1. PURPOSE

1.1. This procedure describes the cleaning activities performed at LiquiGlide's Billerica facility.

2. SCOPE

2.1. This procedure applies to Clean Room within the Manufacturing Room (105), The Analytical Room (103), The Manufacturing Corridor (102), The Sampling Area within the Warehouse (101) located at 34 Sullivan Road, Billerica MA, 01862.

3. RESPONSIBILITIES

Role	Responsibility
GMP Associates	– Understand and follow the cleaning requirements, methods, and frequencies defined in this procedure – Update logbooks as cleanings are performed
Head of Manufacturing, or designee	– Ensure compliance with this procedure by all GMP Associates and contract employees – Verification of performance of cleaning tasks according to this procedure
Quality Assurance	– Review of cleaning logs

4. DEFINITIONS

4.1. **IPA:** Isopropyl Alcohol; a commonly used Sanitizing agent.

4.2. **Manufacturing Loft:** The area used for storage above the exit in the Manufacturing Room.

5. EQUIPMENT & SUPPLIES

5.1. Dry-cleaning tool; Sticky Roller
5.2. Tacky mat
5.3. Wet cleaning tool
5.4. Disinfectant cleaners
  5.4.1. 70% IPA
  5.4.2. Decon-Spore 2000
    5.4.2.1. Must be diluted 6.4 ounces of Decon-Spore 2000 to 1 gallon of water.
  5.4.3. Stat Clean
5.5. Cleanroom Wipes

6. PROCEDURE

6.1. **General Considerations**

6.1.1. Daily and weekly cleaning shall be documented on [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form.

6.1.1.1. [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form shall be generated at the beginning of every week.

6.1.1.2. [QA-044-FRM-02] Monthly and Semiannual Facility Cleaning Form shall be generated at the beginning of every month and must be completed before the end of the first full week of every month.

6.1.1.3. Quality Assurance or designee must review that cleaning has been performed and that the necessary documentation has been completed on weekly basis and fill in the “Reviewed By (QA)” on the cleaning form [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form.

6.1.1.4. Head of Manufacturing or Designee will ensure that cleanings are performed on schedule.

6.1.1.5. If upon inspection, the room is not deemed clean, a rejection is recorded in the comments section and the clean repeated of [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form.

6.1.1.6. If cleaning cannot be performed or is not required document in the Comments section of [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form.

6.1.1.7. Document cleaning solutions used in the comments section of [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form.

6.1.2. Fresh, clean, disinfectant solutions must be prepared for the individual rooms.

6.1.3. If any spill occurs, an ad hoc clean may be requested.

6.2. Cleaning schedule

6.2.1. Daily Checks and Cleaning

6.2.1.1. All daily cleaning is done on an as needed basis Monday through Thursday

6.2.1.1.1. Initialing on [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form for cleaning days Monday through Thursday signifies that the respective portion of the checklist has been confirmed to be clean at the time of initialing

6.2.1.1.2. Initialing does not necessarily signify that a cleaning has been actively performed that day.

6.2.1.2. Clean all horizontal surfaces and door handles with IPA and Lint free wipes as needed.

6.2.1.3. Cleaning the floor with a broom as needed.

6.2.1.4. Remove and replace tacky mats whenever it has become visibly soiled or is no longer tacky.

6.2.1.5. Empty waste bins and place a new bag in the trash cans, if waste has accumulated. Place trash bags into the waste accumulation dolly located by Warehouse (101) bay door.

6.2.1.6. Dispose of any loose trash or discarded packaging materials in the facility.

6.2.1.7. Wipe down the curtains of the cleanroom in the Manufacturing Room (105) and The Sampling Area within the Warehouse (101) using 70% IPA if they are visibly dirty.

6.2.2. Weekly

6.2.2.1. Weekly cleaning will be done on every Friday (or the last day of the work week, note in the comments if this does not fall on the Friday of the week)

6.2.2.2. Initialing on [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form for weekly cleaning confirms that the cleaning has been performed on that day

6.2.2.3. Cleaning of Surfaces

6.2.2.3.1. Spray all surfaces and equipment (curtains, shelving units, tables, door handles, trash cans, etc.) with 70% IPA. Wipe the surfaces and equipment with a lint free cleanroom wipe.

6.2.2.3.1.1. This includes spraying and wiping down all surfaces of GMP manufacturing equipment and connecting lines (Slurry Tank, Pump Skids, Scales Used for Manufacture, etc.)

6.2.2.3.2. Ensure that the equipment and surfaces are cleaned in an aseptic manner, which includes one singular stroke in one direction and no overlaps between strokes.

6.2.2.3.3. Dispose of soiled cleanroom wipes in the appropriate clean room trash bin after cleaning is complete.

6.2.2.4. Cleaning of Floors using the dry-cleaning tool

6.2.2.4.1. Verify that the adhesive pad on the sticky roller is new.

6.2.2.4.1.1. In the case of the Manufacturing Room, an additional step of sweeping using the cleanroom assigned broom is necessary before using the sticky roller.

6.2.2.4.2. Start the cleaning process in each room in the location furthest away from the exit

6.2.2.4.3. Start in the corner of the room furthest from the door and work your way to the door.

6.2.2.4.4. Ensure that the entire floor, including areas below shelves, tables and equipment, are properly cleaned by the dry-cleaning tool.

6.2.2.4.5. Peel and dispose of adhesive pad after the cleaning of each room. If the adhesive pad is severely soiled before finishing one room, change immediately and dispose of it in a trash can.

6.2.2.5. Floors using the wet cleaning tool

6.2.2.5.1. Fresh, clean, disinfectant solutions must be prepared for the individual rooms

6.2.2.5.2. When performing a full GMP facility cleaning, the connected rooms are to be cleaned in an order that prevents re-entry into a cleaned space.

6.2.2.5.3. Completely saturate a cleanroom wipe in the Stat Clean before placing it on the wet cleaning tool.

6.2.2.5.3.1. If necessary, use of standard mop is acceptable.

6.2.2.5.4. Start the cleaning process in each room in the location furthest away from the exit

6.2.2.5.5. Always push the wet cleaning tool in one singular direction towards the exit.

6.2.2.5.6. Ensure that strokes do not overlap with one another.

6.2.2.5.7. Ensure that the wet wipe is fully saturated with disinfectant cleaner before starting another stroke.

6.2.2.5.8. Ensure that the entire floor, including areas below shelves, tables and equipment, are properly cleaned.

6.2.2.5.9. Dispose of soiled cleanroom wipes in a trash can after the cleaning process. Log all cleaning and cleaners used into **[QA-044-FRM-01] Daily and Weekly Facility Cleaning Form** upon completion of weekly general housekeeping. should be verified by the Head of Manufacturing or designee and reviewed by Quality Assurance once the Form is complete

6.2.2.6. Empty waste bins and place a new bag in the trash cans. Place trash bags into the waste accumulation dolly located by Warehouse (101) bay door.

6.2.3. **Monthly**

6.2.3.1. Cleaning of Surfaces

6.2.3.1.1. Spray all surfaces and lab equipment (shelving units, tables, door handles, etc.) with Decon-Spore 2000

6.2.3.1.2. Wipe the surfaces and equipment with a lint free cleanroom wipe.

6.2.3.1.3. Ensure that the equipment and surfaces are cleaned in an aseptic manner, which includes one singular stroke in one direction and no overlaps between strokes.

6.2.3.1.4. Dispose of soiled cleanroom wipes in the appropriate clean room trash bin after cleaning is complete.

6.2.3.1.5. Ceiling (Manufacturing Clean Room and Sampling Room only)

6.2.3.1.5.1. In rooms with HEPA filter ceilings, wipe only the filter grid using unidirectional strokes, avoiding contact with the HEPA filter surfaces.

6.2.3.2. Floors using the dry-cleaning tool

6.2.3.2.1. When performing a full GMP facility cleaning, connected rooms are to be cleaned in an order that prevents re-entry into a cleaned space.

6.2.3.2.2. Start the cleaning process in each room in the location furthest away from the exit

6.2.3.2.3. Start in the corner of the room furthest from the door and work your way to the door.

6.2.3.2.4. The Manufacturing Room requires an additional step in between sweeping and mopping. This process uses the Sticky Roller to pick up any additional fine powders, within the clean room.

6.2.3.2.5. Dispose of adhesive pads as needed or by the end of cleaning session, determined by which comes first.

6.2.3.2.6. Ensure that the entire floor, including areas below shelves, tables and equipment, are properly cleaned by the dry-cleaning tool.

6.2.3.3. Floors using Wet-Cleaning Tool

6.2.3.3.1. When performing a full GMP facility cleaning, the connected rooms are to be cleaned in an order that prevents re-entry into a cleaned space.

6.2.3.3.2. Prepare Dilution of Decon Spore using water at the ratio of 6.4 ounces of Decon-Spore 200 to every gallon of water.

6.2.3.3.3. Completely saturate a cleanroom wipe in Decon Spore Dilution before placing it on the wet cleaning tool.

6.2.3.3.3.1. If necessary, use of standard mop is acceptable.

6.2.3.3.4. Start the cleaning process in each room in the location furthest away from the exit

6.2.3.3.5. Always push the wet cleaning tool in one singular direction towards the exit.

6.2.3.3.6. Ensure that strokes do not overlap with one another.

6.2.3.3.7. Ensure that the wet wipe is fully saturated with disinfectant cleaner before starting another stroke.

6.2.3.3.8. Ensure that the entire floor, including areas below shelves, tables and equipment, are properly cleaned.

6.2.3.3.9. Dispose of soiled cleanroom wipes in a trash can after the cleaning process.

6.2.3.3.10. A monthly clean is required for rooms coming back to service from Out of Service status.

6.2.3.3.11. Monthly cleaning tasks are to be done in addition to the daily cleaning tasks (Section 2.1).

6.3. Semi-Annual Cleaning of Clean Rooms and Controlled Environments

6.3.1. Use Sticky roller to clean walls .

6.3.2. Clean the Manufacturing Loft in the Manufacturing Room using Sticky Roller

6.4. A product-change over (PCO)

6.4.1.1. The Daily (Section 6.1.1) and Monthly (Section 6.1.2) cleaning tasks are performed.

6.4.1.2. This clean is performed upon request from Manufacturing and is used to change a room from Product A to Product B.

