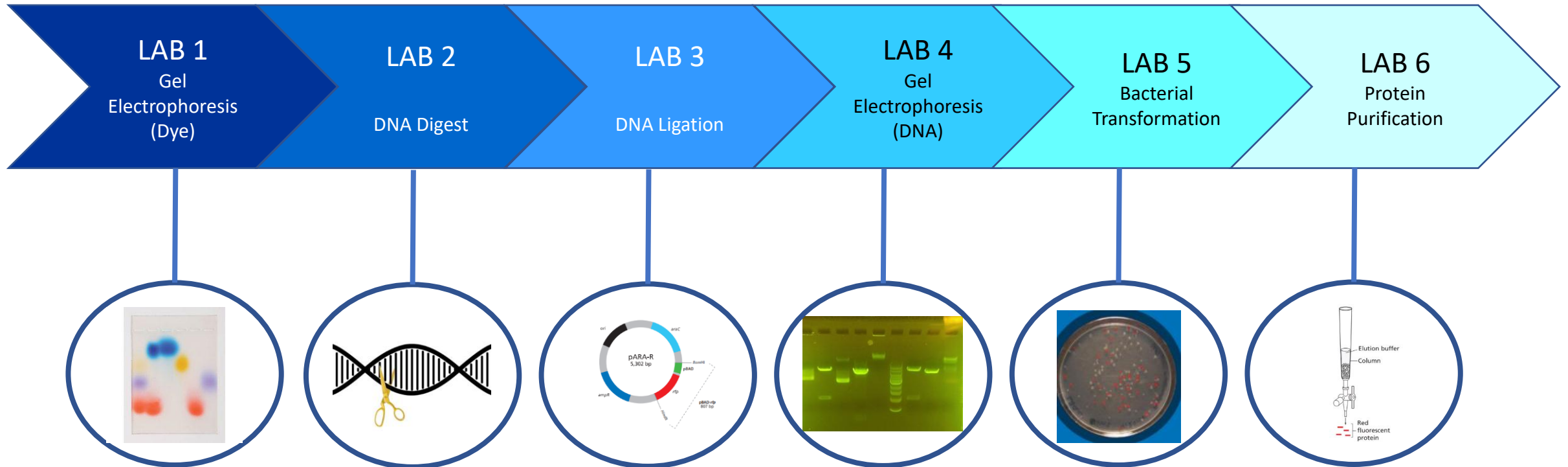




Biomanufacturing Kit

Teacher Intro Materials

ABE Labs 1-6 (or BioRad pGLO kit)





Biomanufacturing Kit

Development Team:

Jan Chalupny – Shoreline CC

Jodie Spitze – Juanita HS

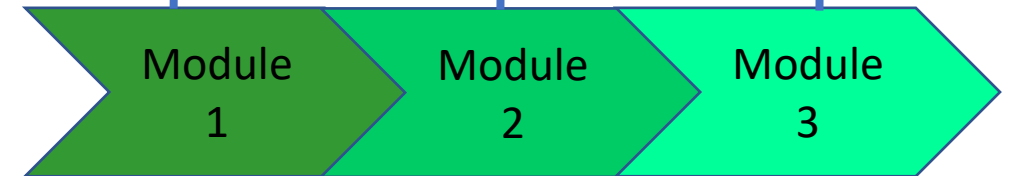
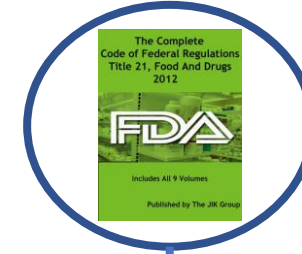
Dianne Thompson – Meadowdale HS

Jamie Olson – Woodinville HS

Training/Regulations

Upstream Process

Downstream Process



Module
1

Module
2

Module
3

LAB 1
Gel
Electrophoresis
(Dye)

LAB 2
DNA Digest

LAB 3
DNA Ligation

LAB 4
Gel
Electrophoresis
(DNA)

LAB 5
Bacterial
Transformation

LAB 6
Protein
Purification



Biomanufacturing Kit Scenario

- Students work in teams of 4 or 5 (depending on what works best in the classroom).

Job Assignment Procedure:

- Students can choose or be assigned a job and play that role on the team the entire time.
- Students can choose/be assigned a primary job second job as a back-up role (in case of student absence).
- Students can choose/be assigned jobs daily.

Team jobs include:

- Process Engineer
- Quality Control Technician
- Quality Assurance Technician (teacher can play this role)
- Biomanufacturing Associate - Upstream Process
- Biomanufacturing Associate - Downstream Process

- Each group is a team at PPP (Protein Production Partners), a Contract Research Organization (CRO).
- Optional Competition: Each team competes for a contract to produce a protein therapeutic.
 - The different stages of the process are worth points.
 - The CRO that earns the most points wins the contract.
 - Special awards can be given to CROs that had the best performance in specific portions of the challenge.



