November 21, 2025

RE: Inspection of SCA Pharmaceuticals, LLC Little Rock, AR Facility (October 20th – October 30th, 2025) FEI #3010683157

Attached please find the Responses of SCA Pharmaceuticals, LLC (SCA) to the Observations identified by FDA in the Form 483 issued to SCA's Little Rock, Arkansas facility on October 30th, 2025. For those actions still underway, we will provide a progress report no later than 31-Dec-2025, with quarterly updates to follow.

We appreciate the review of our facility and Quality Systems by the FDA Investigator and take the 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.

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.

Additionally, SCA requests that FDA publish this response unredacted when posted to FDA's website. We provide express written permission for full publication of our response to demonstrate our transparency and commitment to regulatory compliance.

Sincerely,

Signed by:
Scott Luce
F856912BA8C1411

Scott Luce, CEO

SCA Pharma, LLC

**OBSERVATION 1 FDA OBSERVATION:**

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

Specifically, your firm failed to establish adequate procedures to monitor personnel who directly interface with the sterile manufacturing environment, particularly during critical operations where personnel actions could impact product sterility.

Video footage (AR01251010251125035913_Beginning.mp4) from the aseptic filling of Lot 1125035913 demonstrates sterile technicians entering the ISO 5 LFH environment between timestamps 9:37-9:56 and performing multiple critical tasks including:

Removing filled syringes from the ISO 5 LFH

Placing and removing the air sampling equipment.

Despite direct contact with the critical aseptic environment, the sterile technician performing these operations was not sampled for recovery of viable microorganisms during or after these activities.

**OBSERVATION 1 RESPONSE**

**Contamination Prevention Procedures and Controls**

SCA has established comprehensive procedures to prevent microbiological contamination throughout sterile manufacturing operations, which were shared during the course of the inspection. These procedures are designed to maintain the integrity of the ISO 5 environment and minimize contamination risk during all critical activities.

**Personnel Role Definitions and Contamination Control**

The personnel referenced in the FDA observation are secondary operators (also referred to as aseptic assistants) who perform ancillary support activities. As proceduralized in SOP COM-061-LR, Roles and Responsibilities of Cleanroom Personnel Section 10.3, Roles and Responsibilities for Secondary Operators (Level 2) (provided to FDA during the inspection, Request 8a), secondary operators have clearly defined and restricted roles that are fundamentally different from primary operators. The strategic design of the secondary operator role serves a critical contamination control purpose: protecting the ISO 5 environment by allowing the primary operator to remain in the hood performing aseptic connections while support activities are handled outside the critical zone.

Secondary operators are procedurally required and trained to perform only the following restricted activities per SOP COM-061-LR Section 10.3 (Roles and Responsibilities for Secondary Operators (Level 2)):

- Work exclusively within the ISO 5/ISO 7 interface area, maintaining physical segregation from aseptic connections

- Change and sanitize gloves when transitioning to work at the ISO 5 interface
- Remove filled product from the ISO 5 hood only after primary operator completes filling and closure
- Place and remove environmental monitoring equipment without contacting product-contact surfaces
- Support material staging while primary operator maintains focus on critical aseptic connections

This functional segregation is a deliberate contamination control strategy. By restricting secondary operators from performing any aseptic connections to sterilizing filters, final containers, filling operations, or closures, SCA maintains strict physical and procedural barriers between support activities and critical aseptic operations. Secondary operators never make direct aseptic connections, ensuring their interactions with the ISO 5 environment are inherently limited and pose minimal risk to product sterility.

**Personnel Monitoring Program**

SCA's personnel monitoring program is comprehensive and strategically designed to capture contamination risk throughout the manufacturing environment. The program is proceduralized in SOP LAB-007-LR, Section 10.6 (ISO 5 Personnel Sampling) and Section 10.7 (ISO 7 Personnel Exit Monitoring (PEM)), Environmental and Personnel Monitoring Program (provided to FDA during the inspection, Request 8a).

*Secondary Operator Monitoring*

Secondary operators are monitored through multiple sampling locations that capture their interactions with the manufacturing environment. Per SOP LAB-007-LR, Section 10.7 (ISO 7 Personnel Exit Monitoring (PEM)) , secondary operators are sampled at the following locations during each compounding session: glove sleeve samples, chest samples, and gown hood surface samples. These sampling locations were strategically selected to detect potential contamination from secondary operator activities while they perform their restricted support functions.

*Primary Operator Monitoring*

Primary operators who perform aseptic connections to sterilizing filters, final containers, filling, and closure undergo enhanced monitoring compared to secondary operators including ISO 5 fingertip and glove sleeve sampling during each compounding session per SOP LAB-007-LR Section 10.6 (ISO 5 Personnel Sampling). The expanded monitoring of these primary operators is appropriate given their direct interaction with critical aseptic connections.

**Comprehensive Environmental Monitoring**

SCA collects extensive environmental monitoring data during each individual compounding session that provides multiple data points to assess both primary and secondary operator

impact on the ISO 5 environment. ISO 5 environmental monitoring samples are collected continuously and strategically during each session:

- Continuous non-viable particle monitoring (cNVP) - real-time detection of particle generation
- Active viable air monitoring (AVA) - positioned to capture personnel activities
- Continuous passive viable air monitoring (PVA) - strategically located plates that capture airborne microorganisms over entire session duration
- Viable surface monitoring (VS) - critical touch points and hood surfaces

This sampling strategy, shown in visual display VD LAB-007-7-LR, Environmental Monitoring Schedule (provided to FDA during the inspection, Request 41), creates an abundance of data that enables SCA to comprehensively evaluate secondary operator behavior and detect any impact on the ISO 5 environment. The strategic placement of AVA samplers and PVA plates, combined with continuous non-viable particle monitoring, provides real-time and cumulative assessment of personnel activities throughout the compounding session.

