

Prepare cybersecurity evidence earlier. Get it accepted faster.

The joint playbook from **Qity IQMS** and **Aikido** for secure-by-design submission acceleration.

Today, the cybersecurity file is assembled **late**.

Cybersecurity evidence for **medical device submissions** is often assembled late, across disconnected systems. Four artefact sets must be reconciled by hand before submission:

- Threat model reporting

- Vulnerability findings

- Risk evaluations

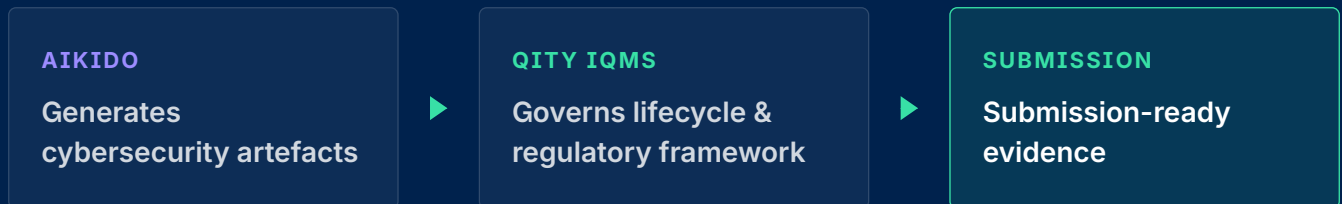
- SBOM records

Most companies spend **weeks before submission** rebuilding the cybersecurity file: producing threat model reports, documenting vulnerability findings, reconciling risk evaluations, and exporting SBOM records.

Your cybersecurity documentation, in **one round trip**.

Connect the cybersecurity artefacts generated in Aikido with lifecycle governance in Qity IQMS, and the same artefacts produced during development become submission-ready evidence.

THE ROUND TRIP



THE RESULT

When submission starts, the cybersecurity file already exists.

40%

of submission cybersecurity
evidence already exists in
your QMS

40% · In your QMS

60% · From Aikido

= 100% submission-ready

— QITY IQMS CONTAINS

- DHR records
- Software & hardware development documentation
- Architecture descriptions
- Risk management files
- Design verification & validation
- Device master record baselines

— AIKIDO CONTAINS

- Dependency inventories
- Machine-readable SBOMs
- Vulnerability findings
- Penetration testing

— Together, these are **continuously ready for submission.**

One Quality Management System. One cybersecurity evidence set.

Cybersecurity documentation and artefacts generated throughout development exist in Qity iQMS as controlled records. Its **Integrated, Dynamic Risk Management** is built in. Aikido feeds it directly:

01 SBOM versions align with release baselines.

02 Vulnerability findings feed risk evaluation.

03 Remediation moves through formal change control, directly into the QMS.

100%

of the cybersecurity file for submission emerges from the same governed environment used to manage development, risk, and post-market monitoring.

Secure-by-design submission acceleration.

Qity iQMS governs the management system and the regulatory framework. **Aikido** generates continuous cybersecurity artefacts during development. Together they produce the cybersecurity evidence required for FDA submissions and MDR technical documentation without rebuilding the file before submission.

01**Earlier readiness****02****Fewer review
cycles****03****Predictable
submissions**