Biomanufacturing Kit

Introduction to Biomanufacturing

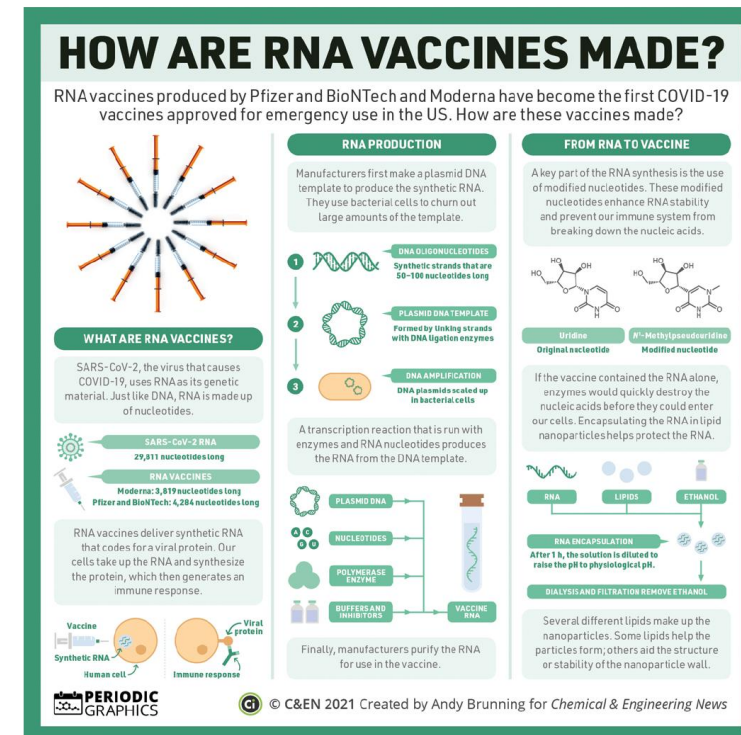
Scenario: Insulin or vaccines

Reading, Videos

- Insulin Storyline

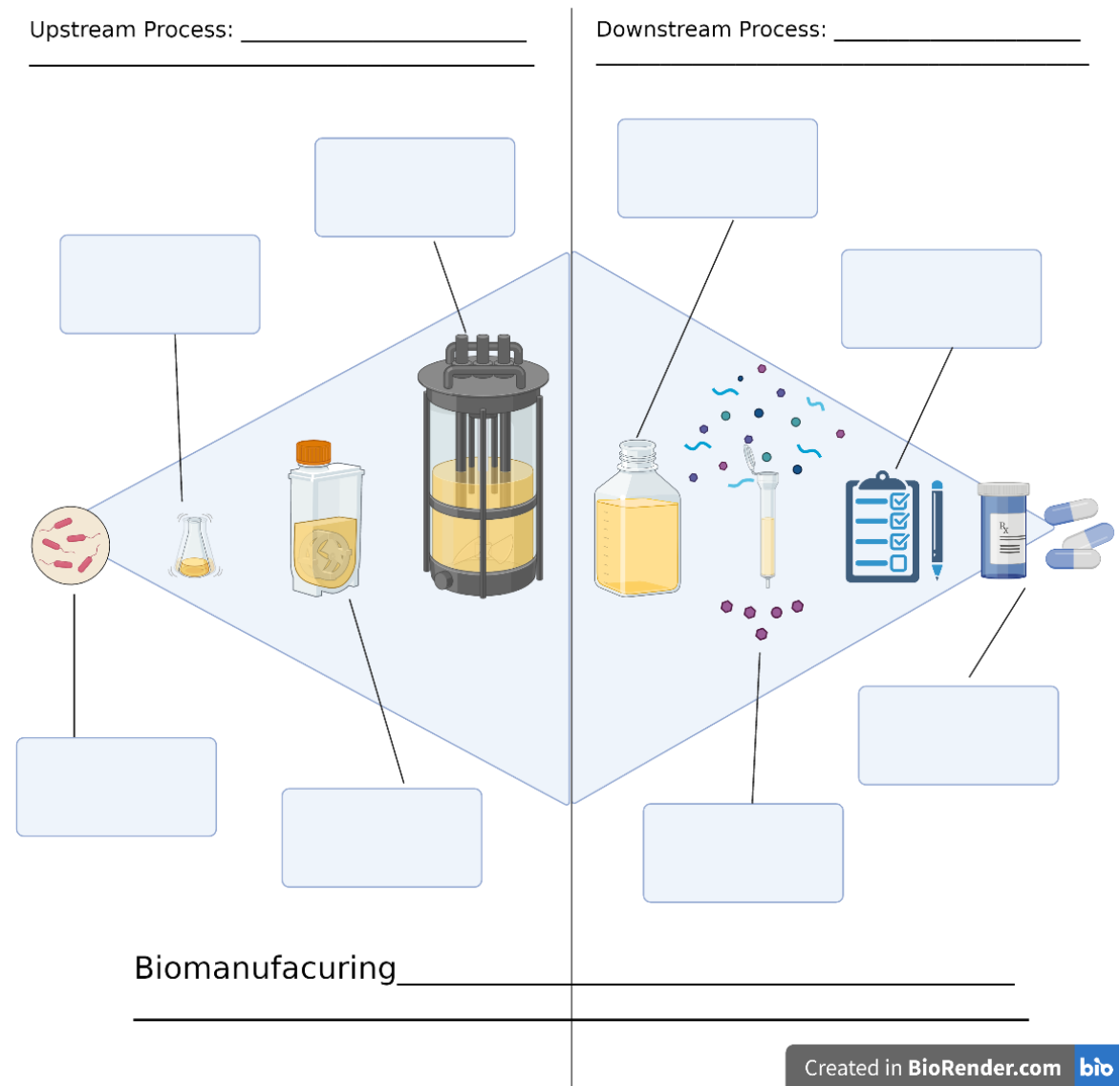


- RNA Vaccine Storyline



Introduction to Biomanufacturing

- Students receive blank graphic organizer
- Teacher uses slide deck to introduce biomanufacturing
- Students add notes to graphic organizer
- Graphic organizer used to orient students as the unit progresses.





Biomanufacturing Kit

Module 1 – Onboarding (Training/Regulations/Career Exploration)

- Welcome to PPP
- Create Team Name and Logo
- Lab Safety Training
- Intro to FDA (Food and Drug Administration) and GMP (Good Manufacturing Process), Quality Systems (Quality Assurance – QA, Quality Control – QC)
 - FDA History – American Chamber of Horrors video
 - GMP card sort
- Job Assignments/Descriptions
 - Career Exploration
- Intro to SOPs (Standard Operating Procedures)
 - Making a peanut butter sandwich video
 - Write an SOP for micropipetting
- Documentation
 - Training record



<https://wp.wpi.edu/betc/training-and-education/microbial-fermentation-development-scale-up-and-manufacturing/>

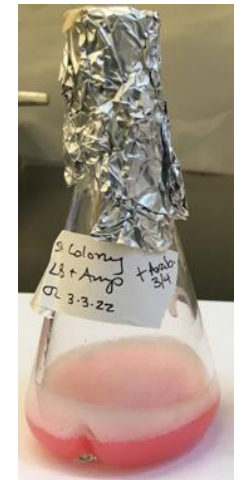
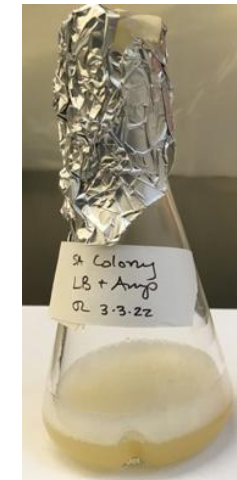