**Risk-Based Monitoring Strategy and Scientific Justification**

SCA's monitoring locations and frequencies are supported by formal risk assessments performed using Failure Mode and Effects Analysis (FMEA) and Hazard Analysis Critical Control Point (HACCP) methodologies combined with principles from ICH Q9 Quality Risk Management. These risk assessments ensure that monitoring strategies are scientifically justified and relevant to the specific processes and personnel interactions at the facility. The assessments and supporting rationale are documented in:

- RA 25-008, Risk Assessment for ISO 7 Personnel Exit Monitoring Impact on Final Products (Reference Exhibit O1-1)
- RA 22-003, Risk Assessment Based Environmental Monitoring Sampling Plan at SCA-LR (Reference Exhibit O1-2)
- RA 23-006, Risk Assessment for Environment and Personnel Exit Monitoring Within the ISO 5 Classified Environment During Aseptic Filling of Final Product Units, (provided to FDA during the inspection, Request 40)
- MAN-001, Quality Manual (provided to FDA during the inspection, Request 1)
- PP-24-002-G, Contamination Control Strategy (Reference Exhibit O1-3)

**Process Validation and Performance Data**

SCA has generated substantial validation and performance data demonstrating that secondary operator activities do not compromise the ISO 5 environment or product sterility:

Airflow Visualization Studies: Dynamic smoke studies are conducted to demonstrate that secondary operator activities maintain unidirectional airflow over critical connections per SOP VAL-014: Performance of Airflow Visualization/Smoke Studies (provided to the FDA during the inspection, Request 8a). Smoke consistently moves away from aseptic connections even during secondary operator interventions, confirming that support activities do not disrupt the protective airflow patterns essential for maintaining sterility. This is demonstrated in airflow visualization study VAL-25-044-FR, Final Report for the Airflow Visualization for the Cleanroom 804/900

Suite and LAFH Used for Compounding and Sterility Activities, Little Rock (provided to the FDA during the inspection, Request 13).

Aseptic Process Simulations (Media Fills): Secondary operator activities are explicitly included as required interventions during media fill validation studies in SOP VAL-009-LR, Process Simulation Program Attachment II (List of Routine / Non-Routine and Critical Interventions) (provided to FDA during the inspection, Request 8a). These interventions are verified by Validation and Quality Assurance to ensure they represent worst-case conditions. The consistent achievement of zero contamination during media fills, with secondary operators performing their standard support functions, validates that these activities do not introduce contamination risk. This is demonstrated in VAL-25-013-FR, Final Report for the Semi-Annual Process Simulations for SCA Pharma, LLC of Little Rock, AR –Process and Personnel Requalification: March 2025.(provided to FDA during the inspection, Request 9)

Historical Environmental Monitoring Data: A cross-functional Environmental Monitoring Action Committee (EMAC) meets weekly to discuss environmental data per SOP LAB-030, Trend Analysis of Environmental and Personnel Monitoring Results (provided to FDA during the inspection, Request 8a). Analysis of this historical data including passive viable air plates, surface samples, and strategically positioned active viable air samplers demonstrates that secondary operator activities consistently maintain environmental control. This historical data provides ongoing verification that secondary operator interactions do not generate detectable increases in microbial recovery or particle counts.

**Comprehensive Sterility Assurance Program**

Environmental and personnel monitoring are critical components of SCA's multi-layered Sterility Assurance program. This comprehensive approach includes complementary controls that collectively safeguard product sterility and patient safety:

**Strategic Controls and Documentation:**

- Documented Contamination Control Strategy (CCS) (PP-24-002-G, Contamination Control Strategy, Reference Exhibit O1-3) driving continuous review and improvement of controls
- Comprehensive aseptic training program (SOP COM-100-LR, Compounding Technician Technical Qualification and Advancement, provided to FDA during the inspection, Request 8a) for all cleanroom personnel emphasizing proper aseptic technique and cleanroom behavior, with formal technical qualification and advancement requirements
- Quality Assurance oversight of cleanroom operations (SOP QA-020, Quality Oversight, provided to FDA during the inspection, Request 8a) including real-time monitoring of primary and secondary operator adherence to procedures and aseptic technique, supported by defined Quality Unit responsibilities (SOP QMS-027, Responsibilities of the Quality Unit, provided to FDA during the inspection, Request 8a)

**Validation and Monitoring Programs:**

- Aseptic Process Simulations (media fills) verifying proper aseptic technique execution and confirming acceptable state of control, with risk-based approach documented in RA-24-006, Risk Assessment for Aseptic Process Simulation/Media Fill (Reference Exhibit O1-4).
- Individual Microbial Recovery Rate (MRR) program for all primary and secondary operators to detect personnel-associated contamination trends and drive corrective actions per SOP 030, Trend Analysis of Environmental and Personnel Monitoring Results (provided to FDA during the inspection, Request 8a)
- Routine trend analysis of microbiological data (SOP LAB-030) by Quality Management to detect trends in classified areas and ensure prompt corrective and preventive action, reviewed systematically through Quality Management Review process (SOP QMS-022, Quality Management Review, provided to FDA during the inspection, Request 8a)

**Engineering and Environmental Controls:**

- Engineering controls ensuring classified environmental standards maintained per ISO 14644-1 (Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration), 21 CFR 211.113, 21 CFR 211.42, and USP <1116> (Microbiological Evaluation of Clean Rooms and Other Controlled Environments), with HEPA filter certification to technical specifications (SOP FAC-003-LR, Technical Specifications for HEPA Filter Certification)
- Validated cleaning procedures and sanitizing agents (SOP SAN-001-LR, Cleaning of Classified Areas, provided to FDA during the inspection, Request 8a) executed by dedicated cleanroom personnel to maintain controlled environmental conditions

