AI-ready submissions: A MedTech leadership series
Episode 2 - AI and the regulatory roadmap: why structured submissions win

From documents to defensible evidence

The Context, Argument, Evidence

What is CAE?

Watch episode 2 on-demand: AI and the regulatory roadmap: why structured submissions win

Definition

Regulators evaluate submissions through three pillars: **Context**, **Argument**, and **Evidence**. **Context** defines what the device is and its intended use, encompassing claims and descriptions that must be verifiable. **Argument** explains why the device is safe and effective, supported by structured justifications and risk assessments. **Evidence** provides the proof, including laboratory data, clinical trials, and real-world performance metrics.

This model applies across frameworks such as EU MDR, FDA requirements, and IMDRF Table of Contents standards. Operationally, each pillar should become a first-class object in your content system, not a paragraph buried in a PDF. For example, a post-market surveillance update that impacts a General Safety and Performance Requirement (GSPR) must be traceable back to the original notified body opinion. Structured content enables this traceability, ensuring that changes do not breach prior regulatory judgments.

Why this matters

- Regulators do not approve documents.
- They approve **claims**, **justifications**, and **proof**.
- If those elements are tangled together, your content cannot scale, reuse, or survive AI.

Most regulatory delays, audit findings, and rework cycles come from one root cause:

Context, Argument, and Evidence are mixed and managed as narrative text. If you cannot separate Context, Argument, and Evidence, neither can a regulator or an AI system.

This guide helps you identify those elements.

The CAE model explained

Context - The concept layer

What is being claimed?

Context defines:

- What the product is
- What it does
- Who it is for

- Where and how it is used

Typical Context elements:

- Intended use
- Indications
- Device description
- User population
- Environment of use
- Key performance claims

Context states facts and claims.
It does not justify them.

Argument – The justification layer

Why should a regulator believe this is safe and effective?

Arguments explain:

- How risks are addressed
- Why benefits outweigh risks
- How standards and guidance are applied
- Why the evidence is sufficient

Arguments connect Context to Evidence.
They explain logic and reasoning.

Evidence – The proof layer

What objectively proves the argument?

Evidence includes:

- Test reports
- Validation results
- Clinical data
- Risk analyses
- PMS outputs
- Audit records

Evidence proves.
It does not explain.

The rule that matters the most

Every Context must be supported by an Argument.
Every Argument must be supported by Evidence.

If one is missing, the claim is weak.

Simply put:

- Context states.
- Argument explains.
- Evidence proves.

The CAE extraction drill

Activity 1: extract CAE from your own text

Instructions:

Paste one paragraph from your IFU, CER, or technical documentation.

Choose something meaningful, not a heading or summary.

Then answer the following:

Context

- What product claim is being made?
    - Product or feature:
    - Intended purpose:
    - User or environment:
    - Performance or safety claim:
- Is it explicit or implied?

Argument

- What reasoning is used to justify the claim?
    - Risk-based justification:
    - Standards applied:
    - Clinical or usability rationale:
- Safety logic: technical, clinical, or regulatory?

Evidence

- What proof is referenced or implied?
    - Test reports:

- Analyses:
- Validation activities:
- Document identifiers:

- Is it specific or vague?

The Gap analysis

Activity 2: find what is broken.

Item	Yes	No
Every Context has a clear Argument	☐	☐
Every Argument is supported by Evidence	☐	☐
Evidence is referenced consistently	☐	☐
Is the same Evidence reused elsewhere?	☐	☐
Claims appear in multiple documents with different wording	☐	☐
Could you update this safely under change?	☐	☐

Reflection:

- What is missing, duplicated, or disconnected?
- What happens today if:
  - The intended use changes
  - A test result is updated
  - A standard is revised
- Where would rework start, and how far would it spread?

Write your answer:

Red flag checklist. Did you find any of the following:

- **Evidence** without an argument
- **Argument** without evidence
- Claims with neither

Self-assessment: are you content-ready?

