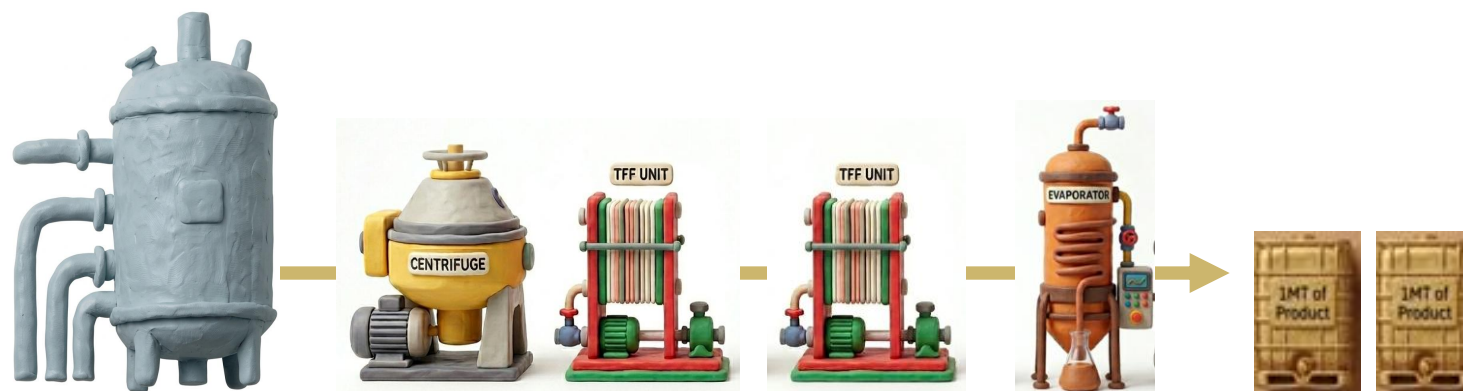
Indirect Impacts

CAPEX

OPEX

OPERABILITY

HIGH PURITY PROCESS



YIELD

PURITY

COST

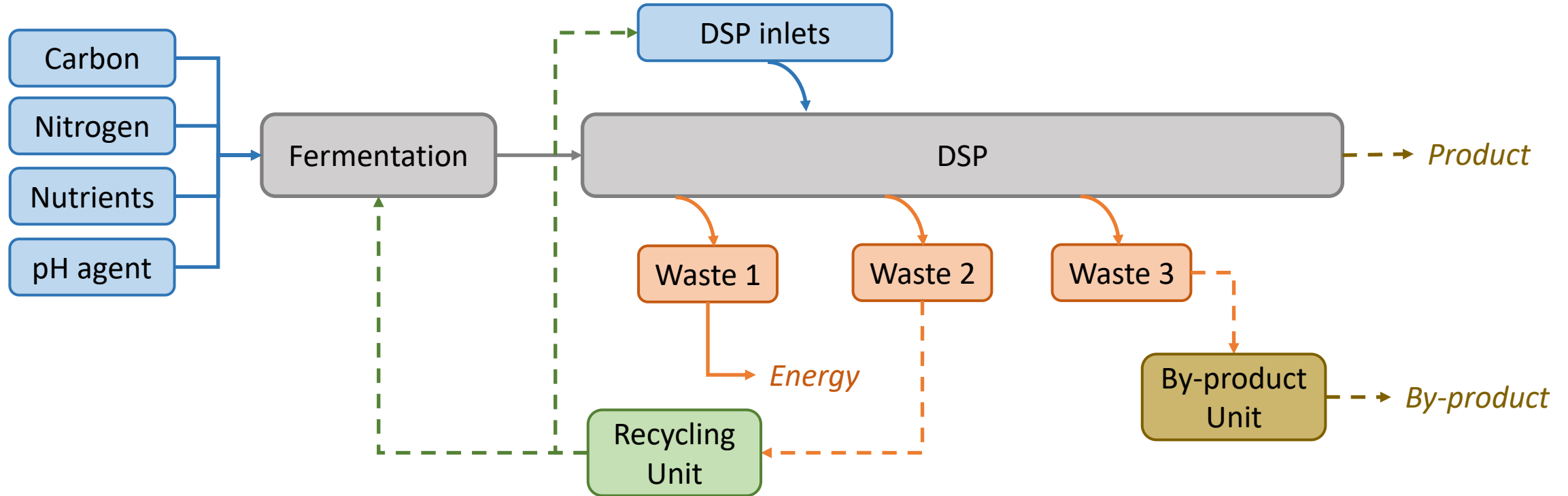
CAPEX

OPEX

OPERABILITY

What drives a successful bioprocess ?

