Site Master File (SMF)

Harmonized with
Pharmaceutical Inspection Co-operation Scheme (PIC/S)
PE 008-4, Annex 1, January 01, 2011

&

An integrated QMS based on ISO 9001-2015, ISO 22716, & 21 CFR Part 210 & 211 (cGMP)

Solésence, Inc.

400 Crossroads
Bolingbrook, Illinois 60440

630-771-6700/ Fax 630-771-0825
www.Solésence.com

PREPARED AND MAINTAINED BY
QUALITY ASSURANCE DEPARTMENT

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0.1 APPROVALS

APPROVALS This document is electronically signed	DATE
_____ Prepared By	
_____ Reviewed By	
_____ Director, QA	

0.2 REVISION HISTORY

Quality Manual Revision #.	Date	Section	Page	Amendment	Authorization
000	12/19/2022	all	all	Original-DRAFT .	Mohammad Nadir Ali
001	01/22/2023	all	all	Original	Mohammad Nadir Ali
002	01/23/23	1.0 and Appendix 5	4, 29, 32	Contact Info, Org Chart, Site Map	Mohammad Nadir Ali
003	6/13/2023	4.3, 5.2, 6.3,8.1	16,19,20, 24, 32, 35	Corrected typographical errors. Added revised Appendix 7. Include Org chart as a separate attachment	Mohammad Nadir Ali
004	1/2/2024	4.1(b)	14	Added new section for Bulk Kit	Mohammad Nadir Ali
005	1/17/2024	4.1 (d)	14. 34, 35, 37	Added new section for Bulk Lotion Mfg. Updated Appendix 2, 6a, 6b, and 8 to incorporate Lotion Mfg. Process 820.	Mohammad Nadir Ali
006	07/08/2025	all	all	Change corporation name from Nanophase to Solésence and added name of contact Edmund Sieracki.	Nataly Cochran
007	9/10/25	All	All	Revised to remove nanophase as entity, replaced with Solesence, Inc. Added official in-house micro lab. Change implementation period for bulk processes.	Nadir Ali
008	5/12/26	Section 4.1, Attachment 9	13,14,40	Added Regulatory status for domestic and international compliance Added FDA Audit History. Added PVS processes to section 4.1.	Nadir Ali

1.0 GENERAL INFORMATION ON THE MANUFACTURER

1.1 Contact Information on the manufacturer

Solesence, Inc. (former name: Nanophase Technologies Corporation) .is located at Bolingbrook, IL in a standalone structure. The total covered area is roughly 265,000 SF. A portion of this building is leased to a third party. Current Corporate head office is located at Romeoville, IL in a standalone structure. The total covered area is roughly 35000 SF with total premises are about 65,000 SF.

Name and Address of Site

Solésence, Inc.
400 Crossroads
Bolingbrook, IL 60440
630-771-6700/ Fax 630-771-0825
www.solesence.com

Contact Person(s)

Customer Relation

Yoolie Park
Vice President, Brand Partnerships
Solésence, Inc.
1319 Marquette Drive
Romeoville, IL 60446
□: 847-502-9046 □: 630-771-0825
□: esieracki@solesence.com

Quality and Regulatory

Nadir Ali
Director, Quality & Regulatory Compliance
Solésence, Inc.
1319 Marquette Drive
Romeoville, IL 60446
□: 630-771-6747 □: 630-771-0825
□: mali@solesence.com

24-hour number

Facility main number, 630-771-6700 is manned during business hours (8-5 M-F), CDT. Calls received after hours can be recorded on voice mail. For emergencies related to the materials shipped, both domestic and international 24-hour contact information is provided on the relevant Safety Data Sheet (SDS).

1.2 Authorized pharmaceutical manufacturing activities of the site

Solesence, Inc. currently operates packaging & assembly of finished sunscreens as “White Label Products” that are marketed under various Private Label Distributors (PLD). Site is registered with US FDA and annual renewal is kept current. Future operations are planned to produce Active Pharmaceutical Ingredients (API) in powder & liquid forms and semi-solid/solid dosage form of OTC-topical products for human use only. Operations related to dispersions and lotions are underway and planned to be fully operational by end of 2026. A number of new equipment is installed and/or being installed to address capacity and going through validation stages.

Solesence, Inc. operates on-site QC laboratory and routinely performs RM and FG tests as applicable to incoming Raw Materials and Packaged Finished Goods. In 2025, microbiology laboratory was started to test microbial testing based on Rapid Micro Method (RMM) along with USP 61. Method adopted from current USP are considered validated, however, suitability studies are performed on applicable. Non compendial methods are developed in house and method/instrument validation are executed. Solesence, Inc. manages all stability storage and testing based on ICH guidelines in-house at its Romeoville location. Certain Microbial testing is performed at authorized FDA registered laboratories and the testing follows the USP methodologies.

1.3 Any other manufacturing activities carried out on the site

Warehousing of raw materials, packaging components/materials, WIP including Sunscreen lotions, dispersions, metal oxide powders with all activities related to Shipping and Receiving.

2.0 QUALITY MANAGEMENT SYSTEM OF THE MANUFACTURER

2.1 The quality management system of the manufacturer

Solesence, Inc. quality management system is based on and in compliance with ISO 9001-2015, and cGMP 21 CFR Part 210/211 and 21 CFR Part 11 as selected for specific requirements under cGMP. In addition, Solesence, Inc. fully complies with all legal requirements related to the product and services it offers, and any contractual/quality agreements mutually agreed with its suppliers and customers. Compliance to all applicable safety and environmental regulations is an integral part of the Solesence, Inc. management system, processes, and products.

With regards to cGMP compliance, Solesence, Inc. recognizes the importance of FDA guidance documents, such as Q7A and others and uses these guidance documents as applicable to its quality management system. Guidance documents are not regulations and should be consulted based on business needs, customer requirements and in cases where legal regulations do not provide an effective method for implementation of certain cGMP elements. Solesence, Inc. quality management system is certified to ISO 22716 *Cosmetics Good Manufacturing Practices (GMP)-Guidelines on Good Manufacturing Practices* that is more specific to EU/International markets.

Solésence was Nanophase wholly owned subsidiary, until May 2025 when company officially changed its name t Solsesene, Inc. Solesence, Inc continue to operate under all applicable quality, safety, environmental, and legal requirements as established under previous name, Nanophase Technologies Corporation. Drug Establishment has been changed to Solesence, Inc. from former Nanophase name in mid 2025.

Solesence, Inc. on a routine basis, monitor and address internal and external issues related to its business. Example of external issues generally include development of products and services

based on current market trends and applicability of Solesence, Inc. technologies and products, IP, compliance to regulations related to domestic and international domains, and supporting current customer needs.

Internal issues are focused on employee retention (talent/knowledge), empowerment at departmental cross functional levels, performance monitoring and corrections based on KPI.
Solesence, Inc.is committed to establish, document, implement and maintain a quality management system, and continually improve its effectiveness, in conformance with requirements of ISO 9001-2015 International Standard and current Good Manufacturing Practices (cGMP) 21 CFR Part 210 and 211. Solesence, Inc. QMS is documented in **QMS-000**.

2.2 Release procedure of finished products

Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Operational Procedure **QP-825**, Final Inspection, defines the system for final product verification and release. QA/QC is authorized and responsible for all product releases, rejections, and management of delivery under quarantine (if applicable).

Director of Quality and Regulatory Compliance is responsible for setting procedures, roles, and responsibilities of QA/EHS staff in compliance with 21 CFR Part 211.22 as listed below.

"Quality department and has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit is responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company."

"The quality control unit has the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product."

For decision affecting the release of materials for FDA application (as required under 21 CFR Part 211.22) only QA/QC staff are authorized to release products for distribution and use. There are cases when Engineering trail materials, R&D development batches, and/or industrial grade products may be evaluated, released, and distributed/used by respective departments as needed. Normally, any product with a defined specification and testing performed by Quality department is release by Quality staff. **(Ref SOP: QA-700)**

In any circumstance, manufacturing, R&D, and/or Engineering and any other department within the company are not authorized to assume a function of releasing.

QA/QC staff is competent and knowledgeable via work experience, training, and/or education. Minimum qualification for QA/QC technical staff is 4-year college in related scientific discipline.

An approved Master Batch Record is used for all drugs and API manufacturing with 2 level of supervisory review and approval by manufacturing followed by 2 level review and approval by QA/QC.

2.3 Management of suppliers and contractors

Solesence, Inc. conducts a supplier partnership program that encourages high performance on the part of its suppliers. Augmented by sound receiving inspection practices, Solesence, Inc. maintains high confidence that purchased product conforms to specified requirements.

