



Comprehensive Guide for Transitioning from Manual to Semi-Automated Visual Inspection (SAVI)

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Date: February 19, 2026

Document Version: 1.0

1.0 Purpose and Scope

This document provides a comprehensive, general-purpose framework for transitioning a pharmaceutical product's 100% visual inspection process from a fully manual method (MVI) to a semi-automated method (SAVI). The guidance is intended for quality assurance professionals, validation engineers, and inspection supervisors who are planning or executing this transition. It is grounded in established regulatory expectations and industry best practices from the U.S. Food and Drug Administration (FDA), the European Commission's GMP Annex 1, the United States Pharmacopeia (USP), and leading industry bodies such as the Parenteral Drug Association (PDA) and the European Compliance Academy (ECA).

This guide addresses the following critical questions in detail:

- 1 What studies are required to establish a manual inspection baseline?
 - 2 How many inspection cycles are needed for a Knapp study, and why?
 - 3 If a Knapp study was already conducted for a fully automated (AVI) transition, can it be reused for SAVI?
 - 4 What specific testing and validation activities are required to qualify the SAVI process?
 - 5 What are the numerical acceptance criteria at each stage?
 - 6 What routine monitoring is required after the transition is complete?
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2.0 Key Definitions

Term	Abbreviation	Definition
Manual Visual Inspection	MVI	A process in which a human inspector manually picks up, rotates, and inspects each container against black and white backgrounds under controlled lighting conditions.
Semi-Automated Visual Inspection	SAVI	A process in which a machine automates the handling and presentation of containers (spinning, transport, lighting) while a human operator makes the accept/reject decision. [1]
Automated Visual Inspection	AVI	A fully automated process in which cameras and machine vision algorithms detect defects and automatically reject non-conforming units without human judgment.
Probability of Detection	PoD	The statistical likelihood that a specific defect in a specific container will be detected in a single inspection event, expressed as a value from 0.00 to 1.00. [2]
Reject Zone Efficiency	RZE	The average PoD across all containers classified in the Reject Zone ($PoD \geq 0.70$). This is the primary metric for comparing inspection methods. [2]
Knapp Study	—	A structured, statistically rigorous study methodology, originally developed by Knapp and Kushner (1980), used to determine the PoD of individual containers through repeated manual inspections and to compare the performance of an alternative inspection method against the manual baseline. [2] [3]
Threshold Study	—	A study to determine the detection capability (process capability) of the manual inspection process under routine conditions. Per USP <1790>, this is a required element of inspection qualification. [4]
Acceptable Quality Limit	AQL	The maximum percentage of defective units in a batch that is considered acceptable for release, used in statistical sampling plans per ISO 2859-1.

3.0 The Core Principle: Manual Baseline as the Gold Standard

Before any transition to a semi-automated or automated process can occur, a robust and statistically significant baseline of the existing manual visual inspection process must be established. This manual process, performed by qualified human inspectors under controlled conditions, serves as the **gold standard** against which any new inspection system is measured. The fundamental acceptance criterion, stated consistently across all major regulatory and industry guidance documents, is that the performance of the new system must be **equal to or better than** the established MVI baseline [1] [5] [6].

The FDA's 2021 Draft Guidance for Industry states that automated inspection machines should be "validated to meet or surpass human inspection capabilities" [1]. For SAVI systems specifically, the FDA requires that equipment be "properly calibrated and qualified at a specific vial-spin and belt speed" and that "lighting should also be qualified to allow for accurate human detection of defective products" [1]. The ECA Q&A on semi-automated inspection confirms that "qualified employees for manual control must be available" before the SAVI process can be qualified, and that the same principle applies whether qualifying a SAVI or AVI system [5].

The PDA D/A/CH Chapter Webinar (2025) summarizes this principle succinctly: "Operator qualification for MVI is the foundation for the inspection of containers at each site" and serves as "a standard to qualify semi-automated and automated inspection" [6].

