A Biotechnology-based Manufacturing Business-Training Enterprise

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Purpose
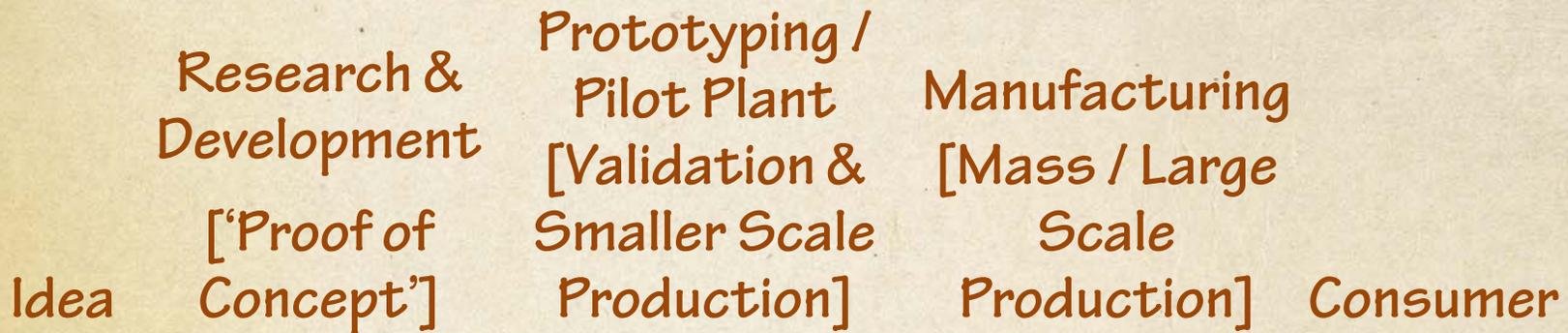
- Create a "regulated / GMP" training environment
- Offer industry-relevant practical training
- Manufacture products that support / enhance biotechnology instruction

Product Lifecycle

Salt Lake Community College — Step Ahead.

Research & Development

['Proof of Concept']

Prototyping / Pilot Plant [Validation & Smaller Scale Production]

Manufacturing [Mass / Large Scale Production]

Idea

Consumer

GMP

Regulations

Customers

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

In the Beginning . . .

Salt Lake Community College Step Ahead.

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

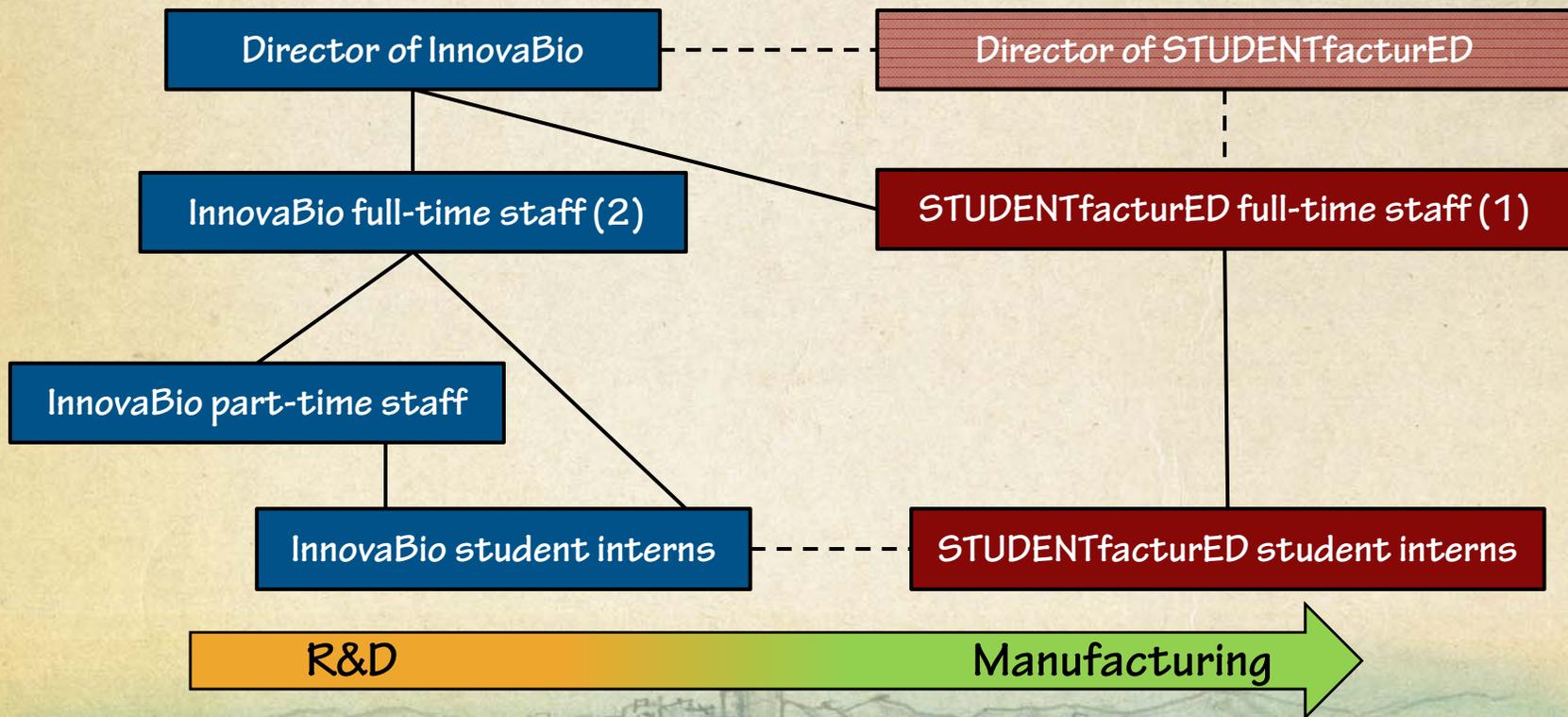Salt Lake Community College Step Ahead.