A process does not stop at the product



CIRCULARITY
SUSTAINABILITY
BIOREFINERY

The scale-up challenges

The microorganism experiences a completely different environment at industrial scale

Oxygen Mass Transfer

Mixing Efficiency &
Shear Stress

Raw Material
Variability



Heat Transfer &
Thermal Control

Sterility & Aseptic
Maintenance

Genetic &
Metabolism Stability

The scale-up methodology at ARD



Vivescia Biotech: ARD

From process design to biomanufacturing



35+
Years



30
Active
Projects



2-3
Worldwide
launches/year



130
people



80
Patents



International
Start-up to Corporations



CDMO
Process design,
scale up & tolling



Boosting & Securing
your sustainable growth



**Process
Design**



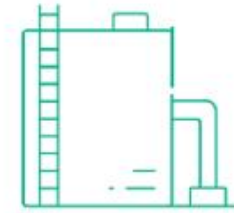
Lab
10-150 L



Pilot
500-10 000 L



Demo
50 000 - 300 000 L



Tolling



LABS & Admin

Analytical, Microbiology,
environment,
fermentation,
DSP/Fractionation,
Chemistry

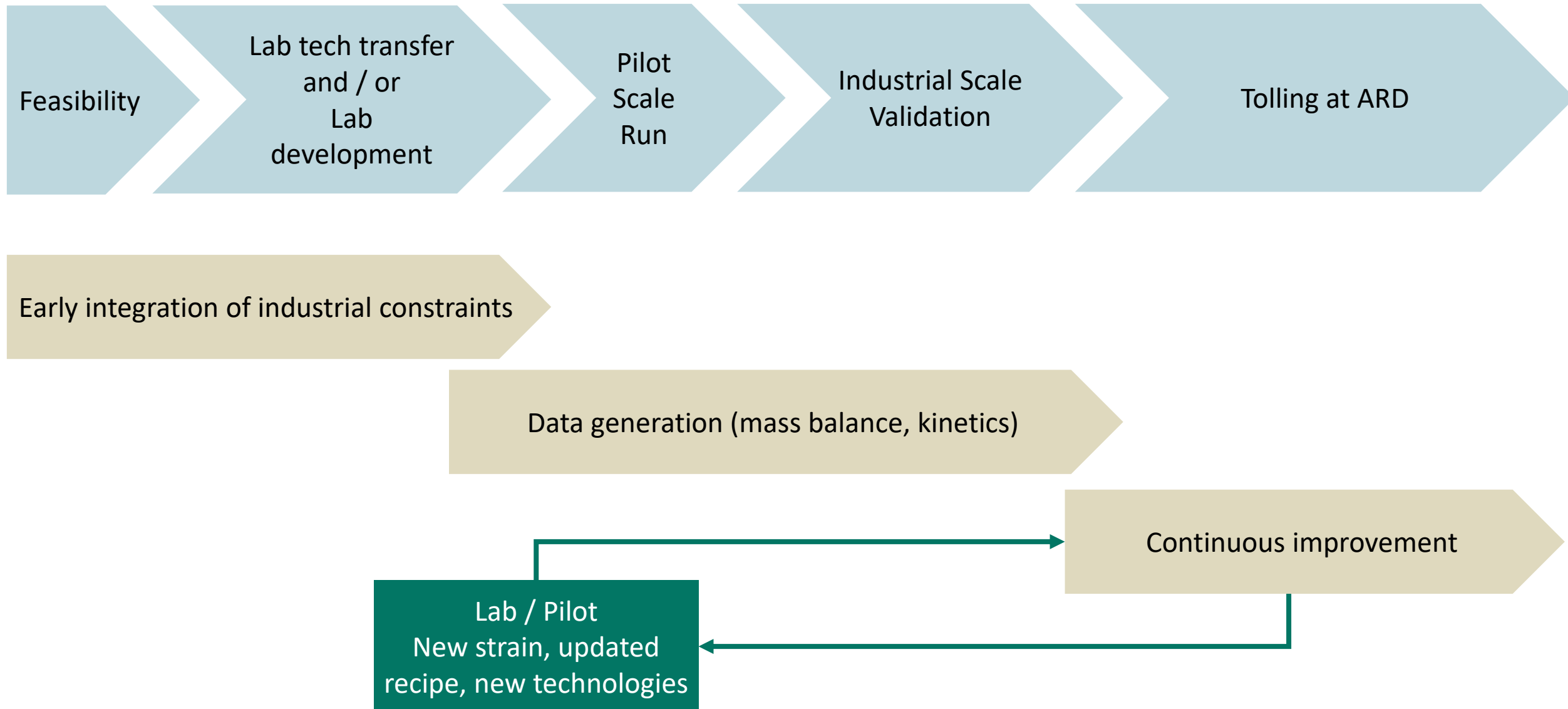
Pilot DSP « Hall »

All you can get in skid (i.e.
HHP, UF/NF, filter press,
centrifuge, decantor,
sedicator, IX, extraction...)

