



FOOD SAFETY REGULATORY PROFESSIONAL CREDENTIAL SERIES

MFRC MANUFACTURED FOODS REGULATOR CERTIFICATION STUDY GUIDE 77 COMPETENCIES



cGMP Inspections (29 competencies)

Inspection Process (7 competencies)

1. Review facility history.
2. Determine what parts of 21 CFR 117 are applicable.
3. Verify firm processes.
4. Explain exemptions to the regulation.
5. Develop inspectional approach.
6. Recognize compliance vs. non-compliance.
7. Determine the criticality of cGMP violations.

CFR 117 Requirements (Subparts A & F) (3 competencies)

1. Compare training received with requirements of applicable Subparts of 21 CFR 117.
2. Compare training received with individual job responsibilities.
3. Determine 21 CFR 117 Subpart F record-keeping compliance.

CFR 117 Requirements (Subpart B) (9 competencies)

1. Explain 21 CFR Subpart B section 117.10: Personnel.
2. Explain 21 CFR Subpart B section 117.20: Plant and grounds.
3. Explain 21 CFR Subpart B section 117.35: Sanitary operations.
4. Explain 21 CFR Subpart B section 117.37: Sanitary facilities and controls.
5. Explain 21 CFR Subpart B section 117.40: Equipment and utensils.
6. Explain 21 CFR Subpart B section 117.80: Processes and controls.
7. Explain 21 CFR Subpart B section 117.93: Warehousing and distribution.

8. Explain 21 CFR Subpart B section 117.95: Holding and distribution of human food by-products for use as animal foods.
9. Explain 21 CFR Subpart B section 117.110: Defect action levels.

Facility Records (2 competencies)

1. Identify processing records.
2. Identify administrative records.

Record Analysis (4 competencies)

1. Select a representative sample of records to review.
2. Determine record adequacy.
3. Verify process adherence.
4. Identify potential public health implications.

Documentation for Final Report (4 competencies)

1. Select agency regulatory forms.
2. Select records for inspection report.
3. Compile evidence.
4. Comply with agency document control procedures.

Food Processing Technology (14 competencies)

Processing Systems (7 competencies)

1. Explain thermal processing.
2. Explain non-thermal processing.
3. Explain purification systems.
4. Explain the fermentation process.
5. Explain conveyance systems.
6. Explain packaging systems.
7. Explain storage requirements.

Sanitary Systems (4 competencies)

1. Distinguish between sanitary systems.
2. Correlate safety hazards with sanitary systems.
3. Confirm sanitation processes.
4. Evaluate sanitary systems.

Processing Controls (3 competencies)

1. Determine potential hazards.
2. Identify control measures.
3. Evaluate control measures for identified hazards.

Laws, Regulations, & Guidance (10 competencies)

Laws (4 competencies)

1. Identify laws for manufactured foods.
2. Establish inspection authority.
3. Interpret laws for manufactured foods.
4. Apply laws.

Regulations (3 competencies)

1. Select regulations for a process.
2. Differentiate between laws and regulations.
3. Apply regulations.

Guidance (3 competencies)

1. Determine which guidance applies to a product or process.
2. Differentiate between regulation and guidance.
3. Use guidance for a process.

Preventive Controls Inspections (24 competencies)

Regulatory Requirements (7 competencies)

1. Explain 21 CFR 117 Subpart A: General Provisions.
2. Explain 21 CFR 117 Subpart B: Current Good Manufacturing Practice.
3. Explain 21 CFR 117 Subpart C: Hazard Analysis and Risk-Based Preventive Controls.
4. Explain 21 CFR 117 Subpart D: Modified Requirements.
5. Explain 21 CFR 117 Subpart E: Withdrawal of a Qualified Facility Exemption.
6. Explain 21 CFR 117 Subpart F: Requirements Applying to Records That Must Be Established and Maintained.
7. Explain 21 CFR 117 Subpart G: Supply-Chain Program.

Inspectional Activities (13 competencies)

1. Review facility history.
2. Construct a process flow diagram.
3. Write a process flow narrative.
4. Determine potential hazards.
5. Determine the scope of inspection.
6. Identify relevant Subparts.
7. Inspect against 21 CFR 117 Subpart A: General Provisions.
8. Inspect against 21 CFR 117 Subpart B: Current Good Manufacturing Practice.
9. Inspect against 21 CFR 117 Subpart C: Hazard Analysis and Risk-Based Preventive Controls.
10. Inspect against 21 CFR 117 Subpart D: Modified Requirements.
11. Inspect against 21 CFR 117 Subpart E: Withdrawal of a Qualified Facility Exemption.
12. Inspect against 21 CFR 117 Subpart F: Requirements Applying to Records That Must Be Established and Maintained.
13. Inspect against 21 CFR 117 Subpart G: Supply-Chain Program.

Documentation for Final Report (4 competencies)

1. Select agency regulatory forms.
2. Select records for inspection report.
3. Compile deviation evidence.
4. Comply with agency document control procedures.