A Biotechnology-based Manufacturing Business-Training Enterprise

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Purpose

• Create a “regulated / GMP” training environment
• Offer industry-relevant practical training
• Manufacture products that support / enhance biotechnology instruction
Product Lifecycle

Idea
Research & Development
[‘Proof of Concept’]

Prototyping / Pilot Plant
[Validation & Smaller Scale Production]

Manufacturing
[Mass / Large Scale Production]

Consumer

GMP

Regulations
Customers

1. **Student interns**
2. **Buyers of product & their students**
In the Beginning . . .

A collaboration

• Biomanufacturing / Biotechnology
• Accounting
• Business Management
• Marketing

Faculty mentors & student interns
First Products

- Cheek cell DNA extraction kit
- Assessment plasmid – coded unknown samples
Lessons Learned

• Student work pace = slow!
• Student enrollment low
• Business students/faculty do not understand biotechnology
• Cost-effective instructional supplies vs. business philosophy differences
STUDENTfacturED 2.0

• **School of Business withdrawal**

• **Partnership with InnovaBio**
  - ✓ **INNOVABiO** = product development (R&D)
  - ✓ **STUDENTfacturED** = manufacturing

• **Full quality management system**
  - ✓ Based on **ISO 13485** (for medical device)
  - ✓ Facilitates “**GMP compliance**”

• **MasterControl**: management software
What’s Happening Now

• **Partnership = Restructuring**

Diagram:
- Director of InnovaBio
- InnovaBio full-time staff (2)
- InnovaBio part-time staff
- InnovaBio student interns
- Director of STUDENTfacturED
- STUDENTfacturED full-time staff (1)
- STUDENTfacturED student interns
- R&D
- Manufacturing
What’s Happening Now

• QMS Completion a la ISO 13485
What’s Happening Now

• QMS show & tell
  ✓ Quality manual
  ✓ Design Control SOP & Form
What’s Happening Now

• New product development under design control – per 21 CFR 820.30
New Product

• DNA ladder

bp:
500
400
*300 (2x)
200
100
MasterControl Software

• Management of
  ✓ Documents
  ✓ Training
  ✓ Suppliers
  ✓ Changes
  ✓ Nonconformances / complaints
  ✓ CAPA
  ✓ Audits
  ✓ Risk
Next Steps

• Curriculum adjustments
• New product ideas
• Logistics for product sales
• ???