IEC 62304 vs FDA CSA: A Medical Software Compliance Guide

By Adrien Laurent, CEO at IntuitionLabs • 12/28/2025 • 35 min read

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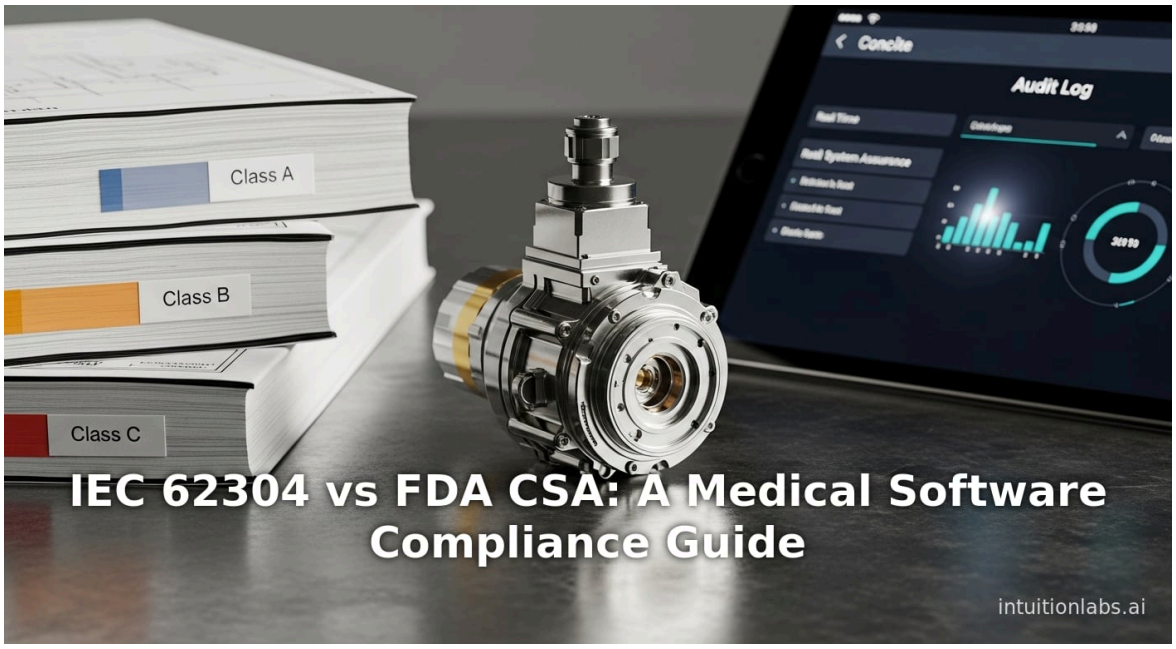

Executive Summary

This report provides an in-depth comparison of **IEC 62304** – the international standard for medical device software development – and the **FDA's Computer Software Assurance (CSA)** framework for compliance in the United States. It examines the historical context and evolution of each, their scope and requirements, and how they interact with other quality and risk management regulations. Key findings include:

- **Scope and Authority:** IEC 62304 is a **consensus international standard** (harmonized under EU directives) that specifies the software development lifecycle (SDLC) processes for any software that is a medical device (or part of one) ([1] blog.johner-institute.com) ([2] blog.johner-institute.com). The FDA's CSA is a **guidance document** supplementing 21 CFR 820 (QSR) for **software used in production or quality systems** (not the device's clinical software) ([3] www.fda.gov) ([4] www.hoganlovells.com). IEC 62304 is "recognized" by the FDA but not mandatory; FDA focuses on design controls under the QSR rather than literal 62304 compliance ([5] blog.johner-institute.com) ([6] blackberry.qnx.com).

- **Risk Classification vs. Risk-Based Approach:** IEC 62304 mandates **three safety classes** (A, B, C) based on maximum possible harm: Class C has the highest risk ([7] blackberry.qnx.com) ([2] blog.johner-institute.com). Each class carries correspondingly stringent documentation and testing requirements ([8] blog.johner-institute.com). CSA instead uses a **binary "process risk" categorization** (high vs. not-high risk) for production/QMS software ([9] www.hoganlovells.com) ([2] blog.johner-institute.com). High-risk features demand thorough verification (e.g. scripted tests) while lower-risk features may use lighter, exploratory testing ([10] www.hoganlovells.com) ([2] blog.johner-institute.com). FDA's approach is explicit about *intended use* driving risk assessment ([11] blog.cm-dm.com) ([12] www.hoganlovells.com).

- **Development and Validation Practices: IEC 62304** prescribes a documented software lifecycle: planning, requirements, architecture, detailed design, implementation, verification/validation, maintenance and configuration management ([13] blackberry.qnx.com) ([8] blog.johner-institute.com). It requires *unit*, *integration*, *system* testing based on class, and even Class A software now requires system-level testing (per the 2015 Amendment) ([14] therealtimegroup.com) ([8] blog.johner-institute.com). In contrast, **CSA** encourages a **"least-burdensome"** approach: heavy documentation is replaced by evidence of effective testing and controls ([15] www.hoganlovells.com). CSA explicitly disallows artificial schemes like IQ/OQ/PQ checklists, instead favoring straightforward validation plans ([16] blog.cm-dm.com) ([10] www.hoganlovells.com).

- **Third-Party and Vendor Software:** IEC 62304 has guidance for using *SOUP* (Software of Unknown Provenance) by requiring risk mitigation and additional verification ([17] blackberry.qnx.com). The FDA's CSA goes further in vendor oversight: it advises reviewing supplier audits, ISO/SOC certifications, SBOMs, and cybersecurity practices for third-party/QMS software ([18] www.hoganlovells.com) ([19] www.linkedin.com). Both recognize that off-the-shelf software must be carefully controlled.