7. ATTACHMENTS

7.1. N/A

8. REFERENCES

8.1. [QA-044-FRM-01] Daily and Weekly Facility Cleaning Form
8.2. [QA-044-FRM-02] Monthly and Semiannual Facility Cleaning Form

REVISION HISTORY

Version 01 Effective on 26-Jun-2020
New Document

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

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Required Workflow Steps for this Category

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1. PURPOSE:

The purpose of this procedure is to describe the procedures used to clean the manufacturing equipment at LiquiGlide's manufacturing facility located at 34 Sullivan Road Suite 19 in Billerica, MA 01862, including Clean in Place (CIP) of the Slurry Tank (TK-0101), cleaning of all product lines and ancillary process equipment, cleaning of the homogenizer suction wand (FX-0404, SP-0413, and SP-0414), and sanitizing external components that make contact with coating product or raw materials.

2. SCOPE:

2.1. This procedure applies to equipment cleaning, including Clean in Place (CIP) of the Slurry Tank (TK-0101) and coating production lines, cleaning of the homogenizer suction wand (FX-0404, SP-0413, and SP-0414), and sanitizing external components that make contact with coating product or raw materials at Liquiglide's manufacturing facility located at 34 Sullivan Road Suite 19 in Billerica, MA 01862.

3. RESPONSIBILITIES

Role	Responsibility
Manufacturing Associate	– Ensure execution of CIP activities according to plan/protocol – Record data that is gathered during the execution of a CIP procedure.
Head of Manufacturing or Designee	– Ensure that employees performing the CIP procedure have appropriate training on this procedure the equipment and the equipment involved in this procedure – Ensure that the CIP procedure is executed according to protocol and done so in a safe manner
Quality Assurance	– Review of cleaning documentation

4. DEFINITIONS

4.1. **Clean In Place (CIP)** – A cleaning procedure that is performed on equipment without moving the equipment out of its position during set up.

5. PROCESS OVERVIEW

5.1. Each procedure is to be performed following its respective purpose. Every procedure listed does not necessarily need to be run together or on the same day and should only be performed as needed.

5.1.1. The associated form for each procedure should be filled out when performing the cleaning for tracking purposes.

5.1.2. The full series of cleanings described in 5.5 must be performed between manufacturing campaigns, but not necessarily between batches of a single campaign or technical batches, as described under each portion.

5.2. The Clean In Place (CIP) process of the manufacturing equipment at Billerica involves circulating fresh additions of the same or similar oil used in the product through the manufacturing equipment. Different volumes, circulation times, temperature thresholds, and oil types are used depending on the goal of the respective cleaning. Small volume flushes are described in section **6.1** and the sanitization clean in place is described in section **6.2**.

5.3. Any external portion of the process that contacts product or raw materials and any dead-zones where oil cannot freely circulate must be wiped down with Decon-Spore 200 plus and IPA in succession and then dried prior to use to minimize any contamination risks.

5.3.1. Dead-zones are to be wiped down prior to manufacturing campaigns but then are not to be opened again or cleaned until the end of manufacturing when a full system cleaning is performed

5.3.2. The drum pump (P-0301), Harvest pump outlet (SP-0502), and outside of the suction lance (SP-0414) must be wiped down before every day of use to minimize contamination risks.

5.3.3. Due to potential of solids raw material residue congealing upon contact with moisture, the suction lance (SP-0414) should be thoroughly wiped down with a dry wipe prior to wiping down with IPA.

5.4. The Homogenization Pump Skid (SK-0401) suction lance cleaning for FX-0403, SP-0413, and SP-0414 involves blasting foam projectiles through with high pressure to remove powder residues and is described in section **6.4**.

5.5. The following combination and order of cleaning procedures should performed prior to use of equipment for GMP product production if the equipment has recently been used for any type of production. If only maintenance has been performed and there is no coating residue in the system, performing the cleaning steps described in 5.5.5-5.5.8 is sufficient for production. If consecutive batches are being run, then only the cleaning described in step 5.5.8 needs to be performed between each batch.

5.5.1. Wipe down of just the drum pump, both outside and spray down of inside, following section **6.3** and filling out MFG-002-FRM-003 (must be done prior to use of the drum pump on any given day if the oil flushes are spread out).

5.5.2. A Small Volume CIP Flush using greater than 26 kg of oil heated to at least 70°C and no spray ball circulation following section **6.1** and filling out MFG-002-FRM-001

5.5.3. A Small Volume CIP Flush using greater than 26 kg of oil heated to at least 70°C and with spray ball circulation following section **6.1** and filling out MFG-002-FRM-001

5.5.4. Homogenizer Suction Lance assembly (FX-0403, SP-0413, and SP-0414) cleaning (can be done at any point before 6.5.5) following **6.4** and filling out MFG-002-FRM-004

5.5.5. Complete wipe down of product contacting equipment and dead-zones following section **6.3** and filling out MFG-002-FRM-003

5.5.6. A Sanitization CIP with greater than 85kg of L115 circulated above 85°C for an extended period of time following section **6.2** and filling out MFG-002-FRM-002

5.5.7. A small volume CIP Flush using greater than 26 kg of oil heated to at least 90°C and with spray ball circulation. Should be done as close to the start of production as possible, preferably the morning of, prior to starting. Follow section **6.1** and fill out MFG-002-FRM-001 during execution.

5.5.8. Final Product Contacting External Element Cleaning (P-0301, SP-0502, and SP-0414). This must only be on the day of production prior to using the equipment. Follow section **6.3** and fill out MFG-002-FRM-003 during execution

6. PROCEDURE

6.1. Small Volume CIP Flush

6.1.1. Purpose

6.1.1.1. To flush the Slurry Tank (TK-0101), the Homogenization Pump Skid (SK-0401), the Harvest Pump Skid (SK-0501), and all ancillary and connecting components. The Clean In Place (CIP) Pump Skid (SK-0601) is cleaned by this procedure during spray ball circulation as well, but this is only done if there is already minimal residue remaining in the equipment prior to the start of this procedure by a bulk flush performed after the most recent production (manufacturing batch or technical batch).

6.1.1.2. This portion of the procedure should be executed in situations such as, but not limited to:

6.1.1.2.1. Clearing out the bulk of leftover coating residue from a recent production (in this case, circulation through the spray balls will NOT be performed).

6.1.1.2.2. Changeover of raw materials used for production (i.e. the most recent oil in the system is not the same as the oil used in the formulation to be produced next, including oil used in cleaning).

6.1.1.2.3. Recent reassembly or maintenance of associated equipment prior to coating production.

6.1.1.3. A small volume flush will be performed over a sanitization CIP (section **6.2**) when the equipment is significantly sullied (typically with leftover coating residue) or when the equipment is clean and only a small volume circulation is needed to remove residue from a different oil previously in the equipment.

6.1.2. Preparation

6.1.2.1. Print **[MFG-002-FRM-001] Small Volume Clean In Place (CIP) Flush** to be filled out during the execution of this procedure. Generate a document ID for the executed cleaning form following MFG-002-XXX-PYY.

6.1.2.1.1. XXX identifies the series of consecutive cleanings the document belongs to and is the next sequential number from the most recently performed series of consecutive cleaning activities.

6.1.2.1.1.1. Typically, a new series of cleaning documents is initiated at the end of a GMP production campaign.

6.1.2.1.2. YY is the next sequential number in the cleaning series of XXX, starting at 1.

6.1.2.2. MV-0101 will remain open during this entire process. MV-0102 will remain closed during the entire process

6.1.2.3. Ensure that MV-0103, MV-104, MV-0105, MV-0401, and MV-0403 are closed.

6.1.2.4. Ensure that the Manway (MW-0101) is securely closed and the clamps tightened.

6.1.2.5. Ensure that the Slurry Tank (TK-0101), the Homogenization Pump Skid (SK-0401), the Harvest Pump Skid (SK-0501) are connected to their respective power sources and are turned on.

6.1.2.6. Ensure that all connections within the circulation line are tight.

6.1.2.7. Tare the Slurry Tank (TK-0101) and add the oil to be used for cleaning using the drum pump (P-0301). At least 26 kg of oil is needed for this portion. Any larger volume is allowable for this portion. Record the volume added and batch information in the “Flushing Oil Information” section of **[MFG-002-FRM-001] Small Volume Clean In Place (CIP) Flush.**

6.1.3. Circulation using the Homogenization Pump Skid (SK-0401)

6.1.3.1. Open MV-0105 and MV-0401

6.1.3.2. Turn on the Homogenizer to 60 Hz to begin circulation. As the homogenizer circulates the oil at 60 Hz, it will also heat the oil. Continue circulating oil until a temperature of 70°C is reached

on TI-0401. Record the relevant information every ten minutes circulation is performed in **MFG-002-FRM-001.**

6.1.3.2.1. If this is the last flush prior to GMP production, a temperature of 90°C must be reached instead.

6.1.3.3. (Optional) Take a 40ml rinsate sample using the sample port S-0401 during the circulation for information purposes only. If the sample is to be used for additional testing, fill out the appropriate sample submission form (if applicable).

6.1.3.4. Turn off the homogenizer and close MV-0401.

6.1.4. **IF** there was no bulk coating residue remaining in the system at the time of starting this section of the protocol (i.e. a previous cleaning was performed to remove the bulk of coating residue) then the Clean In Place (CIP) Pump Skid (SK-0601) and spray ball assembly (SB-0101A and SB-0101B) should be circulated through as well with the following procedure and logged in **MFG-002-FRM-001.** Otherwise, N/A the section and continue to 7.1.5 Draining the System.

6.1.4.1. Open MV-0104 to allow oil to flow to the Clean In Place Pump Skid (SK-0601).

6.1.4.2. Turn on the Clean In Place Pump to a set point of 46 Hz.

6.1.4.2.1. If a rattling sound is heard, restart the CIP pump at a set point of 25 Hz and slowly ramp up the frequency to 46 Hz

6.1.4.3. Ensure that the spray balls are active by looking through the sight glass (SG-0101) and confirming that splashing is visible. Record the pressure generated by the CIP pump by reading pressure gauge (PI-0601) in **MFG-002-FRM-001**. A value between 19 and 29 psi is expected. Notify head of manufacturing if a value outside of this range is observed. The pump set point may then be increased to as much as 50 Hz and recorded in the appropriate section of the form.

6.1.4.4. While SK-0601 is active, open MV-0401 to empty the homogenizer lines. When opening the valve, listen for air to be pulled by the pump characterized by a sharp loss in pressure on the pressure readout of PI-0601. Close MV-0401 once more and repeat cycling MV-0401 until the pressure drop is observed within one second.

6.1.4.5. Continue circulation through the CIP pump for at least 10 minutes.

6.1.4.6. Turn off the CIP pump. Close MV-0104 about 75% of the way.

6.1.4.7. Open MV-0401 and turn on the Homogenizer to a run speed of 60 Hz.

6.1.4.8. As soon as the flow rate on the flow indicator on the outlet line of the homogenizer (FI-0401) drops, close MV-0104 the remaining amount.

