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FDA PCCP Explained: Managing Medical Device Changes

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Published by IntuitionLabs · 2026-02-09 · fda pccp · medical device regulation · ai/ml devices · section 515c · fdora 2022 · software as a medical device · regulatory compliance · 510(k) submission · change management

Original article: <https://intuitionlabs.ai/articles/fda-predetermined-change-control-plan-pccp-guide>



In this article

1. Executive Summary
 2. Introduction and Background
 3. Regulatory and Legislative Framework
 4. FDA Guidance Overview and PCCP Content
 5. Regulatory Submission Process and Manufacturer Implications
 6. Case Studies and Real-World Examples
 7. Data Analysis and Industry Insights
 8. International Harmonization and Future Directions
 9. Conclusion
-

Executive Summary

The U.S. Food and Drug Administration's Predetermined Change Control Plan (PCCP) is an emerging regulatory tool that enables manufacturers to predefine and preapprove planned device modifications within a single marketing submission. Authorized by the 2022 Food and Drug Omnibus Reform Act (FDORA) and codified in Section 515C of the FD&C Act, the PCCP aims to reconcile traditional device regulations – which assume static devices – with modern, adaptive products, especially those incorporating artificial intelligence (AI) and machine learning (ML) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (www.boleary.com). Under a PCCP, manufacturers submit a documented plan outlining the specific changes to be made, the methods for implementing and verifying those changes, and an impact assessment of safety and effectiveness. When FDA authorizes a PCCP as part of a device marketing submission, changes implemented consistently with that plan can proceed without separate marketing submissions. Marketing authorization means 510(k) clearance, a granted De Novo classification request, or PMA approval, depending on the pathway ([FDA guidance](#)).

The PCCP framework aims to reduce the regulatory burden of iterative device updates: FDA reviews the planned modifications in advance so that implementing each modification consistently with the authorized PCCP does not require another marketing submission ([FDA guidance](#)). This describes a regulatory mechanism, rather than demonstrated reductions in approval time or cost. Changes must be validated and implemented according to the authorized plan. Changes outside that plan must be assessed under the applicable submission rules; an out-of-plan change does not automatically require a new submission ([FDA guidance, Section V.D](#)).

FDA's guidance describes PCCPs for AI-enabled device software functions, including planned model modifications supported by validation methods and an impact assessment. These changes must remain within the authorized plan ([FDA guidance](#)).

This report provides a comprehensive analysis of FDA's PCCP framework tailored to medical device manufacturers. It covers the historical and international regulatory context, the statutory basis and FDA guidance (both draft and final), and the specific components of a PCCP. We discuss implementation strategies, risk-management expectations, and real-world considerations from industry and expert sources. Historical

public-record searches illustrate PCCP use, and illustrative case scenarios highlight practical uses. We also compare the U.S. approach with relevant policies in the EU and other jurisdictions. Finally, we explore the implications for manufacturers and future directions for adaptive regulatory pathways.

Introduction and Background

Medical device regulation in the United States has traditionally been predicated on the assumption that a device remains essentially unchanged after market approval. Under statutes and regulations (e.g. 21 CFR 807.81 for 510(k) changes and 21 CFR 814.39 for PMA supplements), any significant modification to a device's design, materials, energy source, or software that could affect safety or effectiveness typically triggers a new submission or supplement (www.boleary.com). This model has worked for hardware-centric devices but poses serious challenges for modern, software-enabled devices – especially those incorporating AI/ML that continually improve with new data.

AI- and ML-enabled devices can change behavior as they learn: for example, a diagnostic algorithm might self-adjust sensitivity when exposed to more patient images. Under legacy regulations, *each* such learning-induced change could be viewed as a “new” device change requiring regulatory review. As a result, manufacturers of AI-driven products face an untenable tradeoff: stifle innovation with frequent applications, or risk noncompliance (www.complizen.ai) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). The dire nature of this problem has been widely recognized. For instance, a 2025 review notes that FDA's conventional paradigm “assumes devices remain static after approval,” whereas AI/ML algorithms improve through real-world use (www.complizen.ai). The same review observes that requiring separate submissions for each AI update “would stifle innovation while creating regulatory bottlenecks,” spurring the development of specialized frameworks to balance continuous improvement with patient safety (www.complizen.ai).

The response has been to create new pathways for software lifecycle regulation. In 2019 the FDA published a discussion paper on AI/ML-based Software as a Medical Device (SaMD), explicitly proposing a “change control plan” concept for machine-learning algorithms (orthogonal.io). This “predetermined change control plan” would allow certain planned updates to be pre-authorized. In parallel, international regulators (FDA, Health Canada, MHRA) released guiding principles for AI/ML device quality control, of which Principle 10 and associated PCCP guidance stressed that deployed AI models should be monitored and managed for continuous learning (www.fda.gov) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).