- 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
    - ✓ INN⊛VABiO = product development (R&D)
    - ✓ STUDENTfacturED = manufacturing
       Made by STUDENTS for STUDENTS

- ## Full quality management system
    - ✓ Based on ISO 13485 (for medical device)
    - ✓ Facilitates "GMP compliance"

- ## MasterControl : management software

What's Happening Now

Salt Lake Community College — Step Ahead.

- ## Partnership = Restructuring

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Director of InnovaBio - - - - - - - Director of STUDENTfacturED

InnovaBio full-time staff (2)        STUDENTfacturED full-time staff (1)

InnovaBio part-time staff

InnovaBio student interns - - - - -  STUDENTfacturED student interns
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R&D → Manufacturing

What's Happening Now

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- QMS Completion a la ISO 13485

What's Happening Now

Salt Lake Community College — Step Ahead.

- ## QMS show & tell
  - ✓ Quality manual
  - ✓ Design Control SOP & Form

What's Happening Now

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- New product development under *design control* – per 21 CFR 820.30

New Product

- ## DNA ladder

New
ladder

2-log
ladder

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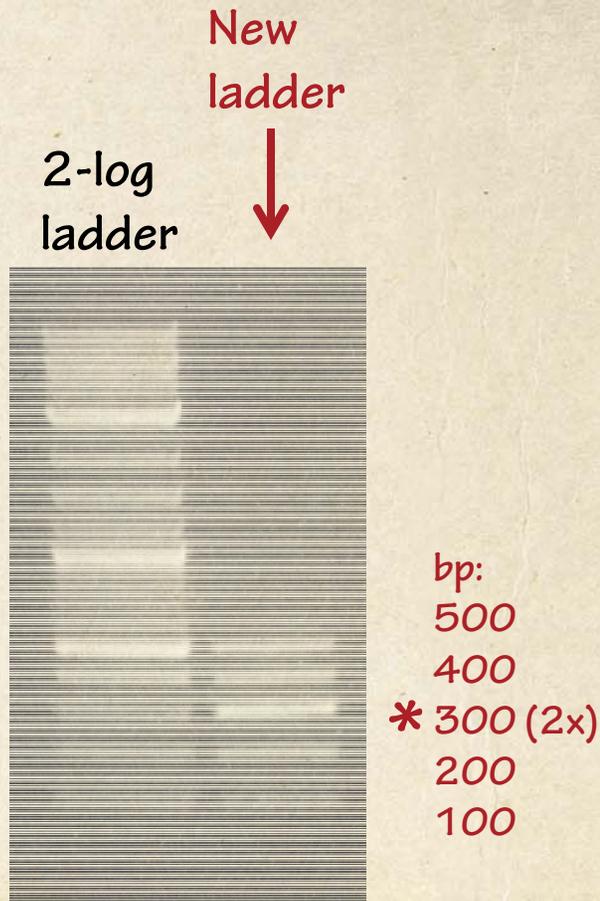
MasterControl Software

- **Management of**
  - ✓ Documents
  - ✓ Training
  - ✓ Suppliers
  - ✓ Changes
  - ✓ Nonconformances / complaints
  - ✓ CAPA
  - ✓ Audits
  - ✓ Risk

Next Steps

Salt Lake Community College — Step Ahead.

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