SCA pharma

November 10, 2023

Lisa Harlan
10 Waterview Blvd.
3rd Floor, Suite 300
Parsippany, NJ 07054

RE: Inspection of SCA Pharmaceuticals, LLC Windsor, CT Facility (September 18th – October 20th, 2023) FEI #3013736415

Dear Ms. Harlan,

Attached please find the Responses of SCA Pharmaceuticals, LLC (SCA) to the Observations identified by FDA in the Form 483 issued to SCA's Windsor, Connecticut facility on October 20th, 2023. For those actions still underway, we will provide a progress report no later than December 8th, 2023, with quarterly updates to follow, and will be glad to report at earlier intervals as and if circumstances so warrant or FDA so requests.

We appreciate the review of our facility and Quality Systems by the FDA Investigators and take their discussion items and observations seriously. SCA is committed to operating in a manner that is consistent with FDA regulations, guidance and expectations for 503B Outsourcing Facilities and this commitment emanates throughout our organization, starting at the top. We trust the actions outlined in our Response, along with ongoing improvement initiatives, support our commitment to producing safe drug products in an environment that meets cGMP requirements.

SCA is fully committed to providing patients with high-quality compounded preparations. The enclosed responses to FDA's 483 observations demonstrate SCA's sincere and comprehensive focus on continuous improvement. If FDA would like to further discuss any items discussed between SCA and the investigators during the closeout, SCA welcomes a meeting with the Agency at any time.

We look forward to the close-out of this inspection and issuance of an EIR.

If you should have any questions, please do not hesitate to reach out.

Sincerely,

DocuSigned by:
Scott Luce
F856912BA8C1411...

Scott Luce
CEO

OBSERVATIONS

OBSERVATION 1

There is no quality control unit.

Specifically,

A. The firm's investigation process is deficient in that the firm does not require identification of particulates found during the visual inspection process.

B. The firm's visual inspection process governed by SOP ILP-001-W "Product Inspection and Defect Classification" effective 2/22/2023 is deficient in that the SOP does not require the opening of an investigation after a failure of the 100% visual inspection.

   For example, in the last 6 months your firm has performed 100% visual inspection on approximately 3663 batches and approximately 783 failed 100% visual inspection. These batches were released without an investigation because the firm's visual inspectional AQL passed.

   Furthermore, your SOP does not require an investigation after an AQL failure, unless a critical defect is found, or an investigation after a second 100% inspection failure. In the last 6 months you have had approximately 55 instances where you had a 100% visual inspection failure, AQL failure, a second 100% visual inspection failure, and a passing tightened AQL and an investigation is not always opened. Examples of products released by Quality are included in the following chart[1].

C. In addition, your visual inspection process is deficient. For example:
   a. The visual inspection SOP ILP-001-W "Product Inspection and Defect Classification" is deficient in that an AQL failure after a passing of 100% visual inspection does not trigger a retraining your Visual Inspector employees.

   b. Production employees perform the AQL and tightened AQL, Quality does not perform the AQL Visual inspection.

OBSERVATION 1 RESPONSE

SCA's Windsor location has an independent Quality Control Unit that reports to SCA's SVP of Quality and is governed by MAN-001, *Quality Manual*, and SOP QMS-027, Responsibilities of the Quality Unit. Reference Exhibits O1-1 and O1-2. The Quality department includes approximately 83 personnel with 22 personnel that monitor Windsor production activities on all shifts. Batch records, visual inspection results and associated test results are reviewed and approved by Quality. Product does not leave SCA's Windsor location for distribution without review and release by trained Quality personnel.

[1]Chart omitted for response purposes.

SCA notified the Agency of the intent to recall on 06Nov23 and formally initiated Recall 23-004-W on 09Nov23 for products within expiry that did not meet Acceptable Quality Limit (AQL) specifications or that had a <95% post visual inspection yield.

Prior to the FDA's inspection, SCA self-initiated CAPA-2022-0034 on 23Sep22 related to the visual inspection process. The following activities were completed by SCA's Operations Department as part of that CAPA:

- Formalized a logbook requirement to document eye breaks for visual inspection employees;
- Implemented daily light box LUX verification to ensure brightness of lights comply with USP <1790> requirements; and
- Installed and validated "pacing lights" (located within view of inspectors) to operate as timers to instruct inspectors to switch between black and white background, in order to standardize amount of time each inspector examines each unit for consistency.

Once all such activities were complete, the CAPA was transferred to the Quality department, which completed the following activities:

- Identified and vetted potential third-party consultants specializing in visual inspection to assist in identification and execution of enhancements;
- Selected and qualified a well-known visual inspection industry expert to assist SCA (who was then added to SCA's Approved Supplier List);
- Enrolled Quality and Operations employees in Parenteral Drug Association (PDA) conferences to continue educating SCA employees on industry standards and best practices on visual inspection;
- Examined potential changes and enhancements to "defect kits" used to train visual inspectors; and
- Examined USP <1790>, USP <790> and FDA Draft Guidance on Visual Inspection and identified enhancements that could be made to SCA's visual inspection program based on same.

The visual inspection consultant (who had already been assisting SCA remotely) was scheduled to arrive at the Windsor facility on 23Oct23. Reference Exhibit O1-3. However, the FDA inspection was still ongoing in early and mid-October and it was unclear to SCA whether FDA would still be onsite in Windsor on 23Oct23. As such, the visual inspection consultant was rescheduled and arrived at SCA's facility on 01Nov23 and began working with SCA on the implementation of CAPA-2022-0034.

MOC-2023-0129 was initiated on 01Nov23 to implement the following as part of the revision to SOP ILP-001-W, *Product Inspection and Defect Classification*:

- Requirement to investigate if the 100% visual inspection for any lot that exceeds the relevant criteria for each category;
- Requirement to initiate an investigation for any lot that fails AQL inspection;
- Requirement to identify particles during investigations for particulate;
- Requirement for scientific rationale to be included in investigations and approval by Quality prior to performing a second 100% visual inspection and tightened AQL;
- Requirement to retrain visual inspectors when an AQL failure follows a prior 100% visual inspection that met the relevant criteria. This retraining will be tracked and trended per Visual Inspector for assessment of competency; and

- Requirement that the Quality Assurance unit assume all responsibilities related to performance of the AQL process.

SOP ILP-001-W was revised per DAR-23-271 and made effective on 09Nov23. Reference Exhibit O1-4. Inspection, Labeling and Packaging employees were trained starting on 09Nov23. SCA will not permit anyone to perform inspection, labeling and packaging duties until all training requirements have been completed.

Prior to 08Dec23, the Quality department will perform a minimum of three (3) observations of the visual inspection process (including AQL) to ensure compliance.

To supplement the revision to SOP ILP-001-W, the following forms were revised per DAR-23-521. Reference Exhibit O1-5:

- Form ILP-001-4-W, *ILP Signature Log and Bag 100% Inspection Form*
- Form ILP-001-5-W, *Bag AQL Inspection Form*
- Form ILP-001-6-W, *Bag Additional 100% Inspection Form*
- Form ILP-001-7-W, *Bag TAQL Inspection Form*
- Form ILP-001-8-W, *ILP Signature Log and Syringe 100% Inspection Form*
- Form ILP-001-9-W, *Syringe AQL Inspection Form*
- Form ILP-001-10-W, *Syringe Additional 100% Inspection Form*
- Form ILP-001-11-W, *Syringe TAQL Inspection Form*
- Form ILP-001-12-W, *ILP Signature Log and CADD 100% Inspection Form*
- Form ILP-001-13-W, *CADD AQL Inspection Form*
- Form ILP-001-14-W, *CADD Additional 100% Inspection Form*
- Form ILP-001-15-W, *CADD TAQL Inspection Form*

OBSERVATION 2

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

Specifically,

The visual inspection % yield is not calculated or established in the batch record or is an established quality parameter. For example, the following batches were compounded and released.

A. Batch record for Hydromorphone HCL mg/mL in 0.9% Sodium Chloride 30mL fill 35mL Plungerless Syringe, Lot number 1223048865, shows 372 compounded units released to visual inspection and after the visual inspection rejection the amount of product released to labeling was 249 units, which had an approximate yield of 70%.

B. Batch record for Fentanyl 50mcg/mL 50mL bag, Lot number 1223048351, shows 286 compounded units released to visual inspection and after visual inspection rejection the amount of product released to labeling was 246 units, which had an approximate yield of 86%.

C. Batch record for Hydromorphone HCL 0.2 mg/mL in 0.9% Sodium Chloride 30mL fill 35mL Plungerless Syringe, Lot number 1223049559, shows 306 compounded units released to visual inspection and after visual inspection rejection the amount of product released to labeling was 226 units, which had an approximate yield of 74%.

OBSERVATION 2 RESPONSE

At the time of the inspection, compounding production yields were being calculated and recorded in the manufacturing batch record and an investigation is initiated when the cause of the yield is unknown.

Prior to the FDA inspection, as detailed above, SCA engaged a third-party expert to assist with enhancements to our visual inspection process. As such, and in response to Observation 2, our already-engaged third-party consultant worked with us to define the appropriate yield requirement of not less than (NLT) 95%.

