



WEBINAR

From Requirements to Regulatory: How AI Is Transforming Submission Readiness

Today's Speakers



Adam Smith

Founder & CEO

Agent Astro



Tom Rish

Head, GTM Strategy - Medical Device & Life Sciences

Jama Software

Jama Connect Modern Medical Device Development

Live Traceability of Requirements

Medical Device Frameworks

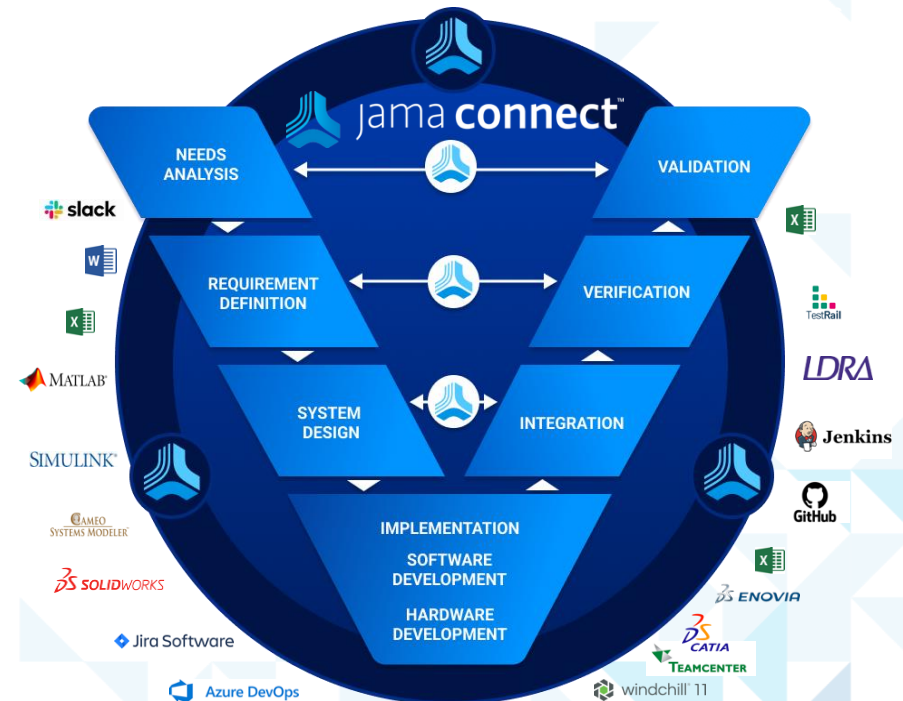
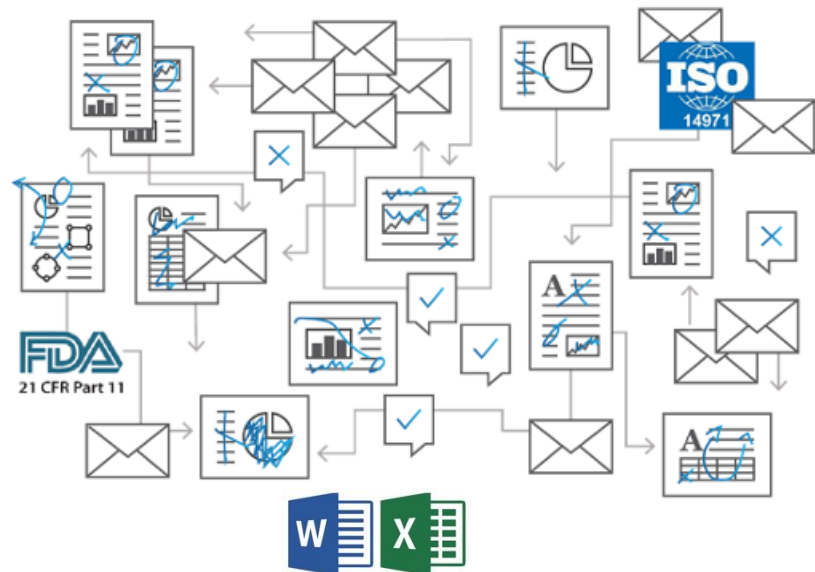
Seamless Integrations

Real-time Collaboration & Review

Library Reuse & Release Management

AI Guidance

Expert Consulting Services



Jama Connect Advisor Requirements AI Initiatives

Requirements Quality Intelligence

Available with Jama Connect Advisor

AI enhances the quality and clarity of requirement language, guiding those new to writing requirements and significantly reduces a major source of defects.

Learn More →

1 Distinguishable color usage
AIS-FLD-35 • Version 4

DESCRIPTION ▾ Hide scores

LATEST SCORE: INCOSE 87% EARS 0
INITIAL SCORE: INCOSE 50% EARS 4

Make it easier for users to see and hear content including separating foreground from background LEVEL A 1.