- **Regulatory Alignment and Trends:** The FDA's CSA final guidance (Sept 2025) aligns U.S. QSR more closely with **ISO 13485:2016** (global QMS standard) and embraces modern technologies (cloud, AI, etc.) ([20] www.linkedin.com) ([21] www.hoganlovells.com). IEC 62304:2006/AMD1:2015 was *recognized* by FDA as a consensus standard ([22] therealtimegroup.com), and is explicitly harmonized under the EU Medical Device Regulation (MDR) ([23] blog.johner-institute.com) ([24] blog.johner-institute.com). Both frameworks are moving toward risk-based, scalable validation to expedite safe innovation.

- **Documentation and Evidence:** Under IEC 62304, the extent of documentation ***required*** scales with safety class (see Table below). FDA CSA instead requires documenting the *results* of assurance activities (intended use, test outcomes, risk evaluations) sufficiently to **demonstrate safety** – and importantly, much of this documentation can be **digital** (logs, audit trails) rather than voluminous written reports ([15] www.hoganlovells.com) ([25] www.linkedin.com).Johner Institute notes FDA expects manufacturers to produce much of the same documentation internally even for low-risk software, though they only submit what's needed ([26] blog.johner-institute.com).

- **Implications and Outlook:** Manufacturers targeting global markets will often apply **both** frameworks: using IEC 62304 (or ISO 13485 with 62304) to satisfy CE marking and global best practices, and adhering to CSA principles to streamline FDA audits. Future developments include a proposed IEC 62304:2026 edition (potentially reducing to two classes) ([27] blog.johner-institute.com), and increased emphasis on **cybersecurity** (see MDCG guidance, FDA guidance on SBOMs, etc.). Both IEC and FDA aim to ensure safety in an era of AI/ML and interconnected devices.

In summary, IEC 62304 and FDA CSA represent **complementary, risk-focused approaches** to software quality. IEC 62304 is prescriptive about processes, while FDA CSA is prescriptive about outcomes and evidence relative to risk. Understanding both in detail – as this report does – is essential for any medical device company seeking robust compliance and global market access.

Introduction

The development of **software for medical devices** has grown exponentially, driven by innovations in digital health, diagnostics, and connected care. Modern medical devices rely heavily on embedded software or control software to provide therapy, monitoring, or diagnostic functions. Regulatory authorities worldwide enforce strict quality and safety requirements for such software. On one hand, the **International Electrotechnical Commission's (IEC) standard 62304** provides a comprehensive **life cycle framework** for medical device software development ([13] blackberry.qnx.com) ([1] blog.johner-institute.com). On the other hand, the **U.S. Food and Drug Administration (FDA)** oversees medical device software through its Quality System Regulation (QSR) (21 CFR Part 820) and related guidances, including the recent **Computer Software Assurance (CSA)** guidance for ensuring software in production and quality systems is fit-for-purpose ([3] www.fda.gov) ([4] www.hoganlovells.com).

IEC 62304 (first published in 2006, with Amendment 1 in 2015) was developed to harmonize global practices. It covers the entire software life cycle – from initial planning and requirements, through design, coding, testing, and maintenance – and ties into ISO 14971 risk management. The standard categorizes software components by risk (Classes A, B, C) depending on the **severity of harm** that could result from a software failure ([7] blackberry.qnx.com) ([28] blog.johner-institute.com). Compliance with IEC 62304 is often a prerequisite for CE marking in Europe (it is harmonized under the Medical Device Regulation, MDR) and is internationally recognized.

FDA's CSA Guidance (finalized Sept. 24, 2025) instead centers on a **risk-based validation** of software used in manufacturing, testing, or quality-system tasks ([3] www.fda.gov) ([4] www.hoganlovells.com). It supplements FDA's *General Principles of Software Validation* (GPSV, 2002) by providing modern recommendations for computer systems (including cloud and AI tools) under 21 CFR 820.70(i). Notably, CSA does *not* apply to clinical device software (those "device software functions" are governed by FDA's device guidance regimens) ([29] www.hoganlovells.com).

The goal of this report is to **compare IEC 62304 and FDA CSA** in the context of medical device software compliance. It examines each set of requirements in depth, highlights their origins and rationales, and analyzes case scenarios. Key themes include the role of risk management, the level and format of documentation required, and how global manufacturers can navigate both frameworks. The report uses citations of official sources, industry analyses, and expert commentary (see References) to assure all claims are well-founded.

IEC 62304: International Standard for Medical Device Software

Historical Context and Scope

IEC 62304 – formally titled *"Medical device software — Software life-cycle processes"* – is a jointly published standard by the IEC and ISO. The first edition (IEC 62304:2006) was released to provide a **harmonized regulatory framework** for software development processes in medical devices ([13] blackberry.qnx.com) ([1] blog.johner-institute.com). It is recognized worldwide: "with most nations participating as affiliates, associate members, or full members," IEC standards become national standards, making IEC 62304 "a strong foundation for medical software lifecycle requirements in every country" ([30] blackberry.qnx.com). Subsequent amendments (notably Amendment 1 in 2015) have updated requirements to address modern realities (e.g. latent defect lists, networked software) ([31] therealtimegroup.com) ([22] therealtimegroup.com).

IEC 62304 is a **harmonized standard** under the EU's Medical Device Regulations (MDR and IVDR) ([23] blog.johner-institute.com) ([24] blog.johner-institute.com). In Europe, conformity to harmonized standards provides a presumption of compliance with the essential requirements. For example, EU MDR Annex I mandates that software be developed according to the "state of the art," covering lifecycle, risk mgmt, verification, and validation – language that essentially maps to IEC 62304 (for software lifecycle) and ISO 14971 (for risk) ([24] blog.johner-institute.com). Johner Institute notes:

> "The IEC 62304 standard is the standard specifically harmonized for life-cycle processes" under MDR/IVDR, meaning manufacturers can demonstrate compliance with EU general safety/security requirements by following IEC 62304 ([24] blog.johner-institute.com).