Statement	Yes	No
We can clearly separate Context, Argument, and Evidence	☐	☐
We avoid duplicating claims across documents	☐	☐
Evidence is referenced, not copied	☐	☐
Change impact is predictable	☐	☐

Submissions reuse approved content

Self-assessment scorecard:

- 0–1: Document-centric
- 2–3: Transitional
- 4–5: Structured-ready

Short interpretation for each score band.

The takeaway

- If you can extract Context, Argument, and Evidence from your documents, you are already thinking in structured content.
- If you can manage Context, Argument, and Evidence independently, you are ready to scale submissions, change, and AI safely.

If you cannot, AI will not fix that. It will amplify the problem.

This guide does not require new tools.
But it will make clear when your current tools are no longer enough. The CAE exercise teaches **how to think**.

A CCMS gives you the **mechanism to scale that model without breaking compliance, timelines, or teams**.

Appendix

Catalogue of Context, Argument and Evidence elements

Context	Argument	Evidence
Cover Letter	Regulatory Strategy / Pathway	Risk Management File
Glossary of Terms, Definitions & Abbreviations	Classification	Risk Management Plan
Appendices Overview	GSPR Checklist	Use FMEA
List of Applicable Regulations, Standards & Guidance	Declaration of Conformity MDR (Draft)	System FMEA
Summary of Technical Documentation (STED)	Device Equivalence	Design FMEA
Device Description	Interface Control Document (ICD)	Process FMEA
Intended Use	Combination Product Responsibility Matrix	Fault Tree Analysis
Use Specification	Bridging Study Report	Identification of Hazards, Harms and Severities of Harm
Device Data Sheet	Combination Product Submission Tracker	SW Hazard Analysis
Technical Systems Requirement Specification	Risk Management Report	Common Vulnerability Threat Model
Patient and Indication Insights	Risk Management Reviews	Unresolved Vulnerabilities List
Summary of Intended Clinical Benefits	Risk Evaluation and Assessment	SW Risk Classification
Alternative practices and procedures	Safety Risk Analysis	Software Bill of Materials
Design and Development Plan	Security Risk Analysis	SW Version History
SW Development Plan	Safety Assurance Case Report	SW Change Log
Design Verification Plan	Shared Risk Management Summary (Drug-Device)	SW Anomaly List
Design Validation Master Plan	Design Verification Summary Report	Software Test Plan
Design Validation Plan	Design Validation Summary Report	Software Test Procedure and Report
Process Validation Master Plan	Software Test Summary Report	SW Test Protocol
Clinical Development Plan	Sterile Packaging Summary Report	SW Test Report
Usability Engineering Plan	Biological Safety Evaluation Summary Report	OTS / SOUP Validation Report
Quality Plan	Process Validation MASTER Summary Report	IQ Protocol (Intern / Extern)
Design Transfer Plan	Clinical Evaluation Plan (CEP)	OQ Protocol (Intern / Extern)
Document Plan Matrix (Plan)	Clinical Evaluation Report (CER)	PQ Protocol (Intern / Extern)
Component Specification	PMCF Report	Process Validation Report (Intern / Extern)
Assembly and Inspection Specification	PSUR	First Article Inspection
Raw material specification	SSCP	First out of Tool

Electronics Description	Design Review Checklist and Report	Clinical Literature Review
User Interface Specification	Milestone Review Checklist and Report	Study Synopsis
Packaging Labeling Requirements Specification	SW Design Review Report	Clinical Investigation Plan (CIP)
Label Specifications	SW Requirements Specification Review Report	Clinical Investigation Report (CSR)
Calibration and Control Procedures	–	PCAF Detailed Task Analysis
–	–	URRA Use-Related Risk Analysis
–	–	Use Case Report
–	–	Formative Study Protocols and Reports
–	–	Summative Study Protocol and Report
–	–	Categorization of Device Components
–	–	Biocompatibility Data Gap Analysis
–	–	Biological Safety Evaluation Plan
–	–	Biocompatibility Protocol
–	–	Biocompatibility Test Report
–	–	Material Certificates
–	–	Material Compliance Checklist
–	–	MSA Report
–	–	Measurement System Qualification Report
–	–	Test Plan
–	–	Test Protocol
–	–	Test Report