Supplier evaluation

Critical new suppliers are evaluated with regard to their quality and process capability. Critical suppliers are defined as suppliers whose products are consumed in the process or have direct contact with finished products. Purchasing and Quality Assurance establish the criteria for selection of suppliers and conduct supplier evaluation. Suppliers are rated APPROVED or PENDING. The Approved and Pending suppliers are entered on the approved supplier list. Existing suppliers with a satisfactory quality performance history are exempted from the initial evaluation and are initially rated as APPROVED or PENDING. Records of the initial supplier evaluation are maintained. Supplier evaluation process is governed by Procedure **QP-741**, Supplier Evaluation

Supplier quality performance monitoring

Quality performance of suppliers is monitored. Suppliers showing inadequate performance are notified annually and asked to implement corrective actions and are downgraded to the PENDING rating. If the requested corrective actions are not implemented and there is no improvement, the supplier is further downgraded to the NOT APPROVED rating and is discontinued. Records of supplier monitoring and reevaluations are maintained. The system for monitoring suppliers is defined in Procedure **QP-741.**

Outsource suppliers are located in the critical supplier category. They are evaluated on their ability to produce product or provide service that is equal to the product or service provided by Solesence, Inc.Technologies processes or services.

Approved supplier list

Purchasing maintains an approved supplier list for critical raw materials and supplies. Orders are only placed with vendors that are on the list.

Information for external provider (*Purchasing information*)

Solesence, Inc. purchase orders require that the originator includes where applicable:

a) precise identification of product ordered.
b) positively identified specifications, drawings or other technical documents required to establish full acceptability; and
c) pertinent standards and codes including quality system standards by title, number, and issue.

Verification of Purchased Product

Solesence, Inc. purchasing policies provide that a decision not to inspect incoming material or the failure to detect a supplier-generated nonconformity before receipt does not relieve the supplier of responsibility for quality of the supplied goods.

Critical key purchased products are inspected by quality control. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all

requested certificates and quality records are available. Designated products are further inspected or tested by QC.

QC inspection or testing is not necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

Supplier Verification at Subcontractors

Solesence, Inc. may stipulate in any contract that purchased material is subject to source inspection. When electing to do so, the details for such an inspection and subsequent release of accepted material are stated in the purchase agreement.

Quality Assurance is responsible for selecting appropriate methods for purchased product verification and acceptance. Operational Procedure **QP-743**, Verification of Purchased Products, sets forward detailed rules for selecting product verification methods and for performing receiving and QC inspections.

When verification of purchased product is to be performed at supplier's premises, purchasing documents specify the intended verification arrangements and method of product release

Outsourced processes

When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate: evaluation and pre-qualification of suppliers; assessment of supplier realization processes and quality system; monitoring of supplier quality performance; requirements for inspection, testing or other records demonstrating product conformity; or containment and verification of the supplied product. Section 8.4 of this quality manual and the corresponding operational procedures define such purchasing control system.

Supporting services

Supporting services required by Solesence, Inc. include transportation, communication, and IT services:

Transportation services are usually purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators. Purchasing these services is managed by Shipping and is conducted in accordance with operational procedures **QP-741**, Supplier Evaluation, and **QP-742**, Purchasing.

Communication services are provided by various telephone, wireless, and internet access companies. Purchasing and Human Resources is responsible for administrating and coordinating these contracts.

IT systems are designed and implemented by internal IT group and are operated internally by Human Resources. If external IT support is necessary, IT consultants are selected, and are contracted with, in accordance with applicable purchasing procedures (**QP-741 and QP-742**).

2.4 Quality Risk Management

General

Assessment of Risk and opportunities are integral part of product, processes and service provisions (when applicable). Risk assessment is normally carried out during product development, change control, management review process and by other mechanisms for elements that are critical to Solesence, Inc. business, Risk Assessment process is defined under **SOP NTC-300**.

Improvements and risk-based approach

Solesence, Inc. deploys continual improvement philosophy throughout the entire organization. The quality and EH&S systems are designed to incorporate all elements necessary to identify opportunities for improvement and to implement improvement projects. An approach for improvements is provided in **QP-851** while maintaining a balance between risk and reward. Risk assessments activities are carried through **NTC-300,** and reviews of risk and opportunities are presented in Management Review (**QP-561).**

2.5 Product Quality Reviews or Annual Product Reviews (APR)

On an annual basis, quality records related to all components, containers, closures, and labeling are used for evaluating, at least annually, the quality standard of each drug product to determine the need for changes in product specification, manufacturing, or control procedures. This review is recorded in form **QP-562A & B** by complying with cGMP 211.180 requirements.

The following criteria is utilized to complete Form **QP-562A**.

- "*A review of representative number of batches; whether approved or rejected, each product must have at least one batch included in the annual review." (21 CFR 211.180 (e) (1).* ***NOTE****: Different products are not grouped by "similar processes" or any other similar approach.*
- *"A review of complaints, recalls, returned or salvaged products, and investigation conducted under 211.192 for each product." (21 CFR 211.180 (e)(2).*
- *Any investigation conducted under 21 CFR 211.198, 211.204, 211.208, and any recalls, reports of inspectional observation issued by the FDA, or any regulatory actions relating to cGMP brought by FDA are submitted to the Senior Leadership Team*
- *A summary report is generated (****QP-562B****) to record various elements as related to a specific drug product(s).*

3.0 PERSONNEL

3.1 Organization Chart

The organizational chart in **Appendix 5** provides for the independence of all who manage, perform, and verify work affecting quality. That work includes the following activities:

- preventive action for the products, the processes and the quality system.
- detection of any problems in the products, the processes and the quality system.
- problem-solving participation.
- verification of corrective actions; and stop shipment.

Attachment 1 reflects the most current version of Solesence, Inc.Technologies Corporation functional organizational chart. Departmental organization charts are an extended version of this attachment and are not included with SMF.

Employee

Solesence, Inc. employees a permanent staff of +20 at this site, with the breakdown for each departments as listed below; This site is currently being constructed ad number of employee with associated discipline is subject to change.

- Manufacturing: +90
- Quality Control/Quality Assurance: +6
- Shipping/Warehouse: +12
- Engineering & Maintenance: +6
- Research and Development: None
- Sales/Marketing/Business Development: None
- Finance/HR/Administration: None

4.0 PREMISES AND EQUIPMENT

4.1 Premises

The Solesence, Inc. company operates across multiple plants. The newest addition at Bolingbrook, IL. has a total covered area of roughly 280,000 SF. This location focusses on manufacturing operations with a portion leased to a third party. Shipping and Receiving are centralized at this location providing logistical support for raw materials, WIP and finished goods.

The current corporate head office is a 65000 SF facility located in Romeoville, IL which houses R&D and a segment of manufacturing operations.

Upon completion, Bolingbrook site is designed to operate a dedicated cGMP compliant, API, Bulk, and filling/assembly process for packaging finished sunscreens under white label products. Solésence Inc. operates under regulatory requirements as mandated by FDA, IEPA, OSHA, and DOT.

The site is registered with FDA as API Manufacturer, Manufacturer, and Packaging of OTC human drug products.

Facility layout is shown in **Appendix 6a/6b,** which includes areas dedicated to future activities related to Filling/Assembly, Sunscreens formulations (bulk), offices, labs. Currently, warehouse operations along with limited Filling and Assembly, and QC processes are operational.

REGULATORY STATUS

Solesence, Inc. Bolingbrook site is registered with FDA and applicable products are submitted to FDA under Drug Product Listing. The white label lotions (bulk sunscreens) are produced under private label for various customers.

This site operates under ROSS Illinois state permit and other air emission sources will be identified and permitted according to the IEPA rules and regulations and reporting requirement of state and federal EPA.

Solesence, Inc. practices and promotes safe work environment for its employees by following the OSHA requirements and applicable Best Industry Practices.

Comprehensive ingredients review and approval program (**SP-02-1500**) is in place to authorize only safe, effective, and regulatory suited ingredients to final formulations.

REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances) compliance is followed for EU market, as applicable. Nanophase has secured "Chemservice" as REACH "***Only Representative (OR***)" in Europe. Solesence, Inc. has completed and/or secured via downstream suppliers, the registrations of selected metal oxide and other solvents, monomers, and dispersants.

