

A Biomanufacturing Enterprise for Innovative Student Training in Quality Systems & Regulatory Compliance

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Biotechnology

Definition

“technology based on biology”

“uses cellular and biomolecular processes to develop technologies and products that help improve our lives and the health of our planet”



Biotechnology

- Broad applications:
 - ✓ Agricultural & food
e.g. transgenic crops, food safety
 - ✓ Industrial & environmental
e.g. biofuels, bioremediation, nanotechnology
 - ✓ Healthcare
e.g. drugs, vaccines, biopharma, personalized medicine, regenerative medicine, diagnostics & medical devices



Biotechnology

- Fast growing STEM field
 - ☐ US net income : \$4.9 billion (↑33%)
 - ☐ US number of employees : 112,200 (↑5%)
 - ☐ US number of companies : 1,726 (↑1%)

Source: Ernst & Young, *Beyond borders: global biotechnology report 2011*



A Highly Regulated Industry

FDA :

- Center for Food Safety & Applied Nutrition
- Center for Biologics Evaluation & Research
- Center for Drug Evaluation & Research
- Center for Devices & Radiological Health

OSHA

EPA



Effective Preparation for Biotechnology Career

- Appropriate selection of science, technology, engineering, and math coursework
- Solid foundation in quality & regulations concepts and skills



Quality & Regulations

Design Specifications, Inputs, Outputs Documentation (e.g. SOPs, batch records) 21 CFRs (Parts 110&111, 210&211, 606, 820)

Supply Chain Management Good Manufacturing Practices

Quality Assurance vs. Control Good Laboratory Practices ISO 9001 Certification

Verification & Validation Lean Manufacturing



Typical Sources of Q&R Training

- In-house “special” delivered by consultant
- On-the-job, by experienced coworkers


Not optimal



SLCC's Biomanufacturing Program

- Provides a solid foundation in quality & regulations to support a diverse local biotechnology manufacturing industry
 - 7 core courses:
 - ✓ Introduction to Biomanufacturing
 - ✓ Basic Biomanufacturing Skills
 - ✓ Bioman Quality Systems & Regs
 - ✓ Biomanufacturing Experience
 - ✓ Good Manufacturing Practices
 - ✓ Verification & Validation
 - ✓ Measurement Fundamentals
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But . . .

- Mastery of Q&R concepts is challenging, mainly because
 - the subject matter is pretty DRY
 - Q&R are not appreciated for its value to the typical student –
Do I really need to know this? Why?
 - the complexity of Q&R and their application can be confusing/frustrating
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A Solution . . .

- A novel problem-based learning strategy
- Provides a comfortable and supportive, yet real-world but low stakes learning atmosphere
- Allows *learning by doing*, mistakes and all

STUDENTfacturED



What is STUDENTfacturED ?

A real contract manufacturing company
run by students
that will manufacture instructional biotechnology
reagents and supplies
to sell to college and local high school instructors



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What's with the name?



Purpose

To provide a contextual manufacturing environment for students to learn, apply, and reinforce industry-specific concepts & skills :

- ✓ Compliance with GMP & other regulations
- ✓ Quality system: structure & documentation
- ✓ Production: planning, management, supply chain, lean
- ✓ Finances: profit/loss vs. income/expenses
- ✓ Business development & marketing
- ✓ Legal concerns



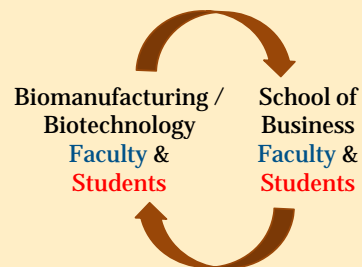
Collaboration with SLCC's School of Business

Biomanufacturing Program / Biotechnology Dept :
provides **technical** expertise
(product development & production)

School of Business :
provides **business** expertise
(accounting, business development, market research, marketing, legal)



Unique Learning Community



STUDENTfacturED Project Objectives

1. Creation of the business-training enterprise
2. Creation of the learning community
3. Development of the curriculum
4. Development of the business plan
5. Implementation of STUDENTfacturED



Progress to Date

- Identified key technical & business personnel
- Created STUDENTfacturED steering committee
- Preparing **project manual** (policies & procedures)
- Identified key functions of STUDENTfacturED
- Defining these key functions (i.e. job descriptions) & required competencies in these functions



Progress to Date (cont.)

- Drafting STUDENTfacturED **quality manual** (business mission statement, policies, & quality system description)
- Setting up STUDENTfacturED infrastructure: “production facility” & MasterControl management software
- Implemented ad hoc STUDENTfacturED – synergy with NSF STEP grant and needs



Progress to Date (cont. 2)

- Trained first participants in production document writing: procedures, batch records, bill of materials (BOM)
- Produced first STUDENTfacturED products: *Halorubrum salsolis* DNA sequencing kit modules (6); product demand



Next Steps

- Develop participant evaluation methods & tools – proof of competency
- Determine next products through market research
- Perform cost analysis and determine profit management plan
- Establish systems for accounting, ordering, production scheduling, & distribution

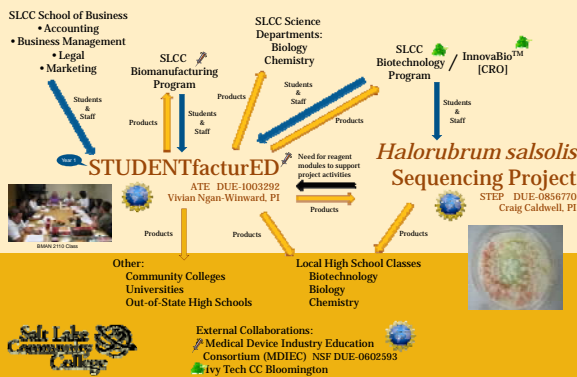


Next Steps (cont.)

- Establish customer service / technical support systems
- Establish enterprise continuous improvement system
- Formulate enterprise sustainability plan
- Establish formal learning community & student club



STUDENTfacturED Impacts



Summary

- Biotechnology is a fast growing STEM field that is highly regulated by the FDA
- Companies rely on customized quality systems to achieve regulatory compliance
- Understanding quality system and regulation basics empowers workers to strive for compliance
- STUDENTfacturED is an innovative project-based learning strategy for teaching quality and regulatory concepts and skills that will support this STEM industry