The post visual inspection % yield target of NLT 95% was implemented on 09Nov23 as part of DAR-23-271 for SOP ILP-001-W, *Product Inspection and Defect Classification.* Reference Exhibit O1-4. Any batch that does not meet the established visual inspection yield criteria will result in the initiation of an event per SOP QMS-039, *Event Reporting and Disposition*. Events are evaluated for potential product impact by Quality Assurance personnel and then, when required, elevated to a deviation and investigated following SOP QMS-003, *Deviation Management*.

Prior to and at the time of the inspection SCA did (and still does) record the number of units sent to Inspection, Label, Pack (ILP) for inspection as well as the number of discarded units (rejects). As such, SCA conducted a retrospective review of this data, to identify any lots in the market that did not meet the yield requirement of NLT 95%. Although SCA is not aware of any adverse events associated with these products, in an abundance of caution, SCA notified the Agency of the intent to recall specific lots on 06Nov23 and formally initiated Recall 23-004-W on 09Nov23 of any Windsor product within expiry where the retrospective data analysis indicates failure to meet the post inspection yield outside of the NLT 95% criteria.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your SOP TM 008 "USP <788> Particulate Matter" is deficient in that after a failure of Test Method 1 (Light Obscuration Particle Count Test) than Test Method 2 (Microscopic Particle Count Test) is performed.
    a. Your SOP states that If after a failure of Test Method 1 and a passing of Test Method 2, the product can be released and distributed without opening an investigation.

For example, since 2019 there were approximately 38 instances where there was a failure of Test Method 1 and a Passing of Test Method 2 without opening an investigation. For example, see the chart below[2].

These products have been released and distributed.

B. Since December 2019, the firm has documented twenty-nine (29) Out of Specifications (OOS) results for in-house sterility testing of finished drug products intended to be sterile using a rapid scan method (BioMerieux ScanRDI). All batches were rejected; however, the firm failed to adequately investigate and remediate all potential sources of microbial contamination including spore-forming microbes.

   For example: Out of Specification (OOS-2023-0069) initiated on or about 29-Aug-2023 identified circular spore like structures in lot# 1223048877 (Phenylephrine HCl 40 mcg/mL in 0.9per Sodium Chloride 10 mL fill 12 mL Syringe 400 mcg 10 mL). The firm's accompanying manufacturing deviation (DEV-2023-0435) identified inadequate material sanitization and poor aseptic technique demonstrated by the Compounder as identified causes; however, the firm failed to identify Sanitization Technicians also wiped totes with IPA wipes prior to meeting the firm's established sporicidal disinfectant contact time of 5 minutes. On 26-SEP-2023 via the firm's Avigilon video recordings, sporicidal disinfectant contact times for the 10 totes associated with lot 1223048877 were observed to be as low as 63 seconds before Sanitization Technicians wiped the totes with IPA. The firm's investigation remains open.

   In addition, there is no assurance the firm's remediation actions for all sterility OOSs and accompanying manufacturing deviations are adequate, specifically for spore-forming microbes. For example: the firm's corrective and preventative actions included retraining of individual Compounders, Aseptic Assistants, and Sanitization Technicians associated with specific sterility OOSs, and the firm opened CAPA-2023-0017 in response to a lack of standardized material sanitization by firm personnel, which was associated with five (5) sterility OOSs that occurred in April of 2023; however, the CAPA due date for training of all staff is not until 31-JAN-2024 and six (6) of the firm's last 10 sterility OOSs identified spores or spore-forming microbe morphologies. For additional example, on 1-OCT-2023, the firm opened DEV-2023-0525 as a result of a failed media fill. The firm identified the microbe from the failed media fill as genius Bacillus, a spore-forming bacterial microbe.

C. The firm failed to adequately assess and remediate numerous findings of foreign materials, described as cardboard and hair, found in sterile starting material syringe tray packs from the firm's three (3) syringe suppliers. Since January 2022, the firm documented numerous incidences of foreign materials found in syringe tray packs during production within ISO-5 environments via Form QA-014-01, Foreign Material Documentation forms. The firm trends starting material lots found with foreign materials and rejects in-process product found to be associated with tray packs in which foreign material was identified; however, there is no assurance all foreign material is found and removed as the firm does not qualify operators to identified foreign materials, the firm

[2] Chart omitted for response purposes.

does not track or trend operators who identifying foreign materials, and the firm continues to use the same suppliers.

D. The firm failed to adequately address 100% visual inspection and AQL failures. The firm opened CAPA-2022-0034 (Corrective Action and Preventive Action) on 23 Sep 2022 with a CAPA due date of23 JUN 2024. A CAPA action plan was signed by Quality on 23 Jun 23, The action plan includes opening an investigation after 100% Visual Inspection failure. Since 23 Jun 23, the firm has had approximately 480 lots that failed 100% inspection, without an investigation being opened.

OBSERVATION 3 RESPONSE

SCA follows an event reporting and classification process per SOP QMS-039, *Event Reporting and Disposition*. The events are evaluated for potential product impact by Quality Assurance personnel and then elevated to a deviation when required per SOP QMS-003, *Deviation Management*. An impact assessment for the lot and distributed products on the market is required per the procedure and documented in the respective event or deviation.

OBSERVATION 3A RESPONSE

SCA looks forward to the Agency publishing its long-awaited regulations on Current Good Manufacturing Practice for Outsourcing Facilities. In the meantime, SCA follows cGMP Guidance for Human Drug Compounding Outsourcing Facilities which provides for use of USP <788> for particle testing. Per USP <788>, Particulate Matter in Injections, the Method 1 Light Obscuration Particle Count Test Evaluation section states '*If the average number of particles exceeds the limits, test the preparation by the Microscopic Particle Count Test'* which is Method 2. Reference Exhibit O3-1. Therefore, cGMP and USP both indicate that it is appropriate to perform Test Method 2 should Test Method 1 exceed the limit, as is SCA's current process. There is no quality or safety risk to patients for SCA product in the market that exceeded the limit for Test Method 1 and subsequently met the limit for Test Method 2.

However, TM-008, *Particulate Matter,* was revised per DAR-23-511 and made effective on 06Nov23. Reference Exhibit O3-2. This revision requires initiation of an investigation per SOP CHEM-038, *Handling Out of Specification and Out of Trend Results,* when there is an exceedance of particulate matter limits during Test Method 1 – *Light Obscuration,* regardless of whether the Method 2 results are acceptable. This investigation will ensure that there were no laboratory errors during the performance of Test Method 1.

There have been no Test Method 1 or Test Method 2 testing exceedances since the close of the inspection on 20Oct23.

OBSERVATION 3B RESPONSE

SCA has rejected (prior to distribution) all product that has been found to be Out of Specification (OOS) for sterility. SCA notes that the sterility failures referenced in Observation 3B represent a 0.1% failure rate since December 2019. More recently, and specifically over the past year, SCA Windsor's sterility performance has been as follows: Q4 2022: 100% within specification; Q1 2023: 100% within specification; Q2 2023 99.68% within specification; and Q3 2023: 100% within specification.

The investigations into the 29 failures in Windsor over the past ~4 years (0.1% of lots produced in Windsor) were completed per the requirements of QMS SOP-003, *Deviation Management*. On 20Jul23, SCA self-initiated CAPA-2023-0017 in response to the manufacturing trend investigation of sterility failures. SCA's CAPA plan that was already in place at the time of the inspection, included two action items:

- Revision to SOP SAN-002-W, *Movement of Materials Into and Out of Classified Areas*, to implement a sporicidal sanitization step to the IV bag overwrap during the material sanitization process. This action item had an original target due date of 31Dec23. However, this SOP revision per DAR-23-443 has been completed and was made effective on 10Nov23. Reference Exhibit O3-3. Cleanroom personnel training began on 10Nov23. SCA will not permit anyone to perform cleanroom duties until all training requirements listed in all relevant responses have been completed.
- Creation of material sanitization training videos to standardize wiping technique for the material sanitization staff and the cleanroom compounding staff. This action item had an original target due date of 31Dec23. However, the creation of training materials was completed on 08Nov23 and delivery of the training videos began on 10Nov23 and will continue until all cleanroom personnel have been trained. SCA will not permit anyone to perform cleanroom duties until all training requirements have been completed.

At the time of inspection, DEV-2023-0435 had already been initiated and was still open and in the process of being investigated before the Agency made an observation related to totes and contact time. Because the deviation was open at the time of the FDA inspection, SCA was able to include the Investigator's observations, along with corresponding corrective actions (SOP SAN-002-W revision and training referenced in Observation 4B) within the investigation prior to closure on 26Oct23. Reference Exhibits O3-3, O3-4 and O4-2.

In addition, SCA has been migrating from the ScanRDI sterility test to a more advanced methodology using the Celsis Advance II Rapid Microbial Detection System. SCA purchased two Celsis Advance II Rapid Microbial Detection Systems manufactured by Charles River for its Windsor facility, which were installed and qualified on 10Aug22 and 06Oct23. Method suitability has been completed for 28 product families and 4 product families remain. Despite our best efforts, we have been unable to bring the two Celsis instruments online and operational because the specific type of media that is required to be used with this equipment is currently on shortage and backorder.

