VERISTΛ

Top 5 Global Medical Device Manufacturer Implements and Validates Computer Vision Solution in Record Speed

Improving the reliability, speed, and quality of their operations

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CASE STUDY

LANDING AI

CLIENT OVERVIEW

A global leader in medical technology, offering medical devices and therapies across over 100 countries.

CLIENT CHALLENGE

During the manufacturing and assembling operations for implantable medical devices, quality is of utmost importance. In fact, no defects are an imperative when it comes to life saving implantable medical products. As you can imagine, if a company fails to detect defective parts, the cost can be very high. Medical device manufacturers must take action to analyze the root cause and implement corrective procedures to avoid an escape in the future.

The client's multi-stage defect inspection process was manual and required several inspectors. First stage inspectors were less trained and sometimes let defects slip through the cracks. In addition to the inspection process being unreliable and not reproducible, it was costly and training intensive.

REQUIREMENTS

The client sought a computer vision solution that would identify defects and allow for continuous improvement through machine learning to improve the reliability, speed, and accuracy of their manufacturing processes.

An inhibitor to innovation and implementing transformative technology is regulatory compliance – specifically upfront and ongoing validation. Typical validation times for a solution like the one selected could take 2-3 months, and that's if all went smoothly. The client needed a specialized partner who not only understood validation, but also vision automation software that could shorten the time to solution implementation. Since cloud-based software solutions deliver upgrades on a continual basis, the client also needed help with ongoing validation in a timely and cost-effective manner.

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SOLUTION

The combination of LandingLens (Landing AI's computer vision platform) and Verista's validation and vision automation expertise, helped the client achieve their goal to implement and validate an AI vision inspection software that identifies defects and continually improves itself through machine learning in record time and at a cost-effective price.

Landing AI's platform includes a standardized workflow with traceability built in so it's easier to document and validate. This, along with Verista's validation package, allows the customer to scale more quickly and effectively, reducing validation from months to weeks. The combination can be easily replicated from line to line and plant to plant.

Verista was selected as the validation partner for Landing AI due to their expertise in manufacturing equipment validation as well as validation of cloud-based solution platforms, a rare and unique find in the marketplace. The LandingLens system was validated in two parts: the platform and the model. The LandingLens platform is used to collect and tag images into a data set, build and train image models, as well as deploy the models for production use. The model is used to interpret the images collected during the manufacturing process. By qualifying the platform separately, the system can be leveraged by multiple production lines or facilities within the organization while the models are independently validated for each use case.

Verista's unique platform validation package includes functional requirement specifications, installation verification and operation qualification protocol, and requirements trace matrix. This package allows the client to execute the protocol using a standard set of images to give a high degree of confidence in the functionality of the platform without requiring client specific process images.

Deployment and Ongoing Validation
The powerful combination of Landing AI's LandingLens and Verista's validation capabilities to meet FDA compliance reduced the initial deployment validation time from 3+ months to 1-2 weeks. This allowed the client to quickly implement the solution in their production environment.

In addition, since Landing AI is a cloud-based software, they deliver continuous updates and features, requiring the client to revalidate the software in the manufacturing environment. Verista can step in and ensure that the validated state is fully maintained.

Furthermore, when the client makes a manufacturing change, i.e., a change to a product or device, Verista can quickly retrain and revalidate the AI model.

BENEFITS

In addition to improving the reliability, speed, and accuracy of their manufacturing processes, the client experienced the following benefits:

√ Improved quality, reduced product error escapes, and greater insights through the use of automation and Landing AI's vision inspection technology

√ Higher quality yields and increased speed to market through the real-time capture and AI analysis of defects

√ Increased operational efficiency through the reduction of CAPAs

√ Cost-effective price: 2X less due to vision AI and validation expertise

√ Cloud-based technology is easily scalable

√ Faster and easier validation through the use of Verista's comprehensive validation package and expertise

Verista is a leading business, technology and compliance company that enables clients to improve health and improve lives. We help clients solve their most critical and complex challenges across the GxP lifecycle, from preclinical and clinical to commercialization, manufacturing and distribution - bringing together decades of knowledge, the most advanced engagement platforms and transformative technologies. This allows clients to benefit from the ease, efficiency, and trust that results from working with one partner who excels across specialties.

Verista's clients trust the company's 700+ experts to deliver consistent, safe, and high-quality results across the product development lifecycle in the areas of enterprise and lab systems, technology solutions, manufacturing solutions and regulatory compliance & auditing.

Landing AI™ is pioneering the next era of AI in which companies with even limited data sets can realize the business and operational value of AI and move AI projects from proof-of-concept to full scale production. Guided by a data-centric AI approach, Landing AI's flagship product is LandingLens™, an enterprise MLOps platform that offers to build, iterate, and operationalize AI powered visual inspection solutions for manufacturers.

For more information, visit Verista.com

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