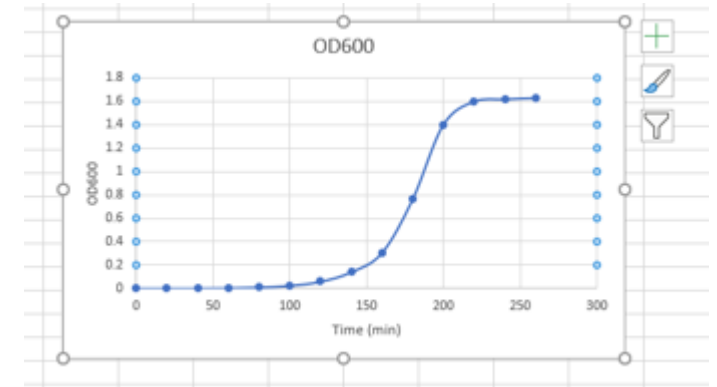




Biomanufacturing Kit

Module 2 – Upstream Process (Cell Culture and Protein Production)

- Test sterility of LB
 - Practice aseptic technique
 - Use SOP
- Inoculate LB with one RFP+ (or GFP+) bacterial colony
- Expand bacterial culture
- Measure bacterial growth over time (OD_{600})
 - Use spectrophotometer (SOP)
 - Graph data to generate a growth curve
- Induce protein production
 - Add arabinose
 - Discuss why inducible protein expression may be desired
- Harvest bacterial culture
 - Measure bacterial yield (cfu/mL) with the spread plate method
- Documentation
 - Aseptic technique results
 - Upstream Process Batch Record





Biomanufacturing Kit

Module 3 – Downstream Process (Protein Purification)

- Spin down bacteria
- Lyse bacteria
- Purify RFP or GFP
 - Column chromatography
 - Capture RFP+ or GFP+ fraction
- Measure protein yield
 - Heat denaturation of protein
 - Coomassie assay to measure protein concentration
 - Use spectrophotometer (SOP)
 - Generate a standard curve
 - Measure OD₅₉₅ of purified protein (heat denatured)
 - Use equation of the line to calculate protein concentration and yield
- Documentation
 - Downstream Process Batch Record
- Create product brand name and label

