

Fully compliant AI-based inspection in GMP environments for highest quality assurance



Current Challenges in quality inspection in aseptic filling

Ensuring the quality of liquid pharmaceutical products demands strict control at every stage of the packaging process. As vials, syringes, and other containers move through the filling line, their integrity, sterility, and compliance with patient safety standards must be fully checked. This creates an ever-growing volume of data to inspect and analyse, far beyond the capabilities of traditional machine vision systems, which struggle with:

- High-speed, high-volume throughput that common rule-based systems cannot handle in a reliable way.
- Subtle, variable, or rare defects that conventional algorithms fail to detect.
- Increasingly complex data management and traceability requirements (e.g., FDA 21 CFR Part 11).
- Limited flexibility to adapt to new formats or inspection needs.
- Multiple sets of non-connected data that inhibits real time insights and process optimization.

While AI driven inspection appears to be the natural evolution to address these challenges, most widely used AI algorithms do not comply with GMP Annex 22 requirements, making them unsuitable for regulated pharmaceutical environments. This gap stresses the need for inspection technologies that combine AI's capabilities with full regulatory compliance.

The Solution: GMP Annex 22 compliant AI-based inspection with OMRON pharma dedicated solution

AI algorithm Conform to Annex 22: **get the best of AI inspection with full compliance.**

Key features

OMRON's AI-based visual inspection for pharmaceutical production comply with Annex 22 requirements by using a static AI model:

- **Static, Annex-22-Ready AI:** Fixed, non-evolving AI model designed to meet Annex 22 requirements for controlled, traceable, GMP-compliant inspection.
- **Deterministic, Repeatable Output:** The same model always delivers the same results—aligning with core regulatory expectations for GMP environments
- **Full Traceability via Checksum:** Each trained model receives a unique checksum “digital fingerprint,” logged in the Audit Trail for secure version control and simplified validation.



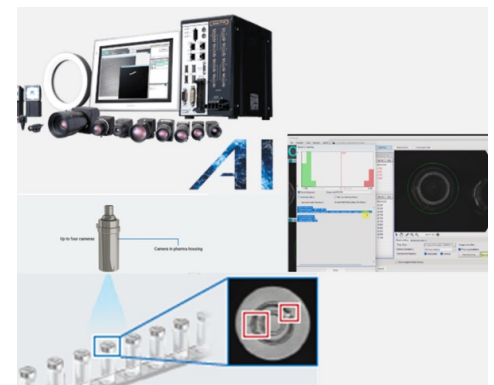
Value & Benefits

- **Annex 22 Compliance by Design:** Static, fully traceable AI models provide deterministic behaviour, simplifying validation and audits and ensuring compliance in regulated GMP environments.
- **Standardized, auditable, and objective data:** Supports Validation and Continuous Process Verification.
- **End to End Visual Assurance:** AI driven inspection covers every stage of the filling line, from counting and checking empty vials, stoppers, and syringe barrels to 360° crimp inspection and label verification, ensuring complete packaging integrity.
- **High Speed, High Accuracy Performance:** Ultra fast evaluation times down to 25 ms per inspection deliver reliable detection without slowing production.
- **Adaptable to Multiple Formats:** Seamlessly supports vial sizes from 2R to 50R and a wide range of cap and closure types to match diverse fill finish operations.

Technology behind the Solution

Advanced Vision System

- Advanced AI Model Conform to Annex 22
- FH controller with Intel®Core™i7 processor for very high performance.
- Wide range of High-Speed/High-Resolution cameras and lighting accessories with hygienic design in 316 SS.
- Customizable inspection tools.
- Communication over EtherNet/IP, ProfiNET, TCP, EtherCAT.
- Processing speeds from 25ms.



Compliance and security

- AI algorithm: deterministic, ensuring repeatability, traceability, and controlled model evolution.
- Audit Trail: Tracks who changed what and when.
- User Access Control: Role-based privileges for operators, engineers, and administrators.
- Encrypted Data Storage: Ensures integrity and traceability of inspection settings.

For more information visit
industrial.omron.eu