4.0 Reusability of Knapp Studies: The AVI-to-SAVI Scenario

A common and critical question arises when a manufacturer originally planned to transition from MVI to AVI, conducted a Knapp study to establish the manual baseline and compare it against the AVI machine, but subsequently decided to implement SAVI instead. The question is: **can the existing Knapp study data be leveraged, or must the entire study be repeated?**

The answer is nuanced, and understanding it requires recognizing that a Knapp study consists of two distinct components.

4.1 Component 1: The Manual Baseline (Reusable)

The first component of any Knapp study is the repeated manual inspection of the test set by qualified human inspectors. This generates the PoD for each container and establishes the zone classifications (Reject, Grey, Accept). This data defines the **inherent capability of your manual inspection process** for a given product, container type, and defect population. It is entirely independent of whatever technology (AVI or SAVI) is subsequently compared against it.

The ECA's guidance on test sets confirms that "a qualification set is used for the qualification of manual (MVI) and semi-automatic (SAVI) visual inspection staff as well as for the qualification of a fully automatic machine (AVI)" [7]. This explicitly establishes that the same qualification set, and by extension the same manual baseline data generated from it, is applicable across all three inspection modalities.

Therefore, the manual baseline portion of your AVI Knapp study is fully reusable for SAVI qualification, provided that:

- 7 The test set has not degraded or been modified since the original study (test sets should be verified every 6-12 months) [7].
- 8 The manual inspection conditions (lighting, background, inspection time, inspector qualifications) have not materially changed.
- 9 The product, container type, and defect population remain representative.

4.2 Component 2: The Machine/Process Comparison (NOT Reusable)

The second component of the Knapp study is the challenge of the alternative inspection method (AVI or SAVI) with the same test set. For an AVI study, this involves running the test set through the automated machine multiple times and calculating the machine's PoD and RZE. This data is specific to the AVI machine, its vision recipe, and its camera/lighting configuration. It has **no applicability** to a SAVI system, which relies on a fundamentally different detection mechanism: a human operator aided by automated material handling.

Therefore, the AVI machine comparison data cannot be used for SAVI qualification. You must conduct a new set of qualification runs on the SAVI system with its operators.

4.3 Summary: What You Save and What You Must Redo

Knapp Study Component	Reusable for SAVI?	Rationale
Manual baseline PoD data (zone classifications)	Yes	Defines the gold standard independent of the comparison technology. Same qualification set is used for MVI, SAVI, and AVI. [7]
Manual baseline RZE calculation	Yes	The RZE benchmark is the acceptance criterion for any new method.
Test set (physical Knapp Kit)	Yes	Same kit can be reused if verified and QA-approved. Must be checked every 6-12 months. [7]
AVI machine PoD/RZE data	No	Specific to the AVI machine and its vision recipe.
AVI machine false reject data	No	Specific to the AVI machine configuration.
SAVI operator qualification runs	Must be newly conducted	SAVI qualification is operator-centric; each operator must be independently qualified on the SAVI system. [6]

5.0 The Qualification Pathway: A Step-by-Step Guide

The transition from MVI to SAVI involves a structured, multi-stage qualification process. The following sections detail each stage, including the required studies, the number of cycles, and the acceptance criteria with numerical examples.

5.1 Stage 1: Establishing the Manual Inspection Baseline (Threshold/Knapp Study)

The first and most critical stage is to quantify the capability of the current manual inspection process. If this has already been completed (e.g., as part of a prior AVI qualification), and the conditions described in Section 4.1 are met, this stage can be bypassed.

5.1.1 Test Set (Knapp Kit) Composition

A dedicated test set must be prepared and approved by the Quality Assurance unit. The composition requirements are well-established across multiple guidance documents and are summarized below.