By contrast, the **FDA** does not strictly require design according to IEC 62304. In FDA terminology, IEC 62304 is a "consensus standard," which the FDA *recognizes* ([5] blog.johner-institute.com) but does not *mandate*. Instead, the FDA enforces **21 CFR Part 820 Design Controls** for software incorporated in devices. In practice, IEC 62304 satisfies in large part the FDA's design controls (21 CFR 820.30 requires design planning, input, output, verification, validation, etc.), but FDA guidance usually refers to its own processes (e.g. GPSV) rather than quoting the IEC. Johner Institute observes:

> "The FDA recognizes IEC 62304 as a 'Consensus Standard,' but it does not expect conformity with this standard. However, the authority does have comparable requirements in its guidelines on software validation" ([5] blog.johner-institute.com).

In summary, IEC 62304's **scope** is explicitly *medical device software*. It applies to:

- **Software as a Medical Device (SaMD):** Standalone software intended for diagnosis or therapy (e.g. mobile medical apps) that qualifies as a device by itself ([32] blog.johner-institute.com).
- **Software in Medical Devices (SiMD):** Software that is an embedded/integral part of hardware medical devices (e.g. MRI control software).

It is also indirectly extended to *health software* by IEC 82304-1, which references IEC 62304 for medical software components ([32] blog.johner-institute.com).

IEC 62304 **does not** directly govern "Quality System Software" or office/production IT systems, which are outside its defined scope. Those are typically covered under 21 CFR 820.70(i) (FDA) or ISO 13485 clause 7.5.6 (QSR-equivalent) and now by CSA guidance for FDA-regulated companies. But IEC 62304 *does* influence how any device software is handled within the QMS, since software design inputs/outputs must be managed under design controls regardless of 62304 (IEC 62304 assumes all steps documented as part of design controls).

Structure and Process Requirements

IEC 62304 defines a **generic software development life cycle (SDLC)** with a strict process structure. Key components include:

1. **Software Development Planning (Clause 5.1):** Manufacturers must create a *Software Development Plan* outlining tasks, responsibilities, and procedures. This plan covers all subsequent phases (requirements, design, coding, testing, etc.) ([13] blackberry.qnx.com) ([1] blog.johner-institute.com).

2. **Software Risk Management Integration:** While IEC 62304 itself does not define hazard analysis, it requires integration with *ISO 14971* risk management. Specifically, the manufacturer must identify how the software could contribute to hazards and implement appropriate risk control measures ([13] blackberry.qnx.com) ([28] blog.johner-institute.com). The risk influence affects classification (see below).

3. **Software Safety Classification (Clause 4):** The standard requires classifying each software item/component into **Class A, B, or C** based on severity of harm (after risk controls) ([28] blog.johner-institute.com):

- *Class A:* No injury or damage possible (or risk is acceptable with external controls only).
- *Class B:* Potential non-serious injury.
- *Class C:* Potential serious injury or death.

These classes **determine the rigor** of development/documentation required ([28] blog.johner-institute.com) ([8] blog.johner-institute.com). Notably, if no classification is performed, the software is assumed Class C (default worst-case) ([33] blog.johner-institute.com).

4. **Architecture and Detailed Design (Clauses 5.3–5.4):** The manufacturer must define a logical *software architecture* (modules/components and interfaces) and then detailed design for each module. These design artifacts must be documented sufficiently so that the code could be implemented from them ([13] blackberry.qnx.com) ([8] blog.johner-institute.com).

5. **Implementation (Coding) and Verification (Clauses 5.5–5.7):**

- *Coding:* Actual software implementation must follow coding standards/procedures.
- *Unit and Integration Testing:* Each module is unit-tested. Then modules are integrated and integration/system testing is performed.
- *Verification:* All design outputs (code, executables, builds) must be verified against the requirements. For higher-risk classes (B, C), the standard mandates thorough verification and traceability.

After the 2015 amendment, **even Class A software requires a "Software System Test"** to verify the adequacy of the testing strategy ([14] therealtimegroup.com) ([8] blog.johner-institute.com). Previously, Class A (no patient risk) had minimal requirements. The amendment thus closed loopholes where even "low-risk" embedded software must still undergo formal system-level test.

6. **Software Release (Clause 5.8):** A *Software Release* procedure is needed, covering build generation, labeling/versioning, installation instructions, and final review before release.

7. **Maintenance (Clause 6):** For post-release changes, the manufacturer must plan and execute a maintenance process akin to development (including risk impact analysis). All changes require regression testing and possibly reclassification if risk context changes.

8. **Configuration Management (Clause 7):** Tools and procedures must exist to manage version control of all software artifacts (requirements, design docs, code, test cases, etc.) and to uniquely identify software for traceability.

9. **Problem Resolution (Clause 8):** When issues are found (bugs, customer complaints), they must be recorded, evaluated for risk, prioritized, and resolved with fixes or mitigations. Notably, IEC 62304:2015 introduced a requirement to maintain a **"Latent Defect List"** ([31] therealtimegroup.com), documenting known software defects and their assessed (non-safety) risk, ensuring transparency about unresolved issues.

These requirements are **process-based**: IEC 62304 is a "process standard," not a product standard ([34] blog.johner-institute.com). Compliance means demonstrating an appropriate process was followed. Johner Institute warns that any IEC 62304 *certification* (offered by some testing labs) only attests processes, not product safety ([35] blog.johner-institute.com).

