

Molecular Biology

Fermentation



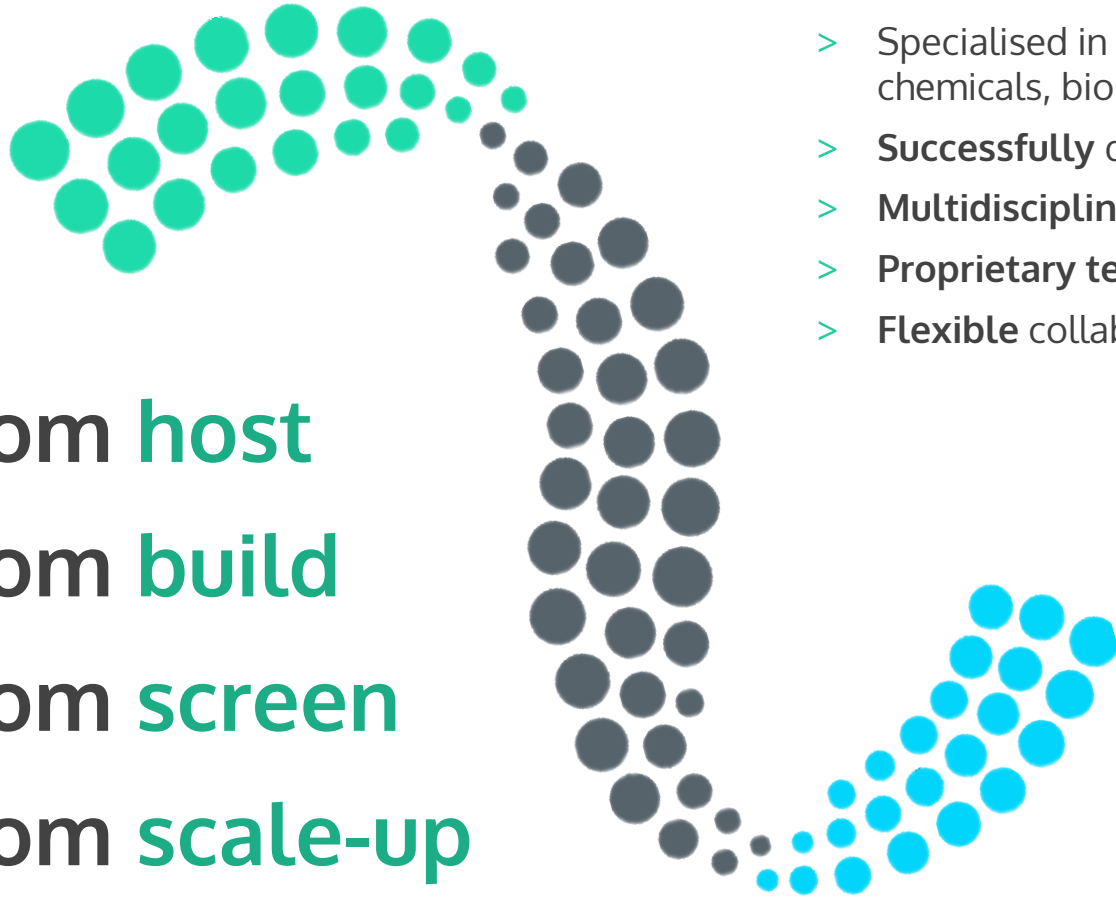
ingenza

ADVANCED BY NATURE®

Chemistry

Process Development

# Ingenza: *Advanced by Nature*®



Custom **host**  
Custom **build**  
Custom **screen**  
Custom **scale-up**

- > World leader in **applied synthetic biology**
- > Specialised in the **design, development and biomanufacture** of chemicals, biologics, pharmaceuticals and biofuel products
- > **Successfully** delivering for our customers since 2003
- > **Multidisciplinary** team
- > **Proprietary technologies**
- > **Flexible** collaboration and business models











## Molecular Biology

- Strain Engineering via Combinatorial Assembly
- Optimised Productivity and Product Recovery
- Product-Tailored Assay Development



## Fermentation

- Expertise in Bacterial, Yeast and Mammalian Cell Culture
- Biocatalyst Screen Development
- Bioprocess Scale Up and Optimisation



## Chemistry

- Chemical Synthesis of Important Metabolites
- Analytical Method Development
- Downstream Processing and Product Isolation



# Why did we change to ELN?

## Paper lab books are:

- ✗ Slow and tedious to write up
- ✗ Non-searchable
- ✗ Expensive and difficult to store
- ✗ Unledgible
- ✗ Difficult to manage/collaborate





# Why did we change to ELN?

## Electronic Lab Notebooks:

- ✓ Fast, efficient and controlled recording of data
- ✓ Quality and compliance
- ✓ Integration of all digital data
- ✓ Improved project management and collaboration