Key registration information

- FDA DUNs# 18812921
- FDA Labeler code# **063931**
- FDA establishment ID# **3003574860**

DESCRIPTION OF CORE MANUFACTRING

(a) Packaging processes for finished sunscreens and other FDA regulated products

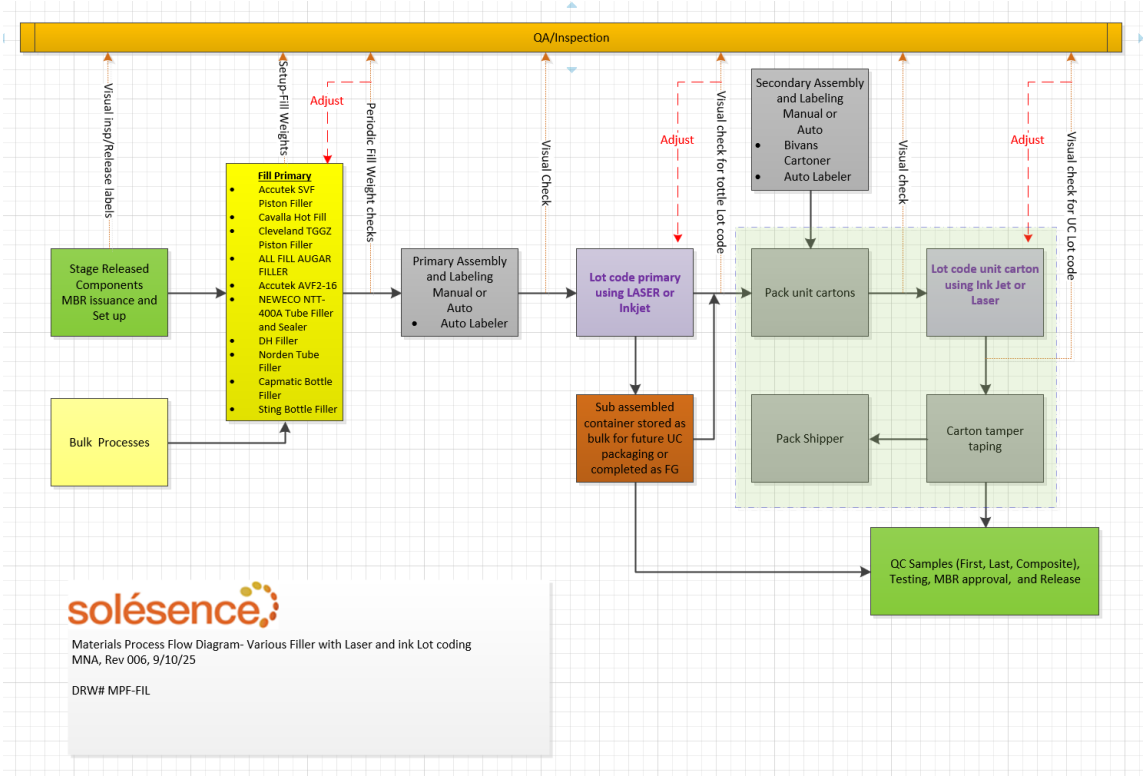
Packaging operations are performed in several Filling Rooms and Assembly areas (as shown in Appendix 6a). There are 8 Filling Rooms build with associated Assembly areas.

The Filling Rooms are designated as FR-1 thorough FR-10 consists of 20x40 modular building that meets Class 7 clean-room construction requirements for wall, ceiling, and HEPA filters. GMP attire is required to enter Filling and Assembly areas. GMP Gowning area is adjacent to FR-1. Walls are embossed with steel pre-painted white panels, floors are covered with epoxy coating and the roof consists of 22-gauge, galvanized steel inter-nesting pans as a dust cover with closure fascia. The Filling room is equipped with many filling and labeling machines that can accommodate semi-solid/solid dosage filling/assembly in tubes, bottles, stick, and other formats. This room meets ISO Class 7.

Lot codes are printed either by using laser etched printer or inkjet printer.

Rooms are kept under positive pressure *(+0.01 In.w.g*) to limit contaminants from general plant side.

All filling equipment is validated (IQ/OQ) with process validations in place for respective manufacturing of various products. This equipment is NOT shared with industrial grade products.



(b) Pre-Weighing and Kitting process for Bulk cosmetic and drug prodcuts

Site operates a GMP controlled Class 7 Clean room for Pre-weigh (Kits) preparations for bulk cosmetics or topical drug products. Kits are prepared and provided to production that is carried out at Romeoville, IL site via RMC-01 sheets. The container closure system included new or multiple use drums and pails. Multiple use containers/closures are used with single use liner. There are dedicated areas for prepared kits and returned kits containers.

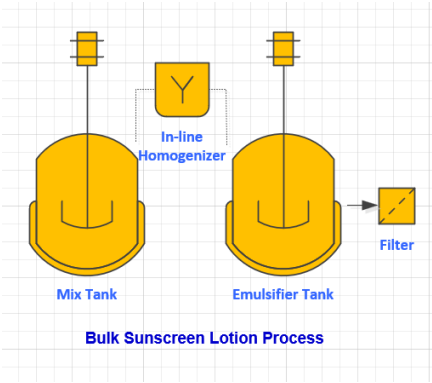
(c) Pre-Weighing and Kitting process for Bulk cosmetic and drug prodcuts

Site operates a GMP controlled Class 7 Clean room for Pre-weigh (Kits) preparations for bulk cosmetics or topical drug products. Kits are prepared and provided to production that is carried out at Romeoville, IL site via RMC-01 sheets. The container closure system included new or multiple use drums and pails. Multiple use container/closures are used with single use liner. There are dedicated areas for prepared kits and returned kits containers

(d) White Label Lotion process (bulk sunscreen manufacturing)

In early 2025, work begins to install dedicated bulk lotion manufacturing and dispersion manufacturing suites.

There are total of 6 suites dedicated to various bulk manufacturing processes ranging from small to large capacity tanks. Each suite is physically separated by walls. Compressor and chillers are kept in the middle room that supply utilities to 6 suits.



Office and lab areas maintained by one rooftop units to provide comfort heating and cooling (MERV 9). Upon completion, Filling areas will be serviced by individual air handlers equipped with HEPA filter, positive pressure currently at >0.01 inches of water). Each room is fitted with a 3T of electric heating and cooling. Packaging Assembly area is similar to warehouse space with respect to heating/cooling. For Interim use, few soft wall rooms are added for F/A operations, until permanent hard wall F/A rooms are operational, (expected 2Q-2023)

Warehouse area is maintained by 2 air handlers (with internal gas powdered heating).

SOP MFG-02-021 is used to address HVAC Filter Monitoring and Change schedule.

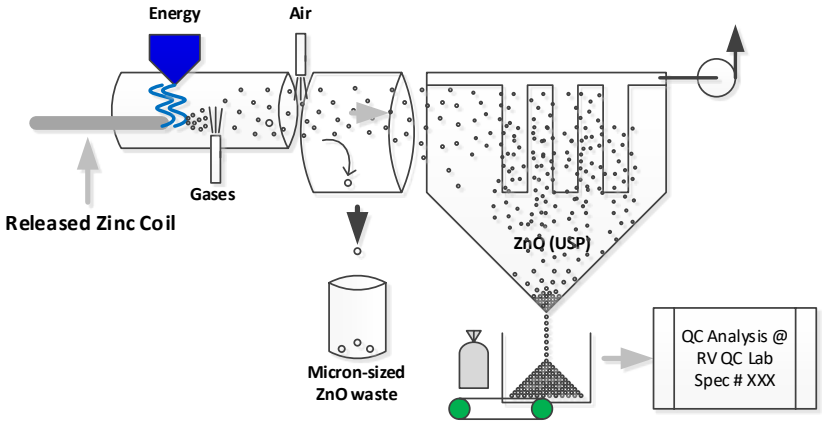
(e) PVS Reactors for Metal Oxide Powders (Api for sunscreen)

This site operates 8 PVS reactors, all reactors are dedicated for Zinc Oxide USP production. Additional reactors may be used to manufacture industrial grade Aluminum oxide. PVS production lines are located in south area of the plant, the Plasma Vapor Synthesis (PVS) method employ transferred and non-transferred electric arcs to vaporize precursor materials, which are then carefully condensed to produce metal oxides with desired properties. The PVS method has been used to produce both simple and complex, multi-component mixed metal oxides. PVS reactors are operated in a closed system fashion and do not allow generation of fugitive dust. Jet PVS process has been validated (IQ/OQ) with process validations in place for API manufacturing. PVS equipment for ZnO (USP) is not shared with industrial grade products.

FIG A- PVS Reactor

Plasma Vapor Synthesis @ Burr Ridge, IL

FDA Registration# 3001451638



Example of Lot number scheme

EHQD1501

EH = Product designator

Q = 2017, 04= April, 15 = date

01 is a sequential batch number

Year: 2001 = A

Zinc oxide is produced as nano and non-nano sizes and it is marketed by customers as uncoated or surface treated API. Surface treatment processes are operated at Solésence/Nanophase Romeoville site and at FDA registered contract manufacturer. Surface treated Zinc Oxide is also used as an API for Solésence brand white label sunscreens and API ingredients. A Material Flow diagram, illustrating grouping of PVS as unit Cell with flow of materials is shown as Appendix 7.