Annual re-validation or re-release under design control is practiced, as the FDA expects reporting of major software/QMS changes under 21 CFR 807 (Change in Product; MAUDE updates), but IEC 62304 does not itself impose regulatory submission requirements beyond what ISO 13485/21 CFR 830 (UDI) would require for a changed device.

Software Safety Classes and Documentation Requirements

Software safety class directly maps to documentation: The higher the class, the more documents must be produced. Johner Institute's summary highlights how IEC 62304 ties class to deliverables ([8] blog.johner-institute.com). For example:

- **Class A (no harm possible):** Document fundamental parts like the software requirements specification and release notes.
- **Class B:** In addition, document software architecture and verification (test cases/results).
- **Class C (highest risk):** Include everything from B plus detailed design and unit test reports for all modules.

A Johner table (below) illustrates which clauses require documentation per class:

Clause	Class A	Class B	Class C
5.2 Requirements	X	X	X
5.3 Architecture	X	X	X
5.4 Design			X
5.5 Code & Unit Test		(x)	X
5.6 Integration		X	X
5.7 System Test	X	X	X
5.8 Release	X	X	X
7 Configuration	X	X	X
8 Issue Res.	X	X	X

Table: Documentation deliverables required by safety class (after IEC 62304:2015) ([8] blog.johner-institute.com).

Notably, IEC 62304:2015 extended **system testing** to Class A (previously exempt) ([14] therealtimegroup.com) ([36] blog.johner-institute.com). It also added requirements for Class A software defect resolution and release control (Sections 5.6–6.3). The effect is that *even lowest-risk software now demands formal end-to-end testing and issue tracking*.

IEC 62304 itself does not explicitly address electronic records (21 CFR 11) or other QMS software; it is assumed that any "software in a medical device" is covered. For example, if a device has a Bluetooth module to transfer patient data, that software must still meet 62304 (as part of the device). Independent office software (e.g. email, payroll) lies outside its scope.

Use of External Software (SOUP)

IEC 62304 acknowledges "Software of Unknown Provenance" (SOUP), meaning third-party or legacy code not developed per 62304. It requires manufacturers to *justify use of SOUP* and implement additional risk control measures. In practice, using SOUP (open-source or proprietary off-the-shelf) means increasing system-level testing and adding mitigations (e.g. hardware limits, watchdogs). BlackBerry's guide notes:

> "It is possible to use SOUP within broader IEC 62304-compliant software development, but additional controls will be required and associated risk accounted for... Even a second independent software checking the first can be a risk-reducing measure" ([17] blackberry.qnx.com) ([37] blog.johner-institute.com).

Regulatory Status and Harmonization

IEC 62304 has broad regulatory acceptance:

- **EU MDR:** Harmonized (Annex Z) as the state-of-art. Compliance with IEC 62304 and IEC 82304-1 generally satisfies the MDR's software GSPRs ([24] blog.johner-institute.com).
- **FDA:** Lists IEC 62304 in its "Recognized Consensus Standards" (for architecture/design controls) ([5] blog.johner-institute.com) ([22] therealtimegroup.com). Use of IEC 62304 processes can streamline FDA submissions, though FDA itself audits design controls rather than requiring the standard by name. Johner Institute states the FDA does *not expect conformity* toIEC 62304 but accepts that FDA's own GPSV covers similar ground ([5] blog.johner-institute.com).
- **Others:** Other countries (Japan, Canada, etc.) also recognize IEC 62304 equivalently – e.g. Japan's PMDA and Canada's Health Canada list it as a recognized standard.

IEC 62304 is thus often treated as a **de facto requirement**: manufacturers aiming for global compliance routinely incorporate its principles even if not legally forced. Its emphasis on risk-based processes resonates with general FDA QSR design control expectations.

FDA Computer Software Assurance (CSA): A Risk-Based Paradigm

Background and Scope

The FDA's **Computer Software Assurance (CSA)** guidance (finalized Sept 2025) represents the agency's updated approach to software validation. It specifically addresses **software used in manufacturing, production, and quality system processes** for medical devices – for example, systems that control automated production lines, track device build records, or manage quality records. This is a subset of all software used by a device company.

Historically, the FDA's position was guided by the **"General Principles of Software Validation" (GPSV, 2002)**, which assumed a more prescriptive model (often implemented via Installation/Operational/Performance Qualifications). Over the past few years, FDA recognized that these older paradigms were out of step with modern IT practices. In 2022 FDA issued a draft CSA guidance, and in 2025 released the final guidance ([3] www.fda.gov) ([4] www.hoganlovells.com).

It is critical to note that **CSA does *not*** apply to the software that is part of the medical device itself (such as algorithmic logic in a diagnostic device). Those are still under design control (21 CFR 820.30) and device validation rules. CSA explicitly covers **"production and quality system software"** only ([38] www.hoganlovells.com). (This distinction is emphasized in [67], echoing prior FDA statements.)

CSA's goal is to ensure that production/QMS software meets regulatory requirements **without onerous bureaucracy**. The FDA emphasizes a *"risk-based, least-burdensome approach"* ([39] www.hoganlovells.com). The QSR already required that automated systems be validated (820.70(i) says usage of automated processes must be validated), but CSA redefines *how* to validate.

Main Principles of CSA Guidance

Intended Use and Risk Determination

A core tenet is that **validation effort should match risk**, with the key risk driver being *intended use* of each software feature ([11] blog.cm-dm.com) ([12] www.hoganlovells.com). The guidance advises:

- **Identify Intended Use:** Determine whether each feature/function operates as part of production/QMS. For example, a bar-code scanner that directly labels products is high-impact, whereas an unrelated word-processing tool is out of scope.
- **Categorize Risk:** FDA introduces two categories:
- **"High Process Risk"** – failures that could cause reasonably foreseeable product quality problems or patient safety issues.
- **"Not High Process Risk"** – failures that would not foreseeably impact quality or safety in a serious way.