From CAE thinking to CAE at scale

Why structured component content management systems matter once you get the logic right

CAE asset	What breaks without structure	CCMS capability that fixes it
Context	Claims drift across documents and markets. Small wording changes create big regulatory risk.	Single-source, controlled content. One approved Context reused everywhere, with versioning and history.
Argument	Justifications are buried in narrative text and re-reviewed repeatedly.	Modular content with explicit relationships. Arguments are reviewable, reusable, and linked to the Context they justify.
Evidence	Proof is copied, summarized, and paraphrased. Traceability is manual and fragile.	Reference-based reuse and automated traceability. Evidence is linked once and reused consistently.

"If Context, Argument, and Evidence are assets, they need asset management."

AI in Regulatory submissions

The FDA has already started processing new submissions with AI.

AI retrieval test: failure vs success using the same example

This section shows why AI struggles with document-centric content, and why it succeeds when Context, Argument, and Evidence are explicit.

- Same device.
- Same regulatory intent.
- Same underlying evidence.
- Different structure. Very different outcome.

Scenario

A regulator, auditor, or internal reviewer asks:

"What evidence supports the safety of the intended use for Device X?"

You ask an AI assistant to retrieve the answer.

Case 1: AI retrieval failure

Document-Centric Content

Source text (typical paragraph):

"Device X is intended to be used by trained healthcare professionals for monitoring condition Y in adult patients in a clinical environment. The device has been designed in accordance with applicable safety standards, and risk controls have been implemented to reduce potential hazards. Verification and validation activities demonstrate compliance with the relevant requirements."

What the AI sees

- Claims, logic, and proof mixed
- No explicit links between intended use and evidence
- No document identifiers
- No traceable structure

Typical AI response

"The device is considered safe because it follows applicable standards, includes risk controls, and has undergone verification and validation testing."

Why this fails

- No evidence is **retrieved**
- No reports are **named**
- No sections are **traceable**
- A regulator cannot verify anything

This is summarization, not retrieval.
It sounds confident and proves nothing.

Case 2: AI retrieval success

CAE-Structured Content

Context (Annex II, Section 1.1)

Device X is intended to be used by trained healthcare professionals for monitoring condition Y in adult patients in a clinical environment.

Argument (Annex II, Sections 4 and 5)

The intended use is considered safe and effective because identified risks associated with monitoring condition Y have been reduced to acceptable levels through defined risk control measures, in accordance with ISO 14971. Residual risks are outweighed by the clinical benefits of timely detection and monitoring.

Evidence (Annex II, Sections 5 and 6)

- Risk Management Report **RMR-023**, Section 6.2
- Verification Test Report **VTR-045**, Sections 4.1–4.4
- Usability Validation Summary **UVS-012**

What the AI sees

- A clear intended use claim
- An explicit safety justification
- Named, scoped, retrievable evidence
- Stable identifiers instead of narrative prose

Typical AI response

"The safety of the intended use for Device X is supported by the Risk Management Report RMR-023 (Section 6.2), which demonstrates that identified risks have been reduced to acceptable levels in accordance with ISO 14971. Verification of safety-related requirements is documented in Verification Test Report VTR-045 (Sections 4.1–4.4). Use-related risks for healthcare professionals in a clinical environment are addressed in Usability Validation Summary UVS-012."

Why this succeeds

- Evidence is **retrieved**, not paraphrased
- Sources are **named and auditable**
- Logic is **explainable**
- The answer can survive regulatory scrutiny

This is retrieval with accountability.

The Key Insight

AI does not fail because it is weak.
AI fails because the content it sees is structurally ambiguous.

When Context, Argument, and Evidence are explicit:

- Retrieval is precise

- Reasoning is transparent
- Outputs are defensible

When they are mixed together:

- AI guesses
- Confidence increases
- Trust decreases

Reality check

If your content looks like Case 1, AI will only ever **summarize**.
If your content looks like Case 2, AI can **retrieve, explain, and defend**.

AI does not create regulatory rigor.
It exposes whether you already have it.