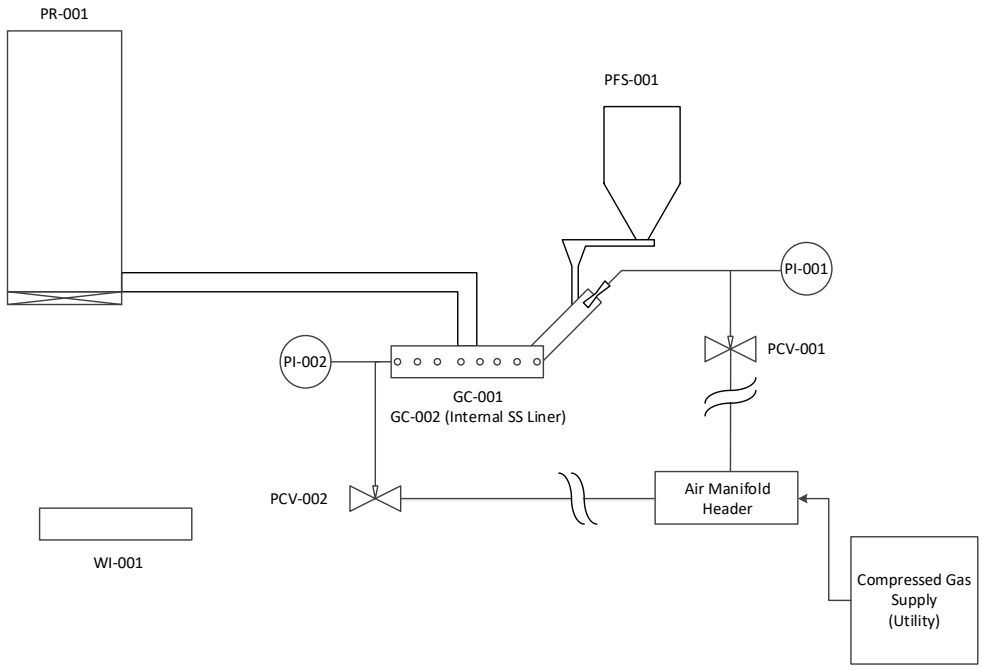
(f) Post Processing-Jet Milling process

Powder is fed to the hopper of feeder to initially set up the desired feed rate (kg/hr). Once the feed rate is established, powder is feed to jet mill through Hopper in continuous fashion, at a given **feed pressure** and **grind pressure** connected to air compressor are considered critical to mill the powder to obtain a desired particle size. Jet milled particles are carried to the product receiver (dedicated filer bag) and collected in an HDPE drum via continuous discharge from the product receiver in a closed system. Care is taken to avoid contamination during loading of powder into

Hooper, other parts of this jet mill equipment operated under closed system. A lot is completed when nominal amount of FG has been collected.

FIG C- 8-inch Jet Mill set up

Jet Milling process has been validated (IQ/OQ) with process validations in place for API manufacturing. This equipment is not shared with industrial grade products.



(g) Blending and Sifting

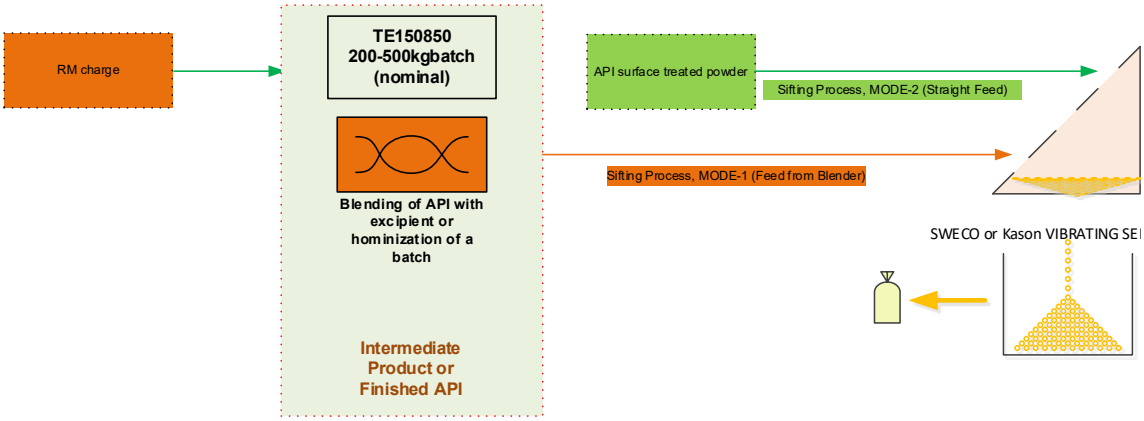
The blending process employed to further assure consistency and uniformity of a batch or to homogenize the multi-component system for a desired wt.% loading. Blender is used for both post processing activities and a step during production of a API batch.

JAYGO PADDLE BLENDER (71 cf) is installed with PVS area of the plant on a mezzanine. Powder is loaded via hopper from the top of the blender. Jaygo blender contact surfaces are made of stainless steel and all contact seals are made with food materials. Almost all products blended are passed through either Kason or Sweco sifter before packaging or use.

KASON or SWECO VIBROSCREEN is designed to separate different sizes of particles in an ensemble by utilizing one or more screens with a well-defined openings. These devices are used in conjunction with blending product schemes or straight feed fashion for separation of particles for a specific specification.

Blending/Sifting equipment and processes have been validated (IQ/OQ) and use for API, cosmetic, and food contact ingredients and manufacturing. This equipment is not shared with industrial grade products.

FIG D- Example of Use of Blender & Sifter for an API



Water systems for PVS Process

A USP Water system is planned for installation in 2023-24. USP water for use in formulation is brough ion from Romeoville site in FDA approved poly drums.

Steam, compressed air, compressed gases for PVS Process

Process areas are available with Air compressor that is considered oilless type (controlled via filtration), compressed air can be used in key steps of filling operation, for example cleaning of bottle before fill.

4.2 Equipment

All Manufacturing equipment is selected based on the application type, business demand, and any regulatory constraints. The table below illustrates the type of equipment related to each core process.

Equipment and Material flow diagrams are included under Appendix 7 or in section 4.1..

Equipment types and uses based on core processes are shown in Appendix 8.

The Quality Control laboratory and Microbiology Laboratory is equipped with many instruments to facilitate in-house testing of raw materials, in-process and finished products and analyses of R&D formulations. Compendial testing is performed by Quality Control per USP methods.

Instruments currently selected for use in QC laboratory are listed below.

- X-ray Florescence, *energy dispersive* (EDXRF)-*Validation is in process*
- Fourier-transform infrared spectroscopy (FTIR)-*Validated*
- Rapid Micro, based on ATP, Charles River
- Various Incubators, microscopes, and associated lab hoods to support USP 60, USP 61, USP 62, and RMM microbial testing.

4.3 Cleaning and sanitation

Equipment used in production is cleaned manually with validated cleaning methods. Equipment are used for non-sterile applications only. Cleaning Acceptance criteria is based on MAC calculation and are specific to product grouping and/or equipment type.

QA-125 General Cleaning and Housekeeping for Production Facility and Equipment outlines the general requirement. Equipment cleaning is performed according to their specific cleaning SOP or MBR. Equipment cleanings are verified on MBR or on QC forms and status of cleaning is posted on the equipment.

A metered approved soap/city water solution station provides consistent chemistry to mop water. An active Pest Control program is followed via SOP, MFG-05-510 Pest Control, pest control inspections are performed on monthly basis.

Line Clearance procedure and inspections are outlined in associated Master Batch Record, which is designed and intended to control cross contamination and mix-up of products and materials. Manufacturing, formulations, and processes do not use or intentionally add any allergens, such as, penicillin and peanut.

4.4 Critical computerized systems

None present, expect some equipment are semi driven by PLC. The PLC is not intended to replace the required elements for MBR, which is paper based.

5.0 DOCUMENTATION

5.1 Paper vs Electronic

To follow up with the FDA recommendation (5.10.1 (II), Nanophase has reviewed cGMP regulation to determine records required under predicate rule of 21 CFR Part 210 and 211. **TABLE 1** is used to show the list of Predicate and non-predicate records that are used by Nanophase QMS. Table 1 documents the applicability of records that must comply with 21 CFR Part 11 when used electronically.

TABLE 1

Review and Determination of data/records for 21 CFR Part11 compliance

Record Name	*Predicate Rule? (per 211, subpart J)	Regulatory Reference	Record Format	Compliance to "CFR Part 11" Required?
Training Records	**No**	**211.25**	**Electronic**	**Yes**
Standard Operating Procedures (SOP)	**No**	**211.25**	**Electronic**	**Yes**
Equipment cleaning and use log, including maintenance	Yes	211.182	Paper	No
Component, drug product container, closure, and labeling records	Yes	211.184	Paper	No
Master production and control records	Yes	211.186	Paper	No
Batch production and control records	Yes	211.188	Paper	No
Production record review	Yes	211.192	Paper	No
Laboratory records	Yes	211.194	Paper	No
Distribution records	Yes	211.196	Paper	No
Complaint files	Yes	211.208	Paper	No

*A predicate rule is FDA regulation that requires companies to maintain certain records and submit information to the agency as part of compliance. For example, 211.180 of 21 CFR Part 211 (subpar J) lists records requirements that are considered Predicate Record.