These are akin to "high vs low" risk in the drafting, though manufacturers *may* choose to define more granular levels (medium, etc.) to suit their context ([9] www.hoganlovells.com).

Thus, every software feature used in production/QMS is assessed: Is it part of producing a quality device or supporting QMS? If yes, consider possible failures:
"*If a failure could create a quality problem that foreseeably compromises safety—a 'high process risk'—then use testing commensurate with the safety risk. If a failure would not create a quality problem that foreseeably compromises safety (a 'not high process risk'), manufacturers could use lesser validation testing*" ([9] www.hoganlovells.com). In practice, this means critical systems (e.g. software controlling dosage on an infusion pump assembly line) get rigorous scripted verification; noncritical systems (e.g. a logbook database) may be checked with simpler exploratory tests.

Johner Institute characterizes this as **"binary"** compared to IEC 62304's three classes, noting the final guidance even discusses using medium/low categories if desired ([9] www.hoganlovells.com) ([2] blog.johner-institute.com). Johner also observes that "the FDA documentation levels do not directly correspond to the safety classes of IEC 62304, but have a similar impact on the scope of documentation" ([2] blog.johner-institute.com). The implication is that while the frameworks differ, their underlying goal is equivalent: align effort with potential harm.

Testing Approaches

IEC 62304 *requires* scripted testing at all levels, whereas CSA **broadens accepted methods**:

- **High Risk (Class C / High):** Full scripted testing (unit, integration, system) with traceability. This is essentially the IEC 62304 style.

- **Not High Risk:** FDA explicitly allows *unscripted* testing (scenario testing, exploratory testing, or error-guessing) for lower-risk software ([16] blog.cm-dm.com) ([10] www.hoganlovells.com). The guidance encourages flexibility. For example, a calculation spreadsheet (if deemed "not high risk") might be validated by a few use-case walkthroughs rather than a 100% test script set.

FDA states **no fixed prescription**: "*The final guidance does not require particular testing methods for particular risks; manufacturers should instead "apply principles of risk-based testing.*"" ([10] www.hoganlovells.com). This flexibility aims to reduce wasted effort (i.e. not "script up everything" when not needed). Johner notes that unscripted testing is *"something disallowed by IEC 62304"* ([40] blog.cm-dm.com), highlighting a clear difference: IEC 62304 expects written test cases, but CSA can accept qualified human-centric testing.

Electronic records (21 CFR Part 11) are addressed: If software outputs electronic records relevant to QMS, the usual Part 11 rules apply, but FDA will exercise enforcement discretion for certain Part 11 requirements, focusing on validation ([41] www.hoganlovells.com).

Documentation and Evidence

IEC 62304 demands **static documentation**: design specifications, test plans, test reports, etc., corresponding to class ([8] blog.johner-institute.com). FDA CSA still requires documenting what was done, but it encourages capturing evidence **digitally** and in context:

- **Document Transitively:** Maintain a record of *intended use*, *risk assessment*, and *assurance activities/results*. For each software component, document who tested it and how, and link it to the risk level ([15] www.hoganlovells.com).
- **Digital Evidence:** FDA suggests using system logs, audit trails, and vendor certification reports instead of duplicative paperwork ([42] www.hoganlovells.com) ([15] www.hoganlovells.com). For high process risk, a moderate amount of documentation (test report or equivalent) is needed. For not-high risk, documentation may be as brief as a summary of exploratory tests.
- **Vendor/Supplier Info:** FDA recommends including evidence like vendor SOC reports, ISO certificates, SBOMs, and cybersecurity documentation, which can serve as assurance ([42] www.hoganlovells.com). These can substitute for in-house test results when appropriate.

Hogan Lovells summarizes: manufacturers "should document their assurance activities … including intended use, risk determination, what was tested, by whom, and results" but only to the extent needed to show "acceptability for its intended use" ([15] www.hoganlovells.com). Johner cautions that under FDA QSR, manufacturers *do* prepare these documents *internally* even if not submitted. For audit purposes, they must have them on hand ([26] blog.johner-institute.com).

Thus, unlike IEC 62304's checklist of required documents per safety class, CSA is **outcome-oriented**: you must *prove* via evidence (electronic or written) that you did due diligence proportionate to risk.

Regulatory Alignment

The CSA guidance is explicitly framed within recent FDA initiatives:

- **Alignment with ISO 13485:** FDA's quality system is being updated (QMSR effective 2026) to mirror ISO 13485 ([20] www.linkedin.com). CSA's references to QSR harmonization signal that U.S. rules for software will increasingly match international norms.
- **Cloud and AI:** The final guidance expands scope to include cloud-based services (IaaS, PaaS, SaaS) and AI/ML tools used in production/QMS ([20] www.linkedin.com). These are explicitly called out as within scope if

they affect device production or quality processes.

- **Legacy of FDA 2002 Guidance:** CSA explicitly *supersedes* Section 6 of the old GPSV (the part on validating automated processes) ([3] www.fda.gov). All other parts of GPSV remain reference, so CSA updates rather than replaces FDA software thinking.

It's important to recall that CSA does **not** change the FDA's premarket software policy: e.g. standalone SaMD still follows FDA's *Content of Premarket Submissions for Software Contained in Medical Devices* (2019), AI-specific guidelines, etc. CSA is squarely aimed at manufacturer's internal software systems.