**Product Release and Quality Systems:**

- Sterility testing per USP <71>, Sterility Tests, conducted on appropriate sample sizes prior to batch release per SOP LAB-058-LR, Operation and Maintenance of the Celsis Advance II Rapid Microbial Detection System for Sterility Testing (Reference Exhibit O1-5).
- Endotoxin testing prior to batch release per SOP LAB-005-LR, Bacterial Endotoxin Testing Procedure (provided to FDA during the inspection, Request 8a)
- Comprehensive batch record review and product disposition process (SOP QA-009-LR, Batch Record Review and Product Disposition, Reference Exhibit O1-6) ensuring all critical quality attributes are verified before release
- Supplier quality program (SOP QMS-029, Supplier Evaluation Program, provided to FDA during the inspection, Request 8a) ensuring incoming materials meet specifications and contamination control requirements
- Customer complaint program (SOP QMS-013, Handling of Customer Complaints and Adverse Events, provided to FDA during the inspection, Request 8a) providing post-distribution surveillance and additional quality assurance layer through feedback monitoring and adverse event tracking

This approach aligns with FDA's Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (September 2004) and cGMP

requirements under 21 CFR 211, which emphasize robust contamination control supported by comprehensive, risk-based monitoring strategies.

**Continuous Improvement**

In response to this observation and to further demonstrate our commitment to continuous improvement beyond our comprehensive existing programs, SCA has initiated change control MOC-2025-0112 to implement fingertip sampling for secondary operators by January 31, 2026. While our current environmental and personnel monitoring program is comprehensive and scientifically justified, this proactive enhancement will provide additional data points to further strengthen our contamination control program and demonstrate our commitment to exceeding regulatory expectations for aseptic processing.

**OBSERVATION 2 FDA OBSERVATION:**

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

Your firm has not performed airflow visualization studies inside each of the LFH that are used during aseptic production of products intended to be sterile, and has only performed these smoke studies inside three LFH, under dynamic conditions, used during aseptic production.

## OBSERVATION 2 RESPONSE

SCA **has** conducted airflow visualization studies inside each LFH used during aseptic production.

### Initial Qualification and Comprehensive Dynamic Studies

In 2021, SCA executed a comprehensive dynamic smoke study program that included all worst-case compounding processes in each of the five Laminar Flow Hoods (LFH). This qualification study was captured in VAL-21-029-FR, Final Report for the Airflow Visualization for Laminar Air Flow Hood & Cleanroom 900 Area Impact (provided to FDA during the inspection, Request 99). This initial study evaluated the impact of compounding activities on internal airflow patterns in each ISO 5 LFH at their installed locations and demonstrated that all LFH met the acceptance criteria for unidirectional airflow. These comprehensive dynamic studies were reviewed during the March 2023 FDA inspection as documented in the associated Establishment Inspection Report, with no observations regarding our dynamic airflow visualization approach.

### 2025 Requalification Study Design

In 2025, SCA executed a requalification study (VAL-25-044-FR, Final Report for the Airflow Visualization for the Cleanroom 804/900 Suite and LAFH Used for Compounding and Sterility Activities, Little Rock, provided to FDA during the inspection, Request 19) performed per SOP VAL-014, Performance of Airflow Visualization/Smoke Studies (provided to FDA during the inspection, Request 8a). This requalification employed a scientifically justified bracketing approach to verify that airflow patterns remained consistent and compliant across all LFHs.

The bracketing strategy was designed based on the following scientific rationale:

Equipment Equivalency: All five LFHs are the same make and model, with identical internal dimensions, HEPA filter specifications, airflow velocity profiles, and installed configurations. This homogeneity creates the technical basis for representative sampling rather than requiring redundant testing of functionally equivalent units.

Worst-Case Process Coverage: The study evaluated the two most challenging loading patterns currently performed across all compounding processes: syringe filling operations and IV bag compounding. These worst-case scenarios represent the maximum potential for airflow disruption, ensuring that validation data captures boundary conditions applicable to all hood operations.

Comprehensive Hood Characterization: **Static (empty) smoke studies were conducted in all five hoods to confirm that baseline airflow patterns remained unchanged**. **Dynamic studies with product loading were then performed in three representative hoods.** Additionally, perimeter studies (evaluating airflow at the front, back, and sides of each hood) were performed on all hoods to verify that internal airflow patterns were unaffected by hood location within the cleanroom environment.

Full-Scale Dynamic Validation: Dynamic smoke studies were performed with the cleanroom operating at maximum capacity (full material staging and maximum personnel occupancy), with video documentation consistently demonstrating that airflow patterns inside all LFHs remained unidirectional and uncompromised under these challenging conditions.

This bracketing approach was determined to establish equivalency among the five hoods from a functionality perspective. The comprehensive data package demonstrates that unless changes are made to hood make, model, or compounding processes, continued monitoring through semi-annual requalification provides assurance of ongoing performance without requiring redundant dynamic studies in functionally equivalent units.

**Scientific and Regulatory Support**

This approach aligns with FDA's Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (September 2004), which states that airflow visualization studies should be conducted during initial qualification and periodically thereafter under dynamic conditions to demonstrate unidirectional airflow and sweeping action over critical areas (Section IV.C). The guidance supports ongoing verification through periodic requalification but does not mandate identical dynamic studies for equipment demonstrably proven to be functionally equivalent.

FDA's Process Validation: FDA’s Guidance for Industry: General Principles and Practices (January 2011) supports a lifecycle approach to validation, including initial qualification and scientifically justified requalification strategies based on risk assessment and historical performance. The guidance explicitly recognizes that validation activities should be commensurate with risk and that well-characterized processes with demonstrated consistency may employ risk-based revalidation strategies.

**Ongoing Performance Verification**

All LFHs undergo semi-annual requalification by certified specialists in accordance with ISO 14644-1:2015, Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration, acceptance criteria per SOP FAC-003-LR, Technical Specifications for HEPA Filter Certification (Reference Exhibit O2-1), which FDA recognizes as an acceptable consensus standard for cleanroom qualification. Historical data from the past four years, including airflow velocity measurements, dynamic total particle counts, induction leak testing, back streaming tests, filter integrity testing, and periodic airflow visualization under dynamic conditions, consistently demonstrate that all hoods have met required standards with no degradation in performance (provided to FDA in classified room and hood certifications during the inspection, Request 18).

