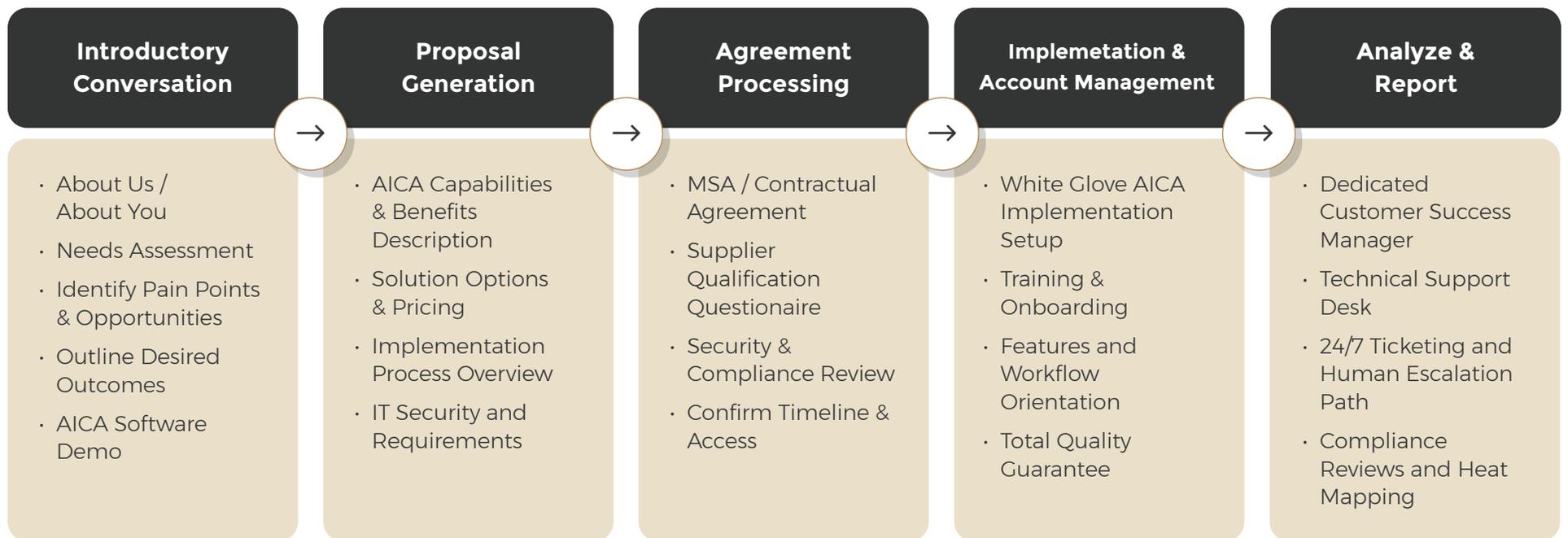


Proven Process for AICA Implementation



Auditing needs an upgrade. Meet AICA.

WHAT IS AICA?

AICA (Audit Intelligence Compliance Assistant) is a powerful AI tool purpose-built for pharmaceutical and biologic compliance auditing. Unlike generic AI tools, AICA was trained by 15+ regulatory professionals on real quality documentation. Upload your policies and procedures, select which regulations to audit against, and AICA identifies gaps between what your documents say and what regulations require—in minutes instead of days or weeks.

HOW AICA TRANSFORMS COMPLIANCE AUDITING:

- Audit 100% of your QMS documentation against selected regulations, not just samples.
- Process 1,000+ pages in minutes, instantly flagging gaps and remediation actions.
- Generate inspection-ready reports with precise regulatory observations and criticality.
- Customize audits by regulation to match products, markets, and inspection focus.

HOW AICA WORKS:

AICA accepts direct document uploads to analyze your QMS documentation. The AI systematically evaluates documents against each applicable regulation, identifying gaps and best-practice opportunities. You then review the AI-generated observations, include or exclude findings as appropriate, and generate an audit report complete with regulatory citations, suggested corrective actions, and a full list of documents reviewed.

The screenshot displays the AICA interface. On the left, under 'Observation #1', there is an 'Explanation' section stating that the SOP section does not mention any written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products, as required by § 211.130. Below this is a 'Suggestion' to include a section in the SOP that outlines the written procedures to prevent mixups and cross-contamination during packaging and labeling operations. On the right, under 'Document & CFR preview', there is a table for 'Document Management Lifecycle' with columns for SOP No., Revision No., and Effective Date. Below this is a '4. Responsibilities' section with sub-sections for Author, Reviewers/Approvers, and Quality Assurance (QA). At the bottom, there is a '5. List of Abbreviations and Definitions of Terms' table.

Definition	
Document	A Standard Operating Procedure (SOP), Form, Template, Work Instructions, Product Specification, and Product Formulation Sheet. Documents are version controlled and revised independently from the governing SOP.
Form	Contains fixed fields and/or checkboxes used to capture specific information or decisions related to GxP responsibilities.
Master Document	A document that is effective with original signatures.
SOP	Written instruction to achieve uniformity in the performance of a specific function and to describe functions carried out in order to ensure compliance with applicable regulatory requirements. SOPs are the current instructions for performance of a specific function.
Template	Contains fixed fields or modified fields as required, used to capture specific information or decisions related to GxP responsibilities.

→ Reports include gap analysis, regulatory citations, prioritized actions, and executive dashboards. AICA supports internal and supplier audits and prepares your organization for official government regulatory inspections.

WHY THE FDA GROUP?

The FDA Group is in business to enhance the quality of people's lives. Our purpose lies in discovering meaningful ways to apply our experience, expertise, and passion for quality in everything we do. AICA represents the next evolution of that mission—bringing decades of regulatory expertise into an AI-powered platform that makes compliance faster, more accurate, and more accessible for life science companies of all sizes.

THE FDA GROUP'S AWARDS AND ACCREDITATIONS:



▶ Watch a demo ☎ 1-833-FDA-GROUP