BioDém (Pilot, Demo & tolling)

Pilot & industrial capabilities
Fermenters: 150L, 200L, 2m³, 10m³, 180m³,
220m³ (Fed batch from 10 to 60m³)
Bioconversion: from 5m³ to 350m³
DSP: UF/NF (800m²), Centrifuge,
evaporator, crystallizers, ion exchange,
conical drier...

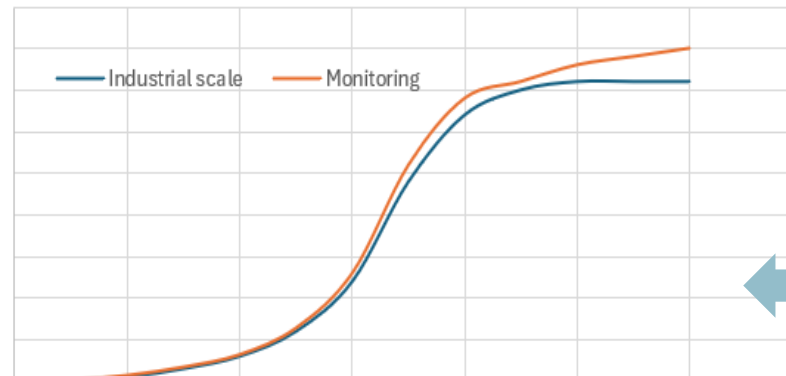
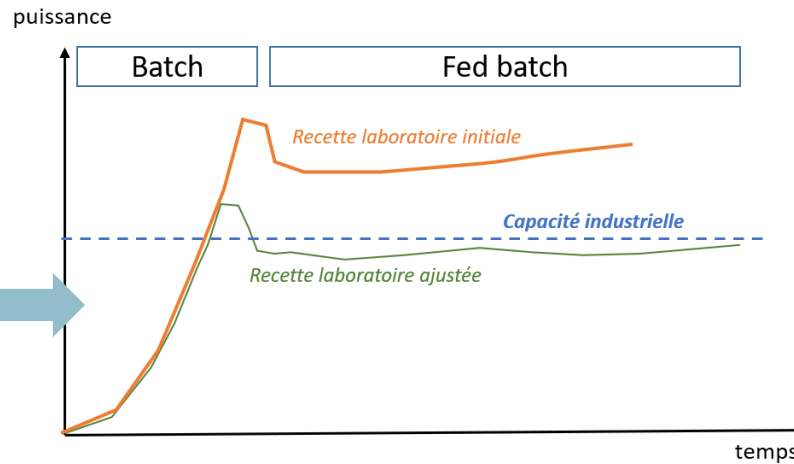
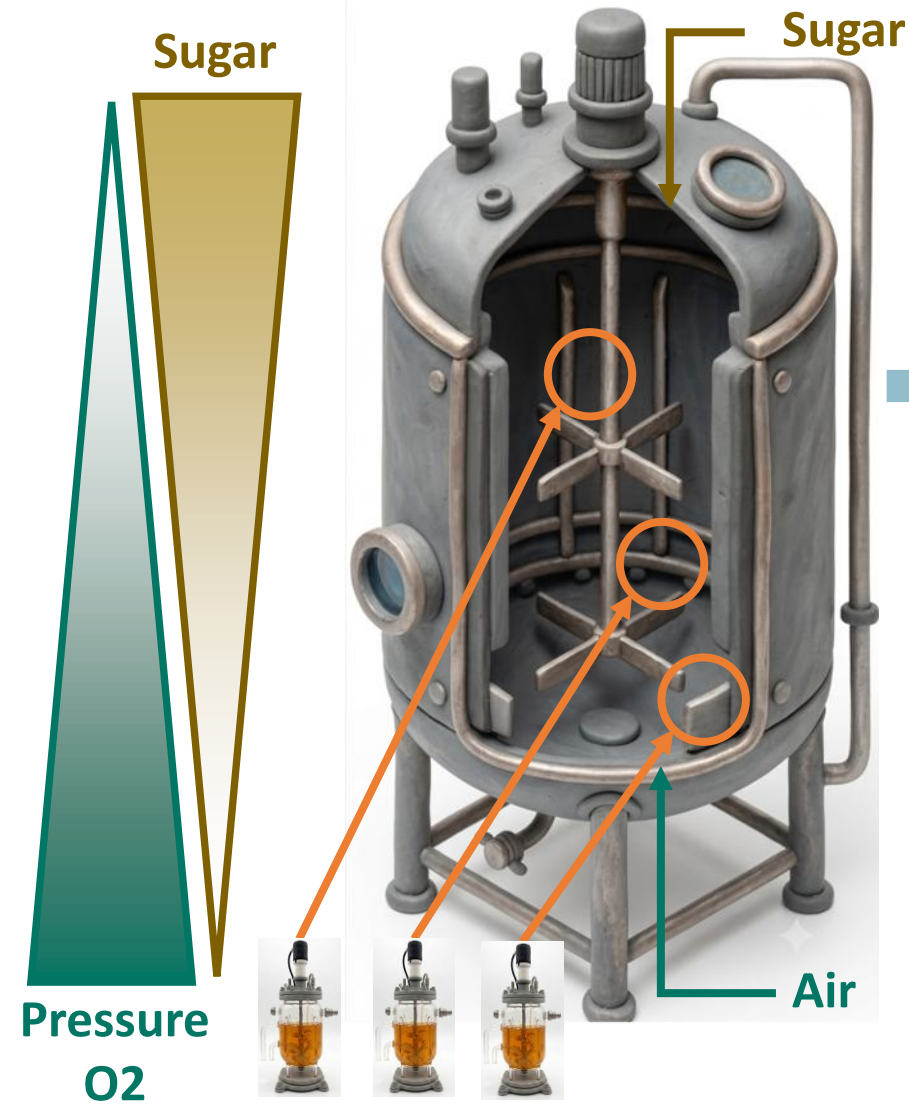
The scale-up methodology at ARD