This risk-based bracketing methodology ensures that revalidation activities are scientifically justified and in compliance with current regulatory expectations, providing assurance that laminar airflow integrity is maintained across all compounding activities and hood locations while avoiding unnecessary redundancy in testing functionally equivalent equipment.

**OBSERVATION 3 FDA OBSERVATION:**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm did not adequately investigate microbial excursions recovered from your ISO 5 classified areas during aseptic production before distributing partial lots. Your firm determined that the probable root cause of the microbial contamination was improper sanitization of materials before transfer into the ISO 5 classified critical areas. In each case, you concluded that only the second portion of the batch was impacted by this contamination and subsequently rejected that portion of the batch. However, your firm did not demonstrate that the contamination was limited to the materials used during the second portion of the batch production, and that there was no impact on the first portion of the batch, despite these materials undergoing the same sanitization process.

| Excursion # | Location | Microbial Recovery | Probable Root Cause |
|---|---|---|---|
| EXC-2025-0045 | Right passive viable air plate | *Bacillus altitudinis/pumilus/safensis* | Improper sanitization of materials |
| EXC-2025-0080 | Right glove sleeve | *Solibacillus silvestris* | Improper sanitization of materials |
| EXC-2025-0111 | Right passive viable air plate | *Penicillium citrinum* | Improper sanitization of materials |

Your firm approved and distributed 1,690 syringes of Ketamine HCl 10 mg/mL in 0.9% Sodium Chloride 5 mL fill Syringe (50 mg/5 mL), lot 1125035065, BUD 07/03/2025, associated with Excursion EXC-2025-0045; 1,200 syringes of Phenylephrine HCl 100 mcg/mL in 0.9% Sodium Chloride 10 mL fill Syringe (1,000 mcg/10 mL), Lot 1125035375, BUD 11/07/2025, associated with Excursion EXC-2025-0080; and 740 syringes of Ketamine HCl 10 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe (50 mg/5 mL), Lot 1125035526, BUD 1/10/2026 associated with Excursion EXC-2025-0111.

## OBSERVATION 3 RESPONSE

### Comprehensive Investigation Process

SCA maintains a rigorous investigation process designed to identify root causes, assess impact, and ensure product quality through data-driven, risk-based decisions. The investigation process is detailed in SOP QMS-039, Event Reporting and Disposition (provided to FDA during the inspection, Request 8a) and SOP LAB-001, Handling Environmental and Personnel Monitoring Excursions (provided to FDA during the inspection, Request 8a).

Upon detection of any microbial recovery in the ISO 5 environment, SCA immediately initiates a comprehensive investigation that includes:

Immediate Response and Quarantine: All potentially affected material is immediately quarantined per SOP QMS-039. The investigation scope is conservatively established to ensure all potentially impacted batches are held pending investigation completion and Quality Assurance disposition decision. The batch quarantine and scope of impact is documented on

Form QMS-039-1, Investigation Criticality Assessment Form (Reference Exhibit O3-1) and is approved by Quality upon opening of all investigations.

Cross-Functional Investigation Team: A multidisciplinary team is assembled including any required representatives from, but not limited to Technical Operations, Manufacturing Operations, Stability, Analytical Chemistry, Microbiology, and Quality Assurance. This team conducts a thorough investigation utilizing systematic root cause analysis tools.

Daily Quality Management Oversight: Investigation findings are presented at daily Quality Management standup meetings where Quality Assurance leaders ensure the investigation is appropriately scoped, adequately resourced, and progressing toward sound conclusions. This real-time oversight ensures investigations remain focused on identifying true root causes rather than superficial explanations.

Systematic Root Cause Analysis: Investigations employ structured methodologies including the 6M (Man, Machine, Material, Method, Measurement, Environment) analysis framework mandated by SOP QMS-039 (provided to FDA during the inspection, Request 8a). This systematic approach ensures all potential contributing factors are evaluated rather than accepting initial assumptions.

Comprehensive Data Review: SOP LAB-001, Handling Environmental and Personnel Monitoring Excursions (provided to FDA during the inspection, Request 8a) details information that investigations include thorough analysis of all relevant data streams: analytical test results and associated records, microbiological results and laboratory records, environmental monitoring data (non-viable particles, viable air samples, surface samples), operator and technician interviews, procedure reviews, training record verification, and GEMBA walks (direct observation) of the implicated processes.

Impact Assessment and Batch Scoping: SOP LAB-001, Handling Environmental and Personnel Monitoring Excursions (provided to FDA during the inspection, Request 8a) describes that the investigation systematically evaluates all potentially impacted batches. Material hold and quarantine decisions are made conservatively based on worst-case assumptions until data analysis supports more refined scoping.

Short-Term and Long-Term Corrective Actions: When immediate corrections are identified during the investigation, they are implemented promptly. When the root cause confirmation identifies the need for further Corrective and Preventive Actions (CAPA) comprehensive plans are developed, implemented, and subject to effectiveness verification per SOP QMS-011, Corrective and Preventive Action Program section 10.5, Effectiveness Check (provided to FDA during the inspection, Request 8a).

This investigation process ensures thorough, science-based evaluation of all excursions and supports sound quality decisions regarding batch disposition.

**Environmental Monitoring Program Design**

SCA's environmental monitoring program is proceduralized in SOP LAB-007-LR, Environmental and Personnel Monitoring Program (provided to FDA during the inspection, Request 8a). The program establishes an ISO 5 action limit of ≥1 CFU per sample, captured in VD LAB-007-8-LR, Alert and Action Levels for Environmental Monitoring (Reference Exhibit O3-2), consistent with industry expectations outlined in FDA's Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (2004), USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments, and PDA Technical Reports TR 13, Fundamentals of an Environmental Monitoring Program and TR 88, Microbial Data Deviation Investigations in the Pharmaceutical Industry. These regulatory and industry standards recognize that any microbial recovery in ISO 5 environments is significant and warrants investigation due to the criticality of aseptic operations.