# How did we select SciNote?

Defined a dedicated person for market search

Established non-negotiables and picked top-candidate(s)

Trial period with team representative of the institution

Group decision

- Can be overwhelming
- Ask your community
- Request referrals

Non-negotiables:

- Browser-based
- Local installation
- FDA 21 CFR part 11 compliance
- Affordability

Other factors:

- Database function
- Possibility to export data easily
- Internal cross-referencing
- User perception

- Trialled with dummy data
- Picked people from all departments
- Close collaboration with SciNote support team
- Defined deadline
- Effort recognition

- Important to ensure team satisfaction

# How did we implement SciNote?



Defined standardised practices

Defined key users

Staff training by key users

Continuously shared tips and troubleshooting approaches

- Different people have different interpretations for each level of SciNote
- Important to map out common processes before implementation
- Very important for successful implementation
- Will do the hand-holding
- Representative of every department
- Have a positive attitude towards change
- Trained by SciNote team
- In-house training promotes uptake and allows use of specific examples and defined practices
- Examples:
  - Spell check: Grammarly
  - Use of symbols



# Current practices

New customer: team is set up

Project Manager defines and creates SciNote 'Projects', assigns timelines and responsibilities

Technical lead introduces task layout

Members of the team fill in data

Project manager audits data and exports reports at the end of the project

Example of task layout template for Fermentations:



# Importance for scaling up processes?

## Lab scale – in-house



Aquila  
biolabs CGQ  
0.1-0.5 L



Ambr®250 single-use  
modular  
0.1-0.25 L



BioBLU®  
1.5-10 L



Glass Autoclavable  
Vessels  
0.3-20 L

## Scale up – with partners



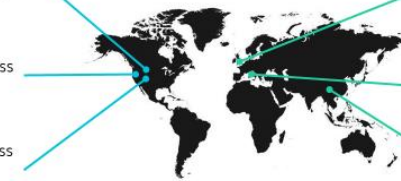
USA - Customer Project  
Pilot: 10 L  
Production: 50,000 L



UK  
Customer Project: 100 L  
Ingenza Process: 1,000 L

USA - Ingenza process  
Production: 100 L

USA - Ingenza Process  
Pilot: 6,000 L  
Production: 2.6m L



Europe - Customer Project  
Pilot: 300L  
Production: 22,000 L

Asia - Ingenza Process  
Production: 5,000 L

Successful Technology Transfer

# Importance for scaling up processes?

Key **technology transfer** tools include:

- > Comprehensive technology transfer documentation/support of customer
- > Confirmation of regulatory compliance and identification of modifications if applicable
- > Manufacturing documentation providing full traceability in all steps of the process, from R+D/process optimisation to GMP production
- > Independent quality review and sign off





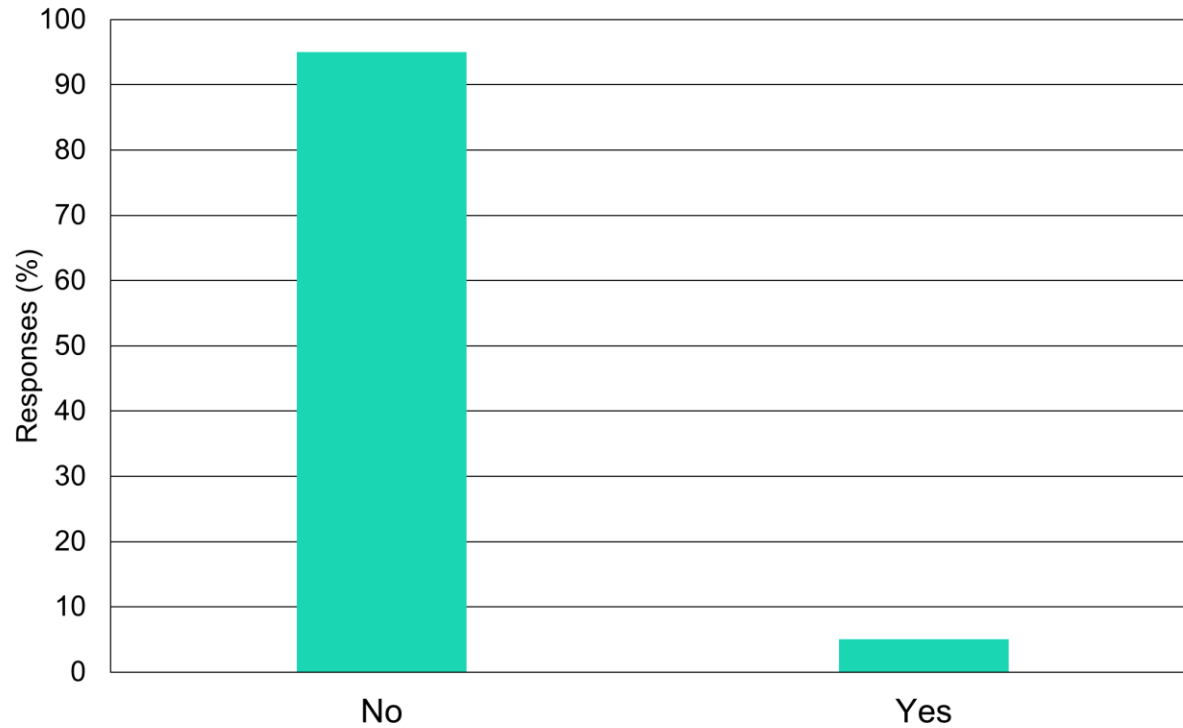
# Importance for scaling up processes?