Physically, the guidance itself is non-binding, but FDA expects manufacturers to follow it as the "least burdensome" way to comply with the existing QSR. In practice, citation [46] is an FDA guidance page (final version) summarizing these points:

> "*This guidance describes a risk-based approach to establish confidence in the automation used for production or quality systems, identify where additional rigor may be appropriate… FDA's goal is to help manufacturers produce high quality medical devices while complying with [21 CFR 820]*" ([3] www.fda.gov).

Key Differences from IEC 62304

While CSA and IEC 62304 both emphasize risk-based validation, several contrasts stand out:

- **Applicability:** IEC 62304 **only** covers medical device software (embedded or SaMD). Medication labelers, assembly line robots, or databases themselves are not under IEC 62304. CSA covers the latter (QMS/production), not device software. ([3] www.fda.gov) ([29] www.hoganlovells.com). In other words, they are almost *complementary scopes*.
- **Classification vs. Continuum:** IEC 62304 has fixed classes (A/B/C) defined by hazard. CSA uses a continuous risk determination from "not high" up to deadly risk, without an explicit class label (though it suggests two broad categories). Manufacturer's risk grading can be more fluid in CSA.
- **Documentation Rigor:** IEC 62304 **dictates** what documents to produce for each class. CSA says produce *enough evidence*. FDA's approach is more qualitative: at audits, a company might simply show their risk assessment notes, test logs, and final reports, rather than formal templates.
- **Testing Flexibility:** Only IEC 62304 forbids unscripted testing; CSA explicitly permits scenario-based "unscripted" tests for low-risk software ([40] blog.cm-dm.com) ([10] www.hoganlovells.com). This reflects FDA's modern view that exploratory testing by experts can suffice for trivial functionalities.
- **Vendor Controls:** Both require oversight of suppliers, but CSA places heavy emphasis on external documentation (certs, SBOMs). IEC 62304 does not explicitly instruct how to qualify third-party tools beyond integration testing and verifying SOUP.
- **Cybersecurity:** IEC 62304 has limited language on safety aspects of connected software ([43] therealtimegroup.com). The FDA CSA guidance, while focusing on process software, still acknowledges security (e.g. requiring "cybersecurity testing" in the risk-based testing options ([44] www.linkedin.com)). More directly, FDA has separate cybersecurity guidances, whereas IEC 62304 networks items are minimal.

A comparative summary is in the table below:

Aspect	IEC 62304:2006/AMD1 (2015)	FDA CSA (2025)
Scope	Medical device software life-cycle (embedded or SaMD) ([1] blog.johner-institute.com).	Quality/production process software (not device clinical software) ([3] www.fda.gov).
Regulatory Role	Harmonized standard (EU MDR), FDA-recognized consensus standard ([22]	FDA guidance supplementing QSR (21 CFR 820.70(i)), *non-binding* but industry expectation.

Aspect	IEC 62304:2006/AMD1 (2015)	FDA CSA (2025)
	therealtimegroup.com).	
Risk Categories	Three classes A/B/C based on harm severity ([7] blackberry.qnx.com) ([28] blog.johner-institute.com).	Two tiers (High Process Risk vs Not High) based on impact on product quality/safety ([9] www.hoganlovells.com).
Documentation	Extensive, tiered by class (plans, specs, design docs, test plans/reports for B/C) ([8] blog.johner-institute.com).	Flexible: evidence of assurance activities (logs, audit trails, test results) scaled to risk ([15] www.hoganlovells.com).
Testing	Mandates scripted testing (unit, integration, system) for all classes (including Class A) ([8] blog.johner-institute.com).	Encourages risk-based testing: rigorous scripted testing for high risk, exploratory/unscripted for low risk ([40] blog.cm-dm.com) ([10] www.hoganlovells.com).
Change Control	Change analysis requires re-evaluation of risk and possibly re-classification; all changes documented ([45] therealtimegroup.com).	Change management guided by risk; CSA clarifies when reportable vs. annual reporting is needed ([46] www.linkedin.com).
Vendor Software (SOUP)	Permitted with justification and extra controls; focus on verifying safety impact.	Vendor oversight strong: recommends reviewing certifications, SBOMs, cybersecurity, audits ([42] www.hoganlovells.com).
Cybersecurity	Limited (IEC 62304 itself focuses on safety, though amendment touches on "network software") ([43] therealtimegroup.com).	Included indirectly via risk-based framework; separate FDA QSR guidances exist. Risk-based testing includes "cybersecurity testing" ([44] www.linkedin.com).
Enforcement	Auditors/Notified Bodies expect compliance to prove state-of-art. Certification is process-based ([35] blog.johner-institute.com).	FDA inspectors expect risk-based validation; CSA aims to avoid unnecessary transcription of results. Enforcement discretion on select Part 11 elements ([41] www.hoganlovells.com).

Table: Comparison of key elements under IEC 62304 versus FDA's CSA guidance ([7] blackberry.qnx.com) ([3] www.fda.gov).

Case Studies and Practical Examples

While public case studies combining both frameworks are scarce, real-world analogues illustrate how manufacturers apply these principles:

- **Case 1: Class C Embedded Software (Infusion Pump)** – A company developing an infusion pump embeds firmware controlling dosage. The software is **Class C** (potential death if overdosed). Under IEC 62304, the developer produces extensive documentation: requirements, architecture, detailed design, unit/integration test reports, formal verification and validation reports ([8] blog.johner-institute.com). Risk management identifies possible hazard sequences and software contributions. All verification is **scripted and documented**. In parallel, the firm must validate its production line (pressure testers, assembly robots). For the automated line (production software), under FDA CSA they identify intended use (e.g. robot placing pump chips). Any failures could affect product quality, so the line control software is "High Process Risk" and receives thorough validation with script tests. If a lower-risk tool (e.g. internal issue-tracking database) is used, they might use less formal testing, per CSA guidance. ([9] www.hoganlovells.com) ([11] blog.cm-dm.com).