OBSERVATION 3C RESPONSE

SCA has revised SOP QA-014 per DAR-23-520 to reference the newly developed visual display VD-QA-014-2, *Visual Display for Defect Examples,* to aid operators in identifying commonly found foreign material. Reference Exhibits O3-5 and O3-6. The SOP revision includes a requirement to update the visual display when operators identify a new unique type of foreign material. Cleanroom personnel will be required to train on SOP QA-014 and VD-QA-014-2 minimally on an annual basis (or sooner if the SOP and VD are updated) to ensure operators are familiar with the types of foreign material they may encounter when compounding. Additionally, cleanroom personnel will be required to attend classroom training beginning on 13Nov23, where examples of defects will be presented. SCA will not permit anyone to perform cleanroom duties until all training requirements have been completed.

SCA will begin tracking and trending cleanroom operators for the identification of foreign material. Form QA-014-01, *Foreign Material Documentation Form,* was revised per DAR-23-520 and made effective on 09Nov23 to document which compounder identified the foreign material. Reference Exhibit O3-7. In addition, SCA revised technical qualification TQ COM-100-2-W, *Aseptic Assistant Technical Qualification,* per DAR-23-527 to require a step for training on defect types for any newly hired cleanroom personnel. This technical qualification was made effective on 09Nov23. Reference Exhibit O3-8.

SCA currently uses three (3) reputable, FDA-registered syringe suppliers (whose names we would be glad to supply upon request) from among the small set of FDA-registered syringe suppliers. Of those three suppliers used by SCA, two manufacture, kit and sterilize syringes, while the third supplier obtains non-sterile, non-kitted syringes from an FDA-registered facility and packages and sterilizes them for SCA.

SCA performed a review of already documented issues regarding foreign material in supplier-provided syringe trays and, on 10Oct23, initiated formal supplier complaints, SUP-2023-0026, SUP-2023-0027 and SUP-2023-0028 to each supplier regarding defects found in their supplied products. SCA has not yet received any corrective actions from two of the suppliers, in response to the complaints issued to them by SCA. Therefore, on 13Nov23, SCA plans to issue escalation letters describing our concerns to those two suppliers. The intent of these letters is to escalate the issue to the suppliers' Quality Leadership team to ensure corrective actions are implemented. SCA has received communication from the third syringe supplier, who, in response to our complaint, has requested a Quality meeting with SCA to discuss the identified defects and the corrective actions in response to the defects. SCA plans to participate in the meeting and, if the corrective actions presented by the supplier are deemed inadequate or not met, SCA will issue an escalation letter to the supplier as above.

Given the relatively small set of FDA-registered suppliers for these products, SCA has very few options for alternatives. That noted, SCA is currently evaluating a fourth syringe supplier, selection of which would require SCA to establish new product stability data using a different container closure type. If the container is a viable option, the project would be a long-term solution and a change control would be initiated at the time of project start.

OBSERVATION 3D RESPONSE

Reference the response to Observation 1.

OBSERVATION 4

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A. There are no established procedures for preparing Spor-Klenz wipes used to sanitize all starting compounding materials, totes, and cleanroom equipment such as the firm's ISO-5 Horizontal Laminar Flow Hoods, to ensure consistency and adequacy of cleaning. The firm prepares Spor-Klenz wipes used to sanitize starting materials and totes by adding an undefined amount of Spor-Klenz from a gallon container into a Contec non-sterile and low linting Sanotex Environmental Surface Wipes container. The firm prepares Spor-Klenz wipes used to perform nightly cleaning of

the ISO-5 hoods by adding an undefined amount of Spor-Klenz from a gallon container into a mop bucket containing an undefined amount of Berkshire Corporation sterile Gamma Wipes.

B. Polypropylene totes used to transfer all compounding materials from an unclassified staging area (room 252) to the ISO-7 compounding suite (rooms 1102, 1104, 1107, & 1110) and placed immediately adjacent to ISO-5 Horizontal Laminar Flow Hoods are not adequately sanitized. Sanitization technicians were observed to wipe totes with IPA wipes prior to meeting the firm's established Spor-Klenz contact time of 5 minutes. For example, Spor-Klenz contact times for 10 totes associated with lot 1223048877 (Phenylephrine HCl 40mcg/ml in Sodium Chloride 10mL fill in 12 mL Syringes) were observed to be as low as 63 seconds before being wiped with IPA. The firm currently has an open sterility OOS for lot 1223048877.

C. The firm uses Spor-Klenz wipes to perform nightly sporicidal cleanings of top, side walls, and deck of the firm's 15 ISO-5 Horizontal Laminar Flow Hoods used to produce product purported to be sterile; however, the firm does not perform periodic sporicidal cleanings of the grate covering the HEPA filter for any of the hoods. The firm has not performed a risk assessment for this practice.

OBSERVATION 4 RESPONSE

SCA has multiple procedures established for the cleaning and maintenance of equipment used in the manufacturing and cleanroom environments. These procedures include instructions on the preparation of sanitizing agents and wipes, laminar air flow hoods and the associated grates, and other utensils used in the manufacture, processing, packing and holding of drug products. SCA is further enhancing its policies and procedures on cleaning and maintenance of equipment Specific cleaning and maintenance procedures are included in the individual responses below.

OBSERVATION 4A RESPONSE

SOP SAN-002-W, *Material Movement into and out of Classified Areas*, currently contains a requirement to ensure the wipe is saturated prior to use. In addition, SOP SAN-001-W, *Cleaning of Classified Areas*, also instructs operators to ensure wipes are saturated during the preparation process. Furthermore, SCA will start utilizing pre-saturated sterile Sporklenz wipes, which have been qualified by the manufacturer and will eliminate the potential for any operator variability in preparing the wipes (including amount of saturation) when we sanitize rooms and materials in advance of resumption of production. SCA has revised SOP SAN-002-W and SOP SAN-001-W, both effective on 10Nov23, to require the use of commercial, pre-saturated Sporklenz wipes. Reference Exhibits O3-3 and O4-1. SCA will also immediately cease the use of the wipes referenced in the Observation in the ISO 8 environment for material sanitization. This change is also captured in the revision to SOP SAN-002-W. Reference Exhibit O3-3. Additionally, cleanroom personnel are required to attend in-person classroom training, where this process change will be presented. The training program was initiated on 10Nov23. SCA will not permit anyone to perform cleanroom duties until all training requirements have been completed.

As a process improvement, SCA initiated ES-23-026, *Engineering Study for the Efficacy of Wipe Preparation and Cleaning of Cleanroom Materials and Equipment*, per TASK-23-1070 on 08Nov23. This engineering study will be performed to develop a cleaning method which will include internal preparation of Sporklenz

wipes using sterile wipes and ready to use Sporklenz solution. The target completion date of this engineering study is 30Nov23. After performance of this study, a cleaning method qualification per VAL-23-074, *Cleaning Qualification of Prepared Sanitization Wipes on Cleanroom Materials and Equipment* will be executed, and relevant procedures will be updated. The target completion date for this study and SOP revisions is 31Dec23.

There is no risk to previously compounded product as current SOPs include instruction to ensure wipes are saturated before use. Additionally, any microbial contamination identified within the ISO 5 environment requires an investigation prior to disposition of the batch.

OBSERVATION 4B RESPONSE

SOP SAN-002-W was revised to specify the requirement for totes to meet the 5-minute sporicidal contact time and became effective on 10Nov23. This procedure update removed an IPA wipe of the totes. Reference Exhibit O3-3. In addition, during the FDA inspection, on 04Oct23, the material sanitization department was immediately re-trained on contact times per SOP SAN-002-W. Reference Exhibit O4-2.

Between 04Oct23 and 02Nov23, cleanroom management performed random surveillance of the material sanitization process to ensure compliance with the requirement for 5-minute sporicidal contact time for totes. All monitoring activities have confirmed compliance with the procedure.

Prior to 08Dec23, the Quality department will perform a minimum of three (3) observations of the tote sanitization process to ensure compliance.

OBSERVATION 4C RESPONSE

Though the FDA Form 483 indicated that SCA does not periodically clean laminar airflow hood (LAFH) grates, SCA does in fact periodically clean LAFH grates on a six-month frequency during bi-annual LAFH and cleanroom recertification activities. Per SOP COM-060-W, *Use and Operation of Laminar Airflow Hoods,* the HEPA diffuser is cleaned as part of containment activities for a drug spill.

SCA will conduct an engineering study per ES-23-027, *Engineering Study for Grate Cleaning Frequency,* to determine whether more frequent cleaning intervals may enhance the cleaning program. The target completion date is 31Jan24.

Per SOP SAN-001-W, *Cleaning of Classified Areas,* specified LAFHs surfaces are cleaned daily with Sporklenz followed by a sterile 70% IPA residual removal clean. LAFH's are cleaned in the following order: inside top, bar and hooks (if present), side walls, hood deck. The HEPA filter diffusers are not required to be cleaned daily to avoid wetting the HEPA media which could compromise the integrity of the filter. Environmental monitoring is performed for all batches compounded in the LAFH ISO 5 environment. Batch related environmental monitoring includes, but is not limited to, active viable air sampling and continuous non-viable particulate sampling, where the air samplers are pointed in the direction of the HEPA diffuser which includes detection of any potential contamination from the filtered air. These samples are used to provide evidence that the LAFH functions as intended and remains in a state of control during

compounding activities. There are no negative trends in active viable air sampling and continuous non-viable particulate sampling demonstrating effectiveness of the process.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written.

