EQUIP Scenarios/ Study Designs

Scenario 1: Small Batch Production for Immediate Use:

Situation: A mobile manufacturing unit produces *multiple small batches* (e.g., 100 doses) of an injectable drug for immediate use in a hospital setting during a public health emergency.

Challenge: Traditional stability testing and reserve sample requirements (21 CFR 211.170) are not feasible due to the small batch size and immediate use.

Study: Stability of Small Batches of Injectable Drugs in Mobile Manufacturing Units

Objective: To determine the stability of small batches (e.g., 100 doses) of injectable drugs produced in mobile manufacturing units for immediate use.

Design:

- A mobile manufacturing unit will produce multiple small batches of an injectable drug.
- Samples from each batch will be stored under various conditions (e.g., room temperature, refrigerated, frozen).
- Samples will be analyzed at regular intervals (e.g., 0, 1, 2, 4, 8, 12 hours) for key quality attributes (e.g., potency, purity, sterility).
- The impact of manufacturing moves on product stability will be evaluated by comparing the stability of samples from batches produced before and after a move.

Data Analysis:

- Stability data will be analyzed to determine the shelf life of the drug product under different storage conditions.
- The effect of manufacturing moves on product stability will be assessed.
- The data will be used to develop alternative stability data requirements for immediate use products.

Expected Outcome:

- The study will provide data to support alternative stability data requirements for immediate use products produced in mobile manufacturing units.
- The study will also help to assess the impact of manufacturing moves on product stability.

Scenario 2: Relocation of a Mobile Manufacturing Unit

Situation: A mobile manufacturing unit, previously qualified and operating at one location, is relocated to a new site (e.g., from one hospital to another).

Challenge: Ensuring continued compliance with cGMP requirements (21 CFR 211) after relocation, particularly regarding building and facilities (Subpart C).

Study: Re-qualification of Mobile Manufacturing Units after Relocation

Objective: To determine the re-qualification steps necessary after relocation of a mobile manufacturing unit.

Design:

- A mobile manufacturing unit will be relocated to a new site.
- The unit will be re-qualified according to a pre-defined protocol.
- The protocol will include steps to verify the integrity of the unit's structure, equipment, and systems.
- Environmental monitoring will be conducted to assess the impact of the new location on the unit's environment.

Data Analysis:

- Re-qualification data will be analyzed to determine the effectiveness of the re-qualification protocol.
- The impact of the new location on the unit's environment will be assessed.
- The data will be used to develop re-qualification requirements for mobile manufacturing units.

Expected Outcome:

- The study will provide data to support re-qualification requirements for mobile manufacturing units.
- The study will also help to assess the impact of relocation on the unit's environment.

Scenario 3: Rapid Changeover between Different Drug Products

Situation: A mobile manufacturing unit needs to quickly switch production from one drug product to another to address changing needs during a public health emergency.

Challenge: Meeting cGMP requirements for cleaning validation and preventing cross-contamination between products.

Study: Cleaning Validation for Rapid Changeover between Different Drug Products in Mobile Manufacturing Units

Objective: To determine the cleaning validation data required for rapid changeover between different drug products in mobile manufacturing units.

Design:

- A mobile manufacturing unit will be used to produce multiple drug products.
- The unit will be cleaned between each product changeover.
- Cleaning effectiveness will be assessed using various methods (e.g., visual inspection, swabbing, rinse sampling).
- The impact of cleaning on product quality will be evaluated.

Data Analysis:

- Cleaning validation data will be analyzed to determine the effectiveness of cleaning procedures.
- The impact of cleaning on product quality will be assessed.
- The data will be used to develop cleaning validation requirements for rapid changeover in mobile manufacturing units.

Expected Outcome:

- The study will provide data to support cleaning validation requirements for rapid changeover in mobile manufacturing units.
- The study will also help to assess the impact of cleaning on product quality.

Scenario 4: Operator Training for On-Site Personnel

Situation: On-site personnel (e.g., hospital staff) with limited formal training in pharmaceutical manufacturing will operate a mobile manufacturing unit.

Challenge: Meeting cGMP training requirements (21 CFR 211) for these personnel.

Study: Operator Training for On-Site Personnel in Mobile Manufacturing Units

Objective: To determine the type of training program appropriate for on-site personnel (e.g., hospital staff) with limited formal training in pharmaceutical manufacturing.

Design:

- A training program will be developed for on-site personnel.
- The program will include both theoretical and practical components.
- The effectiveness of the training program will be evaluated through assessments and performance monitoring.

Data Analysis:

- Training data will be analyzed to determine the effectiveness of the training program.
- The impact of training on operator performance will be assessed.
- The data will be used to develop training requirements for on-site personnel in mobile manufacturing units.

Expected Outcome:

- The study will provide data to support training requirements for on-site personnel in mobile manufacturing units.
- The study will also help to assess the impact of training on operator performance.

Scenario 5: Master Production and Control Record (MPCR) Management

Situation: EQUIP-A Pharma utilizes multiple mobile manufacturing units, each capable of producing multiple drug products.

Challenge: Ensuring clarity and compliance in MPCR management.

Study: MPCR Management in Mobile Manufacturing Units

Objective: To determine the appropriate approach for MPCR management in mobile manufacturing units.

Design:

- Different approaches to MPCR management will be evaluated (e.g., unit-specific MPCRs, product-specific MPCRs).
- The effectiveness of each approach will be assessed in terms of clarity, compliance, and efficiency.

Data Analysis:

- MPCR management data will be analyzed to determine the effectiveness of different approaches.
- The data will be used to develop MPCR management requirements for mobile manufacturing units.

Expected Outcome:

- The study will provide data to support MPCR management requirements for mobile manufacturing units.
- The study will also help to identify the most effective approach for MPCR management in this setting.