Parameter	Requirement	Source
Overall defect rate	10-20% of the total set should be defective; must not exceed 30%.	FDA [1], ECA [7]
Defect types included	Particulate (fibers, glass, metal, stopper fragments), non-particulate/cosmetic (cracks, scratches, missing stoppers, fill volume), and "good" defect-free units.	ECA [7]
Particle size range	50 μm to 1,000-2,000 μm , representing the full spectrum from the limit of visual detection to easily visible. For fibers, 50% should be $>1,000 \mu\text{m}$ and 50% $<1,000 \mu\text{m}$.	IPA [8]
Particle material types	Representative of production: stopper fragments, glass particles, metal, fibers, and other materials typical of the manufacturing process.	ECA [7]
Good units	80-90% of the total set must be defect-free containers.	ECA [7]
Blinding	All containers must be uniquely coded (numbered) and regularly re-blinded. UV markers alone are insufficient.	ECA [7]
QA approval	The test set must be formally approved by Quality Assurance before use.	FDA [1], ECA [7]
Maintenance	Sets must be cleaned after use and verified for integrity at least every 6-12 months. Degraded containers must be replaced.	ECA [7]

Numerical Example of Test Set Composition:

Consider a test set of **300 total containers** for a clear glass vial product:

Category	Number of Units	Percentage	Description
Particulate defects	30	10%	15 units with particles >500 µm, 15 units with particles <500 µm
Container/closure defects	15	5%	Cracks, scratches, missing stoppers, seal defects
Cosmetic defects	5	1.7%	Discoloration, labeling issues
Good (defect-free) units	250	83.3%	Containers with no defects
Total	300	100%	~17% defect rate

5.1.2 Study Execution: Number of Inspection Cycles Required

The number of inspection cycles is the most frequently asked question regarding the Knapp study. The answer depends on the desired statistical confidence, but industry consensus provides clear guidance.

The original Knapp and Kushner (1980) methodology established the principle of repeated inspections to develop a statistically reliable rejection probability for each container [2] [3]. The IPA Best Practices Document provides the most explicit numerical recommendation:

"A run of fifty inspections shall be performed by using five qualified inspectors, i.e., each qualified inspector should inspect the same kit 10 times in order to identify all the types of particulate defects." [8]

The PDA D/A/CH Chapter Webinar (2025) recommends **30-50 inspection runs** for threshold studies, noting that "less is possible, if justified" [6]. The ECA Best Practice Guide recommends a **minimum of 10 repetitions** of the test for PQ/validation of automated systems, which can be extended for additional confidence [9].

The following table summarizes the recommended number of cycles from various authoritative sources:

Source	Recommended Cycles	Configuration	Context
IPA Best Practices (2021)	50 total (5 inspectors x 10 each)	5 qualified inspectors, each inspects the full kit 10 times	Knapp Kit preparation and qualification [8]
PDA D/A/CH Webinar (2025)	30-50 (less if justified)	Threshold study under routine conditions	Baseline/threshold study [6]
ECA Best Practice Guide	Minimum 10 (up to 50 for confidence)	Repeated testing of qualification test sets	PQ/validation of inspection systems [9]
Melchore (2011), PMC	30-50	Multiple inspectors, repeated inspections	Sound practices for consistent human visual inspection [2]

Practical Recommendation: For a new Knapp study, the recommended approach is to use **5 qualified inspectors**, each performing **10 independent inspections** of the complete test set, yielding **50 total inspections per container**. This provides a PoD resolution of 2% (1/50) and generates a highly defensible dataset. If resource constraints exist, a minimum of **30 total inspections** (e.g., 3 inspectors x 10 runs, or 5 inspectors x 6 runs) is defensible with appropriate justification.

5.1.3 Data Analysis and Zone Classification (Detailed Numerical Example)

Once all inspection runs are complete, the PoD for each container is calculated and the container is classified into one of three zones.

Formula:

$$PoD (\text{Container } X) = (\text{Total number of times Container } X \text{ was rejected across all inspections}) / (\text{Total number of inspections})$$

Worked Example with 50 Inspections (5 inspectors x 10 runs each):

Container ID	Defect Type	Particle Size	Times Rejected (out of 50)	PoD	Zone Classification
#001	Glass particle	800 µm	49	0.98	Reject Zone
#002	Fiber	500 µm	42	0.84	Reject Zone
#003	Stopper fragment	300 µm	38	0.76	Reject Zone

Container ID	Defect Type	Particle Size	Times Rejected (out of 50)	PoD	Zone Classification
#004	Metal particle	200 µm	28	0.56	Grey Zone
#005	Fiber	150 µm	18	0.36	Grey Zone
#006	Glass particle	100 µm	12	0.24	Accept Zone
#007	Fiber	75 µm	5	0.10	Accept Zone
#008	Good unit	N/A	1	0.02	Accept Zone (false reject)

