

# Complete FDA Validation Quickly

# LANDINGLENS SIMPLIFIES FDA SOFTWARE COMPLIANCE

Spend less time validating LandingLens with our complete package of requirements, impact analysis, protocols, and experts.



Packaged Simplicity



Domain Expertise



Ongoing Support

We understand how disruptive change can be in your compliance environment. However, software applications must be upgraded to meet your expanding business requirements, new technology, and industry demands. Validation with LandingLens lets you spend more time on your core competency—and less on validating third-party business applications. LandingLens lets you work faster to meet compliance requirements the first time. And, you continue to benefit with every future software release, allowing you to re-validate your LandingLens system with minimal disruption.

Deliverables	Key Benefits
<ul> <li>A comprehensive set of validation documentation including requirements, impact analysis, test plan, and protocols</li> </ul>	Reduces time and costs associated     with developing test cases
<ul> <li>Advance LandingLens release notifications containing risk assessment and impact analysis with respect to validation and updated validation requirements</li> </ul>	Provides you time to evaluate the scope of each upcoming release to assess the impact—no surprises on LandingLens releases
✓ Validation documentation generated, updated, and shared prior to each LandingLens release	Continuing benefits of validation documentation for ongoing LandingLens releases
✓ For each new release, you will gain access to a staging environment with the upcoming features	Allows QA teams to test and validate the upcoming features with zero impact to the production environment, allowing for seamless upgrades
<ul> <li>Senior validation expert assistance through Landing Al's validation partner, Verista, with LandingLens application validation questions and concerns, including best practices and templates</li> </ul>	Ensures ongoing validation support

#### **WHO BENEFITS**

#### **Quality and Regulatory Managers**

Partner with LandingLens validation experts and leverage our comprehensive validation methodology. Whenever LandingLens introduces a new software release, you will receive an updated documentation package to complete the latest LandingLens system validation. Faster system validation gives you greater peace of mind while reducing costs.

#### **Executive Management**

Be confident that your team has the necessary documentation to validate your LandingLens system. Validation with LandingLens is a modern, computer vision solution that is easy to validate. LandingLens ensures that you benefit from continual innovation and software enhancements without fearing long, costly, or difficult validation processes.

#### **Validation Team**

LandingLens reduces the validation burden placed on your team. Our team produces a validation document package which your team can simply take and use to execute the validation greatly reducing the time required to build validation procedures from scratch.





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### Validation With LandingLens: All The Critical Elements You Need

Software validation can be challenging when starting from scratch. Validation with LandingLens is a proven, detailed validation package where we do most of the work of preparing the validation documentation with which our customers can quickly and effeciently execute the validation protocols.

• Validation Test Plan **EXECUTING & IMPACT ANALYSIS** Functional REPORTING • IV/OQ Test Cases Requirements Requirements Specification (FRS) IV/OQ Execution Traceability Matrix Validation Impact Records With Objective Analysis Evidence **PLANNING REQUIREMENTS** 

#### VALIDATION DOCUMENTATION PACKAGE

- Functional Requirements Specification (FRS)
- Requirements Traceability Matrix
- ✓ Software Modification Validation Impact Analysis
- ✓ Installation Verification (IV) Validation Protocols
- ✓ Operation Qualification (OQ) Validation Protocols



# Validiation With LandingLens Release Schedule

LandingLens is on a six-month controlled validation schedule as follows:



- Landing AI provides release notes for upcoming release with in-scope and out of scope features at least 2 weeks prior to validation period
- Landing AI provides QA testing documentation
- Customers review release notes and confirm categorizations



- Customers receive validation documentation from Landing AI
- Customer execute their testing based on the documentation they created
- · Document findings



- Customer moves to production
- Repeat in 6 months