INCOSE RULES ANALYSIS: Score: 87%

Requirement issue	Issue details	Identifier	INCOSE rule
Logical Condition	Use a defined convention to express logical expressions.	and	r15
Avoid Pronouns	Avoid the use of pronouns and indefinite pronouns	it	r24

SI_SOL-CR-1: Cryptography
Jama Connect Advisor™
Stakeholder Requirement • Version 4

ANALYZED REQUIREMENT Rewrite
Solution should have some hardware accelerated crypto to support its standards.

INCOSE RULES ANALYSIS Score: 87%

Requirement issue	Issue details	Identifier	INCOSE rule
Use Active Voice	Use the active voice in the main sentence structure of the requirement.		r2
Avoid Vague Terms	Avoid the use of vague terms.	some	r7
Avoid Pronouns	Avoid the use of pronouns and indefinite pronouns.	it	r24

RECOMMENDED REVISION New score: 100%
The solution shall provide hardware accelerated cryptography supporting the AES, SHA and RNG standards.

Update requirement

Requirement Refinement

Enhanced AI-powered requirement quality analysis generates specific revisions to optimize compliance against INCOSE and EARS standards — providing increased clarity, precision, and consistency across teams.

Coming Soon

Requirement Generation

AI instantly creates clear, concise, and compliant requirements based on your project inputs — saving you time and ensuring accuracy in your documentation.

Coming Soon

GENERATE REQUIREMENTS WITH JAMA CONNECT ADVISOR™

I need new Design Descriptions added to the LCD Controller component inside the Semiconductor project.

Upload Generate requirements

3 requirements Add requirement

#	Name	Requirement
1	Architecture	The LCDC consists of two independent controllers, the raster controller and the LCD interface display driver (LIDD) controller. Each controller operates independently from the other and only one of them is active at any given time.
2	Raster Controller	The raster controller handles the synchronous LCD interface. It provides timing and data for constant graphics refresh to a passive display.
3	LIDD Controller	The LIDD controller supports the asynchronous LCD interface. It provides full-timing programmability of control signals (CS, WE, OE, ALE) and output data.

RFP Requirement Specifications

- 1 Technical Volume
 - 1.0 Technical Approach
 - 1.1 Vertical Lift Aeromechanics Modeling and Analysis
 - 1.1.1 Aeromechanics Simulation Model Development
 - 1.1.2 Simulation Services to Support Wind Tunnel, Flight, and Simulator Testing
 - 1.1.3 Integration of Aeromechanics Simulation Models
 - 1.2 Simulation Facility Hardware
 - 1.3 Aircraft Performance, Handling Qualities, Cockpit Displays
 - 1.4 Operations Effectiveness Analysis

RFP uploading... 75%

Requirement scan complete
Existing components and requirements found that match the specifications of your RFP.

1.1.2 Simulation Facility Hardware

- Component One
- Component Two
- Component Three

1.1.2 Simulation Facility Hardware

- Component One
- Component Two
- Component Three

Build project

PDF Parsing

Harness AI to instantly transform static documents into structured, ready-to-use requirements—supercharging your onboarding and accelerating traceability.

Coming Soon

Jama Connect Advisor **Other AI Initiatives**

Test case 1 of 4
Lane Detection in Clear Conditions
The vehicle is driving at 60 km/h on a straight, well-marked road with clear weather conditions and minimal traffic.

Generate test cases →

Relate to requirement

Lane Detection in Clear Conditions V1

Test Case • Authored by Advisor

DESCRIPTION:
The vehicle is driving at 60 km/h on a straight, well-marked road with clear weather conditions and minimal traffic.

REVIEW STATUS:
Pending review

Test Case Generation

Streamline verification and accelerate to market with AI-generated test cases derived from requirements.

[Learn More →](#)

Jama Connect Advisor Assistant

I want to create new test cases in the UAV Project

I found several Sets that might be appropriate for placing your Test Cases. Based on the results, there are 3 Sets that appear to be specifically for Test Cases:

Mission Validation Tests (ID: 6806) System Test Cases (ID: 6816) Verification Tests (ID: 6721)

You selected Verification Tests, got it. Before we proceed with creating a new Test Case, what requirements would you like to create test cases for?

Show me a list of all the Sets with Requirements in UAV

Set ID	Set Name	Requirement Types
6649	Stakeholder Needs	Contains Stakeholder Requirements (SHRQ)
6650	High Level SW Requirements	Contains High Level Requirements (HLR)
6653	Low Level SW Design	Contains Low Level Requirements (LLR)
6654	High Level HR Requirements	Contains High Level Requirements (HLR) for hardware

Type a message... [Send](#)

AI Assistant

Empowers users to query data, generate content, and receive contextual help within their requirements management workflows—all through an intuitive, conversational interface.

[Coming Soon](#)

Relationship Discovery

AI-powered semantic analysis to identify and suggest missing traceability links between related items, helping ensure complete and compliant requirements coverage.