SCA's program requires ISO 5 fingertip and glove sleeve sampling from each primary operator performing aseptic connections per SOP LAB-007-LR, Section 10.6 (ISO 5 Personnel Sampling) (provided to FDA during the inspection, Request 8a), along with multiple environmental monitoring samples collected continuously or during each individual compounding session: continuous non-viable particle monitoring (cNVP), active viable air monitoring (AVA), continuous passive viable air monitoring (PVA), and viable surface monitoring (VS). This comprehensive sampling strategy, detailed in VD LAB-007-7-LR, Environmental Monitoring Schedule (provided to FDA during the inspection, Request 41), provides extensive data for each compounding session, enabling detailed assessment of environmental control and personnel performance.

**Batch Control and Traceability System**

SCA maintains rigorous physical and administrative controls over distinct portions of each batch throughout manufacturing and holding processes. These controls are proceduralized and begin within the hood during compounding operations.

Hood Load Pattern Qualification: SCA has qualified specific hood load patterns through media fill validation and airflow visualization studies. Each hood load must be completed prior to introducing and staging the next set of final containers to be filled. This sequential approach creates natural separation points within each batch. These requirements are captured in SOP COM-018-LR, Staging of Raw Materials in the LAFH (Reference Exhibit O3-3) and SOP COM-061-LR, Roles and Responsibilities of Cleanroom Personnel (provided to FDA during the inspection, Request 8a).

Individual Tote System: Upon completion of each hood load, filled and closed units are placed into individual totes that are immediately sealed with batch identification and primary operator identification labels, per SOP COM-061-LR, Roles and Responsibilities of Cleanroom Personnel Section 10.3 (Roles and Responsibilities of Secondary Operators (Level 2)) (provided to FDA during the inspection, Request 8a). This system allows each tote to be unambiguously associated with a specific primary operator and their corresponding compounding session, which directly aligns with the environmental and personnel sampling described above.

Maintained Segregation Throughout Processing: These controls and identification are maintained throughout all subsequent manufacturing steps: blind count outside ISO 7 rooms (SOP COM-075-LR, Exit of Compounded Product from Classified Areas, Reference Exhibit O3-4), visual inspection (SOP ILP-001-LR, Product Inspection and Defect Classification, provided to FDA during the inspection, Request 38), final container labeling (SOP ILP-008, Labeling of Finished Products, Reference Exhibit O3-5), finished unit packaging (SOP ILP-006-LR, Packaging of Finished Product, Reference Exhibit O3-6), and holding pending Quality Assurance batch disposition (SOP WHS-013-LR, Retrieval and Storage of Finished Product, Reference Exhibit O3-7, and SOP WHS-014-LR, Processing, Picking, and Staging Sales Orders to Ship, Reference Exhibit O3-8). At each processing step, totes are opened individually, processed, then re-sealed while maintaining batch and primary operator identification. SOP ILP-016-LR, Staging and Movement of Materials in Non-Classified Areas (Reference Exhibit O3-9), addresses foundational segregation requirements for product handling throughout the facility. This proceduralized approach ensures continuous traceability and prevents cross-contamination between separately compounded portions of a batch.

**Data-Driven Impact Assessment**

All environmental and personnel monitoring investigations, including those referenced in Observation 3, undergo systematic data review and risk-based impact assessment per SOP QMS-039, Event Reporting and Disposition and SOP LAB-001, Handling Environmental and Personnel Monitoring Excursions (both provided to FDA during the inspection, Request 8a). Investigations are evaluated on their own merit with conclusions determined through comprehensive analysis of all available data rather than predetermined approaches.

For the investigations specifically referenced in Observation 3, each identified isolated, individual instances of potential technique deficiencies during material sanitization. The thorough investigations identified these single instances as probable root causes rather than broader systemic or procedural inadequacies. The deficiencies were moment-in-time observations during the initial material sanitization step.

It is important to note that SCA's material transfer process includes multiple sanitization steps that provide layered contamination control: initial sanitization before materials enter the cleanroom suite, a second sanitization prior to entry into the ISO 7 buffer room, and a third sanitization as materials transition from the buffer room into the ISO 5 laminar flow hoods. While material sanitization was identified as the probable root cause in these investigations, the multiple sanitization barriers help mitigate the potential for broad-based batch impact.

In each of the referenced investigations, comprehensive review of all ISO 5 environmental and personnel monitoring data demonstrated clear differentiation between impacted and unimpacted compounding sessions. Specifically, portions of batches determined to be unimpacted had zero microbial recoveries from all personnel samples (fingertips, glove sleeves) and all environmental samples (active viable air, passive viable air, surface samples) collected during those compounding sessions. The extensive sampling program provides multiple independent data points that collectively support impact assessment decisions.

**Risk-Based Batch Disposition Decisions**

SCA applies a rigorous, data-driven approach to batch disposition decisions. When Quality Assurance cannot confidently determine that physical segregation was maintained throughout processing, or when data cannot support refined scoping of impact, entire batches are rejected. This occurred in practice when traceability systems did not provide the level of assurance required for partial batch release decisions. Batch disposition and rejection of product by Quality are described in SOP QA-009-LR, Batch Record Review and Product Disposition (reference Exhibit 01-6) and SOP QA-015-LR, Rejected Products Procedure (reference Exhibit 03-10).

The investigations referenced in Observation 3, however, can be distinguished from the other examples of entire batch rejection because of the combination of maintained physical segregation, continuous operator and session identification, and comprehensive environmental monitoring data provided multiple independent lines of evidence supporting the conclusion that specific compounding sessions were unaffected by the identified nonconforming events. Any portion of a batch compounded after microbial recovery was rejected, even when subsequent environmental monitoring showed zero recoveries, because the ISO 5 environment had not been reset through terminal cleaning following the recovery.