6.1.4.8.1. (Optional) Before turning off the homogenizer, take a 40ml rinsate sample using the sample port S-0401 during the circulation for information purposes. If the sample is to be used for additional testing, fill out the appropriate sample submission form.

6.1.4.8.2. If this is the last flush prior to GMP production, continue circulation through the system until a temperature of 95°C is reached on TI-0401.

6.1.4.9. Turn off the homogenizer.

6.1.5. Draining the System

6.1.5.1. Prepare a waste drum in front of the Harvest Pump Skid (SK-0501)

6.1.5.2. Place the Harvest Pump Skid outlet spool (SP-0502) directly into the opening of a waste drum

6.1.5.3. Open MV-0103 and make sure that MV-0401 and MV-0104 are closed.

Set the Harvest Pump Skid to VFD control by turning the control knob to “KP”. Turn on the Harvest Pump and drain the system directly into a waste drum. Take care not to overflow the waste drum and replace as needed.

6.1.5.4. At the start of draining, open MV-0401 to empty the homogenizer lines. When opening the valve, listen for air to be pulled by the pump characterized by a rhythmic sound from the pump compared to the steady sound of liquid pumping and a sharp drop in liquid output from the pump. Close MV-0401 once this is heard. Repeat opening and closing MV-0401 until the sound change occurs within 1 second of opening MV-0401. Repeat for MV-0104 if section 7.1.4 was used, otherwise keep MV-0104 closed.

6.1.5.5. Drain the remaining fluid into the waste drum.

6.1.5.6. If no more CIP cycles will be performed on the system prior to production, the remaining lines must be completely drained.

6.1.5.6.1. For safety reasons, the lines should not be drained until the oil and equipment is sufficiently cooled. Allow the system to cool until the 4-way spool (SP-0103) connecting the Slurry Tank (TK-0101), the Homogenization Pump Skid (SK-0401), the Harvest Pump Skid (SK-0501), and the Clean In Place (CIP) Pump Skid (SK-0601) is no more than warm to the touch. This should take approximately 30 minutes.

6.1.5.6.2. Place a bucket or drip pan under MV-0601, the drainage port of the CIP pump.

6.1.5.6.3. Open the port and allow the oil to flow out and into the steel bucket/pan/container.

6.1.5.6.4. Once no more oil is observed draining, close MV-0601.

6.2. **Sanitization CIP Cycle**

6.2.1. Purpose

6.2.1.1. To clean the Slurry Tank (TK-0101), the Homogenization Pump Skid (SK-0401), the Harvest Pump Skid (SK-0501), and all ancillary and connecting components involved in the coating making process that make contact with the coating.

6.2.1.2. If the equipment was recently used in coating production, the Full Volume CIP Cycle should be executed only after two small volume cleaning flushes has been completed as outlined in **6.1**.

6.2.1.3. This portion of the procedure should be executed in situations such as:

6.2.1.3.1. Following a production campaign after which coating will not be produced for a span of greater than 2 days.

6.2.1.3.2. Prior to GMP production following recent reassembly, maintenance, or other activities that involve exposure of the internals of associated equipment to the outside.

6.2.1.3.3. To remove any potential bioburden within the equipment lines when combined with the full procedure of **6.3**.

6.2.1.3.4. When equipment has not been used for a period of greater than 5 days and GMP production is planned, even if the equipment was otherwise completely clean.

6.2.1.4. A sanitization CIP flush will be performed over other CIP flushes when sanitization of equipment is necessary to minimize bioburden prior to GMP production. The sanitization CIP flush does not need to be performed in preparation for R&D use of equipment.

6.2.2. Preparation

6.2.2.1. Print **[MFG-002-FRM-002] Sanitization Clean In Place (CIP)** to be filled out during the execution of this procedure. Generate a document ID for the executed cleaning form following MFG-002-XXX-PYY.

6.2.2.1.1. XXX identifies the series of consecutive cleanings the document belongs to and is the next sequential number from the most recently performed series of consecutive cleaning activities.

6.2.2.1.1.1. Typically, a new series of cleaning documents is initiated at the end of a GMP production campaign.

6.2.2.1.2. YY is the next sequential number in the cleaning series of XXX, starting at 1.

6.2.2.2. MV-0101 will remain open during this entire process. MV-0102 will remain close during the entire process

6.2.2.3. Ensure that MV-0103, MV-104, MV-0105, MV-0401, MV-0403, and MV-0601 are closed. Ensure that the Manway (MW-0101) is securely closed and the clamps tightened.

6.2.2.4. Ensure that the Slurry Tank (TK-0101), the Homogenization Pump Skid (SK-0401), the Harvest Pump Skid (SK-0501), and the Clean In Place (CIP) Pump Skid (SK-0601) are connected to their respective power sources and are turned on.

6.2.2.5. Ensure that all connections within the homogenizer circulation line and CIP circulation line are tight.

6.2.2.6. Tare the Slurry Tank (TK-0101) and add L115 using the drum pump (P-0301). At least 90kg of oil is needed in this protocol to ensure that all dead zones on the body of he tank (EC-0101, EC-0102, and EC-0103) are submerged in the oil. Any greater number is allowable for this portion. Record the volume added and batch information in the “Flushing Oil Information” section of **[MFG-002-FRM-002] Full Volume Clean In Place (CIP) Cycle.**

6.2.3. Initial circulation and oil heating using the Homogenization Pump Skid (SK-0401)

6.2.3.1. IF a volume of greater than 100kg is used, the Agitator (AG-0101) must be powered on.

6.2.3.1.1. Turn on the Agitator (AG-0101) and set it a speed of 10 Hz. Ensure that there is a strong mixing profile, characterized by turbulence on the surface of the oil as seen from the sight glass (SG-0101). If a significant vortex is visible, such that air becomes entrained and the vortex can be heard collapsing with a “clap” sound, the agitator speed is too high. A mild vortex is acceptable. Adjust as needed. Higher volumes of cleaning oil will require a higher speed.

6.2.3.2. Open MV-0105 and MV-0401

6.2.3.3. Turn on the Homogenizer to 60 Hz to begin circulation. As the homogenizer circulates the oil at 60 Hz, it will also heat the oil. Continue circulating oil until temperature of 97°C is reached. Record temperature from TI-0401 and timing in **MFG-002-FRM-002.**

6.2.3.4. Turn off the homogenizer and close MV-0401.

6.2.4. Circulation through the Clean In Place pump (SK-0601) and spray ball assembly (SB-0101A and SB-0101B)

6.2.4.1. Open MV-0104 to allow oil to flow to the Clean In Place Pump Skid (SK-0601).

6.2.4.2. Turn on the Clean In Place Pump to a set point of 46 Hz.

6.2.4.2.1. If a rattling sound is heard, restart the CIP pump at a set point of 25 Hz and ramp up the frequency to 46 Hz

6.2.4.3. Ensure that the spray balls are active by looking through the sight glass (SG-0101) and confirming that splashing is visible. Record the pressure generated by the CIP pump by reading pressure gauge (PI-0601) in **MFG-002-FRM-002**. A value between 19 and 29 psi is expected. Notify head of manufacturing if a value outside of this range is observed. The pump set point may then be increased to as much as 50 Hz and recorded in the appropriate section of the form.

6.2.4.4. While SK-0601 is active, open MV-0401 to empty the homogenizer lines. When opening the valve, listen for air to be pulled by the pump characterized by a sharp loss in pressure on the pressure readout of PI-0601. Close MV-0401 once more and repeat until the pressure drop is observed within one second.

6.2.4.5. Circulate through the CIP pump and Spray Ball assembly for 5 minutes, recording the start and end time of circulation in **MFG-002-FRM-002**.

6.2.4.6. Turn off the CIP pump and close MV-0104.

6.2.5. Second heating cycle

6.2.5.1. Open MV-0401 and turn on the Homogenizer to a run speed of 60 Hz

6.2.5.2. Continue circulating oil until temperature of 97°C is reached. Record temperature from TI-0401 and timing in **MFG-002-FRM-002.**

6.2.5.3. Turn off the homogenizer and close MV-0401.

6.2.6. Second Sprayball circulation

6.2.6.1. Open MV-0104 to allow oil to flow to the Clean In Place Pump Skid (SK-0601).

6.2.6.2. Turn on the Clean In Place Pump to a set point of 46 Hz.

6.2.6.2.1. If a rattling sound is heard, restart the CIP pump at a set point of 25 Hz and ramp up the frequency to 46 Hz

6.2.6.3. Ensure that the spray balls are active by looking through the sight glass (SG-0101) and confirming that splashing is visible. Record the pressure generated by the CIP pump by reading pressure gauge (PI-0601) in **MFG-002-FRM-002**. A value between 19 and 29 psi is expected. Notify head of manufacturing if a value outside of this range is observed. The pump set point may then be increased to as much as 50 Hz and recorded in the appropriate section of the form.

6.2.6.4. While SK-0601 is active, open MV-0401 to empty the homogenizer lines. When opening the valve, listen for air to be pulled by the pump characterized by a sharp loss in pressure on the pressure readout of PI-0601. Close MV-0401 once more and repeat until the pressure drop is observed within one second.

6.2.6.5. Circulate through the CIP pump and Spray Ball assembly for 10 minutes, recording the start and end time of circulation in **MFG-002-FRM-002**.

6.2.6.6. Turn off the CIP pump and close MV-0104.

6.2.7. Final heating cycle.

6.2.7.1. Open MV-0401 and turn on the Homogenizer to a run speed of 60 Hz.

6.2.7.1.1. Slightly open MV-0104 until the flowrate on FI-0401 drops drastically. Immediately close MV-0104

6.2.7.2. Continue circulating at 60 Hz until a temperature of 95°C is reached on TI-0401. Record temperature from TI-0401 and timing in **MFG-002-FRM-002.** Then, turn off the homogenizer.

6.2.7.2.1. (Optional) Before turning off the homogenizer, take a 40ml rinsate sample using the sample port S-0401 during the circulation for information purposes. If the sample is to be used for additional testing, fill out the appropriate sample submission form.

6.2.8. Shut off and draining the system

6.2.8.1. Prepare a waste drum in front of the Homogenization Pump Skid (SK-0501)

6.2.8.2. Place the Homogenization Pump Skid outlet spool (SP-0502) directly into the opening of a waste drum

6.2.8.3. Open MV-0103 and turn off the Agitator (AG-0101)

6.2.8.4. Set the Harvest Pump Skid to VFD control by turning the switch to “KP”. Turn on the Harvest Pump and drain the system directly into a waste drum. Take care not to overflow the waste drum and replace as needed.

