

Biomanufacturing Kit Set Up and Organization

Biomanufacturing Kit Information for Teachers

Kit Organization

Students work in teams of new-hires for the fictitious company Protein Production Partners (PPP). As a team they have been asked to demonstrate their ability to produce a purified protein (RFP or GFP) in order to qualify for being put on a team producing an actual biologic pharmaceutical product.

Students are introduced to Biomanufacturing using a real product scenario – insulin or mRNA vaccines.

Students work in teams of 4 or 5 to work through the kit curriculum.

The kit curriculum is made up of 3 Modules:

Module 1 – Training, Regulations, Careers

- Introduction to Biomanufacturing
- Team Formation
- Creation of Team Name and Team Logo
- Team On-boarding
- Team Training
 - Lab Safety
 - Regulations – FDA, GMP, Quality Systems (QA, QC)
 - Careers – Job descriptions and career exploration
 - Standard Operating Procedures (SOPs)
- Quality Assurance – Documentation

Module 2 – Upstream Process

- Inoculation of bacteria
- Bacterial culture scale-up
- Quality Control – growth curve graphing, bacterial yield calculation
- Bacterial Harvest
- Quality Assurance – Documentation

Module 3 – Downstream Process

- Bacterial Lysis
- Protein purification (column chromatography)
- Quality Control – Protein yield calculation (Bradford Assay)
- Quality Assurance – Documentation
- Product Name and Label Design

It is estimated that a teacher with class periods that are 50 minutes in length will take 4 weeks to complete the kit curriculum.

Curriculum Organization

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- A Syllabus is provided for each Module, which briefly describes the content (Lessons) in each Module.
- An Outline is provided for each Module, which provides an example of how the module can be scheduled class period by class period. (Please note: Lessons may take more or less time to complete than estimated in the Module Outline.)
- A Teacher guide is provided for each lesson.
- The curriculum is designed to be flexible for teacher use. Teachers can use part or all of the curriculum.
- Curriculum documents are provided in formats that can be edited by teachers - .doc, .ppt etc.
- Font size can be increased to aid students with visual challenges.
- Some extra lessons are provided for teachers who wish to include extra activities that build on specific curriculum areas as well as some topics not covered directly in the kit curriculum such as: Diversity, Equity and Inclusion; Drug Cost etc
- Team size can be somewhat flexible to suit teacher/class organization needs. Possible choices include:
 - Teams of 5
 - Teams of 4 – The teacher takes on the Quality Assurance Technician role for all teams.

(Please note: Teams must be at least 4 students in size. A smaller team size will result in a greater number of teams/class, which then results in a need for more reagents and consumables. The SBE budget is limited, limiting the amount of reagents and consumables that can be supplied per teacher.)

- Team job/role assignment methods can be flexible. Students are sometimes absent for various reasons, so teachers have suggested flexibility with selection/assignment of team roles. Possible choices include:
 - Each student is assigned one role and keeps that role throughout the kit curriculum.
 - Student roles are assigned daily and change from day to day.
 - Each student is assigned a primary role and different back-up role.