Using current good manufacturing practices (CGMPs)

What are current good manufacturing practices and how might we use them to create a snack mix that meets the regulations?

You will be working in groups of three to create a snack mix following CGMPs (aka CG“X”Ps). Each of you will have a role to play, working together to create the mix so that each mix will meet similar standards set by a regulatory agency. The goal of this activity is to create a batch of CGMP-compliant snack mix within a specified time frame, while also gaining an appreciation for the teamwork and cooperation necessary between departments.

Use the following glossary to help you identify the different documents and departments that will be used in this activity:

- **Batch Record:** Controlled document which contains instructions for manufacturing a regulated product. The document also allows for capture of contemporaneous data relevant to the manufacture of that regulated product.
- **CGMP (Current Good Manufacturing Practices):** Quality management regulations put in place by the Food and Drug Administration (FDA) to control the process and conditions for the manufacture of (bio)pharmaceutical drug products.
- **FDA (Food and Drug Administration):** A federal agency of the Department of Health and Human Services. FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. FDA also ensures the safety of the U.S. food supply, cosmetics, and products that emit radiation.
- **Final Product Specification Form:** Controlled document which contains characteristics required of the final product (identity, potency, purity, safety, etc.)
- **Manufacturing:** Department within a drug manufacturing company responsible for making the product. Also sometimes referred to as ‘Production’.
- **Quality Assurance (QA):** Department within a drug manufacturing company responsible for ensuring compliance with CGMP. QA is responsible for reviewing and approving documentation and oversight of personnel training. QA has the ultimate authority to release or reject a product.
- **Quality Control (QC):** Department within a drug manufacturing company responsible for performing all required testing on the product to ensure final product specifications are met.
- **Sample Submission and Tracking Form:** Controlled document that verifies the transfer of a product sample from Manufacturing to Quality Control; chain of custody for product sample testing.
- **Test record:** Controlled document which contains instructions for testing a regulated product following its production. The document also allows for capture of contemporaneous data relevant to the identity, safety, efficacy, potency, purity, and/or quality of that regulated product.

Materials

- Folder that describes each role: Manufacture (MAN), Quality Control (QC), and Quality Assurance (QA) containing documentation
- Snack mix materials
- Plastic sandwich bags
- Paper plates
- Measuring scoops

Procedure

1. Choose your role: Manufacture (MAN), Quality Control (QC), or Quality Assurance (QA).
2. Read through the documentation in the folder for your chosen role. Ask questions about your role prior to the start of the activity.
3. Add a group designation to the batch number. Copy your group designation on all group documents and labels.
    - Batch #: _____ (each group should have unique letters, numbers, or initials in the underlined space to the right of the batch number). These can be assigned by the instructor or chosen at random by each group.
4. Work within your group to complete your assigned tasks and documentation.
5. Complete documents in real time as you complete each step. Do not pre-fill the documents.
6. QA: issue a Product Release label to MAN in your group if results are within specifications. Place the Release label over the Quarantine label on the snack mix bag in such a way that the outline of the quarantine label remains visible.
7. Post status of your product based on QC testing and QA review of the results as instructed.

Reflection

1. What was the most difficult part of this activity?

2. Why are clear and concise directions important in making this type of “regulated” product?

3. In this type of process, how would the use of varying equipment or raw materials affect the product?

4. Why is proper documentation required in manufacturing processes?

5. Is there a difference between food processing and biomanufacturing?