Specifically,

A. Operators failed to follow techniques intended to maintain sterility of items and surfaces during aseptic operations. For example, on 18-SEP-2023, during production of lot 1223049390 Fentanyl 20mcg/mL in 0.9% Sodium Chloride 100mL Bags in bay CT0120, hood #7/2, Aseptic Assistant (PJ) was observed to touch items including totes, a chair, repeater pumps, gowning, and subsequently reached into the ISO-5 hood to provide additional starting materials and retrieve finished product without sanitizing hands or changing gloves. In addition, upon review of the firm's Avigilon video recordings, Aseptic Assistant (PJ) touched the surface of a table where non-sterile paper and label items were located, as well as the paper batch record, and subsequently reached into the ISO-5 hood to provide additional starting materials and retrieve finished product without sanitizing hands or changing gloves. The firm's SOP (COM-001-W) requires operators to don new sterile gloves or sanitize gloves with 70% IPA prior to staging material into and collecting material out of 1SO-5 hoods. Lot 1223049390 was approved by Quality on 26- SEP-2023.

B. The firm failed to ensure adequate cleanroom airflow to not potentially compromise aseptic operations. For example, on 18-SEP-2023, during production of lot 1223049390 Fentanyl 20mcg/mL in in 0.9% per Sodium Chloride 100mL Bags in bay CT0120, hood #7/2, air return vents for the firm's HVAC system, located in half walls separating the firm's ISO-5 hoods, were observed to be obstructed. The firm's SOP (SAN-002-W) requires materials or totes on carts to be stored in a manner that does not block airflow for air return vents.

OBSERVATION 5 RESPONSE

SCA requires all personnel working in classified environments to be trained on SOP COM-001-W, *Aseptic Guidelines and Cleanroom Behavior.* The procedure is detailed in the actions required for proper aseptic techniques and references additional procedurals that contain further requirements for specific actions and operations. SCA is further enhancing its training to include additional training for personnel and formal monitoring processes for aseptic behavior which were implemented as detailed.

OBSERVATION 5A RESPONSE

SCA's entire compounding staff were retrained on proper glove sanitization and glove changes on 01Nov23. Reference Exhibit O5-1. In addition, SCA retrained an aseptic assistant on 19Sep23. Reference Exhibit O5-2.

Additional corrective actions and process improvements include:

- SCA has procedurally defined how far reaching an aseptic assistant can place their hands into the ISO 5 environment. SOP COM-018-W, *Staging of Raw Material in the LAFH*, has been revised per DAR-23-531 to include instructions that the aseptic assistant can only place their gloved hand into the ISO 5 environment and no part of their gown can enter the ISO 5 LAFH. This procedure was made effective on 09Nov23. Reference Exhibit O5-3.

- CAPA-2023-0028 was initiated on 03Nov23 to enhance SCA's current aseptic technique and cleanroom behavior training for all gowning qualified staff. The CAPA includes training on cleanroom design, layout, and engineering controls as well as training on how people and behavior may impact the cleanroom environment. As part of this CAPA, the following actions have been completed:

    - SOP COM-061-W, *Roles and Responsibilities of Cleanroom Personnel*, was revised and made effective on 09Nov23 per DAR-23-512 to require cleanroom pharmacists, supervisors and lead technicians to perform daily observation of cleanroom personnel to ensure adherence to all SOPs. Reference Exhibit O5-4.

    - SCA developed a "Micro on the Floor" program in which the Microbiology department will conduct routine assessments of cleanroom behavior and technique as part of SCA's overall contamination control strategy. Procedure SOP LAB-074-W, *Microbiology Quality Oversight of Critical Areas,* was made effective on 09Nov23 per DAR-23-516. Reference Exhibit O5-5.

    - SCA developed a "Micro 101" training for gowning qualified personnel that provides a refresher on the basics of microorganisms, sources of contamination, how microbes are transmitted, and how hygiene and behavior can increase or decrease the spread of bacteria. Reference Exhibit O5-6.
        - Any new personnel will receive this training prior to being qualified to enter the cleanroom, and existing personnel will be re-trained on a semi-annual basis.

    - SCA developed a "Cleanroom 101" training for gowning qualified personnel that provides a refresher on cleanroom disinfection practices, room classifications and cleanroom engineering controls such as airflow, pressure, and building materials. Reference Exhibit O5-7.
        - Any new personnel will receive this training prior to being qualified to enter the cleanroom, and existing personnel will be re-trained on a semi-annual basis.

Cleanroom personnel were trained on the relevant process changes and SOP revisions starting on 10Nov23. SCA will not permit anyone to perform cleanroom duties until all training requirements listed in all relevant responses have been completed. Routine monitoring and oversight to ensure adherence to these process changes and SOP revisions will be performed as stated in SOP COM-061-W and SOP LAB-074-W.

SCA also commits to implementing long term corrective actions which include:

- Converting paper tote tags to disposable metal tags (MOC-2023-0137) – Target Completion Date of 29Feb24
- Implement a process to autoclave batch records (MOC-2023-0142) – Target Completion Date of 29Feb24

OBSERVATION 5B RESPONSE

SCA conducted thirty-three (33) independent Airflow Visualization (Smoke) Studies for all four (4) ISO 7 compounding cleanrooms used to support the fifteen (15) Laminar Flow Hoods. All rooms were loaded to normal operating conditions including carts, tables, and totes used during compounding activities and included partially blocked returns by waste bins and totes as a worst-case loading condition. Dynamic airflow visualization was performed and included the maximum occupancy of gowned personnel for each room as procedurally required, while operators simulated their routine duties. Though the rooms have non unidirectional airflow, the airflow patterns were assessed to ensure that air was not traveling from less clean areas (such as the floor) or over operators, equipment, or materials into the ISO 5 LAFHs.

All thirty-three (33) Airflow Visualization Studies showed airflow from the HEPA filters moving in a robust downward manner before mixing with room air with no observable adverse airflow patterns. Clear separation of clean spaces was demonstrated between the ISO 5 LAFHs and ISO 7 compounding rooms. No evidence of refluxing or outside air entering the ISO 5 LAFHs was observed. Suitable mixing of tracer particles (representing air flow) was observed and tracer particles in the room flowed away from the LAFHs and into return vents.

Though SCA's Airflow Visualization (Smoke) Studies are suitable, all cleanroom operators were re-trained on the requirement in SOP SAN-002-W, *Movement of Materials Into and Out of Classified Areas*, to store material in a manner that does not block airflow for air return vents on 01Nov23. Reference Exhibit O5-1.

Additional process improvements include:

- SOP COM-005-W, *Compounding Area Clearance* and LG-COM-005-1-W, *Compounding Area and Equipment Use Log*, were revised per DAR-23-512 and were made effective on 09Nov23. Reference Exhibits O5-8 and O5-9. These revisions require the compounder to perform pre and post compounding checks of air returns to ensure they are not blocked. Documentation of each check will be captured in LG COM-005-1-W.

- SOP COM-061-W, *Roles and Responsibilities of Cleanroom Personnel,* was revised per DAR-23-512 to include specific requirements for cleanroom pharmacists, supervisors and lead technicians, to perform checks of air returns continuously throughout their shift. The procedure was made effective on 09Nov23. Reference Exhibit O5-4.

Cleanroom personnel were trained on the relevant process changes and SOP revisions starting on 10Nov23. SCA will not permit anyone to perform cleanroom duties until all training requirements have been completed.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

The firm's environmental monitoring practices of classified and aseptic processing areas do not ensure appropriate levels of environmental cleanliness. For example:

A. Personnel monitoring of gloved fingertips for Aseptic Assistants never occurs as part of the firm's routine personnel monitoring program; however, Aseptic Assistants were observed reaching into ISO-5 hoods to stage starting materials and collect finished products during production.

B. The firm's personnel monitoring action limit for the sleeves of Aseptic Assistants is > 10 colony forming units (CFUs); however, Aseptic Assistants were observed to reach into hoods during production. Since January 2020 there were 30 spore-forming microbial recoveries of < 10 CFUs on the sleeves of Aseptic Assistants. The firm failed to investigate and assess product impact for any of these spore-forming microbial recoveries.

C. The firm does not consider spore-forming bacteria recovered from classified environments as objectionable unless action levels are reached. Since January 2020, the firm documented 404 media plates which identified spore-forming microbial recoveries from ISO-7 environments; however, only recoveries with 10 CFUs or more are investigated.

D. The firm performs viable active air monitoring during compounding via SAS Super 180 Portable Microbial Air Monitors; however, the monitor is placed to the far right of the ISO-5 hood with the probe approximately six inches and directly facing the HEPA filter. The firm did not perform or provided directionality studies or scientific justification for this practice.

E. Cleanroom items such totes, chair, and repeater pumps, observed to be touched by Aseptic Assistants, are never sampled as part of the firm's routine environmental monitoring program.