5.2

In March 2021, Solesence started a process to migrate from paper to electronic document systems including Qx (QMS) and Mx (eBR). SOP and Trainings and Calibrations are electronic based. Deviations reports with eBR implementation is underway and it is anticipated that the project will be completed by mid-2026. Solesence has selected Dot Compliance as eQMS solutions which interfaces with its ERP in real time under Salesforce platform.

Documentation Scheme

A formalized SOP, **QP-421** is used to outline the system for the complete documentation of all required procedures, records, logs, and instructions defining the quality management system, EH&S management system, production processes, and products: and assign responsibilities for establishing and maintaining the documentation.

The scope and extent of quality system documentation is determined on the basis of the complexity and interaction of processes, elements, and activities, and on competence of personnel. The documentation is sufficient to ensure effective planning, operation, and control of the quality and EH&S systems, processes, and products.

Documents related to this policy document include:

Documents are divided in several different categories based on their scope and their relation to specific operations function. Documentation categories of quality system are defined below.

Level 1, System and Policies Documents
This includes Level 1, System and Policies Documents and Operational or Quality and EH&S System Procedures

Level 2, Work Instructions and Departmental Procedures
This includes, Master Batch Records, QC Test Records, Process and EHS work instructions, and Departmental procedure

Level 3, Product realization and control plans
Documents under this category are the output of product realization and verification planning, as defined in Section 7.1 of the quality manual.

Level 4, Product specifications
Specifications are developed for raw materials, in-process, and finished products. Each specific product defines by a name and a specification number. Specifications are issued and authorized by QA Assurance

Level 5, External standards and reference documents
The company maintains a set of standards and other reference materials required to design and manufacture its products and to operate the quality and EH&S system. Quality Assurance maintains regulatory and quality standards. Examples, use of, US Pharmacopeia, ANSI Z.14 ISO 9001, ISO14001, etc.

6.0 PRODUCTION

6.1 Type of products

Currently site managers 1 core process to produce and finished sunscreens and storage of goods in integrated warehouse setting. Two processes are as follows.

- Finished Sunscreens (Packaged and assembled)

For sunscreen, the dosage form is Topical.

Solesence Inc. does not produce any drug products for oral and injectable use, nor a prescription drug is manufactured. Formulation are free from BSE/TSE and use of pestiside inside the facility is prohibited.

List of regulated products are shown in **Appendix 2.**

6.2 Process validation

Solesence, Inc. understands validation as, "a documented program which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes." To this end, validation of all processes, equipment and analytical methods becomes necessary.

The requirement of process validation is implicit in the language of 21 CFR 211.100 of the Current Good Manufacturing Practice regulations which states: "*There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess*."

The key element of validation program practiced by this site are outlined below.

- Validation Master Plan
- Validation Program
- Equipment validation (IQ/OQ) for API and drug process equipment
- Process validation for PQ for API and drug processes
- Method validation and/or Method suitability for relevant Physical, Chemical and Microbiology
- Instrument Validation (IQ/OQ/PQ)

All processing equipment new or used, when utilized for any regulated product, are validated (IQ/OQ) prior to commercial marketing of a regulated product. At least 3 commercial batches are used to perform Process validation related to API or drug product. In limited cases, process validation may include <3 batches due to business demand.

All validations protocols are issued and approved by QA, other approval, such as related R&D, Engineering, Manufacturing are part of the approval process. Validation schedule outlines the past and current protocol development and execution status. The status of validation activities is recorded and presented in each Management Review meeting on a quarterly basis.

6.3 Materials management and warehousing

/Nanophase Technologies Corporation, uses several SOP to manage and control of starting raw materials, packaging componants, bulk and finished products, including sampling, release, and storage.

An integrated warehouse manages storage and distribution of Raw Materials, WIP, and Finished Goods including functionality to support all Shipping and Receiving elements.

Receipt of Materials

Critical key purchased products are inspected by quality control. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available.

Designated products are further inspected or tested by QC. QC inspection or testing is not necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

Quality Assurance is responsible for selecting appropriate methods for purchased product verification and acceptance. Operational Procedure **QP-743**, Verification of Purchased Products, sets forward detailed rules for selecting product verification methods and for performing receiving and QC inspections.

When verification of purchased product is to be performed at supplier's premises, purchasing documents specify the intended verification arrangements and method of product release.

Inspection, Quarantine, Release

Following every inspection or test, products are identified to indicate whether they have passed or failed the inspection. This is to prevent nonconforming products from being used or dispatched. Physical location of product is only used as inspection status identification when the location is designated and contained.

QC inspectors and production personnel authorized to carry out inspections and testing are responsible for identifying product inspection status. All personnel handling products are responsible for maintaining the identification.

Products that have passed the receiving inspection are tagged in place to show their status. Detailed rules for identifying inspection status of purchased products are provided in procedure **QP-743** Verification of Purchased Products and **QA-070** Quarantine Control.

Status of an in-process inspection is usually identified by a sign-off in the batch record and/or in-process quality document. The status is also identified by tagging or labeling or holding products in designated containers. Operational procedure **QP-824**, In-process Inspections, provides more detailed instructions.

Final inspections of Nanophase Technologies Corporation products are carried out in conjunction with final inspection and testing and the applicable quality plans. The product is released only after evidence is available that all requirements of all applicable documents have been achieved. Controls ensure that all requirements are met before product is dispatched.

Rules for identifying inspection status of finished products are provided in procedure **QP-825**, Final Inspection.

Products that fail any inspections or tests are labeled with REJECTED sticker or tag and are segregated and/or quarantined. Whenever a nonconforming product is identified, the nonconformity is documented using a product nonconformity report. Procedure **QP-831**, Control of Nonconforming Product, instructs on how to identify and process nonconforming products.

Product in doubt is segregated using QUARANTINE, MRB QUARANTINE, or QC HOLD tag until final disposition or decision has been assigned.

7.0 QUALITY CONTROL (QC)

7.1 The quality and EHS management systems of the manufacturer

Solesence, Inc., practices an integrated QMS based on ISO 9001, ISO 22716, and FDA cGMP requirements. EHS elements based on ISO14001, EPA, OSHA and DOT are merged in a singular set of requirements, and many elements are shared with QMS.

Solesence LLC, formerly was wholly owned subsidiary of Nanophase Technologies, company formally changes its name to Solesence, Inc in March 2025, all FDA listings have been updated with Solesence, Inc name.

In addition, Quality and EHS management systems are designed to be integral part of daily operations allowing seamless integration with routine business.

- A detailed Quality Management System is documented in QSM-000
- A detailed Environmental, Health, and Safety management system is documented in EHS-000

Key regulatory/statutory along with voluntary elements are outlined below.

Regulatory Elements (mandatory in nature)

- ❑ FDA – Food and Drug Administration, *Registered since 2001*
- ❑ EPA – Environmental Protection Agency (Air, Water, Land, TSCA)
- ❑ OSHA – Occupational Health and Safety (workplace safety)
- ❑ DOT – Department of Transportation (shipments)
- ❑ IEMA – Radiation Safety (X-ray instruments)
- ❑ ECHA – REACH (EU- import/manufacturing of chemicals)
- ❑ REACH- European Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals

Voluntary Elements (proactive in nature)

- ❑ ISO 9001-2015 *Registered since 1997, Recertification, 2026*
- ❑ ISO 14001-2015 *Registered since 2006, Recertification, 2026*
- ❑ ISO 22716-2007 *Registered since 2022, Recertification, 2025*
- ❑ Nanotechnology Standardization Initiatives (ASTM, ANSI, NMSP etc.), *active voting member since 2006*
- ❑ Implementation of advanced Industrial Hygiene (IH) tools for chemical exposure
- ❑ Implementation of advanced PPE at workplace
- ❑ Active member of PCPC

Activities on site (QC Inspection and Testing)

Quality Control/ Quality Assurance is solely responsible for inspection, release, and rejection as related to product and processes. QC/QA operates a QC laboratory that is capable of performing all in-process and finished products per established specification. An onsite lab at Romeoville site is equipment with various analytical instruments/tools to facilitate physical and chemical-based testing of products.

Limited number of activities related to testing Raw Materials and FG are executed in Bolingbrook QC Lab.

An onsite stability study function located at Romeoville site housed several stability chambers to facilitate stability studies of products under Accelerated and Long-term storage conditions (RT

study), the data from stability study is used to establish either the Expiry date or Retest date as relevant to a product type.

Microbial testing is performed at in-house Micro Lab or at FDA registered approved laboratory that is experienced and qualified to perform many microbial tests protocol including but not limited to Rapid Micro Method (USP 1071), USP<60>, USP <61>, USP<62>, USP <51>. Microbial suitability study is an integral part of all microbial testing.