6.2.8.5. At the start of draining, open MV-0401 to empty the homogenizer lines. When opening the valve, listen for air to be pulled by the pump characterized by a rhythmic sound from the pump compared to the steady sound of liquid pumping and a sharp drop in liquid output from the pump. Close MV-0401 once this is heard. Repeat opening and closing MV-0401 until the sound change occurs within 1 second of opening MV-0401. Repeat for MV-0104.

6.2.8.6. Continue draining until no more liquid is being pumped.

6.2.8.7. If no more CIP cycles will be performed on the system prior to production, the remaining lines must be completely drained.

6.2.8.7.1. For safety reasons, the lines should not be drained until the oil and equipment is sufficiently cooled. Allow the system too cool until the 4-way spool (SP-0103) connecting the Slurry Tank (TK-0101), the Homogenization Pump Skid (SK-0401), the Harvest Pump Skid (SK-0501), and the Clean In Place (CIP) Pump Skid (SK-0601) is no more than warm to the touch. This should take approximately 30 minutes.

6.2.8.7.2. Place a bucket or drip pan under MV-0601, the drainage port of the CIP pump.

6.2.8.7.3. Open the port and allow the oil to flow out and into the steel bucket/pan/container.

6.2.8.7.4. Once no more oil is observed draining, close MV-0601.

6.3. **Cleaning for Dead-zones and Product Contacting External Elements**

6.3.1. Purpose

6.3.1.1. To sanitize any surfaces that will make direct contact with the coating product or raw materials that go into the coating product but do not experience hot oil circulation.

6.3.1.2. This section of MFG-002 should be executed prior to any production campaigns and is to be checked off as part of line clearance for a run.

6.3.1.3. This section of MFG-002 covers all portions of equipment that require manual cleaning. Not every element of this section needs to be executed at once or before any use of equipment, but by the end of the full cleaning procedure performed between manufacturing campaigns, every element will be executed at least once. Follow guidelines in section 5.5 for which elements are manually cleaned and when.

6.3.2. Procedure

6.3.2.1. Print **[MFG-002-FRM-003] Product Contacting External Element Cleaning** to be filled out during the execution of this procedure. Generate a document ID for the executed cleaning form following MFG-002-XXX-PYY.

6.3.2.1.1. XXX identifies the series of consecutive cleanings the document belongs to and is the next sequential number from the most recently performed series of consecutive cleaning activities.

6.3.2.1.1.1. Typically, a new series of cleaning documents is initiated at the end of a GMP production campaign.

6.3.2.1.2. YY is the next sequential number in the cleaning series of XXX, starting at 1.

6.3.2.2. Butyl or Neoprene gloves, a face shield, and a respirator must be worn during the execution of this protocol

6.3.2.3. Prepare a solution of Decon-Spore 200 Plus per bottle instruction, spray bottle of 70% or 99% IPA, and plenty of low shed wipes.

6.3.2.4. For each location listed in 6.3.2.6:

6.3.2.4.1. Open the sanitary clamp connecting the piece to the rest of the equipment.

6.3.2.4.2. Soak a low shed wipe with Decon-Spore 200 Plus solution and thoroughly wipe down all internally facing/product contacting surfaces of the piece itself, the connecting sanitary PTFE gasket, and the all surfaces of the dead zone connecting the piece that can be reached.

6.3.2.4.2.1. The Decon-Spore 200 Plus soaked wipe can be wrapped around a sturdy narrow object, such as the head of a screwdriver, if the deadzone is too narrow to be wiped down by hand.

6.3.2.4.3. Soak a fresh low shed wipe with 70% or 99% IPA solution and thoroughly wipe down all internally facing/product contacting surfaces of the piece itself, the connecting sanitary PTFE gasket, and the all surfaces of the dead zone connecting the piece that can be reached.

6.3.2.4.3.1. The Decon-Spore 200 Plus soaked wipe can be wrapped around a sturdy narrow object, such as the head of a screwdriver, if the deadzone is too narrow to be wiped down by hand.

6.3.2.4.4. Carefully reattach the piece to its respective location, ensuring that the piece does not contact anything other than the gloves it is handled with

6.3.2.4.4.1. If the piece is dropped in the process of reattaching, begin 6.3.2.4 for that piece from the beginning.

6.3.2.5. For each unique location, make sure that a fresh wipe is used. Do not reuse wipes between locations, as this can spread any biocontamination that may be present.

6.3.2.6. The following locations are wiped down as part of this procedure when the full wipe down (5.5.5) is executed. Fill out “Dead zones” in MFG-002-FRM-003 when cleaning.

6.3.2.6.1. EC-0101

6.3.2.6.2. EC-0102

6.3.2.6.3. EC-0103

6.3.2.6.4. PI-0101

6.3.2.6.5. PI-0401

6.3.2.6.6. TI-0401

6.3.2.6.7. S-0401

6.3.2.7. The following locations are wiped down prior to use of the piece on a given day with GMP material. Fill out the appropriate section of the “External Element Cleaning” of MFG-002-FRM-003 when cleaning each piece.

6.3.2.7.1. P-0301 – Drum Pump

6.3.2.7.1.1. Use a Decon-Spore 200 Plus soaked lint-free wipe to thoroughly wipe down the entirety of the stainless-steel surface of the end of the drum pump that goes into the barrels. Wipe the inside rim of the inlet and the holster as well.

6.3.2.7.1.2. Use a 70% or 99% isopropyl alcohol soaked lint-free wipe to thoroughly wipe down the stainless-steel surface of the end of the drum pump that goes into the barrels. Wipe the inside rim of the inlet and the holster as well.

6.3.2.7.2. SP-0502 – Harvest Pump Outlet Spool

6.3.2.7.2.1. Use a Decon-Spore 200 Plus soaked lint-free wipe to thoroughly wipe down the entirety of the stainless-steel surface of the end of the harvest pump outlet spool used for harvesting product. Wipe the inside rim of the and the holster inlet as well.

6.3.2.7.2.2. Use a 70% or 99% isopropyl alcohol soaked lint-free wipe to thoroughly wipe down the stainless-steel surface of the end of the harvest pump outlet spool used for harvesting product. Wipe the inside rim of the inlet and the holster as well.

6.3.2.7.3. SP-0414 – Suction Lance Inlet Spool

6.3.2.7.3.1. Do not perform this cleaning until after 6.4 has been completed.

6.3.2.7.3.2. Use a Decon-Spore 200 Plus soaked lint-free wipe to thoroughly wipe down the entirety of the stainless-steel surface of the suction lance. Wipe the inside rim of the inlet and the holster as well.

6.3.2.7.3.3. Use a 70% or 99% isopropyl alcohol soaked lint-free wipe to thoroughly wipe down the stainless-steel surface of the stainless-steel surface of the suction lance. Wipe the inside rim of the inlet and the holster as well.

6.3.2.8. For a more thorough clean, the internals Drum pump (P-0301) and connecting components leading to the Slurry Tank (TK-0101) must flushed through with cleaning agents. Reference section 5.5 for when this is done. Fill out the “Drum Pump Line Cleaning” section of MFG-002-FRM-003 when executing.

6.3.2.8.1. The drum pump sections are disassembled, cleaned, and reassembled in the following sections in the following order.:

6.3.2.8.1.1. The Drum Pump (P-0301)

6.3.2.8.1.1.1. Disconnected at the T connecting the Drum Pump (P-0301) to FX-0001

6.3.2.8.1.1.2. While still in the holster, spray the inside of the T near the motor with no more 3 squirts of Decon Spore 200 Plus. Pivot the drum pump in its holster to better distribute the squirts and allow them to drain into the drainage cup.

6.3.2.8.1.1.3. While still in the holster, spray the inside with at least 10 full sprays of 70% or 99% IPA. Pivot the drum pump in its holster to better distribute the squirts and allow them to drain into the drainage cup.

6.3.2.8.1.1.4. Wipe down the connection point of P-0301, PTFE gasket, and FX-0001 connection with 70% or 99% IPA. Carefully reconnect P-0301 with FX-0001.

6.3.2.8.1.2. SP-0001

6.3.2.8.1.2.1. Disconnect SP-0001 from MV-0001 and SP-0002 and move them out of the way. (Careful – there may still be oil in the bend of FX-0001).

6.3.2.8.1.2.2. While still in its stand, spray the no more 3 squirts of Decon Spore 200 Plus, each from a different angle. Hold a drainage cup beneath to collect the material.

6.3.2.8.1.2.3. While still in its stand, spray at least 10 squirts of 70% or 99% IPA, each from a different angle. Hold a drainage cup beneath to collect the material.

6.3.2.8.1.3. Flex hose (FX-0001) and Manual Valve (MV-0001)

6.3.2.8.1.3.1. Close MV-0001. It should already be disconnected from SP-0001.

6.3.2.8.1.3.2. While holding the manual valve so that it is higher than the T of the drum pump and creates a U shape with the flex-hose, spray no more than 3 squirts of Decon Spore 200 Plus into the valve.

6.3.2.8.1.3.3. Open the valve to allow the Decon Spore to drain into the flexhose to the bottom of the U.

6.3.2.8.1.3.4. Close MV-0001 and invert it. Bend the hose around to distribute the cleaning solution.

6.3.2.8.1.3.5. Lift MV-0001 to drain the cleaning solution out through the drum pump (P-0301) into a drainage cup

6.3.2.8.1.3.6. Repeat with at least 10 sprays of 70% or 99% IPA.

6.3.2.8.1.3.7. Once the bend of the flexhose is drained (no more material draining through P-0301), open MV-0001 and hold it up for another ten seconds.

6.3.2.8.1.3.8. Wipe down the connection point of FX-0001, PTFE gasket, and SP-0001 connection with 70% or 99% IPA. Carefully reconnect P-0301 with FX-0001.

6.3.2.8.1.4. Connecting hoses to tank (SP-0002, FX-0002, SP-0003, SP-0004)

6.3.2.8.1.4.1. Disconnect SP-0004 from SP-0005 to fully remove it from the system

6.3.2.8.1.4.2. Close one end with a clean 1.5” end cap and sanitary gasket and spray at 10 squirts of 70% or 99% IPA into the piece.

6.3.2.8.1.4.3. Close the other end with a clean 1.5” end cap and sanitary gasket as well and swish around the IPA inside for a period of at least 30 seconds.