Zone Boundary Definitions:

Zone	PoD Range	Interpretation
Reject Zone	0.70 - 1.00	Defects that a qualified inspector is highly likely to detect in a single inspection. These are the "must-reject" containers.
Grey Zone	0.31 - 0.69	Defects with intermediate, unreliable detection probability. Detection depends on inspector alertness, particle position, and other variables.
Accept Zone	0.00 - 0.30	Defects that are very unlikely to be detected by manual inspection. These are at or below the practical limit of human visual detection.

Reject Zone Efficiency (RZE) Calculation:

The RZE is the primary metric used to compare inspection methods. It represents the average detection rate across all Reject Zone containers.

$$RZE = (\text{Sum of all rejections of Reject Zone containers}) / (\text{Number of Reject Zone containers} \times \text{Total inspections})$$

Example: If there are 25 containers classified in the Reject Zone, and across 50 inspections these containers were collectively rejected a total of 1,075 times:

$$RZE = 1,075 / (25 \times 50) = 1,075 / 1,250 = 0.86 \text{ (or 86\%)}$$

This RZE of 86% becomes the **benchmark** that the SAVI process must meet or exceed.

5.2 Stage 2: Equipment Qualification (IQ/OQ) of the SAVI System

Before operators can be qualified on the SAVI system, the equipment itself must undergo Installation Qualification (IQ) and Operational Qualification (OQ). These are standard equipment qualification activities.

Installation Qualification (IQ) verifies that the SAVI system has been installed correctly according to the manufacturer's specifications. This includes verification of utilities (power, compressed air), mechanical components (conveyor, spin station, mirrors), and lighting fixtures.

Operational Qualification (OQ) verifies that the SAVI system operates as intended across its defined operating ranges. Key parameters to qualify include:

Parameter	Typical Range	Rationale
Illumination intensity	2,000 - 3,750 lux (clear containers); $\geq 8,000$ lux (amber/opaque)	Must provide sufficient light for human detection without causing glare or fatigue. [1] [5] [8]
Vial spin speed	Product-specific (e.g., 1,200-2,400 RPM)	Must set particles in motion without creating persistent air bubbles.
Conveyor belt speed	Must allow ≥ 2 seconds per unit in the inspection zone	The ECA Q&A confirms that "the maximum speed should mathematically be no less than 2 seconds per object in the inspection area." [5]
Background color	Black (preferred), white, or grey	Black is preferred for reduced reflections and operator fatigue. [5]
Mirror alignment	Top and bottom views verified	Must provide the operator with a complete view of the container.

5.3 Stage 3: Operator Qualification on the SAVI System

With the manual baseline established and the SAVI equipment qualified, the focus shifts to the most critical element of SAVI qualification: **the operators**. Unlike AVI, where the machine makes the accept/reject decision, SAVI relies entirely on the human operator's judgment. The PDA D/A/CH Webinar (2025) illustrates this distinction clearly in its comparison of AVI vs. SAVI qualification approaches [6]:

Aspect	AVI Qualification	SAVI Qualification
Focus	Machine vision recipe	Human operator
Key qualification step	Vision Recipe Qualification (AVI $\geq$ MVI)	Operator Qualification (SAVI $\geq$ MVI)
What is being tested	Camera/algorithm detection capability	Operator detection capability on the SAVI system
Process Qualification	3 batches with extended sampling	3 batches with extended sampling

5.3.1 Operator Qualification Protocol

Each operator who will perform SAVI inspection must be individually qualified. The qualification protocol should include the following elements:

Prerequisites: The operator must have documented normal near visual acuity (with or without corrective lenses) and no impairment of color vision [1]. The operator must have completed the formal SAVI training program, including familiarization with the equipment, the inspection method (sequence of black/white backgrounds, spin observation), and the defect catalog for the product.

Qualification Test: The operator inspects the qualified test set (the same Knapp Kit from Stage 1, or a subset derived from it) on the SAVI system. The PDA D/A/CH Webinar (2025) specifies that qualification requires **3 consecutive successful runs** through the representative test set [6].