OBSERVATION 6 RESPONSE

SCA has a comprehensive Environmental Monitoring program and performs monitoring in all classified areas with a focus on the ISO 5 environment where all aseptic manipulations occur. SCA designed and documented the environmental and personnel monitoring program of the facility's classified areas based on a formal risk assessment, RA-21-001-W, *Risk Assessment for Controlled Environments located at 755 Rainbow Rd, Windsor, CT 06095*. Once sampling locations, method, criteria, and other supplemental parameters were identified, the classified areas were successfully qualified as part of static and dynamic environmental monitoring performance qualification. The product manufacturing processes were also successfully qualified via aseptic process simulation (media fills) and continue to be regularly assessed twice annually.

Since initial implementation, the risk assessment document has regularly been updated as part of the lifecycle approach to the environmental and personnel monitoring program. Microbial trend data analysis

as well as evolving regulatory requirements result in frequent re-evaluation of the monitoring program including, but not limited to, sample frequency, sample site selection, alert/action levels, etc.

OBSERVATION 6A RESPONSE

An Aseptic Assistant is an ISO 7 production operator who supports the ISO 5 Compounder in the manufacturing of a batch. The Aseptic Assistant introduces and removes materials from the ISO 5 Laminar Airflow Hood (LAFH) downstream from the critical compounding zone, thus mitigating risk of potential microbial contamination. The interventions and described routine process flow of the Aseptic Assistant have been successfully qualified in both Airflow Visualization (Smoke) Studies in addition to Aseptic Process Simulations (Media Fills). The Airflow Visualization Studies show that there is no ingress of air into the critical compounding zone by interventions of the Aseptic Assistant. The Aseptic Process Simulations demonstrate that the interventions by the Aseptic Assistant do not result in contaminated final filled units. Reference Exhibit O6-1.

Aseptic Assistants interact with the ISO 5 environment on the left side and right side of the LAFH. Sampling of each batch includes continuous passive viable air monitoring on the left and right sides of the critical zone from the connection of the sterile filter throughout the duration of batch filling. Additionally, a viable surface sample is collected on the left and right side of the hood at the conclusion of compounding.

As part of enhancing SCA's Environmental and Personnel Monitoring Program, SCA has initiated change control MOC-2023-0130 to capture the implementation of new sampling locations within the classified areas including, but not limited to, the gloved fingertips of ISO 7 Aseptic Assistants. As part of MOC-2023-0130, Aseptic Assistant gloved fingertips will be sampled to improve the monitoring of the ISO 7 activities. As per MOC-2023-0131, the results from the Aseptic Assistant's gloves will become batch release criteria and any microbial recovery obtained from the gloves will result in a product impact assessment. To support this process change, Risk Assessment RA-21-001-W and SOP LAB-007-W, *Environmental and Personnel Monitoring of Classified Areas* have been revised per DAR-23-542. These documents were made effective on 09Nov23. Reference Exhibits O6-2 and O6-3.

Training for Cleanroom and Microbiology personnel began on the relevant process changes and SOP revisions starting on 10Nov23. SCA will not permit anyone to perform cleanroom duties or collect personnel monitoring samples until all training requirements have been completed.

OBSERVATION 6B RESPONSE

SCA has procedurally defined how far an Aseptic Assistant may place their hands into the ISO 5 environment. SOP COM-018-W, *Staging of Raw Material into the LAFH*, was revised to include instructions that the Aseptic Assistant can only place their gloved hand into the ISO 5 environment, and no part of their gown can enter the ISO 5 LAFH. This document was made effective on 09Nov23. Reference Exhibit O5-3.

SCA has updated the action limit for ISO 7 personnel monitoring, which includes the Aseptic Assistant's gown sleeves, from <10 CFU to <5 CFU. To support this process change, Risk Assessment RA-21-001-W and SOP LAB-007-W have been revised per DAR-23-542 and made effective on 09Nov23. Reference Exhibits O6-2 and O6-3.

As part of continuous improvement to the contamination control program, SCA has revised SOP LAB-030, *Trend Analysis of Environmental and Personnel Monitoring Results,* per DAR-23-528, to proceduralize the review of bacterial spore forming organisms recovered from the ISO 7 cleanroom and to identify and investigate any potential trends that may develop. The target effective date of this SOP revision is 30Nov23.

Training for Cleanroom and Microbiology personnel began on the relevant process changes and SOP revisions on 09Nov23. SCA will not permit anyone to perform cleanroom duties or collect personnel monitoring samples until all training requirements have been completed.

OBSERVATION 6C RESPONSE

As per RA-21-001-W and applicable governing internal standard operating procedure SOP LAB-007-W, the facility has a no growth policy within the ISO 5 environments that considers any (and all) viable microbial recoveries results actionable, therefore requiring a thorough investigation.

Per SOP LAB-007-W, fungi (including yeast and mold), are considered actionable in the Compounding Rooms. A recovery of one (1) fungal colony forming unit in an ISO 7 Compounding Room results in an actionable result and investigation. Under the risk-based assessment performed by SCA, spore forming bacteria were not found to be, and therefore are not considered, objectionable in the ISO 7 and ISO 8 areas. Bacterial spore forming organisms are thoroughly investigated once the action level with respect to number of colony forming units (CFU) is exceeded.

Between January 2020 to September 2023, approximately eighty-five percent (85%) of bacterial spore forming organism recoveries at the site are comprised of unique species within the genus *Bacillus*. SCA hired an independent third-party microbiological contamination control expert to assess each unique bacterial spore forming genus and species recovered between January 2020 and September 2023 for potential risk to patient. The assessment performed by that independent third-party contamination control expert concluded that bacterial spore forming organisms recovered are not objectionable via injectable mode of administration. Reference Exhibit O6-4.

As part of continuous improvement to the contamination control program, SCA has revised SOP LAB-030 per DAR-23-528 to proceduralize the review of bacterial spore forming organisms recovered within the ISO 7 cleanroom to help identify and investigate any potential trends that may develop. The target effective date is 30Nov23.

OBSERVATION 6D RESPONSE

SCA has a robust ISO 5 environmental and personnel monitoring sampling plan with a high level of detection for viable and non-viable contamination. Each batch includes one active viable air sample during filling of commercial units, continuous passive viable air monitoring which includes multiple sample plates in the immediate critical compounding zone from the connection of the sterile filter throughout the duration of batch filling and continuous non-viable particulate monitoring from connection of the sterile filter throughout the duration of batch filling. SCA considers all samples in totality as part of final product disposition performed by the Quality Assurance Department.

To further enhance SCA's policies, SCA has initiated change control MOC-2023-0132 to capture the improvement and optimization of active viable air sampler positioning. The active viable air sampler will

be repositioned perpendicular to the HEPA Filter in the LAFH to face in the direction of the compounder and the compounding process within 12-18 inches of the critical zone. The results of the active viable air monitoring will continue to be leveraged in totality with remaining environmental and personnel monitoring data and leveraged as part of final product disposition by the Quality Assurance Department. To support this process change, RA-21-001-W, SOP LAB-007-W, SOP LAB-008-W, *Operation and Maintenance of the AES Sampl'Air Lite,* and SOP LAB-041-W, *Operation and Maintenance of the SAS Super 180 Microbial Air Sampler* were revised. The effective date of these procedure revisions was 09Nov23. Reference Exhibits O6-2, O6-3, O6-5 and O6-6.

Cleanroom and Microbiology personnel were trained on the relevant process changes and SOP revisions starting on 09Nov23. SCA will not permit anyone to perform cleanroom duties or collect environmental monitoring samples until all training requirements listed in all relevant responses have been completed.

OBSERVATION 6E RESPONSE

SCA has a robust environmental sampling plan in ISO 7 Compounding Rooms. Sampling within the ISO 7 Compounding Rooms is performed in risk-based sampling locations defined in RA-21-001-W and includes viable and non-viable active air monitoring in addition to viable surface sampling of carts, tables, walls, doors, and floors. Results generated are trended, assessed, and reported as per SOP LAB-030, *Trend Analysis of Environmental and Personnel Monitoring Results.*

As part of process improvement, SCA has initiated change control MOC-2023-0130 to capture the implementation of new sampling locations to include frequently contacted items such as cleanroom totes, chairs, and repeater pumps. The results generated from these new locations will increase detectability and provide an additional mechanism to assess aseptic technique/behavior within the classified area as well as the effectiveness of the sanitization program. To support this process change, RA-21-001-W and SOP LAB-007-W were revised and made effective on 09Nov23. Reference Exhibits O6-3 and O6-2.

Training for Cleanroom and Microbiology personnel on the relevant process changes and SOP revisions began on 09Nov23. SCA will not permit anyone to perform cleanroom duties or collect environmental monitoring samples until all training requirements listed in all relevant responses have been completed.

OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

The firm uses polypropylene totes to transfer all compound materials from non-classified environments into the ISO-7 compounding suite, which are further staged immediately adjacent to ISO-5 hoods. The totes appeared to have scratches, and some were observed with UPC stickers, on the bottom side of the tote and on lids, which appeared to be shedding. In addition, in July 2023, the firm performed a tote study to determine bioburden found on the totes. Sampling results following the firm's standard sanitization process and within the firm's ISO-7 environment found 3% of samples collected yielded microbial recoveries. Of that, 60% were attributed to the genius Bacillus. Bacillus is a spore-forming bacterial microbe.

OBSERVATION 7 RESPONSE

During the inspection, as an immediate containment action, the totes were evaluated, and any stickers found were removed from totes and lids. SOP PICK-003-W, *Picked Raw Material Verification Procedure*, was revised to include a requirement to ensure that no totes or tote lids have stickers. This procedure was made effective on 23Oct23. Reference Exhibit O7-1.