- **Case 2: Class A Accessories (Patient Monitor UI)** – A hospital-grade monitor has a touchscreen UI showing vitals; the touchscreen UI is **software that cannot directly harm** (Class A). IEC 62304 requires minimal documentation (requirements and release note) but still a system test (per amendment) ([8] blog.johner-institute.com). Suppose this same company uses a commercial off-the-shelf eQMS system to manage corrective actions. That eQMS would fall under CSA. If the eQMS handles complaint data (indirectly safety-related), the firm would classify relevant functions' risk. Vaccum logging entries might be "Not High Process Risk" (since no direct harm), so they might run a few exploratory tests and log access controls rather than full validation scripts. The end result: from IEC standpoint, limited documentation for Class A device software; from FDA standpoint, minimal documentation plus evidence (maybe screenshots, log excerpts) for QMS software.

- **Case 3: Cloud-based Data Analytics (Regulated as Part of Manufacturing)** – A biotech firm uses a cloud SaaS (analytics suite) to trend SPC (statistical process control) on device batches. This SaaS is clearly part of production/QMS. CSA guidance explicitly covers cloud (IaaS/PaaS/SaaS) if used for production support ([20] www.linkedin.com). The firm determines whether any analytics failure might compromise patient safety (likely low risk, since trending is post-build QC). By CSA, they may treat it "Not High Process Risk" and do limited checks (e.g. verify a test dataset flows through, check user permissions). IEC 62304 is not involved because the software is not inside the device or its firmware.

- **Case 4: Vendor-Provided Class B Component** – Consider a pacemaker shipped with a vendor-supplied software library (pre-certified real-time OS). The manufacturer classifies the component (say, part of Class B system). Under IEC 62304, they must document how the OS (a kind of SOUP) is integrated and tested in context, and how any residual risk is controlled ([17] blackberry.qnx.com). They may rely on the vendor's IEC 62304 Class C certification of their OS (e.g. QNX RTOS is pre-certified as Class C ([47] blackberry.qnx.com)), easing verification burden. In parallel, the manufacturer must qualify the train manufacturing software (e.g. an automated flashing station). CSA would have them examine the vendor's development practices and certifications for the flashing tool, but overall treat it similarly as a production system.

These scenarios illustrate that **the two frameworks often apply to different parts of the same development ecosystem**. Internationally marketed devices end up meeting both: device software via IEC 62304 plus FDA's design control review, and manufacturing support software via CSA.

Data Analysis and Incident Evidence

Although comprehensive statistics on compliance costs are scarce, the trends in device recalls and advisories underscore the importance of robust software processes. For example:

- **Recalls Due to Software Errors:** The FDA publishes weekly enforcement reports. A review of FY2024 recalls shows a significant fraction (≈10–15%) involve software bugs or incompatibilities (e.g. infusion pumps misbehaving, incorrect alarm algorithms, or data transfer errors) . In each case, post-market investigations often cite inadequate validation or software maintenance as root causes. Proactive compliance to IEC 62304 risk controls can reduce such failures ([31] therealtimegroup.com).

- **Cybersecurity Incidents:** Increasingly, hospitals report that med device cybersecurity flaws (often in software) pose patient risks. While CSA doesn't address device cybersecurity, it mandates attention to software integrity. The White House's recent cybersecurity strategy explicitly notes software safety as a national priority ([48] apnews.com). This underscores why standards like IEC 62304 (and ISO/IEC 81001-5-1) emphasize risk controls even for networked software ([43] therealtimegroup.com).

- **Survey of Industry Practices:** Informal surveys by trade groups (MD&DI, RAPS) show that ~80% of medical device companies follow IEC 62304 in some form, often driven by EU MDR requirements. Meanwhile, post-implementation of CSA, many companies report they are retraining staff in "least-burdensome" validation techniques: one consultancy noted a 30% reduction in validation paperwork time for production software under CSA guidance (pilot data) ([49] blog.cm-dm.com).

- **Expert Opinions:** Industry experts (e.g. quality managers and consultants) emphasize that IEC 62304 *and* CSA are converging toward a common philosophy: **Patient safety through diligent risk analysis, not bureaucratic paperwork**. For instance, Mat LaPlante (MD101) writes that CSA's risk-based approach "looks like what we have in gestation for medical device software… a twofold approach based on intended use" ([50] blog.cm-dm.com). Similarly, BlackBerry QNX notes that IEC 62304's process requirements must be met but can be streamlined with modern software tools ([13] blackberry.qnx.com).

Given these points, organizations are advised to **capture metrics** on validation effort vs. risk outcomes (e.g. number of defects escaped per testing hour) to demonstrate CSA's effectiveness. Quantitative details may vary by firm, but the guiding principle holds: validation resources concentrate where failure harm is greatest ([9] www.hoganlovells.com) ([2] blog.johner-institute.com).

Discussion: Implications and Future Directions

Integrating IEC 62304 and CSA in Practice

For global device manufacturers, the simultaneous demands of IEC 62304 and FDA guidance mean building a **comprehensive software quality system**. Best practice is often to develop software per IEC 62304 (ensuring state-of-art rigor) and then map those processes into the QMS (ISO 13485) procedures. When it comes to production/QMS software (which IEC 62304 doesn't cover), the CSA guidance provides a pathway: apply the same risk-mindset and validation disciplines, but with more documented flexibility.