6.3.2.8.1.4.4. Open one end cap and drain into a drainage cup. Open the other end cap.

6.3.2.8.1.4.5. Take the piece out of the cleanroom and blast compressed nitrogen through to dry it.

6.3.2.8.1.4.6. Wipe down the connection point of SP-0004, a PTFE gasket, and SP-0005 connection with 70% or 99% IPA. Carefully reconnect SP-0004 with SP-0005.

6.3.2.8.1.4.7. Allow the set of connections to air dry for a period of 30 minutes. Then, wipe down the connection point of SP-0002, a PTFE gasket, and SP-0001 connection with 70% or 99% IPA. Carefully reconnect SP-0002 with SP-0001

6.4. **Homogenizer Suction Lance assembly (FX-0403, SP-0413, and SP-0414) cleaning.**

6.4.1. Purpose

6.4.1.1. To remove solid residue from the Homogenizer Suction Lance assembly (FX-0403, SP-0413, and SP-0414) cleaning that accumulates during the addition steps of the coating manufacturing processes and can lead to clogging.

6.4.1.2. This portion of the procedure should be executed after production runs prior to the next use of the Homogenizer Suction Lance assembly (FX-0403, SP-0413, and SP-0414) set.

6.4.2. Equipment and Working Principle

6.4.2.1. The Homogenizer Suction Lance assembly (FX-0403, SP-0413, and SP-0414) is cleaned using a foam pellet gun powered by an air compressor. The air compressor forces the disposable foam pellet through the narrow opening of the suction lance assembly, removing solid residue as it travels. At the outlet, the suction lance assembly is placed inside of a dust collection bucket with the Dust Control Vacuum (DC-0801) preventing any removed solids from escaping.

6.4.3. Procedure

6.4.3.1. Print **[MFG-002-FRM-004] Homogenizer Suction Lance Cleaning** to be filled out during the execution of this procedure. Generate a document ID for the executed cleaning form following MFG-002-XXX-PYY.

6.4.3.1.1. XXX identifies the series of consecutive cleanings the document belongs to and is the next sequential number from the most recently performed series of consecutive cleaning activities.

6.4.3.1.1.1. Typically, a new series of cleaning documents is initiated at the end of a GMP production campaign.

6.4.3.1.2. YY is the next sequential number in the cleaning series of XXX, starting at 1.

6.4.3.2. An N95 mask or respirator must be worn during the execution of this procedure.

6.4.3.3. Carefully remove the clamp connecting FX-0403 from the MV-0403 assembly. Take care to avoid spilling solid residue that may come out as the hosing is disconnected. Remove the plastic suction lance nozzle as well.

6.4.3.4. Place the end of SP-0414 into the large white tubing at the top of the designated dust collection bucket.

6.4.3.5. Set up the Dust Control Vacuum (DC-0801) in the area and hook or insert two of the addition hoses into the two holes in the top of the dust collection bucket.

6.4.3.6. Open the foam pellet gun and place a clean foam pellet inside. Close the foam pellet gun.

6.4.3.7. Push the nozzle of the foam pellet gun up into the inside of FX-0403.

6.4.3.8. Use pressurized CO2 and a regulator set to 90 PSI to fire the projectile through the hose assembly. The setpoint pressure may be changed if necessary so long as the projectile is able to clear the entire hose assembly.

6.4.3.9. Open the dust collection bucket and inspect the foam pellet. Repeat steps 7.4.3.6-7.3.3.9 until the foam pellet comes out of the suction hose with little or no residue.

6.4.3.10. Turn off the air compressor and Dust Vacuum. Reattach the Homogenizer Suction Lance assembly (FX-0403, SP-0413, and SP-0414) to MV-0403

7. ATTACHMENTS

None

8. REFERENCES

8.1. [MFG-002-FRM-001] Small Volume Clean In Place Flush
8.2. [MFG-002-FRM-002] Full Volume Clean In Place Cycle
8.3. [MFG-002-FRM-003] Product Contacting External Element Cleaning
8.4. [MFG-002-FRM-004] Homogenizer Suction Lance Cleaning
8.5. [MFG-007] Setup and Operation of the Slurry Tank (TK-0101)
8.6. [MFG-009] Setup and Operation of the Homogenization Pump Skid (SK-0401)
8.7. [MFG-010] Setup and Operation of the Clean In Place (CIP) Pump (SK-0601)

REVISION HISTORY

Version 01 Effective on 25-Jun-2020
This is a new document

Version 02 Effective on 06-Jul-2020
1) The frequency set-point of the CIP pump to reach the desired pressure range has been updated. 2) Mention of the bypass valve (MV-0402) has been removed as the bypass has been removed from the system. 3) The air compressor used for the homogenizer suction wand cleaning has been replaced with a CO2 tank to reduce contamination risks.

Version 03 Effective on 16-Nov-2020
Document changed per change control CC-20-006

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

Anton Repnikov
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I am the author of this document.
Signed 5:29:04 PM UTC 16-Nov-2020

Required Workflow Steps for this Category

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LiquiGlide Inc / Quality Assurance Approval
I have reviewed and approve this document.
Signed 6:01:13 PM UTC 16-Nov-2020

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LiquiGlide Inc / Head of Manufacturing, or designee, Approval
I have reviewed and approve this document.
Signed 6:05:28 PM UTC 16-Nov-2020

1. PURPOSE

1.1. To describe the procedure for gowning at LiquiGlide's manufacturing facility in Billerica, MA

2. SCOPE

2.1. This procedure applies to all associates who enter the Manufacturing, Analytical and Sampling area at LiquiGlide's manufacturing facility located at 34 Sullivan Road, Billerica MA, 01862.

2.1.1. Only Associates trained on this gowning procedure and QA-016 GMP Access can enter the Analytical Room, Manufacturing Room and Sampling Area without an escort.

3. RESPONSIBILITIES

Role	Responsibility
GMP Associates	– Train on gowning and de-gowning technique – Ensure adequate PPE is available prior to gowning – Remove and dispose of PPE after manufacturing activities are complete – Ensure weekly/as needed disposal of tacky mat
Head of Manufacturing or Designee	– Ensure that this SOP is performed as described – Update the procedure when necessary – Review gowning and de-gowning technique with any non-GMP access individual prior to escorting them into the analytical or manufacturing room
Quality Assurance	– Ensure manufacturing associates are trained prior to entering manufacturing space – Ensure training is documented

4. DEFINITIONS

4.1. **Cleanroom:** A room or area that is maintained virtually free of contaminants, such as dust or bacteria.

4.2. **Warehouse Room:** The area labeled as room 101 on the LiquiGlide manufacturing facility floor plan.

4.3. **Sampling Area:** The area located in the Warehouse Room 101 that is separated from the open area of the Warehouse by a PVC curtain where sampling raw materials is permitted.

4.4. **Manufacturing Corridor:** The area labeled as room 102 which is located between the warehouse room (101) and manufacturing room (105) where gowning and de-gowning activities occur.

4.5. **Analytical Room:** The controlled analytical space identified as room 103 on the LiquiGlide manufacturing facility floor plan.

4.6. **Manufacturing Room**: The controlled manufacturing space identified as room 105 on the LiquiGlide manufacturing facility floor plan.

4.7. **PPE**: Personal protective equipment.

4.8. **IPA**: Isopropyl alcohol. Used for cleaning items and equipment prior to entrance into a clean area.

5. PROCEDURE

5.1. Dress and Personal Hygiene Requirements

5.1.1. Manufacturing associates must comply with the following dress requirements when working in the manufacturing suite:

5.1.1.1. All cuts in skin must be covered with a bandage.

5.1.1.2. Long pants and socks are required.

5.1.1.3. Close-toed shoes are required. No open-toed shoes are permitted.

5.1.1.4. Steel toe shoes are required when working in the Manufacturing room (105).

5.1.1.5. No jewelry that may tear gloves or dangle freely outside of gowning.

5.1.1.6. No excessive makeup or perfume.

5.1.2. All associates are to exhibit thorough personal hygiene. This includes washing hands regularly, arriving to working having bathed and in clean clothes, and avoiding contact between hands, eyes, nose, and mouth.

5.1.3. Associates who are sick and contagious (e.g. fever, vomiting, diarrhea, febrile) should inform their supervisors and refrain from coming into work.

5.2. Movement and Behavior of Personnel in the Space

5.2.1. Eating, drinking, chewing gum, smoking, applying cosmetics, etc. are forbidden in all manufacturing and laboratory spaces.

5.2.2. Movements should be controlled and deliberate, always keeping safety in mind.

5.2.3. In the event of an emergency, use any available exit to leave the area.

5.3. Gowning Materials and Supplies

5.3.1. Hair net

5.3.2. Beard covers (if applicable)

5.3.3. Safety glasses

5.3.4. Lab coat or Tyvek suit

5.3.5. Nitrile gloves

5.3.6. Booties

5.3.7. Steel toe or equivalent ASTM F2413 compliant safety shoes (when necessary)

5.3.8. Dust mask (when necessary)

5.3.9. IPA

5.4. Put on safety glasses prior to entering the Warehouse Room (101). Ensure safety glasses are clean prior to use.

5.5. Gowning Procedure for the Manufacturing Room (105) and Analytical Room (103).

5.5.1. The Manufacturing Corridor (102) is accessed through the Warehouse (101). The Manufacturing Corridor is divided into a clean side and dirty side. Attachment 6.1 Manufacturing Floorplan (Personnel Flow Diagram) describes the flow of personnel from dirty to clean side.

5.5.1.1. Ensure the door from the warehouse to the manufacturing corridor is secure after entering the Manufacturing Corridor.

5.5.2. Remove any garments (e.g. coat, hat, jewelry, or sweater) that will not be worn within Analytical or Manufacturing Rooms prior to entering the Manufacturing Corridor.

5.5.3. Enter the Manufacturing Corridor. Wash hands thoroughly. Use the sink outside of the bathroom (to the right when entering the Manufacturing Corridor) to wash hands.

5.5.4. Step on the tacky mat on the clean side of the Manufacturing Corridor.

5.5.4.1. If sticky mat if visibly soiled, replace before using. Sticky mats are replaced, at a minimum weekly.

5.5.5. Standing on the sticky mat. Put on booties over top of your shoes. Step directly from the sticky mat onto the clean side.

5.5.5.1. Steel toe or equivalent ASTM F2413 compliant safety shoes are required for working within the Manufacturing Room.

5.5.5.2. Steel toe or equivalent ASTM F2413 compliant safety shoes are recommended but not required for working in the Analytical Room.