SCA's Quality Control Microbiology Department has performed an inspection and assessment of totes to identify and remove from use in the cleanroom any that have evidence of scratches and/or damage. The remaining, acceptable totes will be sanitized and prohibited from leaving the cleanroom. Per CAPA-2023-0031, the new tote flow and inspection process, which will be ongoing, is established and is detailed in SOP-SAN-002-W. This interim process will remain in place until new totes are obtained as per below.

SCA has placed orders to procure brand new cleanroom-dedicated totes. Once these totes are received, the new tote flow will be applied per CAPA-2023-0031, and these cleanroom-dedicated totes will not be permitted to leave the classified area and will also be inspected prior to use during material sanitization (ongoing). Reference Exhibit O7-2. To support this process change, SOP SAN-002-W, *Movement of Materials Into and Out of Classified Areas,* was revised per DAR-23-443 and was made effective on 09Nov23. Reference Exhibit O3-3.

In addition to purchasing new totes and dedicating them to the cleanroom, SCA has initiated change control MOC-2023-0130 to capture the implementation of new sampling locations to include frequently contacted items such as cleanroom totes, chairs, and repeater pumps.

Cleanroom personnel are being trained on the relevant process changes and SOP revisions starting on 10Nov23. SCA will not permit anyone to perform cleanroom duties until all training requirements have been completed.

OBSERVATION 8

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

The firm failed to adequately investigate customer complaints. For example:

A. CUS-2023-0066, CUS-2023-0067, and CUS-2023-0068 were initiated on 25-Jul-23 regarding suspected super potency and three patients who experienced loss of consciousness, lethargy and inability to move, and issues moving legs, respectively, following administration of lot# 1223046077 (Fentanyl 2 mcg/mL and Ropivacaine HCl 0.2% in 0.9% Sodium Chloride 100 mL Bag). The firm's investigation stated the complaints were not able to be confirmed; however, the firm failed to test returned products which were identified as integral. The investigation was approved and closed by Quality Assurance 25-AUG-23, 23-AUG-23, and 28-AUG-23 respectively.

B. CUS-2021-0051 (AE-21-009-W and AE-21-010-W) were initiated on 24-May-21 regarding suspected super potency and two patients who experienced severe decrease in heart rate and QRS complexes, respectively, following administration of lot# 1221027041 (Phenylephrine HCl l00mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe). The firm's investigation stated the

complaints were not able to be confirmed; however, the firm failed to test returned products. The investigation was approved and closed by Quality Assurance 30-JUN-21.

OBSERVATION 8 RESPONSE

SCA has revised SOP QMS-013, *Handling of Customer Complaints and Adverse Events*, per DAR-23-493 to require testing of unused returned product associated with adverse events. This procedure was made effective on 04Nov23. Reference Exhibit O8-1.

SCA also reviewed all open adverse events that were being investigated at the time of this response. Of those open adverse events, one open adverse event was identified to have had product returned and within expiry. Therefore, SCA tested returned samples for adverse event CUS-2023-0090 on 30Oct23 with satisfactory results. Reference Exhibit O8-2. SCA notes that the product lots specifically identified in the Agency's Observation were expired and therefore not tested.

OBSERVATION 9

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. Partially completed original GMP documents including but not limited to laboratory sheets and stability study sheets were found in the firm's shred bins. The firm's procedure, SOP QA000l - Good Documentation Practices, prohibits this practice.

B. Multiple copies of blank fillable original GMP documents including but not limited to sterility worksheets and additional laboratory worksheets were found in the firm's shred bins. The firm maintains GMP documents in MasterControl QMIS which allows authorized personnel to download documents to individual computer terminals with a 24-hour restriction; however, there are no restrictions on the number of copies that can be printed.

OBSERVATION 9 RESPONSE

SCA has conducted employee interviews relating to placing documents in shred bins. There was no evidence of ill intent, and SCA's investigation has not identified any action taken to obscure test data or results. In response to FDA's observation, SCA initiated DEV-2023-0478 and performed an immediate awareness training between 25Sep23 and 28Sep23 with the staff in the area where the incident was first discovered. Reference Exhibit O9-1. Additionally, on 28Sep23, the SCA leadership team distributed a company-wide awareness communication for GDP principles highlighted in SOP QA-001, *Good Documentation Practices*, and SOP QMS-002, *Quality Record Issuance and Retention*. Reference Exhibit O9-2.

Additional process improvements include:

- On 27Sep23, SCA initiated CAPA-2023-0020, "Remediation of GxP Document Retention Practices." As part of this CAPA, the following corrective actions have/will be implemented:

- SOP QA-001, *Good Documentation Practices*, was revised per DAR-21-708 to prohibit the destruction of any official controlled documents that have been completed, partially completed, or transcribed and to reference a new visual display, VD QA-001-1, *Shred Bin Signage*, to be displayed on the front of each shred bin. This SOP revision and associated Visual Display were made effective on 28Sep23. The visual display was placed on the front of each shred bin in the facility. All SCA personnel were trained on the revised SOP. Reference Exhibit O9-3, O9-4 and O9-5 for revised SOP, Visual Display, and training record.
- SOP QMS-002, *Quality Record Issuance and Retention*, was revised per DAR-23-466 to specifically require retention of controlled forms that have been uploaded into MasterControl records. The procedure became effective on 28Sep23. Reference Exhibit O9-6.
- On 02Oct23, Quality Management began performing scheduled shred bin checks. SOP QA-020, *Quality Oversight*, was revised per DAR-23-461 to require monthly shred bin checks. This procedure became effective on 08Nov23. Reference Exhibit O9-7. This check is documented on LG QA-020-1-W, *1st Shift MQA Reconciliation Log* and LG QA-020-2-W, *2nd Shift MQA Reconciliation Log*. Reference Exhibits O9-8 and O9-9.
- SOP QMS-046, *Document Shredding Policy*, was created per DAR-23-464. This procedure details the proper and improper use of shred bins, including process surrounding destruction of forms used for training purposes only, and was made effective on 10Nov23. Reference Exhibit O9-10.
- A process surrounding use of controlled forms for training only purposes will also be incorporated into SOP QMS-001, *Controlled Document Management and Change Control* and SOP QMS-002 in conjunction with the corrective actions described in Observation 9B. The target completion date for this process implementation is 31Dec23.

Process improvements include:

- SCA will begin to restrict printing access to all GMP documents that are currently printed from MasterControl and intended for entry of GMP raw data. All applicable documents have been evaluated and will be controlled in one of three ways:
    - Batch-related forms that can be issued through the existing batch record issuance process detailed in SOP LGEN-001, *Generating the Batch Record, Tote Tags, and Test Sample Tags*, will begin being issued as part of that process.
    - Forms that can be bound will be converted into logbooks and issued/controlled per SOP QMS-040, *Documentation and Handling of Logbooks and Laboratory Notebooks*.
    - Documents that cannot be issued with the batch record, bound as a logbook, or converted into electronic forms will be individually issued by the Quality Unit.

SOP QMS-001, *Controlled Document Management and Change Control* and SOP QMS-002, *Quality Record Issuance and Retention,* will be revised per DAR-23-510 to describe the process for controlling fillable documents. Upon these document revisions becoming effective, printing access to all fillable GMP documents in MasterControl will be restricted to individuals in the Quality unit who are authorized to issue documents. The expected completion date of this process change is 31Dec23.

As a long-term process enhancement, SCA will implement use of the LabVantage Laboratory Execution System (LES) Module, which will allow for digitization of all laboratory forms with a complete audit trail. MOC-2023-0135 was initiated on 06Nov23 and the target completion date is 31Jul24.

OBSERVATION 10

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(IO)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

Some of your drug product labels did not include the complete established name of the drug product, as the established name did not include the name of the salt (e.g., citrate, bitartrate, and hydrochloride) in addition to the base on the label.

For example,

A. Fentanyl 100 mcg/2 mL. The label does not include the full name Fentanyl Citrate.
B. Norepinephrine 4 mg in 0.9% Sodium Chloride 250 mL bag. The label does not include the full name Norepinephrine Bitartrate.
C. Ketamine 100 mg/10 mL does not include the full name Ketamine HCL (Hydrochloride).

OBSERVATION 10 RESPONSE

SCA initiated change control MOC-23-0109 on 28Sep23 to update the Fentanyl Citrate and Ketamine HCl products identified by the Agency that do not bear the complete established name of the drug product which includes the name of the salt and/or base. An additional change control, MOC-2023-0110, was initiated on 29Sep23 to update the products self-identified by SCA to also be impacted. The target completion date for the aforementioned change controls is 24May24.