8.0 DISTRIBUTION, COMPLAINTS, PRODUCT DEFECTS AND RECALLS

8.1 Distribution

Solésence, Inc. stores and distribute large quantity bulk API and finished products products from on-site wharehouse. Solesence, Inc. lease area that is caged and secured with access limited to Solesence, Inc. employees only. Warehouse is integreted within the Bolingbrook site and covers 34,000 SF with pest control management program mangaed by third party provider.

Shipping and Receiving activities are limited to this site only.

Products at this location are stored at ambient conditions with temperature and humidity are recorded but not controlled.

Storage areas are maintained in good condition to prevent damage or deterioration of stored products. All products in storage areas are identified and arranged in groups according to their type. Inventory levels of stock are monitored by Rootstock MRP software. In most cases, products are stored on heat treated wood or plastic pallet on floors and racks. Solésence, Inc. practices FIFO system for lot selection.

Products are shipped based on customer selection (as indicated by the written agreement) or Solésence, Inc. prefffered carriers. Shipments mode includes, Air, Sea, and ground via LTL and FTL. Small orders and samples are normally shipped via FedEx, DHL, or UPS. Reference MFG-04-080.

Solésence, Inc. employs trained and certified personnel for supporting Air, Sea, and Ground shipment of both non-hazarous and hazardous types.

Product names, customer informtion, PO number, Lot numbers and other informtion is listed on shipping documents, such as Packaging Slip, Bill of Lading etc. A copy of SDS and COA is provided with each shipment, as applicable.

Orders are inspected and released for shipping by following SOP QA-151, *Finished Products Inspection and Release for Shipping*. Only orders that have been verified and signed off by the QA can be released for shipment. Release of orders for shipment is evidenced by a sign-off on QA-151 form.

Unless required by the customer, placement of more than one lot or batch is not allowed on a single pallet or in a single container.

8.2 Complaints, product defects and recalls

Complaints

Customer Service department is responsible for receiving and processing customer feedback and complaints. All received customer communication is recorded in the customer feedback and complaints log.

Customer feedback and complaints are classified into categories to allow for better tracking of trends and evaluating improvement in specific aspects. Every complaint is communicated to relevant functions within and outside the organization. Customer Service, the department responsible, and Quality Assurance, decide how to respond to the customer and, when appropriate, what corrective or preventive actions are implemented internally.

Procedure **QP-723,** Customer Feedback and Complaints, provides detailed instructions on how to receive, process, and respond to customer feedback and complaints.

Out of Specification Investigation (OOS)

Non- conformity due to specification is investigated by following cGMP requirements. Procedural details are defined in Operational procedure **QA-385** OOS Results.

Deviation Reports (OOS)

Deviation reporting process applies to all steps and phases of production, packaging, labeling, sampling, and Quality Control testing. To be used when any deviation from the normal operating procedure has occurred or is planned, either by mistake, planned act, equipment failure, etc., with or without prior approval. Deviations are recorded and approved on **QA-190A** and logged on **QA- 190B**.

Product returns and recalls

When product nonconformity is detected by the customer after delivery or use has started, the customer may be instructed to return the product, or a part, on a return authorization number issued by customer service. When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed about what to do with the product. In situations when the nonconformity creates a safety or other hazard, the product is recalled. Only the President of the company is authorized to make recall decisions. All returns are processed according to **NTC-050**, whereas **QA-211** is used to handle recall issues.

Nonconforming Products (NCR)

QC staff, Engineering, R&D and Production personnel are responsible for identifying nonconforming products or situations in the course of their normal work activities. In addition, all other personnel are encouraged to watch for, and identify, nonconforming events and products, regardless of their other responsibilities. Nonconforming IP and intermediate products are placed in Quarantine in MRP until a disposition is determined. Not all IP products are regarded or scraped by completing **QP-831A** form, due to the complexity of the use but the decision is made jointly with QA based on the testing and/or use in other processes. API intermediates require initiation of **QP-831A**.

9.0 SELF INSPECTION (INTERNAL AUDITS)

10.1 The Quality Director or assignees is responsible for planning and scheduling the internal audits. Each main activity comprising the quality and environmental management systems is audited at least once every two (2) years. ISO 9001 and 14001 audits are scheduled based on previous audit results as determined by the score for the audit. **Audit scores** are calculated from the number of concerns and nonconformances found during the audit (of concerns + [2 X # of nonconformances]). Audit(s) with a score of 5 and above are given priority in the next audit period. Process and cGMP audits are conducted annually. EH&S audits are conducted based on operations schedule. Reference **SOP QP-822, Internal Audits.**

Planning and scheduling

The Quality Director establishes an internal audit plan and schedule in accordance with Procedure **QP-822**, Internal Quality Audits. Every activity and area are audited as required by the procedure. Selected activities are audited more frequently, depending on their importance and quality performance history.

Audit team and preparation for audit

Only personnel independent of the audited activities are assigned to conduct internal audits. Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Selection of auditors and preparation for the audit are explained in Procedure **QP-822**, Internal Quality Audits.

Conducting the audit

Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

Nonconforming conditions are documented and recorded using the audit findings report form. A model of the form and instructions on how to use it are provided in Procedure **QP-822.**

Audits are conducted in a way that minimizes disruption of the audited activities.

Corrective action and follow up

When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to implement corrective action. Implementation and effectiveness of the action are verified by a follow-up audit. The CAPA form (**QP-852A**) is used for monitoring and recording the implementation of corrective actions.

Reporting

All finding reports established during the audit are compiled and analyzed, and a summary is presented at the management review meeting.

Appendix 1
Copy of valid manufacturing authorization

"Nonavailable or applicable in USA" Sites are registered with FDA for API, OTC drugs and Cosmetics (MoCRA)for Topical human use.

Appendix 2

List of products Manufactured

Scope of Manufacturing Processes Solésence, Inc.			
Manufacturing Site	**Operation**	**Drug Products**	**Notes**
Bolingbrook	Sunscreen Lotion Filling, Packaging and Assembly as Finished Goods	+100 products (see validation list)	Semi-automated at time of US FDA audit. Fully automated line being installed as noted in audit.
Bolingbrook	Sunscreen Bulk Lotion, Manufacturing	+10 products	In process, completion by late 2026. Wen complete will house all bulk prodcuts and dispersions +150 planned.
Bolingbrook	Sunscreen Stick Filling, Packaging and Assembly as Finished Goods	+10 products	Hot pour/hot fill
Bolingbrook	Sunscreen Powder Filling, Packaging and Assembly as Finished Goods	+10 products	Powder fill
Bolingbrook	Process 620 is designed for preparing cold-processed emulsions for personal care products.	+25 products	Lotion Manufacturing-Date implemented January 17, 2024
Bolingbrook	Warehouse Storage of Raw Materials, WIP, and Finished Good Shipping and Receiving 1. Scales 2. Forklift 3. Shrink wrapper. 4. Pallet Jacks	All products and RM used	44,000 SF NOTE: Hazardous and flammable chemicals are not stored in warehouse. The warehouse is equipped with security cameras and an alarm system with restricted entry only. Pest Control is installed and monitored. Temperature and humidity are monitored.
Bolingbrook	Laboratory Operations 1. QC-Phy/Chem Lab 2. QC- Microbiology Lab	All products and RM used	Raw Materials and Finished Good testing is performed in-house Microbiology is performed in-house.

Appendix 3

Copy of valid GMP certificate (if applicable)

ISO 22716 has been implemented.