5.5.6. Take a disposable lab coat and label it with initials and date of use. Put on the lab coat ensuring proper fit. Lab coat must be discarded after 24 hours or excessive soiling that may affect the integrity of the gown components.

5.5.6.1. If the lab coat must be replaced, regown by exiting the Analytical or Manufacturing Room and repeating the steps in this SOP

5.5.7. Put on face mask to cover nose and mouth.

5.5.7.1. N95 dust masks are required for working with any low density solids during coating manufacturing.

5.5.8. Put on a hairnet, ensuring that all hair is covered. Associates with sideburns, mustache or beard must wear a beard cover

5.5.8.1. Use the mirror to verify that all hair is completely covered up.

5.5.9. Put on nitrile gloves. Choose gloves that have a snug, but not overly tight fit.

5.5.10. Associates may now enter either the Analytical or Manufacturing rooms.

5.5.10.1. An additional sticky mat is placed at the entrance to the Analytical or Manufacturing room. Associates are required to step on the sticky mats prior to entering.

5.5.10.1.1. If sticky mat if visibly soiled, replace before using.

Ensure the door from the Analytical and/or Manufacturing Room to the manufacturing corridor is secure after entering.

5.6. De-gowning Procedure within Manufacturing Corridor

5.6.1. Exit the Analytical or Manufacturing room. Ensure the door from the Analytical and/or Manufacturing Room to the manufacturing corridor is secure after entering the Manufacturing Corridor.

5.6.2. Remove your lab coat and hang it on the hooks on the dirty side of the gowning room. Lab coats must be changed within 24 hours at minimum or upon excess soiling.

5.6.3. Step onto dirty side if the Manufacturing Corridor.

5.6.4. Remove and place booties, hairnets, beard covers and gloves in the waste receptacle.

5.6.5. Wash hands prior to leaving the Manufacturing Corridor.

5.7. Gowning Procedure for the Sampling Area

5.7.1. The Sampling Area is located in the Warehouse (Room 101). It is separated from the open area of the Warehouse by a PVC curtain. Attachment 6.2 Manufacturing and Warehouse (Sampling Area) Floorplan describes the location of the Sampling Area within the Warehouse.

5.7.2. Remove any garments (e.g. coat, hat, jewelry, or sweater) that will not be worn within the Sampling Area.

5.7.3. Prior to entering the Sampling Area. Wash hands thoroughly. Use the sink next to the bathroom the Manufacturing Corridor to wash hands.

5.7.4. Step on the tacky mat on the Warehouse side of the Sampling Area.

5.7.4.1. If sticky mat if visibly soiled replace before using. Sticky mats are replaced, at a minimum weekly.

5.7.5. Standing on the sticky mat. Put on booties over top of your shoes

5.7.5.1. Steel toe or equivalent ASTM F2413 compliant safety shoes are recommended but not required for working in the Sampling Area.

5.7.6. Take a disposable lab coat and label it with initials and date of use. Put on the lab coat ensuring proper fit. Lab coat must be discarded after sampling process is complete.

5.7.6.1. If a lab coat must be replaced, regown by exiting the Sampling Area and repeating the steps in this SOP

5.7.7. Put on face mask to cover nose and mouth.

5.7.7.1. N95 dust masks are required for working with any low density solids during sampling.

5.7.8. Put on a hairnet, ensuring that all hair is covered. Associates with sideburns, mustache or beard must wear a beard cover

5.7.9. Put on nitrile gloves. Choose gloves that have a snug, but not overly tight fit.

5.7.9.1. Use the mirror to verify that all hair is completely covered up.

5.7.10. Associates may now enter the Sampling Area

5.7.11. Step directly from the sticky mat on Warehouse side onto the sticky mat inside the Sampling Area.

5.7.11.1. If sticky mat if visibly soiled replace before using

5.8. De-gowning Procedure from the Sampling Area

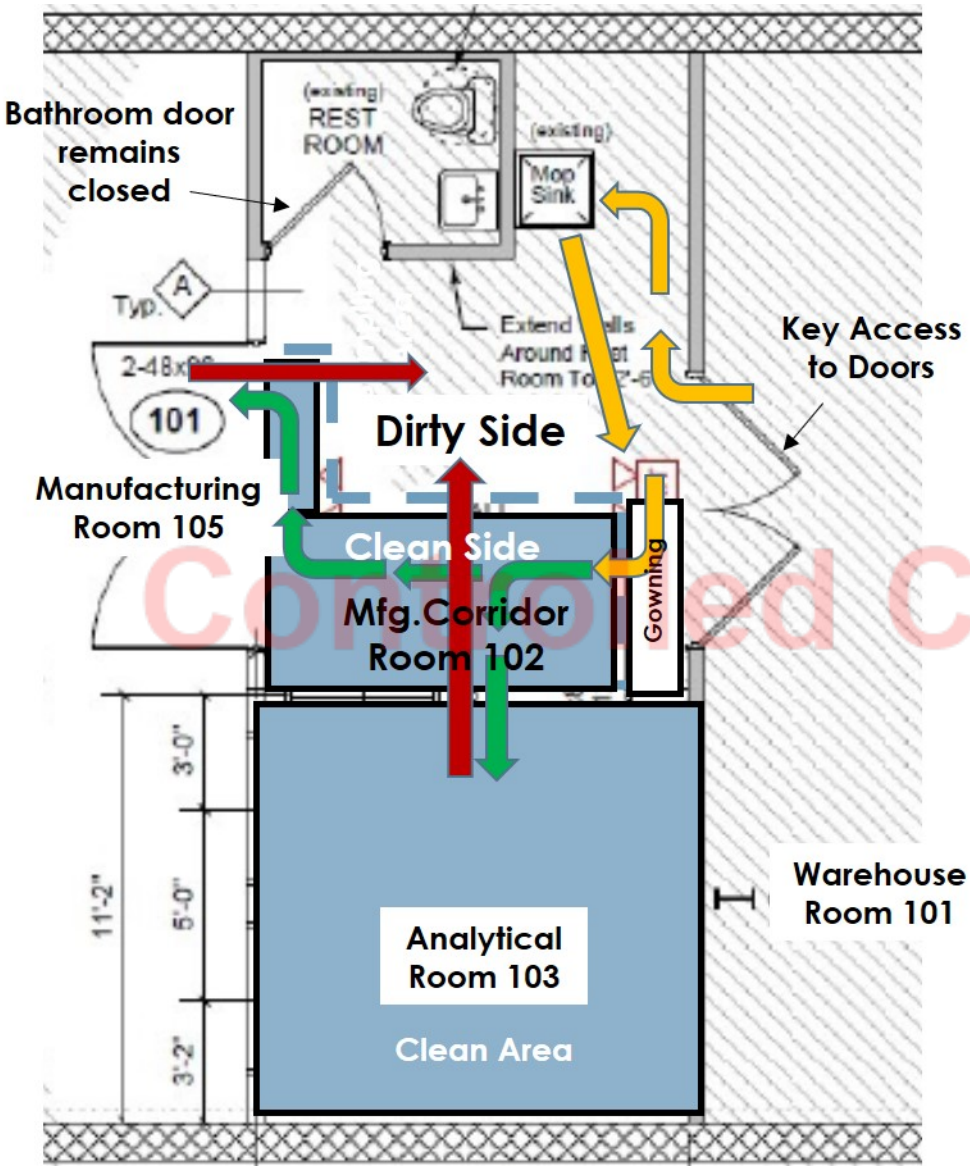
5.8.1. Exit the Sampling Area.

5.8.2. Remove and place booties, lab coat, hairnets, beard covers and gloves in the waste receptacle.

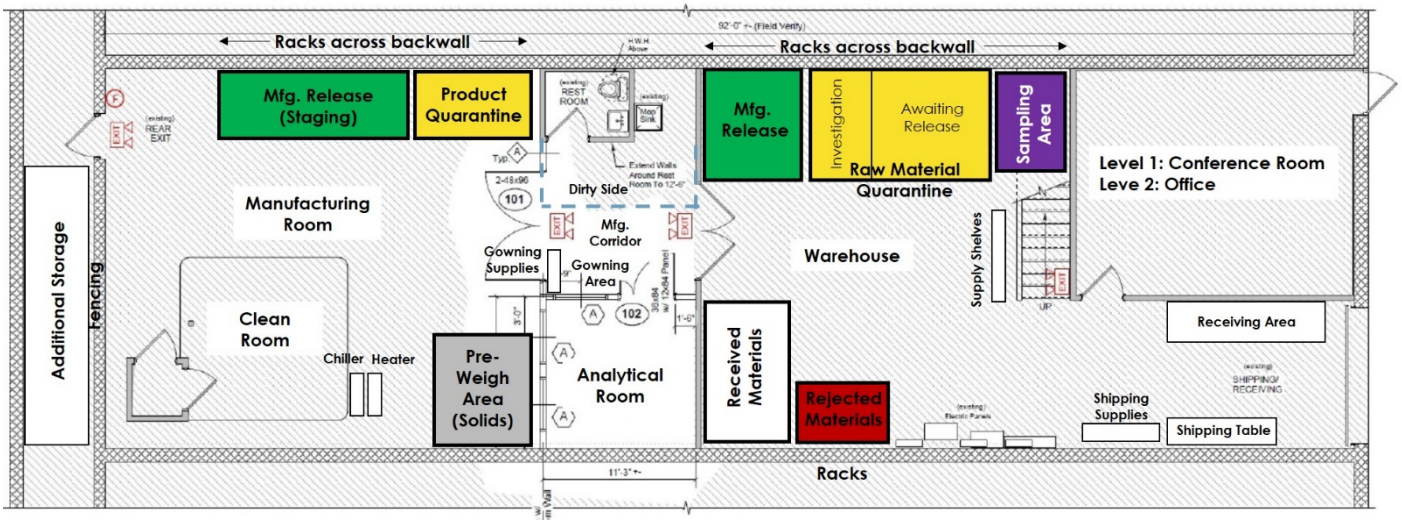
5.8.3. Wash hands after leaving the Sampling Area.

6. ATTACHMENTS

6.1. Attachment 1: Manufacturing Floorplan (Personnel Flow Diagram)



6.2. Attachment 2: Manufacturing and Warehouse (Sampling Area) Floorplan



7. REFERENCE DOCUMENTS

7.1. [QA-016] GMP Access Control

REVISION HISTORY

Version 01 Effective on 05-Jun-2020
First version

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

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Required Workflow Steps for this Category

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I have reviewed and approve this document.
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1. PURPOSE

1.1. This procedure describes the procedure for the prevention of product mix-ups and cross-contamination at LiquiGlide's Billerica facility.