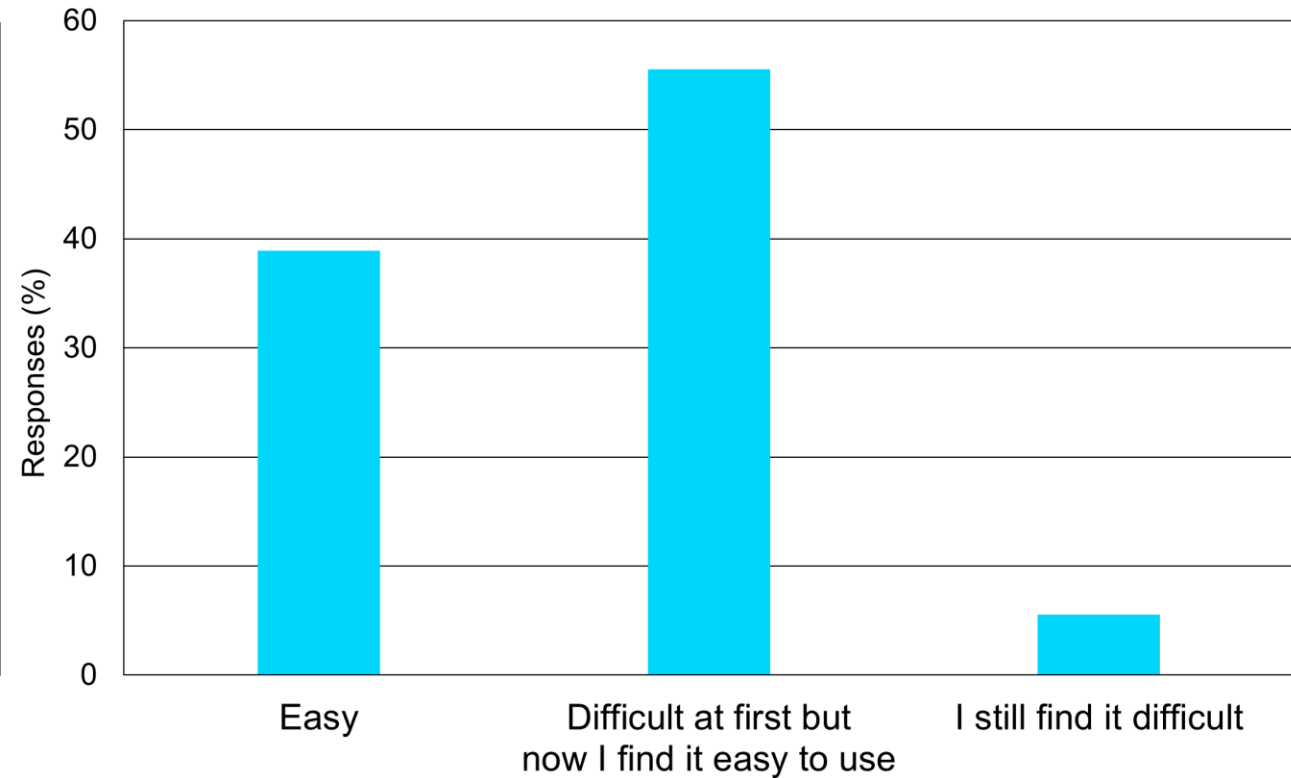
- > Processes designed and documented to allow rapid scale-up with 3<sup>rd</sup> party CMOs
- > Full traceability of process development and manufacturing steps
- > Fully time-stamped audit trail (FDA 21 CFR part 11 compliance) and daily back-up of all organization data.
- > Export of SciNote data directly into:
  - > Development plans
  - > Development reports
  - > Certificate of Analysis
  - > Customer reports and presentations

# Staff survey

Do you want to go back to paper lab books?



How did you find the transition from paper to SciNote?



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