SCA's approach to impact scoping and batch disposition is driven by the principle of ensuring product quality through comprehensive data analysis and risk-based decision making. This approach aligns with FDA expectations for thorough investigations and science-based disposition decisions as outlined in 21 CFR 211.192 (Production Record Review) and FDA's Guidance for Industry: Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production (October 2006).

Based on our comprehensive investigation processes, robust batch control and traceability systems, extensive environmental monitoring data, and rigorous disposition criteria, SCA respectfully maintains that our investigations were thorough and that disposition decisions were appropriately justified by the totality of available data. Importantly, SCA has received no customer complaints or adverse event reports associated with any of the three batches referenced in this observation (Lots 1125035065, 1125035375, and 1125035526), providing additional confirmation that the released portions met all quality specifications and posed no risk to patient safety.

**Continuous Improvement Initiatives**

SCA recognizes opportunities to enhance investigation documentation to more clearly articulate the scientific rationale supporting our conclusions. Change control DAR-25-667 was initiated to implement the following enhancements by March 31, 2026:

Enhanced Scope Evaluation and Documentation: Updated procedures will include explicit guidance on evaluating the scope of identified root causes, requiring investigators to systematically document why contamination is confined to specific batch portions when supported by data. Investigations will include documentation of scope based on the determined root cause.

Structured Investigation Tools: Investigations involving potential deficiencies in personnel execution will be required to employ 5-Why analysis in addition to 6M methodology that is already utilized, ensuring deeper exploration of underlying factors contributing to technique deviations.

These enhancements will strengthen investigation documentation and align with industry best practices outlined in USP <1116> for contamination control and PDA TR 88 for microbial investigations, while reinforcing SCA's commitment to data integrity and transparent scientific reasoning in all quality decisions.

**OBSERVATION 4 FDA OBSERVATION:**

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug product containers conform to appropriate standards of identity, strength, quality and purity.

Specifically,

SOP-ILP-001-LR Product Inspection and Defect Classification defines critical defects as those that may cause serious adverse reactions, including those that compromise the sterility of the drug product. However, your firm's defect classification system contains the following inadequacies:

A. Your firm classifies all particulates/materials in the drug solution as major defects without distinguishing between extrinsic and intrinsic particles during the visual inspection process, some of which may increase risk of serious adverse reactions.

B. Your firm has inappropriately classified foreign material trapped between stopper ribs as a minor defect despite the potential for these particles to impact the drug solution and compromise sterility.

During visual inspection of prefilled syringes, foreign (unusual) material, including cardboard, was observed trapped between the stopper ribs of the syringe plunger assembly and was classified as a minor defect in the following products:

Rocuronium Bromide 10mg/mL 5mL, Lot 1125035241, BUD 08/10/2025; 1420 syringes distributed.

Succinylcholine Chloride 20 mg/mL 5 mL, Lot 1125035825, BUD 12/16/2025; 1400 syringes distributed.

Your firm's three-part syringe design utilizes a rubber tip stopper with ribs intended to form a tight seal against the barrel wall to maintain container closure integrity. The presence of cardboard particulates between the stopper ribs demonstrates that your component control and assembly processes are not adequately designed or maintained to prevent contamination of product contact surfaces.

**OBSERVATION 4A RESPONSE**

SCA maintains a rigorous visual inspection process governed by SOP ILP-001-LR, Product Inspection and Defect Classification, (provided to FDA during the inspection, Request 38). This process utilizes comprehensive supporting documentation to ensure consistency and effectiveness:

- VD-ILP-001-1, Defect Catalog (visual reference guide with photographs of various defect types) (provided to FDA during the inspection, Request 27).
- Form ILP-001-8-LR, Syringe 100% Inspection Form (Reference Exhibit O4-1)
- Form ILP-001-9-LR, Syringe AQL Inspection Form (Reference Exhibit O4-2)
- Form ILP-001-4-LR, Bag 100% Inspection Form (Reference Exhibit O4-3)
- Form ILP-001-5-LR, Bag AQL Inspection Form (Reference Exhibit O4-4)

**Risk-Based Particulate Classification Process**

SCA's particulate classification system employs a deliberate, multi-stage approach designed to ensure patient safety through conservative initial classification followed by systematic investigation and enhanced characterization.

Initial Detection and Conservative Classification: During 100% visual inspection, all units containing visible particulate matter are immediately segregated and assigned a major defect designation per SOP ILP-001-LR (provided to FDA during the inspection, Request 38). This conservative classification ensures a patient safety focused defect threshold for particulate, ensuring exceedances receive heightened scrutiny and investigation rather than being released based solely on visual assessment. The major classification at initial detection serves as a quality gate that prevents release pending comprehensive evaluation.

Inspector Training and Anomalous Particle Recognition: Visual inspection personnel undergo comprehensive training governed by SOP ILP-001-LR (provided to FDA during the inspection, Request 38) and documented in TQ ILP-001-1-LR, Technical Qualification for Manual Product Inspection (provided to FDA during the inspection, Request 27) on particle recognition using defect catalogs that include a variety of particle types, sizes, colors, shape, and presentations. Training materials incorporate photographs and physical examples demonstrating the range of particles that may be encountered. Inspectors are trained to flag unusual or anomalous particles during the initial "bag and tag" process where they document particle shape, size, and color characteristics. When inspectors identify particles that appear anomalous (such as fibers, cardboard fragments, insects, or other unusual materials), these units are specifically flagged for enhanced investigation beyond standard particulate analysis.

Enhanced Particle Identification and Investigation: Following initial detection and segregation, particles undergo enhanced identification to determine their origin and nature. SCA's Little Rock facility utilizes the analytical chemistry capabilities at SCA's Windsor, CT site to perform detailed particle identification testing. The results of the identification testing are then utilized during the investigation to determine if the particle was intrinsic to the manufacturing process or extrinsic to the manufacturing process.