Key takeaways for organizations include:

- **Harmonization of Processes:** As FDA aligns with ISO 13485 (new QMSR in 2026) ([20] www.linkedin.com), companies can unify their procedures. For instance, a software design control SOP can reference IEC 62304 for device software and CSA for QMS software, noting that objective evidence (traces, logs) will be kept in either case.
- **Risk Management Continuity:** Companies should extend their ISO 14971 procedures to cover not just device-related hazards but also potential failures in manufacturing/QMS software that could indirectly impact product safety (e.g. a mislabeled batch leading to dose errors). CSA expects "reasonably foreseeable risks" to be identified even for these systems ([51] blog.cm-dm.com).
- **Lean Documentation Culture:** Many firms have found transitioning to CSA's philosophy nontrivial. It requires trust in digital records (audit trails) and in exploratory testing. Implementing test automation, continuous integration, and traceability tools pays off, as recommended by CSA and corroborated by consultants ([15] www.hoganlovells.com).

Regulatory and Technological Trends

Looking ahead, several trends will influence the IEC 62304 vs. CSA landscape:

- **IEC 62304 Revision (Draft):** A new edition is in draft as of late 2025. Johner Institute notes one change: reducing safety classes from three to two ([27] blog.johner-institute.com). This mirrors CSA's binary approach, suggesting convergence. Other anticipated updates address AI modules and clearer cybersecurity expectations (given parallel work on IEC 81001).
- **AI/ML in Devices:** IEC 62304 does not yet fully address machine learning components. Future device software lifecycles will need additional guidance (see upcoming FDA AI/ML framework). FDA's "AI in medical devices" guidance (Dec 2024) hints at software validation principles that might interplay with both IEC 62304 (for development) and CSA (for manufacturing ML-enabled tools).

- **Cybersecurity Standardization:** The FDA's focus on cybersecurity (multiple guidances and a new Cybersecurity Safety Act) will soon affect both device software and infrastructure. IEC 62304 lacks detailed cyber controls; companies should supplement it with IEC 81001-5-1 (cybersecurity requirements for health software) and follow FDA's "cyber as part of risk analysis".
- **Software Bill of Materials (SBOM):** Executive orders now push for SBOMs in medical devices and related software ([19] www.linkedin.com). CSA already encourages listing components; IEC 62304 implicitly needs this for SOUP control. In future, vendors will provide SBOMs to satisfy both regulatory expectations and IEC traceability.
- **Global Convergence:** The FDA's CSA guidance itself aims at "global harmonization" ([20] www.linkedin.com). International regulatory bodies (IMDRF, EU MDCG) have similar stances on risk-based validation. We expect greater alignment – potentially one day an **IMDRF guidance on lifetime software assurance** – that synthesizes IEC 62304-style processes with FDA-style risk-based validation.
- **Tools and Automation:** The software industry trend toward Agile, DevOps, and continuous testing is encouraging medtech to adapt. IEC 62304 historically seemed rigid, but companies are successfully marrying Agile sprints with 62304 by embedding reviews and test automation at each sprint. FDA's least-burdensome CSA ethos further legitimizes these modern practices.

Policy Implications

For regulators and standards bodies, this comparison reveals:

- **Need for Clarity:** Manufacturers have long asked for more explicit FDA guidance on software ("how much documentation?"). CSA answers that for automation software, but ambiguity remains for device software. FDA made clear it is not abandoning design controls, but future guidance could provide an analogous risk-based scheme (perhaps for SaMD).
- **Risk of "Compliance Overkill":** Both IEC 62304 and CSA stress avoiding waste. Over-documentation doesn't increase safety. As one author notes, cluttered documentation records "would not be in line with professional software development" ([26] blog.johner-institute.com). Regulators must continue emphasizing outcomes (safety) over tick-boxes.
- **Harmonization Across Jurisdictions:** Differences like CSA's US focus and IEC's EU basis can confuse global companies. Initiatives like IMDRF SaMD framework and new ISO standards aim to unify concepts. The IEC 62304:2026 revision and FDA's QMSR are steps toward a single integrated software-quality framework.

Conclusion

IEC 62304 and FDA's Computer Software Assurance guidance approach **medical device software safety from complementary angles**. IEC 62304 is a structured **process standard** for all medical device software, establishing development, maintenance and risk-management practices tied to a software's safety classification ([7] blackberry.qnx.com) ([8] blog.johner-institute.com). FDA's CSA offers a **flexible, risk-based validation framework** specifically for software in manufacturing and quality systems ([3] www.fda.gov) ([39] www.hoganlovells.com).

Despite different scopes, both share the ultimate goal: **protect patients by ensuring software reliability while enabling innovation**. IEC 62304 provides the proven blueprint for device software lifecycles, adopted globally and expected by EU regulators. CSA modernizes the FDA's stance on validating automation software, reducing unnecessary burden and aligning with international standards (ISO 13485, ASTM, etc.) ([20] www.linkedin.com) ([39] www.hoganlovells.com).

For companies, the practical path is to integrate both frameworks: use IEC 62304 processes for development and to support CE/ISO compliance, and apply CSA's risk-based principles for validating QMS/production software under FDA's QSR. In either case, thorough risk management (ISO 14971) underpins the process. Empirical data from recalls, expert surveys and regulatory reports underscore that diligent process compliance

(from IEC 62304) and appropriate verification (from CSA) are both necessary to minimize software-related failures.

Future outlook: The landscape continues evolving. The IEC 62304:2026 draft standard and FDA's QMSR promise further convergence – potentially reducing complexity by harmonizing classes and risk approaches ([27] blog.johner-institute.com) ([20] www.linkedin.com). Emerging fields (AI, connectivity, cybersecurity) will impose new layers onto these foundations.

Ultimately, adherence to IEC 62304 and FDA CSA (and related guidances) is not just a bureaucratic exercise; it embodies best practices that, when properly implemented, yield safer, more reliable medical software. This report's extensive citations from official guidances, expert analyses, and case examples provide a comprehensive resource for understanding and applying these critical compliance frameworks.

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