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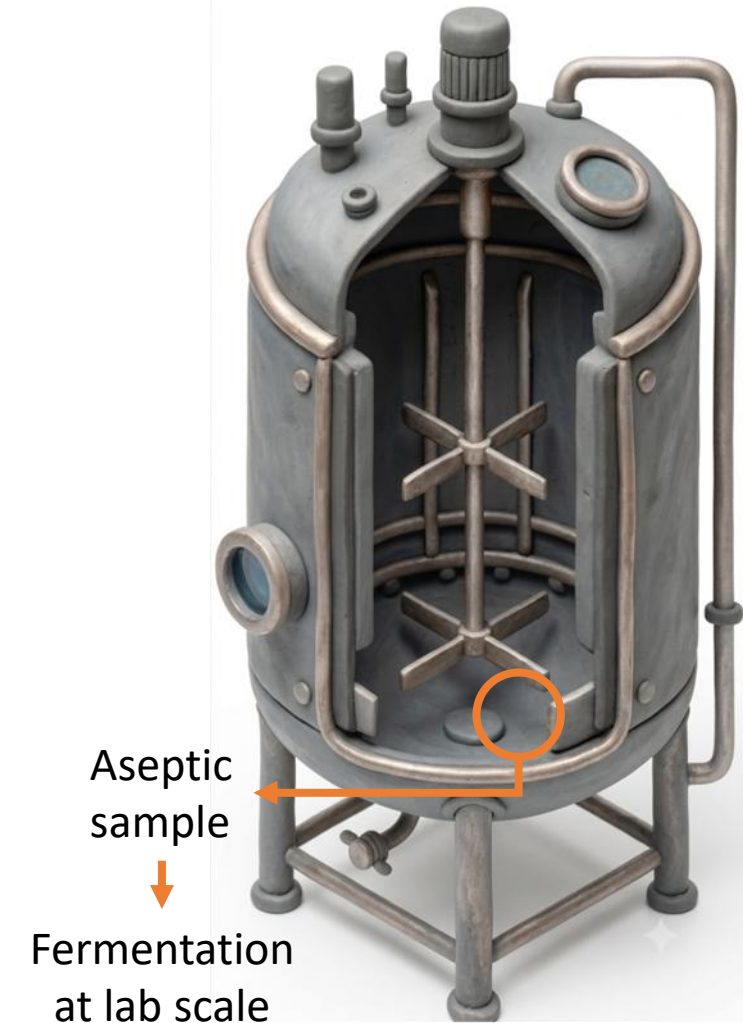
DOWNSCALING

Anticipate industrial scale at lab scale



MONITORING

Aseptic sample from industrial scale cultured at lab scale



ARD deliverables

- Feasibility and performance reports at every scale-up stage
- First product batches for regulatory, market and customer validation
- Techno-economic data for CAPEX, OPEX and business plan development
- Toll manufacturing opportunities and industrial production support
- Roadmap for future process optimization and continuous improvement

Time-to-Market



Build Your Own Demonstration Plant



Up to 24 months faster

Leverage Existing Industrial Assets



From scientific feasibility to industrial profitability

Working with ARD enables you to:

- De-risk industrial investment
- Reduce development costs
- Preserve capital for commercial deployment
- Accelerate market entry
- Strengthen investor confidence
- Increase the probability of industrial success

Thank you for your attention

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