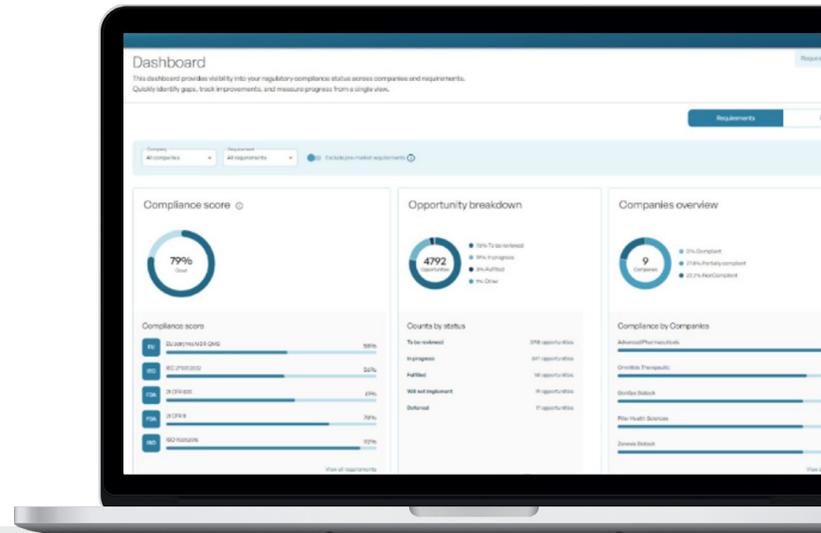SOLUTION OVERVIEW

# Make Your QMS Content AI Inspection Ready

**Prepare for FDA's Elsa by proactively identifying compliance gaps and strengthening quality documentation before regulators arrive for a stronger, more confident inspection posture.**

Advarra's GxP AI app provides automated document review and real-time insights to help maintain a compliant, audit-ready QMS across all facilities, sites, and vendors. In benchmark testing, the solution identified compliance gaps more effectively than FDA's Elsa, enabling organizations to detect issues earlier and reduce inspection risk.

The platform provides:

- Automated detection of compliance gaps against regulations and industry best practices

- Real-time visibility through an easy-to-use dashboard across sites, facilities, and vendors

- Early signals of inspection risk

- Direct handoff to Advarra's quality experts to validate findings and provide tailored solutions



AI-driven insights are reviewed by Advarra's global team of quality experts, who provide strategic support to validate findings, strengthen quality documentation, and help organizations respond efficiently—avoiding inspection-related delays and disruptions.

## More Effective Gap Detection

Identify issues early before inspections or submissions leading to fewer CAPAs and fewer surprises.

## ● Backed by a Global Team of Quality Experts

Advarra is one of the largest and most experienced GxP services providers in the world, completing more than 1,500 quality projects each year. With experience in 75 countries, our auditors speak 32 languages and each have over a decade of experience in international and local regulatory requirements—helping ensure compliance everywhere you conduct studies.

Our team provides comprehensive audit, quality management, and inspection-readiness support tailored to organizations of any size, with flexible engagement models and deep regulatory expertise.

## ● Supported Environments & Audits

- GxP-regulated facilities (GMP, GCP, GLP, etc.)
- Global regulatory frameworks (ISO, ICH, CFR, etc.)
- Internal audits, supplier audits, and regulatory inspections
- Inspection readiness and Elsa preparation

## AI Powered Proactive Compliance

### Operational Efficiency

Leverage AI to automate reviews for faster, more scalable oversight processes

### Continuous, Real-Time Oversight

Provides ongoing visibility into inspection risk across sites, facilities, and vendors through a centralized dashboard.

### Expert-Backed Insights

Findings are reviewed by Advarra's quality experts, ensuring validated results and actionable remediation guidance.