SCA pharma

COMMITMENT INDEX (ORGANIZED BY OBSERVATION NUMBER)

Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O1	Initiate Recall 23-004-W.	N/A	Recall 23-004-W	Complete	09Nov23
O1	Complete CAPA-2022-0034 to implement a remediation plan for the identified inspection improvements.	N/A	CAPA-2022-0034	In-Process	23Jun24
O1	Close MOC-2023-0129 related to implementation of the remediated inspection process.	N/A	MOC-2023-0129	In-Process	30Nov23
O1	Revise SOP ILP-001-W, *Product Inspection and Defect Classification.*	O1-4	DAR-23-271	Complete	09Nov23
O2	Begin training on SOP ILP-001-W revisions.	N/A	N/A	In-Process	Started: 09Nov23
O1	Revise the twelve forms associated with SOP ILP-001-W.	O1-5	DAR-23-521	Complete	09Nov23
O2	Revise SOP ILP-001-W, *Product Inspection and Defect Classification.*	O1-4	DAR-23-271	Complete	09Nov23
O2	Begin training on SOP ILP-001-W revisions.	N/A	N/A	In-Process	Started: 09Nov23
O3A	Revise TM-008, *Particulate Matter.*	O3-2	DAR-23-511	Complete	06Nov23
O3B	Close CAPA-2023-0017 related to the material sanitization improvements.	N/A	CAPA-2023-0017	In-Process	30Nov23
O3B	Revise SOP SAN-002-W, *Movement of Materials into and out of Classified Areas.*	O3-3	DAR-23-443	Complete	10Nov23
O3B	Begin training on SOP SAN-002-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O3B	Create sanitization training videos.	N/A	N/A	Complete	08Nov23
O3B	Begin training on sanitization training videos.	N/A	N/A	In-Process	Started: 10Nov23
O3B	Complete DEV-2023-0435.	O3-4	DEV-2023-0435	Complete	26Oct23

COMMITMENT INDEX (ORGANIZED BY OBSERVATION NUMBER)

Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O3C	Revise SOP QA-014, *Foreign Material Decision Matrix.*	O3-5	DAR-23-520	Complete	09Nov23
O3C	Create VD QA-014-2, *Visual Display for Defect Examples.*	O3-6	DAR-23-520	Complete	09Nov23
O3C	Begin training on SOP QA-014 and VD QA-014-2 revisions.	N/A	N/A	In-Process	Start Date: 13Nov23
O3C	Revise Form QA-014-1, *Foreign Material Documentation Form.*	O3-7	DAR-23-520	Complete	09Nov23
O3C	Revise TQ COM-100-2-W, *Aseptic Assistant Technical Qualification.*	O3-8	DAR-23-527	Complete	09Nov23
O3C	Initiate Supplier Complaints for each syringe tray supplier.	N/A	SUP-2023-0026 SUP-2023-0027 SUP-2023-0028	Complete	10Oct23
O3C	Send out escalation letters to syringe tray suppliers.	N/A	N/A	In-Process	13Nov23
O4A	Revise SOP SAN-002-W, *Movement of Materials into and out of Classified Areas.*	O3-3	DAR-23-443	Complete	10Nov23
O3A	Begin training on SOP SAN-002-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O4A	Revise SOP SAN-001-W, *Cleaning of Classified Areas.*	O4-1	DAR-23-508	Complete	10Nov23
O4A	Begin training on SOP SAN-001-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O4A	Complete ES-23-026, *Engineering Study for the Efficacy of Wipe Preparation and Cleaning of Cleanroom Materials and Equipment.*	N/A	ES-23-026	In-Process	30Nov23
O4A	Complete VAL-23-074, *Cleaning Qualification of Prepared Sanitization Wipes on Cleanroom Materials and Equipment.*	N/A	VAL-23-074	In-Process	31Dec23
O4B	Re-Train material sanitization department on requirement for totes to achieve prescribed contact time per SOP SAN-002-W.	O4-2	N/A	Complete	04Oct23

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COMMITMENT INDEX (ORGANIZED BY OBSERVATION NUMBER)

Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O4B	Revise SOP SAN-002-W, *Movement of Materials into and out of Classified Areas.*	O3-3	DAR-23-443	Complete	10Nov23
O4B	Begin training on SOP SAN-002-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O4C	Perform EA-23-027, *Engineering Study for Grate Cleaning Frequency*	N/A	N/A	In-Process	31Jan24
O5A	Training of Compounding staff on SOP COM-001-W and SOP SAN-002-W.	O5-1	N/A	Complete	01Nov23
O5A	Retrain Operator PJ on SOP COM-001-W.	O5-2	N/A	Complete	19Sep23
O5A	Revise SOP COM-018-W, *Staging of Raw Material in the LAFH.*	O5-3	DAR-23-531	Complete	09Nov23
O5A	Begin training on SOP COM-018-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O5A	Close CAPA-2023-0028 related to aseptic technique.	N/A	CAPA-2023-0028	In-Process	22Dec23
O5A	Revise SOP COM-061-W, *Roles and Responsibilities of Cleanroom Personnel.*	O5-4	DAR-23-512	Complete	09Nov23
O5A	Perform training on SOP COM-061-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O5A	Revise SOP LAB-074-W, *Microbiology Oversight of Critical Areas*	O5-5	DAR-23-516	Complete	09Nov23
O5A	Perform training on SOP LAB-074-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O5A	Create “Micro 101” Training for all gowning qualified personnel.	O5-6	TRNDoc-0056	Complete	08Nov23
O5A	Perform “Micro 101” Trainings.	N/A	N/A	In-Process	Started: 10Nov23
O5A	Create “Cleanroom 101” Training all gowning qualified personnel.	O5-7	TRNDoc-0055	Complete	08Nov23

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Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O5A	Perform "Cleanroom 101" Training.	N/A	N/A	In-Process	Started: 10Nov23
O5A	Complete MOC-2023-0137 to convert paper tote tags to disposable tote tags.	N/A	MOC-2023-0137	In-Process	29Feb24
O5A	Complete MOC-2023-0142 to implement a process to autoclave batch records.	N/A	MOC-2023-0142	In-Process	29Feb24
O5B	Training of Compounding staff on SOP COM-001-W and SOP SAN-002-W.	O5-1	N/A	Complete	02Nov23
O5B	Revise SOP COM-005-W, *Compounding Area Clearance.*	O5-8	DAR-23-512	Complete	09Nov23
O5B	Revise LG COM-005-1-W, *Compounding Area and Equipment Use Log.*	O5-9	DAR-23-512	Complete	09Nov23
O5B	Perform training on SOP COM-005-W and LG COM-005-1-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O5B	Revise SOP COM-061-W, *Roles and Responsibilities of Cleanroom Personnel.*	O5-4	DAR-23-512	Complete	09Nov23
O5B	Perform training on SOP COM-061-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O5B	Revise SOP SAN-002-W, *Movement of Materials into and out of Classified Areas.*	O3-3	DAR-23-443	Complete	10Nov23
O5B	Perform training on SOP SAN-002-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
06A	Close MOC-2023-0130 regarding the implementation of new sampling locations within the classified areas	N/A	MOC-2023-0130	In-Process	31Jan24
O6A	Close MOC-2023-0131 regarding aseptic assistant's glove recovery results batch release criteria.	N/A	MOC-2023-0131	In-Process	31Jan24
O6A	Revise SOP LAB-007-W, *Environmental and Personnel Monitoring of Classified Areas.*	O6-2	DAR-23-542	Complete	09Nov23
O6A	Perform training SOP LAB-007-W revisions.	N/A	N/A	In-Process	Started: 10Nov23

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Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O6A	Revise RA-21-001-W, *Risk Assessment for Controlled Environments located at 755 Rainbow Rd, Windsor, CT 06095.*	O6-3	DAR-23-542	Complete	09Nov23
O6B	Revise SOP COM-018-W, *Staging of Raw Material in the LAFH.*	O5-3	DAR-23-531	Complete	09Nov23
O6B	Perform training on SOP COM-018-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O6B	Revise SOP LAB-007-W, *Environmental and Personnel Monitoring of Classified Areas.*	O6-2	DAR-23-542	Complete	09Nov23
O6B	Perform training SOP LAB-007-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O6B	Revise RA-21-001-W, *Risk Assessment for Controlled Environments located at 755 Rainbow Rd, Windsor, CT 06095.*	O6-3	DAR-23-542	Complete	09Nov23
O6B	Revise SOP LAB-030, *Trend Analysis of Environmental and Personnel Monitoring Results.*	N/A	DAR-23-528	In-Process	30Nov23
O6C	Perform an independent third-party assessment of each unique bacterial spore forming genus and species recovered between January 2020 and September 2023.	O6-4	N/A	Complete	30Oct23
O6C	Revise SOP LAB-030, *Trend Analysis of Environmental and Personnel Monitoring Results.*	N/A	DAR-23-528	In-Process	30Nov23
O6D	Close MOC-2023-0132 regarding the improvement and optimization of active viable air sampler positioning.	N/A	MOC-2023-0132	In-Process	31Jan24
O6D	Revise SOP LAB-007-W, *Environmental and Personnel Monitoring of Classified Areas.*	O6-2	DAR-23-542	Complete	09Nov23
O6D	Perform training SOP LAB-007-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O6D	Revise RA-21-001-W, *Risk Assessment for Controlled Environments located at 755 Rainbow Rd, Windsor, CT 06095.*	O6-3	DAR-23-542	Complete	09Nov23
O6D	Revise SOP LAB-008-W, *Operation and Maintenance of the AES Sampl'Air Lite.*	O6-5	DAR-23-519	Complete	09Nov23