This classification guides investigation scope and corrective action development based on intrinsic particulate sources being product contact materials and potentially being related to the manufacturing process, while extrinsic particulates are not intended to be product contact and likely arise from sources other than product contact materials and outside the manufacturing process.

SCA defines intrinsic and extrinsic particulates in SOP QA-029-W, Defect Categorization and Classification Procedure:

- Intrinsic: particulates that are derived from the manufacturing equipment, product formulation, or container system.
- Extrinsic: particulates that originate from the manufacturing environment and are foreign to the manufacturing

Criticality Determination Through Investigation: The determination of whether a particle represents a critical defect (potentially causing serious adverse reactions or compromising sterility) is made through the comprehensive investigation process and approved by Quality Assurance. This determination may consider variables like particle type, size, location within the container, potential for migration into product-contact areas, sterility implications, and patient safety risk based on route of administration within the investigation.

Units identified with particles are **always** permanently removed and never returned to the batch regardless of investigation findings. All particulate-containing units remain segregated and are permanently rejected from batch disposition, ensuring that investigation and characterization activities do not result in release of questionable product.

This stepwise approach ensures patient safety through conservative initial classification at our Little Rock facility while providing the enhanced characterization at our Windsor facility to drive effective corrective actions and process improvements. The process meets regulatory expectations established in FDA's draft guidance on injectable product inspection (FDA's Guidance for the Industry: Inspection of Injectable Products for Visible Particulates, December 2021) and cGMP requirements under 21 CFR 211, which emphasize that visible particulate contamination poses potential patient safety risk and must be addressed through risk-based, conservative approaches that prioritize product quality.

SCA respectfully maintains that our process includes appropriate identification of particles as intrinsic or extrinsic through the systematic enhanced identification and investigation stages described above. However, we recognize opportunities to improve procedural documentation to more clearly articulate this stepwise progression.

**Continuous Improvement**

Change control DAR-25-640 was initiated to enhance SOP ILP-001-LR, Product Inspection and Defect Classification and related procedures by March 31, 2026 to:

- Explicitly document the stepwise progression from initial detection through enhanced identification and criticality determination

- Clarify that all particulates maintain major classification throughout investigation and that units are permanently rejected (never returned to batches) regardless of investigation conclusions
- Formalize the process for flagging anomalous particles during visual inspection for enhanced investigation
- Strengthen integration between inspection procedures and investigation procedures to ensure seamless handoff when unusual particles are detected
- Enhance documentation requirements for criticality determinations

These enhancements will strengthen procedural clarity, reinforce global procedural alignment between sites, and ensure that the comprehensive nature of SCA's particle identification and classification process is clearly articulated in our governing SOPs.

SCA initiated change control Task-25-706 prior to the FDA inspection to create Risk Assessment RA-25-011, Particulates in Final Product Container Risk Assessment. This risk assessment will determine the risk level associated with the presence of particulate(s) in the final product container, detected during visual inspection and its impact. RA-25-011 will be completed by 31Dec25.

**OBSERVATION 4B RESPONSE**

SCA effectively segregates and rejects units exhibiting the defect "foreign material between stopper ribs" in accordance with SOP ILP-001-LR, Product Inspection and Defect Classification (provided to FDA during the inspection, Request 38). While SCA classifies this defect as minor based on scientific principles demonstrating no impact on sterility or product quality, all units exhibiting this defect are permanently rejected and never released to the market.

**Scientific Basis for Minor Classification**

SCA's classification of foreign material between stopper ribs as a minor defect is supported by fundamental principles of syringe design, validated container closure integrity, and terminal sterilization:

Physical Barrier Properties: SCA receives sealed, sterile syringe trays containing fully assembled syringes with the plunger depressed into the barrel. The syringe design incorporates multiple physical mechanisms that create an impermeable barrier preventing both ingress and egress of foreign material:

Hermetic Seal: The elastomeric plunger tip forms a complete mechanical barrier against the external environment through intimate contact with the internal barrel surface. This seal maintains integrity through the viscoelastic properties of the elastomer material, which conforms precisely to the internal barrel geometry while maintaining sufficient restoring force against the barrel walls. This hermetic barrier ensures that the sterile drug product contact area remains isolated from external contaminants, directly supporting patient safety and compliance with container closure integrity expectations outlined in USP <1207> Package Integrity Evaluation – Sterile Products.

Surface Tension Barrier: Cohesive forces between the plunger and barrel materials create surface tension that actively resists introduction or escape of foreign material. This resistance follows from the Laplace pressure equation, where interfacial tension between the two surfaces generates a pressure barrier against contamination regardless of particulate dimensions. This pressure barrier prevents both ingress of external contaminants and egress of any material that may reside in non-product-contact areas, maintaining product purity and sterility.

Molecular Adhesion: Van der Waals interactions at the plunger-barrel interface create a nanoscale barrier that prevents even submicron particulates from breaching the seal. While individually weak, these molecular forces create cumulative effects that render the interface impermeable to contamination. This nanoscale impermeability ensures that even submicron particles cannot migrate into or out of the product-contact area, preserving sterility and reducing risk of particulate-related adverse events.

Physical Impermeability: This impermeability to foreign material is independent of particulate size. The exclusion mechanism relies not on filtration (which has size limitations) but on the complete absence of an ingress or egress pathway due to the physical principles described above. The design therefore establishes a contamination barrier that maintains sterility and integrity of the internal barrel environment, meeting the high purity standards required for sterile injectable products.

Terminal Sterilization: SCA's syringe suppliers employ gamma irradiation as the terminal sterilization method. Gamma irradiation is widely recognized for its deep penetration capability, ensuring delivery of sterilizing dose throughout the entire product including recessed or dead spaces such as the area between stopper ribs. ISO 11137: Sterilization of Health Care Products – Radiation supports the use of gamma irradiation as an effective sterilization method meeting rigorous sterility assurance requirements. PDA similarly supports the broad applications of gamma irradiation sterilization and its effective high penetration power in the article "Gamma Sterilization of Pharmaceuticals—A Review of the Irradiation of Excipients, Active Pharmaceutical Ingredients, and Final Drug Product Formulations." Therefore, any foreign material present in non-product-contact areas would be sterile and pose no microbiological risk.

