VALSOURCE

From Reactive to Resilient: Designing a Visual Inspection Program Built to Last

A Prevention-First Framework for Pharmaceutical Quality Organizations

Visual inspection is a critical component of sterile injectable product quality and patient safety. Yet many manufacturers still struggle to translate evolving regulatory expectations into a practical, scientifically justified visual inspection program that can be defended throughout the product lifecycle. This gap between policy and practice is often where recurring observations, inconsistent rejection rates, and costly re-inspections originate.

FDA and global regulators expect manufacturers to demonstrate that visible defects and particulate risks are identified, investigated, and reduced through a patient-focused lens. USP <790>, USP <1790>, FDA's Draft Guidance, and PDA technical reports establish important expectations, but none offer a single prescriptive framework for building a mature program. Manufacturers are left to determine, on their own, how to apply these expectations to their specific products, processes, and methods to mitigate patient and regulatory risk.

Moving Beyond Legacy Practices into a Lifecyle Approach

Many visual inspection programs were developed around established practices rather than a prospective, risk-based framework. A site may have trained inspectors, defect lists, qualification kits, and AQL testing in place and still lack the scientific rationale and lifecycle governance needed to support a mature program that would be acceptable to regulatory bodies.

Many companies have questions around which defects should be included in qualification kits, how rare or atypical defects should be handled, when defects should be added to a defect library, how particle types should be classified, and how defects should be trended. Often firms fail to appropriately react to the data being generated by their programs, and this lack of reaction can result in regulatory action. Failure to appropriately respond to signals from the visual inspection program can result in a need to retrospectively assess impact to distributed product, which can have significant business implications.

A mature visual inspection program treats these elements as parts of one integrated system, not as standalone outputs feeding batch release. Built this way, the visual inspection program becomes proactive and data-driven—able to detect its own early warning signs and drive continuous improvement, rather than simply documenting past excursions.

How ValSource Can Help

ValSource Regulatory Strategy consultants bring more than 25 years of visual inspection experience, including experience representing FDA on the USP Dosage Forms Expert Committee and USP Visual Inspection Expert Panel and drafting the 2021 FDA Draft Guidance on Visual Inspection.

ValSource supports organizations across the visual inspection lifecycle, including program gap assessments, defect classification and hazard evaluation, inspector training and qualification strategies, Knapp study design and review, AQL and sampling strategies, particle and defect investigations, supplemental testing, trending program development, regulatory remediation, and inspectional readiness.

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Our experts apply scientifically justified, risk-based approaches to help organizations build visual inspection programs that are practical, sustainable, and aligned with current regulatory expectations.

A mature visual inspection program does more than support compliance. It can reduce recurring deviations, improve consistency in defect classification and batch disposition, enhance manufacturing efficiency, reduce waste, strengthen the rationale behind critical quality decisions, and proactively identify emerging process or component issues. Most importantly, it creates a stronger connection between visual inspection data, product quality, and patient safety.

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