2. SCOPE

2.1. This procedure applies to Manufacturing Room (105), the Clean Room within the Manufacturing Room, The Analytical Room (103), The Manufacturing Corridor (102), and the Sampling Area within the Warehouse (101) located at 34 Sullivan Road, Billerica MA, 01862.

3. RESPONSIBILITIES

Role	Responsibility
GMP Associates	– Understand and perform the activities described in this procedure
Head of Manufacturing, or designee	– Ensure that all associates have appropriate training to perform the activities described in this procedure – Ensure all GMP Associates and contract employees understand and perform the activities described in this procedure
Quality Assurance	– Ensure compliance with this procedure by all GMP Associates and contract employees

4. DEFINITIONS

4.1. **Contamination:** The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.

4.2. **Cross-Contamination:** Contamination of a starting material, intermediate product or finished product with another starting material or product during production.

5. EQUIPMENT & SUPPLIES

5.1. N/A

6. PROCEDURE

6.1. **General Considerations**

6.1.1. Cross contamination of products may be harmful & life threatening.

6.1.2. The main source of cross contaminations in drug manufacturing are Human beings, air, Equipment, Water and Raw materials.

6.1.3. Adherence to SOPs and the careful control and documentation of all GMP materials and cGMP processes is essential in minimizing cross contamination risks.

6.2. **Personnel**

6.2.1. All associates must receive the appropriate training to perform activities at LiquiGlide's Billerica facility. **[QA-004] Training Management** will be followed to ensure compliance.

6.2.2. Proper gowning procedure shall be followed to prevent personnel contamination as outlined in [**QA-041] Gowning Billerica**

6.2.2.1. Proper gowning with clean lab coats, nitrile gloves, hairnets, boot covers, cleanroom shoes, and beard covers as applicable prevents foreign matter from personnel to contaminate controlled areas.

6.2.2.2. Gloves must be changed once sullied.

6.2.2.2.1. Activities such as the sampling of powders and the handling of powders during production quickly sully gloves with powder residues. Gloves must be changed between handling different boxes of material, even if the lot # is the same.

6.2.3. Access to controlled areas such as the Manufacturing Room (105) and Analytical Room (104) by unauthorized persons is restricted following **[QA-016] GMP Access Control**.

6.3. **Facility**

6.3.1. The design of the facility and equipment is critical in preventing contamination and cross-contamination **[Attachment 1: Facility Layout]**

6.3.1.1. All cGMP Manufacturing and Storage Areas are suitable for use and have adequate space for:

6.3.1.1.1. Segregation of Materials

6.3.1.1.2. Placement of equipment.

6.3.1.1.3. Personnel flow.

6.3.1.2. Interior surfaces of walls, floor and ceiling are free from cracks and open joints, do not shed paint or particulate matter, and permit easy and effective cleaning.

6.3.1.3. Cleaning procedures are in place**. [QA-031] Line Clearance, [MFG-002] Equipment Cleaning, and [QA-044] Facility Cleaning** are followed and documented using associated forms.

6.3.1.4. Environmental Monitoring Program are in place. **[QA-045] Environmental Monitoring – Billerica** guides environmental monitoring.

6.3.1.4.1. All rooms and surfaces are maintained and monitored for viable and non-viable particulates and the facility must be recertified on a semi-annual basis.

6.3.1.4.2. Airborne contaminants are controlled through effective ventilation and filtration.

6.3.1.4.3. The effectiveness of facility cleaning procedures are validated and verified by environmental monitoring.

6.3.1.5. Quality Assurance will perform at a minimum monthly checks of good housekeeping practices, cleaning and compliance to procedures to ensure prevention of mix-ups or cross-contamination following **[QA-022] General Housekeeping and Compliance Walk-through**

6.4. **Material Management**

6.4.1. All raw materials shall be procured only from approved suppliers.

6.4.2. Associates receiving the material shall follow all steps with respect to handling and of storage of raw materials and packing materials as outlined in **[QA-009] Materials Management Billerica.**

6.4.3. While storing the material, care shall be taken to ensure segregation based on disposition and type

6.4.3.1. Received, In Quarantine, Released, and Rejected materials are stored in separate and clearly labeled areas.

6.4.3.2. Materials shall be clearly labeled and further grouped by material and lot.

6.4.4. Any rejected or obsolete materials shall be suitably disposed within the shortest possible time and record shall be maintained accordingly **[QA-009-FRM-03] Billerica Material Disposal Form.**

6.5. **Sampling**

6.5.1. All sampling of raw materials will be performed in a dedicated, controlled space. The cleaning log will be checked by the associate performing sampling and verified by Quality Assurance the sampling area is fit for use.

6.5.2. Associates will follow the steps described in **[QA-018] Billerica Sample Handling and Submission**

6.5.2.1. Only Dedicated or single use sampling equipment shall be used for sampling.

6.6. **Manufacturing and Packing**

6.6.1. Manufacturing associates receiving the materials issued for production shall verify the labels on the containers and tally them with the batch record bill of materials.

6.6.2. Line clearance procedures shall be strictly followed and documented by manufacturing and verified by Quality Assurance following **[QA-031] Line Clearance** and associated forms.

6.6.3. The manufacturing area will be checked on a monthly basis following **[QA-022] General Housekeeping and Compliance Walk-through**

6.6.4. All materials inside the controlled areas of the facility shall be stored and sealed in clean secondary polyethylene bags in closed drums, in food grade HDPE containers wiped down with 70% IPA, in HFPE lined pails wiped down with 70% IPA, or sterile sample containers with proper identification status.

6.6.5. Staging procedures will follow their respective batch record and be done in a controlled fashion. Though secondary containers and drums will be reused, only clean and new polyethylene bags will be used to line the secondary containers.

6.6.6. Manufacturing documents and SOPs will be written with foreign matter prevention in mind and will minimize any contamination risks.

6.6.7. In-process materials and finish drug products shall be stored with clear identification status labels.

6.6.8. All the materials in the manufacturing room (105) shall be stored on plastic pallets, metal/plastic racks, or in plastic drums/bins (no wooden pallets or carboard is allowed in the manufacturing area).

6.6.8.1. S400 (Hydrophobic Silica) is received in large paper bags and must be stored as such. The paper bags are placed in secondary polyethylene bags prior to being moved into the manufacturing area.

6.6.8.2. Care must be taken that the paper bags do not leave the secondary polyethylene bags and do not get torn beyond what is necessary to access the material for sampling or manufacturing purposes.

6.6.8.3. Silica is added into the process using negative addition. Take care to not damage the bag with the suction lance used for the negative addition. If fraying of the paper bag is observed, take extra and avoid moving the suction lance near that portion of the bag if possible.

6.6.9. All the remains of previous packed materials (such as labels, left-over, cartons, caps etc.) shall be removed before the starting of next operation.

6.6.10. All label printing shall be authorized in writing from production and quality assurance.

6.6.11. Any OOS or atypical results obtained by QC during the analysis of raw materials, intermediates, and finished products shall be investigated in detail before the batch is accepted or released.

6.7. **Prevention and handling of contamination with metal objects**

6.7.1. Restrict the use of metal like objects to the minimum.

6.7.2. Wherever it is unavoidable, use the metal objects with strict control. Items like knives, scissors, pins, nuts, bolts, dispensing wands, and sampling equipment should be used with care and caution.

6.7.3. Before start of operation and after completion of operation, check nuts and bolts, which are used for the equipment for its absence and / or loosening. Wherever nuts and bolts are loosened, the

same should be tightened. In case any nuts and bolts are missing, the same should be investigated.

6.7.4. During regular preventive maintenance or breakdown maintenance, special attention should be given to nuts and bolts to prevent contamination with the same. After preventive maintenance or breakdown maintenance, Quality Assurance should give line clearance to ensure that the area / equipment is free from grease, nuts, bolts and any other maintenance tools.

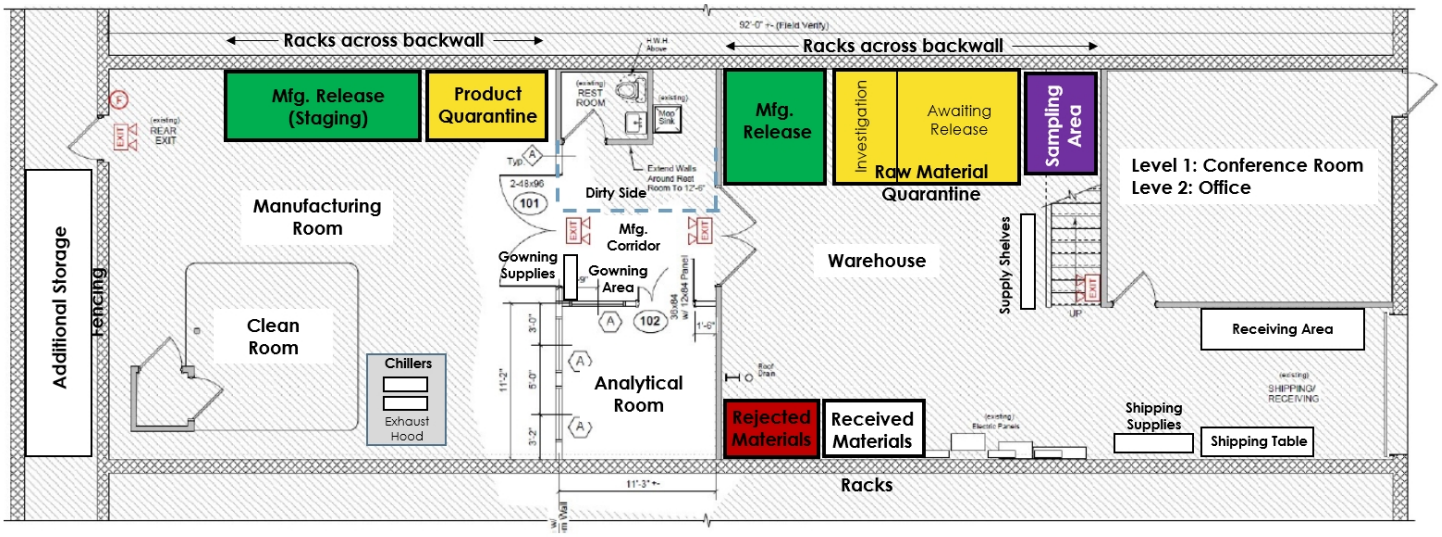
7. ATTACHMENTS

7.1. Attachment 1: Facility Layout

8. REFERENCES

8.1. [QA-004] Training Management
8.2. [QA-041] Gowning Billerica
8.3. [QA-016] GMP Access Control
8.4. [QA-031] Line Clearance
8.5. [MFG-002] Equipment Cleaning
8.6. [QA-044] Facility Cleaning
8.7. [QA-045] Environmental Monitoring – Billerica
8.8. [QA-018] Billerica Sample Handling and Submission
8.9. [QA-022] General Housekeeping and Compliance Walk-through

Attachment 1: Facility Layout



REVISION HISTORY

Version 01 Effective on 25-Jun-2020
New Document

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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Required Workflow Steps for this Category

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LiquiGlide Inc / Quality Assurance Approval
I have reviewed and approve this document.
Signed 2:24:48 PM UTC 25-Jun-2020

1. PURPOSE

1.1. The purpose of this plan is to establish the rationale, strategy, scope, and procedures for the prevention of microbial contamination at LiquiGlide.