[Learn More →](#)

1 dB maximum limit

AIS-FLD-35 • Version 5

DESCRIPTION
The device shall produce a maximum sound output of 100 decibels (dB).

Show related items ▶

Hide recommended items ▼

3 of 12 selected

Item type	ID	Name	Project
<input type="checkbox"/>	SI_J1-18	Keyboard Activation Support	Medical Device Set
<input checked="" type="checkbox"/>	SI_J1-19	Visible Focus Styling	Medical Device Set
<input type="checkbox"/>	SI_J1-15	Screen Reader Name Complian...	Medical Device Set
<input checked="" type="checkbox"/>	SI_J1-12	Contrast Ratio	Automotive Set
<input checked="" type="checkbox"/>	SI_J1-20	Descriptive Labeling	Medical Device Set
<input type="checkbox"/>	SI_J1-21	ARIA Role Accuracy	Medical Device Set
<input type="checkbox"/>	SI_J1-22	Target Size Minimum Compliance	Medical Device Set

Intelligent Reviews

AI automatically detects high-risk areas in requirements by analyzing review comments, helping teams focus their attention where it matters most.

[Learn More →](#)

Sentiment analysis of 118 comments

The conversations on this review have been analyzed to identify requirements that need attention.

59 comments suggest additional rework
25 comments are neutral
34 comments are approving

[View comments](#)

Summary Comment analysis Unanswered 14

This is the second round of review for the LCD Controller component. The suggested rework from the first review has been addressed, but Jason and Robin of the Product group have additional concerns, specifically on the newly added Block Requirements items. Changes have been requested and a new review will be required.

Next steps

- Moderators need to review unanswered questions.
- Robin plans to confirm the Design Descriptions for the LCD Controller with the Architecture group.
- Josh and Jennifer will pull their teams together and work through the suggested edits.
- Send a new review with corrections; include related items to understand downstream impact of changes.



AGENTASTRO.AI

From Requirements to Regulatory: How AI Is Transforming Submission Readiness

Embedding regulatory intelligence into requirements-driven development



About Agent Astro

Regulatory intelligence built by technologists and domain experts

- Focused on connecting requirements, regulatory precedent, and lifecycle signals
- Surfaces FDA decisions, guidance, and post-market context to inform upstream decisions
- Designed to sit alongside requirements and QMS tools, not replace them
- Supports experienced regulatory, quality, and engineering teams with structured insight
- Used by teams globally to reduce rework, uncertainty, and late-stage surprises



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Agenda

- Why submissions still feel like a scramble
- Where most development systems stop short
- Where most development systems stop short
- Regulatory intelligence as a continuous input
- How AI shifts regulatory work upstream
- Building readiness into the process
- Why Submission Readiness Is a System, Not a Phase



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Why submissions still feel like a scramble

Even in well-run, requirements-driven organizations

- Requirements and design decisions are well controlled
- Regulatory expectations are often interpreted late
- Submission narratives are reconstructed under pressure
- Risk concentrates near the finish line



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Where most development systems stop short

Internal traceability vs external regulatory reality

- Requirements tools manage **internal truth**
- Regulators evaluate **external precedent and context**
- Predicate decisions, guidance updates, and post-market signals evolve
- These signals rarely flow upstream in real time



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Regulatory intelligence as a continuous input

Augmenting requirements systems, not replacing them

- Agent Astro sits **alongside** requirements and QMS tools
- It surfaces regulatory precedent and expectations early
- It helps teams test decisions against likely reviewer logic
- It supports submission readiness throughout the lifecycle



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AI shifts regulatory work upstream

From reactive assembly to proactive alignment

- Earlier visibility into relevant predicate patterns
- Continuous alignment with guidance and regulatory signals
- Traceable rationale for key regulatory decisions
- Fewer late surprises during submission preparation



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Building readiness into the process

Requirements discipline plus regulatory intelligence

- Jama ensures requirements integrity and traceability
- Agent Astro ensures regulatory context and precedent awareness
- Together, teams reduce rework and submission stress
- Readiness becomes continuous, not episodic



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Submission Readiness Is a System, Not a Phase

Requirements discipline plus regulatory intelligence

- Strong requirements are necessary but not sufficient
- Regulatory expectations evolve outside development systems
- Readiness improves when both are addressed continuously



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Q&A



THANK YOU!



Jama Software® is focused on maximizing innovation success in multidisciplinary engineering organizations. Numerous firsts for humanity in fields such as fuel cells, electrification, space, software-defined vehicles, surgical robotics, and more all rely on Jama Connect® requirements management software to minimize the risk of defects, rework, cost overruns, and recalls. Using Jama Connect, engineering organizations can now intelligently manage the development process by leveraging Live Traceability™ across best-of-breed tools to measurably improve outcomes. Our rapidly growing customer base spans the automotive, medical device, life sciences, semiconductor, aerospace & defense, industrial manufacturing, consumer electronics, financial services, and insurance industries.