1. **Title**: GMPs for small scale cosmetics manufacturers
	1. **Target delivery date, if applicable**:
2. **Form contents last revised date**:
3. **Catalog/ website course description**: Producers of handcrafted cosmetics products have become more popular over the past ten years. Cosmetics offer higher margins, less risky production, and less FDA regulatory scrutiny than food manufacturing. Or do they? The Modernization of Cosmetics Manufacturing Act (MoCRA) is the most significant expansion of the FDA’s authority to regulate cosmetics since the Food, Drug, and Cosmetics Act of 1938. This new regulation gives the FDA expanded authority, including access to records and mandatory recall authority. This new regulation includes adverse event reporting, facility registration, product listing, and safety substantiation. This overview will discuss some of the most critical topics, including good manufacturing practices, label claims, quality management, and the new regulations posed for cosmetics producers.
4. **Course length**:
	1. 0.75 Lecture hours
	2. 0.75 Lab hours
	3. 1.5 total contact hours
5. **Student to Instructor/Technician ratio**: 20:1
6. **Learning objectives**:
	1. Recognize the requirements for Modernization of Cosmetics Manufacturing Act (MoCRA)
	2. Explain how the regulation affects them
	3. Identify good manufacturing practices, safety and quality management systems, lab testing
	4. Understand the draft guidance for cosmetics manufacturers
7. **Target industry**: Cosmetics
8. **Primary audience**: (relevant job titles)
9. **Portability?**: Y
	1. **If N to Q9 above, location taught**:
10. **Prerequisites, if applicable**: n/a
11. **Instructor credentials or qualification requirements, if applicable**:Understand MoCRA, GMPs, and product safety
12. **Is there an industry standard, state, or national certification for this course**?:no
	1. **If yes to Q12 above, list certification entity & website URL**:
	2. **Learning outcomes/requirements**:
13. **Standards and reference material**:MoCRA, Cosmetics draft guidance, good lab practices for cosmetics
14. **Suggested key terms**:
	1. Cosmetics manufacturing
	2. Lab testing
	3. Quality
	4. Product Safety
	5. GMPs
15. **Description and objectives of student hands-on exercises**:
	1. Let’s play GMP Candyland.

Colored squares are associated with each P.

Pull a card to find what square you will move to and answer the question on the card, if correct stay on the square, if wrong move back to previous space.

Special squares trigger special events.

* 1. Roll a die to determine the number of points you get

Hold a card on your head.

Have your partner describe the card which has a picture of someone violating a GMP (they cannot state the regulation).

Guess which GMP standard is being violated You get points for a correct answer, negative points for a wrong answer.

Most points wins.

* 1. YEAH or Nah lab practices.

Read aloud best practices.

If you are already doing them, it’s a YEAH.

You get one point and get to pick a card for the chance to win potential bonus points (some of the cards give points, and some take away points.

If you’re not already doing them, it’s a NAH.

You don’t get a point unless you choose a card from the NAH deck, which requires you to do something to earn your point.

1. **Text and supplies needed**: Candyland game, card game, dice, handouts
2. **Recommended images used for course promotion**:
3. **Outline**:
4. Introduction
	1. Housekeeping
	2. Class agenda and objectives
5. Regulations
	1. MoCRA
	2. Cosmetics Draft Guidance
	3. FDA
6. Fundamentals of Cosmetic Product Safety
	1. Reports, recalls, and warning letters
	2. Cross contamination
	3. Safety Hazards
7. GMPs
8. Sanitation
9. Quality Lab Testing

Change tracking log:

| Version | Preparation Date  | Prepared By | Reviewed By | Effective Date | Related Docs Updated? |
| --- | --- | --- | --- | --- | --- |
| Sept. 2019 | MM.DD.YYYY | Init | N/A | MM.DD.YYYY | Y |
| Description of revision: Outline template updated to combine previous outline and syllabus templates, incorporate FY 2019-20 logo, and introduce change tracking. |
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