Acceptance Criteria:

Criterion	Requirement	Source
Detection Rate (RZE)	RZE on SAVI $\geq$ RZE on MVI (i.e., SAVI $\geq$ MVI)	PDA [6], IPA [8]
False Reject Rate (FRR)	$\leq 5\%$	PDA [6], FDA [1]
Consecutive passes	3 consecutive successful runs	PDA [6]

Numerical Example of Operator Qualification:

Assume the MVI baseline RZE = 86% (from the example in Section 5.1.3). An operator is qualified on the SAVI system by inspecting a test set containing 25 Reject Zone containers,

10 Grey Zone containers, and 65 Good containers (100 total, 35% defect rate for the qualification subset).

Run	Reject Zone Detections (out of 25)	RZE	Good Units Falsely Rejected (out of 65)	FRR	Pass/Fail
Run 1	23	92%	2	3.1%	Pass (RZE $\geq$ 86%, FRR $\leq$ 5%)
Run 2	22	88%	1	1.5%	Pass
Run 3	24	96%	3	4.6%	Pass

The operator achieves 3 consecutive passes and is therefore **qualified** to perform SAVI inspection for this product.

5.3.2 Failed Qualification and Remediation

If an operator fails a qualification run, the PDA D/A/CH Webinar (2025) provides the following remediation pathway [6]:

- 10 The failed run is documented as a deviation.
- 11 The operator may repeat the qualification attempt **up to 2 additional times**.
- 12 The repeat attempt should be performed no earlier than the **next working day** (to avoid fatigue bias).
- 13 If the operator fails a **second time**, they must undergo **re-training** before attempting again.
- 14 If the operator fails a **third time**, they are **disqualified** from performing visual inspection activities.

5.3.3 Requalification

Operators must be requalified **at least annually** using the representative test set [1] [5] [6]. Requalification is also triggered if the defect catalog changes (e.g., a new defect type is identified in production) or if the SAVI system undergoes a significant change (e.g., lighting modification, new conveyor speed). For requalification, **one successful pass** through the test set is typically sufficient [6].

5.4 Stage 4: Performance Qualification (PQ) — Process Validation

The final stage of the qualification pathway is the Performance Qualification (PQ), which demonstrates that the entire SAVI inspection process performs reliably under real-world manufacturing conditions with actual product batches.

5.4.1 PQ Batch Requirements

The industry standard for PQ is the successful inspection of **three (3) consecutive commercial-scale batches** using the qualified SAVI process [6]. This aligns with the general FDA process validation guidance, which expects manufacturers to demonstrate process consistency across multiple batches [10].

During PQ, the following activities are performed:

- 15 **100% SAVI Inspection:** Each of the three batches is inspected using the qualified SAVI system with qualified operators, following the approved Standard Operating Procedure (SOP).
- 16 **Extended AQL Sampling:** After the 100% SAVI inspection, an extended AQL sampling plan is applied. The ECA recommends that, for additional security, **up to 5,000 units** from the inspected batch (or combined from the three validation batches) can be subjected to manual re-inspection [9].
- 17 **Data Recording:** All inspection data (reject rates, defect types, operator performance, equipment parameters) are recorded and analyzed.

5.4.2 PQ Acceptance Criteria

Criterion	Requirement
Batch AQL	Must meet the pre-established AQL for the product (e.g., AQL 0.65% for critical defects, AQL 1.0% for major defects).
SAVI reject rate	Must be consistent with historical MVI reject rates (within an acceptable range, e.g., ± 2 standard deviations).
False reject rate	Should not exceed the established limit (typically $\leq 5\%$).
No missed critical defects	The extended AQL manual re-inspection should not identify any critical defects that were missed by the SAVI process.
Consecutive success	All 3 batches must meet all criteria.

6.0 Consolidated Summary of Required Studies and Runs

The following table provides a consolidated overview of all studies, the number of runs required, and the acceptance criteria at each stage of the MVI-to-SAVI transition.