Incoming Material Release Process: SCA maintains a robust incoming material release process governed by SOP WHS-002-LR, Releasing Incoming Raw Materials (Reference Exhibit O4-5). Quality Assurance reviews manufacturer certificates of analysis and conformance to verify that SCA requirements have been met, including confirmation of terminal sterilization. This process ensures that materials have been sterilized prior to release for manufacturing use.

Container Closure Integrity Validation: SCA has executed a comprehensive container closure integrity study on units exhibiting the defect "foreign material between stopper ribs." Defective finished units were collected and submitted to an independent testing laboratory for container closure integrity testing. Results confirmed that syringes exhibiting this defect maintained their sterile seal with no compromise to container closure integrity. This validation study was documented in Engineering Study ES-25-020-FR, Final Report for the Evaluation of The Effect of Particulates Between the First Stopper Rib and Syringe Barrel (provided to FDA during the inspection, Request 88). This study was supplied during the inspection.

Manufacturer Verification of Impermeability Principles: The impermeability principles described above are not merely theoretical constructs but have been verified and validated by the syringe manufacturers through comprehensive engineering studies and quality control testing. Syringe manufacturers conduct extensive container closure integrity testing during product development and as part of ongoing quality assurance programs to demonstrate that the plunger-barrel seal maintains hermetic integrity under a range of conditions including storage, transportation, and handling. These manufacturer validation studies confirm that the physical mechanisms of elastomeric seal formation, surface tension barriers, and molecular adhesion forces function as designed to prevent both ingress of external contaminants and egress of any material from non-product-contact areas.

Furthermore, syringe manufacturers validate that gamma irradiation penetration is complete throughout all portions of the assembled syringe, including recessed areas such as the space between stopper ribs. Dosimetry studies performed during sterilization validation demonstrate that the minimum sterilizing dose is achieved in all locations within the syringe assembly, confirming that any material present in dead spaces would be rendered sterile. These manufacturer validations are documented in certificates of conformance and sterilization validation reports that SCA reviews as part of the incoming material release process governed by SOP WHS-002-LR (Reference Exhibit O4-5).

Based on the syringe's fundamental design principles (providing physical impermeability through hermetic seal, surface tension, and molecular adhesion), validated container closure integrity demonstrating maintained sterile seal in units with this defect, and terminal sterilization via gamma irradiation ensuring any material in non-product-contact areas is sterile, any foreign material present in the dead space between stopper ribs poses no risk to product quality, sterility, or patient safety. These factors collectively confirm that the defect does not compromise container integrity, does not affect the product-contact portion of the syringe, and presents no pathway for contamination of sterile drug product.

SCA respectfully maintains that classification of foreign material between stopper ribs as a minor defect is scientifically justified given the demonstrated lack of impact on critical quality attributes. It is important to emphasize that the classification determination is academic from a patient safety perspective because regardless of classification—minor or major—all units exhibiting this defect are permanently rejected and never released. The classification does not drive the disposition outcome; SCA's practice ensures zero patient risk through complete rejection of all affected units. Nevertheless, SCA maintains this conservative approach to uphold the highest quality standards.

**Supplier Quality Management and Continuous Improvement**

While SCA's scientific assessment supports the minor classification and demonstrates no patient safety risk, we recognize that the presence of foreign material in syringe components represents an opportunity for supplier process improvement. SCA actively monitors defect trends and engages our supplier quality system, governed by SOP QMS-024, Supplier Complaint Procedure (Reference Exhibit O4-6), to drive corrective actions at the component manufacturer level. This ongoing engagement reinforces our commitment to continuous

improvement in component quality and demonstrates our expectation that suppliers maintain processes that prevent contamination of all portions of medical device components, including non-product-contact areas.  We have seen the number of these supplier defects decrease dramatically based on our efforts.

Supplier engagement through SCA's quality system has demonstrated measurable results. By ensuring that our syringe suppliers implement CAPAs to address their component control and assembly process, SCA has seen a decrease in foreign material related to syringes by 47% over the 18-month period from January 2024 through June 2025, demonstrating effective supplier quality management in driving component manufacturer improvements.  SCA will continue to reject 100% of units exhibiting foreign material between stopper ribs, maintain rigorous trend analysis of this defect type, and work collaboratively with component suppliers to eliminate the root causes of this defect through enhanced manufacturing controls and quality systems at the supplier site.

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## COMMITMENT INDEX

(Organized by Observation Number)

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| 1 | Implement fingertip sampling for secondary operators | TBD | MOC-2025-112 | In Progress | January 31, 2026 |
| 3 | Enhance SOP LAB-001 to clearly articulate scientific rationale | TBD | DAR-25-667 | In Progress | March 31, 2026 |
| 4 | Enhance SOP ILP-001-LR | TBD | DAR-25-640 | In Progress | March 31, 2026 |
| 4 | Complete RA-25-011 | TBD | Task-25-706 | In Progress | December 31, 2025 |

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## EXHIBIT MATRIX

(Organized by Observation Number)

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| 1 | O1-2 | RA 22-003, Risk Assessment Based Environmental Monitoring Sampling Plan at SCA-LR | 22 |
| 1 | O1-3 | PP-24-002-G, Contamination Control Strategy | 47 |
| 1 | O1-4 | RA-24-006, Risk Assessment for Aseptic Process Simulation/Media Fill | 26 |
| 1 | O1-5 | SOP LAB-058-LR, Operation and Maintenance of the Celsis Advance II Rapid Microbial Detection System for Sterility Testing | 29 |
| 1 and 3 | O1-6 | SOP QA-009-LR, Batch Record Review and Product Disposition | 21 |
| 2 | O2-1 | SOP FAC-003-LR, Technical Specifications for HEPA Filter Certification | 5 |
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