The legislative basis for PCCPs was solidified in late 2022. Section 3308 of FDORA added Section 515C to the FD&C Act. For PMA devices, Section 515C(a)(2) permits approval of a PCCP submitted in an application, including a supplemental application, if the device remains safe and effective without any change. For 510(k) devices, Section 515C(b)(2) permits clearance of a PCCP submitted in a notification if the device remains safe and effective without the changes and would remain substantially equivalent to the predicate. Sections 515C(a)(3) and (b)(3) permit labeling, notification, and performance requirements ([21 U.S.C. 360e-4](https://www.govinfo.gov/constitution/21-usc/360e-4)). FDA guidance also describes PCCPs in De Novo classification requests ([FDA guidance](https://www.fda.gov/guidance)).

PCCPs remain bounded. For 510(k) comparisons, FDA guidance initially requires comparison with the predicate version cleared or approved before PCCP changes. However, a version incorporating PCCP changes can become an eligible predicate after a subsequent 510(k) clearance ([FDA guidance](https://www.fda.gov/guidance), [Sections V.B and V.F](#)). Manufacturers should track device versions and their authorization history when selecting predicates.

The PCCP is a proactive change-management tool: it allows specified future modifications to be reviewed in a marketing submission. Changes implemented consistently with the authorized plan can avoid additional submissions; changes outside the plan require the normal assessment of whether a submission is necessary ([FDA guidance](#)).

Regulatory and Legislative Framework

Statutory Authority: Section 515C of the FD&C Act

Section 3308 of FDORA 2022 added Section 515C to the FD&C Act on December 29, 2022. The statute provides separate PCCP provisions for approved and cleared devices ([21 U.S.C. 360e-4](#)).

Under Section 515C(a)(2), FDA may approve a PCCP submitted in a PMA application or supplement if the device remains safe and effective without any change. Under Section 515C(b)(2), FDA may clear a PCCP submitted in a 510(k) notification if the device remains safe and effective without the changes and would remain substantially equivalent to its predicate. Sections (a)(1) and (b)(1) provide the corresponding exemptions from additional submissions for changes consistent with the approved or cleared plan. Sections (a)(3) and (b)(3) permit FDA to require labeling for safe and effective use, notification when the device does not function as intended under the plan, and performance requirements for changes ([statutory text](#)).

Section 515C(c) addresses predicate comparisons. FDA guidance explains that a device incorporating PCCP changes can become an eligible predicate after a subsequent 510(k) clearance; PCCP-modified versions are not permanently excluded ([FDA guidance, Sections V.B and V.F](#)).

FDA Guidance Development

Initial FDA Discussion (2019). The concept of the PCCP first surfaced in FDA's 2019 discussion paper for AI/ML-driven SaMD ([orthogonal.io](#)). That document outlined the idea of obtaining “pre-clearance or pre-approval” for certain postmarket software changes. It explicitly framed how manufacturers could embed well-defined change protocols into their quality systems to accommodate adaptive AI, unlocking continuous improvement while ensuring safety ([orthogonal.io](#)). This set the stage conceptually, though it had no regulatory force.

2019–2021: Good Machine Learning Practices. Although not binding, FDA and international partners (Health Canada, MHRA) published guiding principles on AI/ML in medical devices. The 2021 Good Machine Learning Practice (GMLP) guidelines, for example, laid out 10 principles for AI systems, one of which emphasized continuous monitoring and risk management across the lifecycle. In 2023, these agencies released *five cross-cutting guiding principles* specifically for PCCPs in ML devices ([www.fda.gov](#)). That document defined PCCP as a plan specifying planned modifications, the control protocol, and impact assessment ([www.fda.gov](#)), mirroring how FDA would later articulate it. These principles underscored that PCCPs should be “focused and bounded,” risk-based, and evidence-driven ([www.fda.gov](#)).

FDORA 2022: New Legal Authority. Section 3308 of the Food and Drug Omnibus Reform Act of 2022 (Title III of Division FF of the Consolidated Appropriations Act, 2023), enacted on December 29, 2022, added Section 515C on PCCPs to the FD&C Act ([FDA guidance](#)). As one industry analysis notes, the law's scope is broad – covering “all medical devices requiring premarket submissions” (including 510(k), De Novo, and PMA

products) (orthogonal.io). This was welcome news to stakeholders: it cleared the way for PCCPs well beyond AI software and into any field where iterative changes are expected. Established device classes (Class II, III, and certain IVDs) can now include a PCCP in their initial or supplemental filings under that statute.

Draft Guidance: AI/ML Devices (April 2023). Leveraging this new authority, FDA issued draft guidance in April 2023 titled “*Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions*.” This draft, intended for AI-enabled functions specifically, proposed how manufacturers should document planned modifications in their submissions (www.fda.gov). It emphasized agreeing on changes that might occur post-market, with clear validation methods and impacts. This was the first public framework for PCCPs, and it explicitly described the concept as a “least burdensome approach” to iterative changes (www.ketryx.com). The guidance is advisory only (as of its draft release) but outlines FDA expectations for PCCPs around AI-ML software.

