Some principles for SUCCESSFUL Scaling-Up Bioprocesses

Ricardo Egea
Director – BIONET
Msc Engineering & INSEAD MBA
1. BIONET
BIONET is an independent SME. We are specialists in bioprocesses engineering, founded in 1999. Located in Murcia, in SE of Spain.

**Bioprocess Equipment**
- Bioreactors/Fermentors
- Membrane Filtration Systems
- Cleaning in Place Systems
- Ancillary vessels (harvest, media preparation, extraction..)
- Process Automation

**Services**
- Process development
- Process Engineering
- TurnKey of Process lines
- Training
- Maintenance and troubleshooting
BIONET has developed a complete range of bioprocess equipment that, while keeping the highest technical standards, are oriented to availability and easy maintenance.

All models are available from Pilot to Industrial scale, for Microbiology and Cell Culture and in Food grade (A) and cGMP (P).

- **F Series – Bioreactors and Fermentors**
- **Series M – Membrane Filtration Systems**
- **Series C – Cleaning In Place Systems**
The objective of BIONET process development services is to **reduce risks** in the scale-up, “time-to-market” and ensure/asses the **viability** of new developments.

**Resources:**
Dedicated Process Department, Pilot Plant with fermentors, bioreactors and downstream equipment to work from 2 l to 200 l and network of scientific and technological partners.

**Deliverables:** Process selection and design and equipment selection, Industrial OPEX and CAPEX models, feasiblity studies and production of validation or commercial batches.
From the bench to the full production suite, BIONET can be the sole provider to design, construct and start-up your complete process line.

Our scope of services is:
- Process Engineering
- Supply by BIONET of key process units and ancillary vessels and equipment
- Integration of leading vendors equipment (centrifuges, chromatography...) as customer preferences
- Knowledge of bio-processes and understanding of user needs
- One house seamless automation for complete plants, reducing risks between process interfaces and validation.
1. BIONET

2. SCOPE
For industrial products:

— Industrial Enzymes
— Building blocks
— Biomaterials
— Agrochemicals
— Food aditivies

What they do have in common?

— Innovative but non disruptive
— There is a reference product
— Medium to large scale production
— Small to medium price per unit
KEY PHASE FOR A SUCCESSFUL BUSINESS CASE

SCIENCE & PROCESS

Lab R&D

Pilot & modelling

Test Scale-up

Real Scale-up

ENGINEERING & FINANCING

R&D

Ind process definition, Basic engin. & Financing

Detailed eng. & construct

Start-up

Optimization

MECSCIENCE & PROCESS

Lab R&D

Pilot & modelling

Test Scale-up

Real Scale-up

ENGINEERING & FINANCING

R&D

Ind process definition, Basic engin. & Financing

Detailed eng. & construct

Start-up

Optimization
1. BIONET
2. SCOPE
3. ABOUT PROJECT SUCCESS
IGNORANCE

We enjoy while it lasts... and (sometimes) we love it!
A CLEAR GOAL & STRONG COMMITMENT
Better than resources & knowledge?
1. BIONET
2. SCOPE
3. ABOUT PROJECT SUCCESS
4. IN THE PROJECT
CLEAR OBJECTIVES?

- Product Specifications (prioritized)
- Price
- Production target
R&D DELIVERS?

Full process (Up&Down) defined with KPIs
Feasible and tested at a relevant scale
INDUSTRIAL PROCESS DEFINITION

Process selected (technology and key process parameters – CIP..)

Mass and Energy Balance

Production schedule
ECONOMIC EVALUATION (modelling)

CAPEX

OPEX
ITERATE = OPTIMIZE
1. BIONET
2. SCOPE
3. ABOUT PROJECT SUCCESS
4. IN THE PROJECT
5. CONCLUSIONS
1. SET CLEAR & MARKET-BASED OBJECTIVES
2. FULL PROCESS DEFINITION
3. PILOT
4. MODEL ASAP CAPEX AND OPEX (ignorance..)
5. ITERATE
Thanks to SYNPOL & BIONET TEAM
¿questions?