Stage	Study/Activity	Number of Runs/Cycles	Acceptance Criteria	Notes
1. Manual Baseline	Threshold/Knapp Study	30-50 inspections per container (recommended: 5 inspectors x 10 runs = 50)	Establishes PoD and zone classifications for each container in the test set.	Can be reused from a prior AVI Knapp study if conditions are unchanged.
2. Equipment Qualification	IQ/OQ of SAVI system	Per manufacturer's protocol	All parameters within specified ranges (lighting, spin speed, belt speed, etc.).	Standard equipment qualification.
3. Operator Qualification	Operator test set runs	3 consecutive successful runs per operator	$RZE_SAVI \geq RZE_MVI$; $FRR \leq 5\%$.	Each operator must be individually qualified. Annual requalification required.
4. Process Qualification (PQ)	Commercial batch inspection	3 consecutive batches with extended AQL sampling	Batch AQL met; no missed critical defects; reject rate consistent with historical data.	Up to 5,000 units can be manually re-inspected for additional assurance.

7.0 Post-Transition: Routine Monitoring and Continued Process Verification

Following the successful completion of PQ and the formal transition to SAVI, the inspection process enters the routine monitoring phase. This is consistent with the FDA's lifecycle approach to process validation (Stage 3: Continued Process Verification) [10].

AQL Sampling After Every Batch: After each 100% SAVI inspection campaign, a manual AQL sampling inspection must be performed. The ECA Q&A on semi-automated inspection confirms: "after a 100% semi-automated inspection is completed, a manual inspection based on ISO 2859-1 should be performed... Inspection Level II should be used" [5]. The sample size depends on the batch size per ISO 2859-1.

Batch Size Range	Sample Size (Inspection Level II, AQL 0.65%)
501 - 1,200	80
1,201 - 3,200	125
3,201 - 10,000	200
10,001 - 35,000	315
35,001 - 150,000	500

Annual Operator Requalification: All SAVI operators must be requalified at least annually, as described in Section 5.3.3.

Equipment Requalification: The SAVI system should be periodically requalified (e.g., annually or after significant maintenance) to confirm that lighting, spin speed, and belt speed remain within qualified ranges.

Trend Monitoring: Ongoing monitoring of reject rates, defect type distributions, and operator performance should be performed to detect any drift in the inspection process. Significant deviations should trigger an investigation and, if necessary, requalification.

8.0 Decision Framework: When to Stay on MVI vs. Transition to SAVI

Not every product or situation warrants a transition to SAVI. The following decision framework can help determine the appropriate path.

Factor	Favors Staying on MVI	Favors Transitioning to SAVI
Production volume	Low volume (e.g., <5,000 units/batch)	Medium to high volume (>5,000 units/batch)
Product diversity	Very high diversity with frequent changeovers	Moderate diversity with stable production runs

Factor	Favors Staying on MVI	Favors Transitioning to SAVI
Inspector fatigue risk	Low (short campaigns)	High (long campaigns, repetitive inspection)
Consistency requirements	Standard	High (need to reduce inter-inspector variability)
Throughput	MVI throughput is sufficient (~4 units/min)	Need higher throughput (~25 units/min for SAVI) [6]
Existing qualification status	MVI is well-established and validated	New product or new facility with no existing MVI qualification
Regulatory expectation	No regulatory pressure to change	Regulatory feedback suggesting improved process control

9.0 Conclusion

Transitioning from manual to semi-automated visual inspection is a structured, data-driven process that enhances consistency and reliability while retaining the critical judgment of a human inspector. The cornerstone of this process is the establishment of a robust manual inspection baseline through a comprehensive Threshold (Knapp) Study, which requires **30-50 inspection cycles** to achieve statistical validity. If a Knapp study has already been conducted for a planned AVI transition, the **manual baseline data is fully reusable** for SAVI qualification, saving significant time and resources. However, the SAVI system and its operators must be **independently qualified** against that baseline through **3 consecutive successful test set runs per operator**, followed by a **3-batch Performance Qualification** with extended AQL sampling.

By adhering to this rigorous, multi-stage approach and maintaining ongoing monitoring through AQL sampling and annual requalification, manufacturers can confidently implement a compliant and effective SAVI process that improves product quality and ensures patient safety.

10.0 References

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