Appendix 4

List of contract manufacturers and laboratories

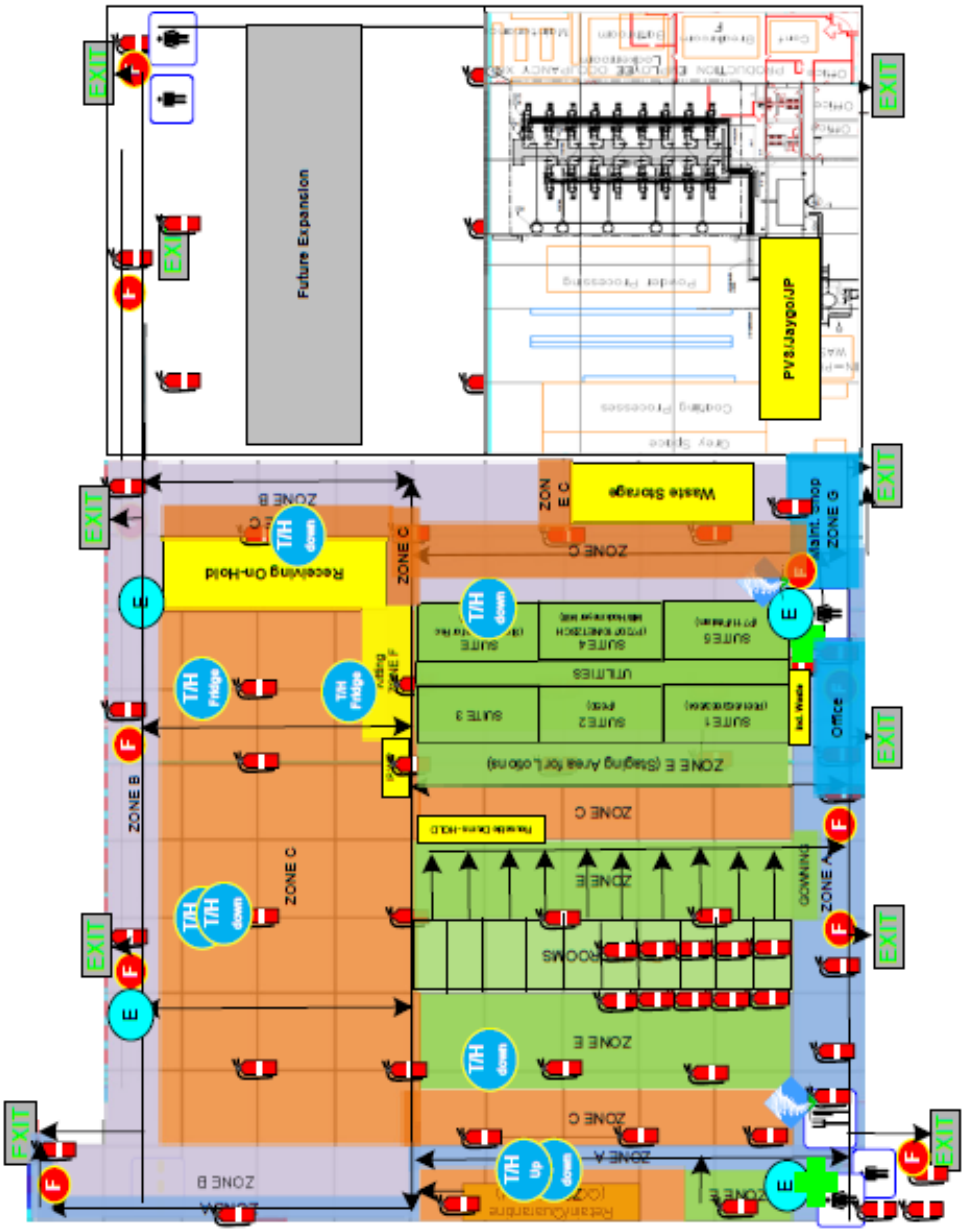
Business Name	Address	Contact Information	Type of Service	FDA Registered?
Amcol Health & Beauty Solutions, Inc. (MTI)	301 Laser Ln Lafayette, LA 70507	337-354-1061 Fax: 337-354-1055 www.amcolhpc.com	API Manufacturing	Yes
MPL Laboratories	12 Wilson Drive, Sparta, NJ, 07871	(973) 300-9715, 1-800-548-1874, Fax: (973) 300-9830 pgriffin@mpllaboratories.com	Microbial Testing	Yes
Accugen Laboratories, Inc.	2121 W. Army Trail Road, Addison, IL 60101	800-282-7102 Fax: 630-812-2219 info@accugenlabs.com	Microbial Testing	Yes
Florida Skincare Testing	101 N Bay St, Bunnell, FL 32110	(386) 492-2959	SPF Testing UVA Testing (Primary)	Yes
CPT Labs	70 New Dutch Lane, Fairfield, NJ 07004	(973) 957-3250	HET-CAM Testing Toxicological Assessments Phototoxicity testing	Yes
Essex Testing Clinic	799 Bloomfield Avenue, Verona NJ 07044	(973) 857-9541	HRIPT Testing Phototoxicity testing	Yes
Eurofins CRL	371 Hoes Ln #100, Piscataway, NJ 08854	(732) 981-1616	Phototoxicity testing Comedogenicity Testing SPF and UVA Testing	Yes
Bioscreen	3904 Del Amo Blvd Suite 801 Torrance, CA 90503	(310) 214-0043	Moisturization testing HRIPT testing SPF testing	Yes
Cantor Research Labs	630 Route 303 Blauvelt, NY 10913	(845) 727-4100	SPF and UVA Testing (recently qualified) Comedogenicity Testing	Yes

Appendix 5 (subject to change)

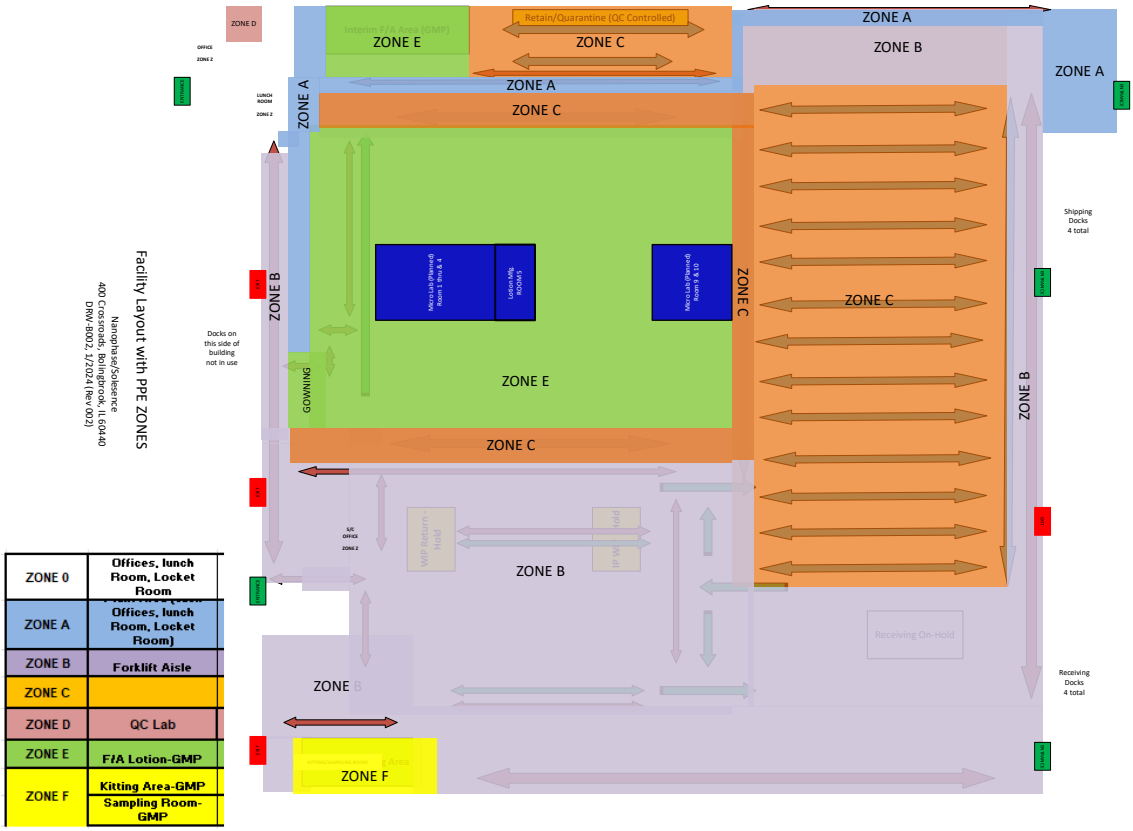
Included as a separate Attachment

Appendix 6a

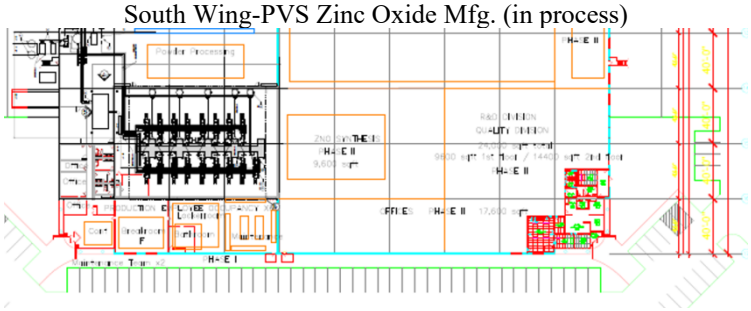
(note F/A Rooms 1-8 and 9&10 used as Chem/ Micro Labs, 6 suits for Bulk Lotions/Dispersions, and 8 PVS reactors for Zinc Oxide API)