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Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O6D	Perform training on SOP LAB-008-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O6D	Revise SOP LAB-041-W, *Operation and Maintenance of the SAS Super 180 Microbial Air Sampler.*	O6-6	DAR-23-519	Complete	09Nov23
O6D	Perform training on SOP LAB-041-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
06E	Close MOC-2023-0130 regarding the implementation of new sampling locations within the classified areas.	N/A	MOC-2023-0130	In-Process	31Jan24
O6E	Revise SOP LAB-007-W, *Environmental and Personnel Monitoring of Classified Areas.*	O6-2	DAR-23-542	Complete	09Nov23
O6E	Perform training SOP LAB-007-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O6E	Revise RA-21-001-W, *Risk Assessment for Controlled Environments located at 755 Rainbow Rd, Windsor, CT 06095.*	O6-3	DAR-23-542	Complete	09Nov23
O7	Close CAPA-2023-0017 related to the material sanitization improvements.	N/A	CAPA-2023-0017	In-Process	30Nov23
O7	Revise SOP PICK-003-W, *Picked Raw Material Verification Procedure.*	O7-1	DAR-23-471	Complete	23Oct23
O7	Perform training on SOP PICK-003-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O7	Complete CAPA-2023-0031 regarding the implementation of a new tote flow.	N/A	CAPA-2023-0031	In-Process	31Jan23
O7	Revise process flow of cleanroom totes.	O7-2	N/A	Complete	10Nov23
O7	Revise SOP SAN-002-W, *Movement of Materials Into and Out of Classified Areas.*	O3-3	DAR-23-443	Complete	10Nov23
O7	Perform training on SOP SAN-002-W revisions.	N/A	N/A	In-Process	Started: 10Nov23
O7	Re-Train material sanitization department on requirement for totes to achieve prescribed contact time per SOP SAN-002-W.	O4-2	N/A	Complete	04Oct23

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Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
07	Close MOC-2023-0130 regarding the implementation of new sampling locations within the classified areas.	N/A	MOC-2023-0130	In-Process	31Jan24
O8	Revise SOP QMS-013, *Handling of Customer Complaints and Adverse Events.*	O8-1	DAR-23-493	Complete	04Nov23
O8	Complete CUS-2023-0090.	O8-2	CUS-2023-0090	Complete	05Nov23
O9	Perform immediate awareness training with the staff where the incident was first discovered.	O9-1	N/A	Complete	25Sep23 28Sep23
O9	Send out awareness communication for GDP principles highlighted in SOP QA-001 and SOP QMS-002.	O9-2	N/A	Complete	28Sep23
O9	Complete CAPA-2023-0020 to remediate GxP document retention practices.	N/A	CAPA-2023-0020	In-Process	30Jan23
O9	Revise SOP QA-001, *Good Documentation Practices.*	O9-3	DAR-21-708	Complete	28Sep23
O9	Create VD QA-001-1, *Shred Bin Signage.*	O9-4	DAR-21-708	Complete	28Sep23
O9	Revise SOP QMS-002, *Quality Record Issuance and Retention.*	O9-6	DAR-23-466	Complete	28Sep23
O9	Revise SOP QA-020, *Quality Oversight.*	O9-7	DAR-23-461	Complete	08Nov23
O9	Create SOP QMS-046, *Document Shredding Policy.*	O9-10	DAR-23-464	Complete	10Nov23
O9	Develop a process surrounding use of controlled forms for training only purposes.	N/A	N/A	In-Process	31Dec23
O9	Revise SOP QMS-001, *Controlled Document Management and Change Control.*	N/A	DAR-23-510	In-Process	31Dec23
O9	Revise SOP QMS-002, *Quality Record Issuance and Retention.*	N/A	DAR-23-510	In-Process	31Dec23
O9	Complete MOC-2023-0135 regarding the implementation of LabVantage Laboratory Execution System (LES) Module.	N/A	MOC-2023-0135	In-Process	31Jul24

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Observation Number	Response Action	Exhibit Number	Quality System Reference	Status	Date Completed/ Projected Completion Date
O10	Complete MOC-2023-0109 regarding updating labels that do not bear the complete established name of the drug product which includes the name of the salt and/or base.	N/A	MOC-2023-0109	In-Process	24May24
O10	Complete MOC-2023-0110 regarding updating additional self-identified labels that do not bear the complete established name of the drug product which includes the name of the salt and/or base.	N/A	MOC-2023-0110	In-Process	24May24

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Observation Number	Exhibit Number	Title	Pages
O1	O1-1	MAN-001, *Quality Manual*	19
O1	O1-2	SOP QMS-027, *Responsibilities of the Quality Unit*	11
O1	O1-3	Consultant's Schedule	7
O1/O2	O1-4	SOP ILP-001-W, *Product Inspection and Defect Classification*	35
O1	O1-5	Twelve (12) Forms associated with SOP ILP-001: Form ILP-001-4-W, *ILP Signature Log and Bag 100% Inspection Form* Form ILP-001-5-W, *Bag AQL Inspection Form* Form ILP-001-6-W, *Bag Additional 100% Inspection Form* Form ILP-001-7-W, *Bag TAQL Inspection Form* Form ILP-001-8-W, *ILP Signature Log and Syringe 100% Inspection Form* Form ILP-001-9-W, *Syringe AQL Inspection Form* Form ILP-001-10-W, *Syringe Additional 100% Inspection Form* Form ILP-001-11-W, *Syringe TAQL Inspection Form* Form ILP-001-12-W, *ILP Signature Log and CADD 100% Inspection Form* Form ILP-001-13-W, *CADD AQL Inspection Form* Form ILP-001-14-W, *CADD Additional 100% Inspection Form* Form ILP-001-15-W, *CADD TAQL Inspection Form*	15
O3A	O3-1	USP <788>	4
O3A	O3-2	TM-008, *Particulate Matter*	15
O3B/O4A/O4B /O7	O3-3	SOP SAN-002-W, *Movement of Materials into and out of Classified Areas*	27
O3B	O3-4	DEV-2023-0435	72
O3C	O3-5	SOP QA-014, *Foreign Material Decision Matrix*	5
O3C	O3-6	VD QA-014-2, *Visual Display for Defect Examples*	5
O3C	O3-7	Form QA-014-1, *Foreign Material Documentation Form*	1
O3C	O3-8	TQ COM-100-2-W, *Aseptic Assistant Technical Qualification*	18
O4A	O4-1	SOP SAN-001-W, *Cleaning of Classified Areas*	25
O4B/O3B/O7	O4-2	Material sanitization department contact time retraining	2
O5A/O5B	O5-1	Training of Compounding staff on SOP COM-001-W and SOP SAN-002-W	4
O5A	O5-2	Retraining of PJ on Aseptic Behavior	1
O5A/O6B	O5-3	SOP COM-018-W, *Staging of Raw Material in the LAFH*	15
O5A/O5B	O5-4	SOP COM-061-W, *Roles and Responsibilities of Cleanroom Personnel*	13

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Observation Number	Exhibit Number	Title	Pages
O5A	O5-5	SOP LAB-074-W, *Microbiology Oversight of Critical Areas*	8
O5A	O5-6	"Micro 101" Training Presentation	18
O5A	O5-7	"Cleanroom 101" Training Presentation	19
O5B	O5-8	SOP COM-005-W, *Compounding Area Clearance*	5
O5B	O5-9	LG COM-005-1-W, *Compounding Area and Equipment Use Log*	100
O6A	O6-1	Media Fill Results Table	3
O6A/O6B/O6D O6E	O6-2	SOP LAB-007-W, *Environmental and Personnel Monitoring of Classified Areas*	27
O6A/O6B/O6D O6E	O6-3	RA-21-001-W, *Risk Assessment for Controlled Environments located at 755 Rainbow Rd, Windsor, CT 06095*	95
O6C	O6-4	Independent third-party assessment of each unique bacterial spore forming genus and species recovered between January 2020 and September 2023 for risk to patient	23
O6D	O6-5	SOP LAB-008-W, *Operation and Maintenance of the AES Sampl'Air Lite*	12
O6D	O6-6	SOP LAB-041-W, *Operation and Maintenance of the SAS Super 180 Microbial Air Sampler*	11
O7	O7-1	SOP PICK-003-W, *Picked Raw Material Verification Procedure*	6
O7	O7-2	Process flow of cleanroom totes	1
O8	O8-1	SOP QMS-013, *Handling of Customer Complaints and Adverse Events*	35
O8	O8-2	CUS-2023-0090	134
O9	O9-1	Immediate awareness training with the microbiology staff where the incident was first discovered.	3
O9	O9-2	Awareness communication for GDP principles highlighted in SOP QA-001 and SOP QMS-002	1
O9	O9-3	SOP QA-001, *Good Documentation Practices*	10
O9	O9-4	VD QA-001-1, *Shred Bin Signage*	1
O9	O9-5	Training on SOP QA-001	12
O9	O9-6	SOP QMS-002, *Quality Record Issuance and Retention*	7
O9	O9-7	SOP QA-020, *Quality Oversight*	6

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Observation Number	Exhibit Number	Title	Pages
O9	O9-8	LG QA-020-1-W, 1st Shift MQA Reconciliation Log	56
O9	O9-9	LG QA-020-2-W, 2nd Shift MQA Reconciliation Log	55
O9	O9-10	SOP QMS-046, *Document Shredding Policy*	5