2. SCOPE

2.1. This plan applies to all areas which may influence or affect product performance and/or quality - including, raw materials, the facility, equipment, cleaning, environmental monitoring and personnel at LiquiGlide's manufacturing facility located at 34 Sullivan Road, Billerica MA, 01862.

3. RESPONSIBILITIES

Role	Responsibility
GMP Associates	– Understand and perform the activities described in this procedure
Head of Manufacturing, or designee	– Ensure that all associates have appropriate training to perform the activities described in this procedure – Ensure all GMP Associates and contract employees understand and perform the activities described in this procedure
Head of Quality Assurance or designee	– Ensure compliance with this procedure by all GMP Associates and contract employees

4. DEFINITIONS

4.1. **Microbial contamination:** The non-intended or accidental introduction of microbes such as bacteria, yeast, mold, fungi, virus, prions, protozoa or their toxins and by-products.

5. PROCEDURE

5.1. **General Considerations**

5.1.1. Microbial contamination of products may be harmful & life threatening.

5.1.2. The main source of microbial contamination in drug manufacturing are Human beings, air, Equipment, Water and Raw materials.

5.1.2.1. Water is not used in LiquiGlide manufacturing process.

5.1.3. Adherence to SOPs and the careful control and documentation of all GMP materials and cGMP processes is essential in minimizing microbial contamination risks.

5.1.4. **Raw Materials**

5.1.4.1. All raw materials shall be procured only from approved suppliers.

5.1.4.2. All raw materials require an approved material specification containing the Microbiological specifications. **[QA-033] Specifications.**

5.1.4.2.1. Associates receiving the material shall follow all steps with respect to handling and of storage of raw materials and packing materials as outlined in **[QA-009] Materials Management Billerica.**

5.1.4.2.1.1. Upon receipt the vendor supplied CoA is reviewed using the LiquiGlide generated specification to ensure the material description and microbial results match the LiquiGlide specification.

5.1.4.2.2. While storing the material, care shall be taken to ensure segregation based on disposition and type

5.1.4.2.2.1. Received, In Quarantine, Released, and Rejected materials are stored in separate and clearly labeled areas.

5.1.4.2.3. Raw Materials are sampled and submitted to a 3rd party testing facility for microbial testing prior to release for manufacturing.

5.1.4.2.3.1. All sampling of raw materials will be performed in a dedicated, controlled space. The cleaning log will be checked by the associate performing sampling and verified by Quality Assurance the sampling area is fit for use.

5.1.4.2.3.2. Associates will follow the steps described in **[QA-018] Billerica Sample Handling and Submission**

5.1.4.2.4. Only Dedicated or single use sampling equipment shall be used for sampling.

5.1.4.3. All raw materials to be used in cGMP manufacturing must be released per **[QA-009] Materials Management Billerica** prior to release and disposition of final product.

5.1.5. **Facility**

5.1.5.1. The design of the facility and equipment is critical in preventing contamination and cross-contamination **[Attachment 1: Facility Layout]**

5.1.5.1.1. All cGMP Manufacturing and Storage Areas are suitable for use and have adequate space for:

5.1.5.1.1.1. Segregation of Materials

5.1.5.1.1.2. Placement of equipment.

5.1.5.1.1.3. Personnel flow.

5.1.5.2. Interior surfaces of walls, floor and ceiling are free from cracks and open joints, do not shed paint or particulate matter, and permit easy and effective cleaning.

5.1.5.3. Cleaning procedures are in place. **[QA-031] Line Clearance** and **[QA-044] Facility Cleaning** are followed and documented using associated forms.

5.1.5.4. Quality Assurance will perform at a minimum monthly checks of good housekeeping practices, cleaning and compliance to procedures to ensure prevention of mix-ups or cross-contamination following **[QA-022] General Housekeeping and Compliance Walk-through**

5.1.6. **Equipment**

5.1.6.1. The activities for equipment cleaning, including Clean in Place (CIP) of the Slurry Tank (TK-0101) and coating production lines, cleaning of the homogenizer suction wand (FX-0404, SP-0413, and SP-0414), and sanitizing external components that make contact with coating product or raw materials are documented in **[MFG-002] Equipment Cleaning**.

5.1.6.2. Cleaning validation is performed to verify and document that the equipment used to produce, cGMP materials can be cleaned effectively. **[MFG-016] Cleaning Validation Program.**

5.1.7. **Environmental Monitoring**

5.1.7.1. An Environmental Monitoring program is in place to mitigate the potential introduction of microbial contamination to finished product during manufacturing activities in the LiquiGlide GMP manufacturing area. **[QA-045] Environmental Monitoring – Billerica.**

5.1.7.1.1. Air is sampled for viable and nonviable particulates. In addition, surfaces are sampled for microbial contamination.

5.1.7.1.2. Trends will be monitored to assist in ensuring that the procedures for preventing contamination are effective and that the facility is in a state of control

5.1.7.1.3. A procedure is in place to design an investigation plan, timelines, responsibilities, and acceptance criteria for Out of Specification results. **[QA-040] Out of Specification (OOS)**

5.1.7.1.4. The measures to prevent of cross-contamination and/or the potential introduction of foreign particles to finished product during manufacturing activities are described in **[QA-046] Foreign Matter Prevention**.

5.1.8. **Personnel**

5.1.8.1. All associates must receive the appropriate training to perform activities at LiquiGlide's Billerica facility. **[QA-004] Training Management** will be followed to ensure compliance.

5.1.8.2. Proper gowning procedure shall be followed to prevent associate contamination as outlined in **[QA-041] Gowning Billerica**

5.1.8.2.1. Proper gowning with clean lab coats, nitrile gloves, hairnets, boot covers, cleanroom shoes, and beard covers as applicable prevents foreign matter from associates to contaminate controlled areas.

5.1.8.3. Access to controlled areas such as the Manufacturing Room (105) and Analytical Room (104) by unauthorized persons is restricted following **[QA-016] GMP Access Control**.

5.1.9. **Continuous Improvement**

5.1.9.1. Key elements to review and assess the effectiveness of the of the microbiological control plan should include:

5.1.9.1.1. Audit and assessment results, if applicable.

5.1.9.1.2. Data analysis and monitoring of trends.

5.1.9.1.3. The status of corrective or preventive actions

5.1.9.1.4. Changes to the environment or practices which may impact the microbial contamination prevention plan.

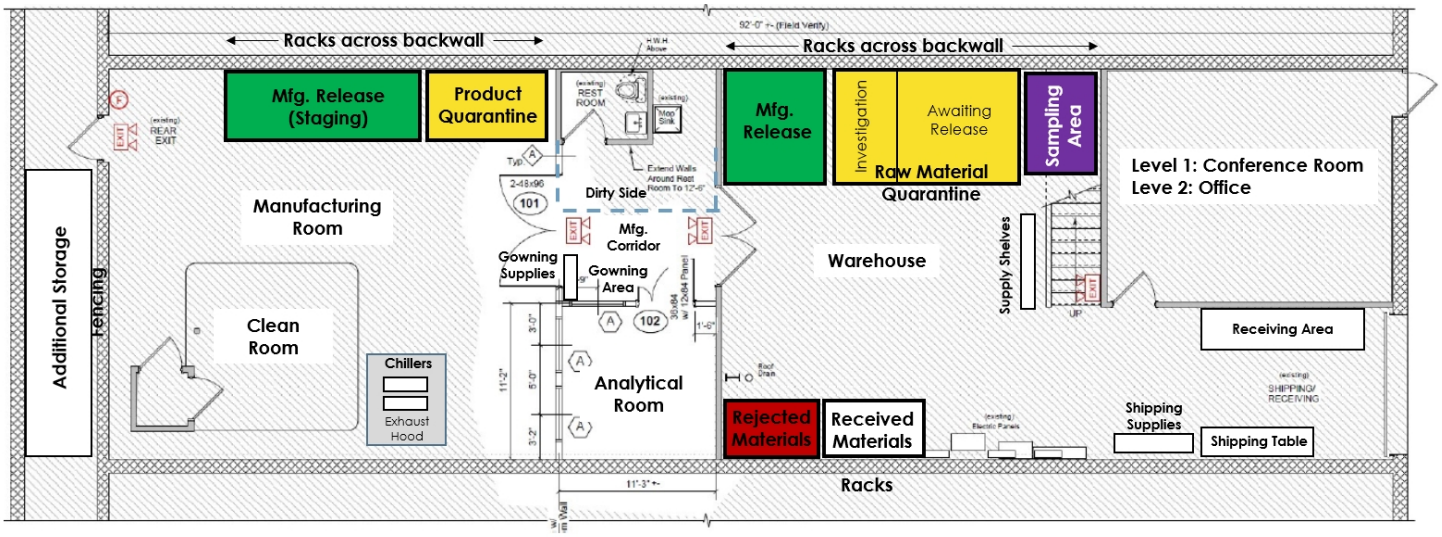
6. ATTACHMENTS

6.1. Attachment 1: Facility Layout

7. REFERENCES

7.1. [QA-004] Training Management
7.2. [QA-041] Gowning Billerica
7.3. [QA-016] GMP Access Control
7.4. [QA-031] Line Clearance
7.5. [MFG-002] Equipment Cleaning
7.6. [QA-044] Facility Cleaning
7.7. [QA-045] Environmental Monitoring – Billerica
7.8. [QA-018] Billerica Sample Handling and Submission
7.9. [QA-022] General Housekeeping and Compliance Walk-through
7.10. [QA-046] Foreign Matter Prevention.
7.11. [QA-040] Out of Specification (OOS)
7.12. [MFG-016] Cleaning Validation Program.
7.13. [QA-009] Materials Management Billerica

Attachment 1: Facility Layout



REVISION HISTORY

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New document

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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Required Workflow Steps for this Category

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