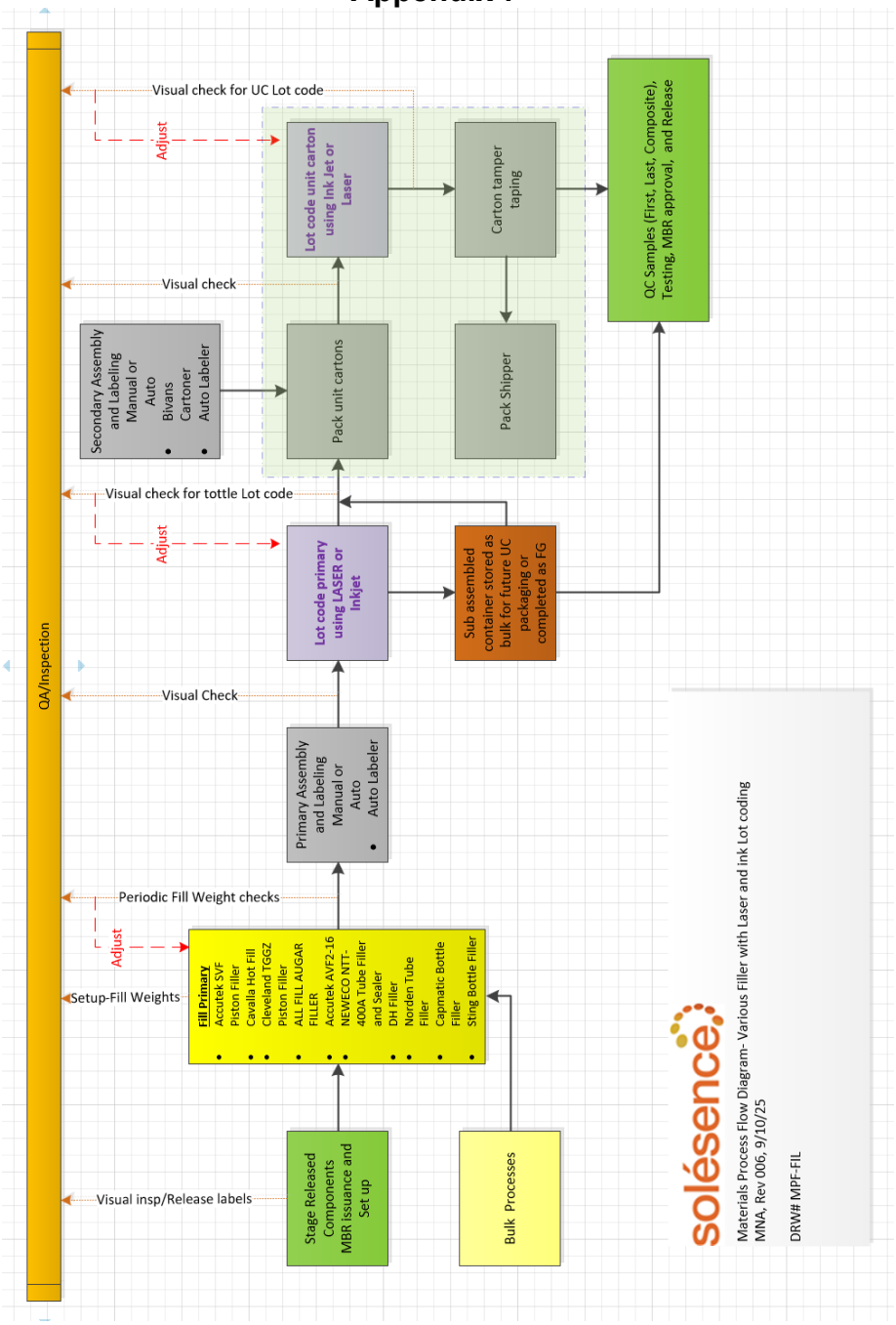
Appendix 6b



South Wing-PVS Zinc Oxide Mfg. (in process)



Appendix 7


QA/Inspection
Visual check for UC Lot code
Adjust
Lot code unit carton using Ink Jet or Laser
Carton tamper taping
QC Samples (First, Last, Composite), Testing, MBR approval, and Release
Visual check
Secondary Assembly and Labeling Manual or Auto Bivans Cartoner Auto Labeler
Pack unit cartons
Pack Shipper
Visual check for tottle Lot code
Adjust
Lot code primary using LASER or Inkjet
Sub assembled container stored as bulk for future UC packaging or completed as FG
Visual Check
Primary Assembly and Labeling Manual or Auto Auto Labeler
Periodic Fill Weight checks
Adjust
Setup-Fill Weights
Fill Primary
Accutek SVF Piston Filler
Cavalla Hot Fill Cleveland TGGZ Piston Filler
ALL FILL AUGAR FILLER
Accutek AVF2-16 NEWECO NTT-400A Tube Filler and Sealer
DH Filler Norden Tube Filler
Capmatic Bottle Filler
Sting Bottle Filler
Visual insp/Release labels
Stage Released Components MBR Issuance and Set up
Bulk Processes
solésence
Materials Process Flow Diagram- Various Filler with Laser and ink Lot coding
MNA, Rev 006, 9/10/25
DRW# MPF-FIL

Appendix 8

Core Process	Equipment/ Process Name		Intended Purpose	Contact Surfaces / Type	Sterile (Y/N)
Filling & Assembly	801	Small single-head piston filling operation	Finished Sunscreen packaging per Customer package	Stainless steel, plastic Semi-automated, Automatic Filling equipment for packaging bottles, tube, stick, and other forms.	N
	802	BS-G450 heat shrink operation			
	805	ALL-FILL Auger Filler			
	806	Accutek AVF-16 filler			
	807	Neweco NTT-400 tube filler			
	808	Cavalla 30-L Hot-Filling Unit			
	809	Small dual-head piston filling operation			
	810	Norden NM702HA			
	811	Capmatic Bottle Filler-Automated			
	812	Sting Bottle Filler-Automated			
	813	Cavalla-Large Hot-Filling Unit			
	814	All Fill- Powder Filler			
Lotion Manufacturing	Vary	Partially in place. In-process for completion by Late 2026	Bulk Sunscreen	Stainless steel, jacketed tanks, mixers, pumps, hoses, and in-line homogenizer	N

Appendix 9

Listed below is the FDA Audit History, dated 2002-current. Also included is the Firm Drug Establishment Identification (FEI) for Burr Ridge (not in service), Bolingbrook, and Romeoville site.

Date of FDA Audit	Number of Observations listed on 483 Site: Romeoville Site FEI#: 3003574860 Registration Status: Current for 2023 **Product Manufactured:** Surface treated API, API dispersions, White label Sunscreens, packaging, and assembly of Sunscreen FG --- **Equipment Used:** PK-100 and LD-600 are used primarily for surface treatment of zinc oxide and titanium dioxide. Dispersions/Lotions lines and packaging equipment are used for white label and FG Sunscreens.		Number of Observations listed on 483 Site: Burr Ridge FEI#: 3001451638 Registration Status: Current for 2023 **Product Manufactured:** Zinc Oxide (USP) Various Surface treatment API powders Sifting and blending processes --- **Equipment Used**: Dedicated PVS reactors for Zinc Oxide (USP) manufacturing only. Various powder processing/treatment equipment including Jet Mill, Jaygo blender, and Kason/Sweco Sifters.		Number of Observations listed on 483 Site: Bolingbrook FEI#: 3003574860 Registration Status: Current for 2023 **Product Manufactured:** Filling and Assembly of Sunscreens FG and Warehousing --- **Equipment Used**: Bottle Filler, Tube Filler, Powder Fillers, Laser and Ink Jet Labeling machines, Cartoners, Capers etc. Date of Operation: Jan 2023	
	NCR (483)	**FDA Classification**	**NCR (483)**	**FDA Classification**	**NCR (483)**	**FDA Classification**
7/24/2002	1	VAI	0	NAI		
2/09/2006	0	NAI	0	NAI		
9/28/2009	2	VAI	1	VAI		
11/16/2011	0	NAI	Not audited			
5/2/2013	Not audited		0	NAI		
9/3/14-9/10/14	2	VAI	0	NAI		
11/28-11/30/18	Not audited		0	NAI		
6/4-6/7/19	0	NAI	Not audited			
5/31-6/13/23	2	VAI	Not audited		0	VAI
1/6-1/9/26	1	VAI	Site no longer in operations		1	VAI
Total NCR to date (2002-present)	**8**		1		**1**	

NAI = No Action Indicated (means, no objectionable conditions or practices were found during the inspection)
VAI = Voluntary Action Indicated (means objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action)
OAI = Official Action Indicated (means regulatory and/or administrative actions will be recommended)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Candice Glickstern	QA and Regulatory Specialist	12-May-2026 16:06
Review	QA (Nadir Ali)	Director Quality Assurance & Regulatory Compliance	12-May-2026 16:44
Send for Approval	Nadir Ali	Director Quality Assurance & Regulatory Compliance	12-May-2026 16:49
Approve	QA Management (Nadir Ali)	Director Quality Assurance & Regulatory Compliance	12-May-2026 16:49
QA Approval	Nadir Ali	Director Quality Assurance & Regulatory Compliance	12-May-2026 16:50
Sign Training Completion	Candice Glickstern	QA and Regulatory Specialist	12-May-2026 16:54

* Dates are displayed according to the system time zone: (GMT-05:00) Acre Standard Time (America/Eirunepe)