

Biomanufacturing Module 1

Lesson 3 - New Hire Training

Lesson objectives:

Students will understand:

- What type of training is needed for biomanufacturing jobs.
- Why the biomanufacturing industry is regulated.
- What types of rules/regulations govern the biomanufacturing industry.

Essential Questions

- Why is the biomanufacturing industry regulated?

Materials:

- Lab Safety Training slide deck - or - your own personal lab safety slide deck
- Paper for laboratory safety mapping
- Lab Safety Assignment
- The FDA and the Origins of GMP slide deck
- Intro to the FDA Assignment
- Intro to GMP Assignment
- GMP Biomanufacturing Card Sort Activity board and cards
- Team Training Record Document
- Documentation file folder for each team

What Students Will Do

- Listen to/watch the Lab Safety Training slide deck
- Work with their team to create a Lab Safety Map (Lab Safety Assignment)
- Listen to/watch the FDA and the Origins of GMP slide deck
- Listen to the 'Chamber of Horrors' video about the creation of the FDA
- Work with their team to discuss the questions in the Intro to the FDA assignment
- Work with their team to carry out the GMP Card Sort Activity
- Fill out the appropriate sections of their Team Training Record
- File their Team Training Record in their team file

Teacher Preparation

- Make copies of the Lab Safety Assignment - one per team
- Make copies of the Intro to the FDA Assignment - one per team
- Make copies of the Team Training Record - one per team
- Make sure the video about the creation of the FDA is ready to play.
- Make sure the video(s) about GMP are ready to play.

Organizer

| Time | Activity | Materials |
|------------|---|--|
| 10 minutes | Lab Safety slide deck (if needed) | Slide deck |
| 10 minutes | Lab Safety Assignment - Lab mapping | Lab Safety Assignment document, pens |
| 10 minutes | The FDA and the Origins of GMP slide deck | Slide deck |
| 25 minutes | Intro to FDA Assignment Chamber of Horrors video | Intro to FDA Assignment document, video |
| 10 min | Intro to GMP Assignment Video(s) | Intro to GMP Assignment document, video(s) |
| 15 minutes | Assignment discussion GMP Card Sort Activity | GMP Card Sort board and cards |
| 10 minutes | Team Training Record - Documentation | Team Training Record Document |

Procedure

Lab Safety Training

1. Display the Lab Safety Training slide deck. If you have your own classroom lab safety presentation, feel free to use it instead. Or if your students are well versed in lab safety, feel free to skip this.
2. Ask the student teams to complete the Lab Safety Assignment

Introduction to the Food and Drug Administration (FDA) and Good Manufacturing Practices (GMP)

3. Display The FDA and Origins of GMP slide deck.
4. Tell the students you will watch a video about the creation of the FDA.
5. Play the 'Chamber of Horrors' video about the creation of the FDA.
<https://www.youtube.com/watch?app=desktop&v=jFwhoT1hr0Q>
6. Ask the production teams to discuss the questions in the Intro to the FDA Assignment
7. Play the short intro to GMP video and one of the two longer videos that lists the principles of GMP

Short Intro (3 min): <https://www.youtube.com/watch?v=vv-77usj0rw>

12 min <https://www.youtube.com/watch?v=XiOP7ihBOyM>

14 min <https://www.youtube.com/watch?v=JHkGgFUuZwE>

8. Ask the production teams to discuss the questions in the Intro to GMP Assignment
9. Ask the production teams to do the GMP Card Sort Activity
10. Ask each team to fill out the appropriate sections of their Team Training Record. NOTE that the training record is not yet complete.
11. Ask each team to file their partially completed Team Training Record in their team file.