Draft Guidance: All Medical Devices (August 2024). On August 21, 2024, FDA published a broader draft guidance “*Predetermined Change Control Plans for Medical Devices*” (www.fda.gov). This document reiterated and expanded the PCCP concept to **all** device types requiring a 510(k), De Novo, or PMA (including device-led combination products) (www.fda.gov). Its core definitions mirror the AI-specific draft: “A PCCP is the documentation describing what modifications will be made to a device and how the modifications will be assessed” (www.fda.gov). The draft provides nonbinding recommendations on the structure and content of a PCCP (see below). It notes that FDA will review the PCCP components in the marketing submission to pre-authorize the listed changes (www.fda.gov). Importantly, this guidance remains *draft* (as of early 2026), intended to solicit comments before a final version.

Final Guidance: AI/ML Devices (Dec 2024 / Aug 2025). FDA finalized its guidance specific to AI-driven device software. On December 3, 2024 FDA announced posting a final guidance on PCCPs for AI-Enabled Device Software Functions (www.fda.gov), and held a clarifying webinar in January 2025 (www.fda.gov). The guidance’s preamble (as publicly posted in mid-2025) states that FDA expects PCCPs to describe planned modifications to AI-DSFs, including methodology and impact assessment (www.fda.gov). It stresses that the approach supports iterative improvement of AI-enabled devices while continuing to assure safety and effectiveness (www.fda.gov). This final guidance (August 2025) applies to AI-DSFs across 510(k), De Novo, and PMA pathways, and explicitly builds on FDA’s commitment to adaptive regulation for AI devices (www.fda.gov).

Using an Authorized PCCP. FDA guidance distinguishes changes implemented consistently with an authorized PCCP from changes outside the plan. Out-of-plan changes must be evaluated under the applicable statutory and regulatory requirements and the device-modification guidance; they do not invariably require another submission ([FDA guidance, Section V.D](#)).

Comparison with International Regulations

The EU Artificial Intelligence Act is the enacted **Regulation (EU) 2024/1689**, with phased application. Article 113 retains general application from August 2, 2026. As amended by Regulation (EU) 2026/1744, Chapter III, Sections 1–3, except Article 6(5), apply from December 2, 2027 for Article 6(2)/Annex III high-risk systems and August 2, 2028 for Article 6(1)/Annex I high-risk systems ([current Article 113](#)). Under Article 6(1), product-

related high-risk classification requires both that the AI system is a product or safety component covered by Annex I legislation and that the product must undergo third-party conformity assessment. Medical AI is therefore not categorically high-risk solely because it uses AI.

Article 43(4) requires a new conformity assessment for substantial modifications to high-risk AI systems, but excludes specified changes to systems that continue learning after deployment when those changes were predetermined at the initial conformity assessment and documented under Annex IV, point 2(f). That AI Act exception must be distinguished from obligations under the MDR or IVDR; it does not itself remove those separate obligations ([Articles 43\(3\)–\(4\) and Annex IV](#)).

Aspect	European Union	United States
Regulatory framework	MDR/IVDR as applicable, alongside the enacted AI Act and its phased applicability.	FDA device pathways with PCCP authority.
Marketing route	Applicable conformity assessment and CE marking.	510(k) clearance, a granted De Novo classification request, or PMA approval.
AI Act classification	Article 6(1) product/safety-component and third-party-assessment conditions must both be met.	PCCP guidance addresses AI-enabled device software functions across the FDA device pathways.
Changes and reassessment	Article 43(4) excludes qualifying predetermined, technically documented learning changes from substantial modification; separate MDR/IVDR obligations remain relevant.	Consistent implementation of an authorized PCCP can avoid a new marketing submission; out-of-plan changes require the ordinary submission assessment.
Advance change planning	Annex IV 2(f) technical documentation supports the Article 43(4) exception for qualifying learning changes.	A PCCP documents planned modifications, implementation methods, and their impact.

Table 1. Comparison of AI-device change mechanisms ([AI Act](#); [FDA guidance](#)).

The U.S. approach is not internationally exclusive. Health Canada's MLMD guidance permits changes made according to an authorized PCCP without a significant-change medical device licence amendment application. Other licence-amendment requirements, such as device-identifier changes, and post-market oversight still apply; intended-use changes are outside the permitted scope ([Health Canada guidance](#)).

FDA Guidance Overview and PCCP Content

FDA's PCCP guidance documents – both draft and final – provide detailed recommendations on what a PCCP must contain. Although the specific requirements may evolve, several core elements are repeatedly emphasized. Below is an annotated summary of the major components FDA expects in a PCCP. (Many of these were first articulated in the draft guidance for AI devices (www.ketryx.com) and reiterated in later documents.)

- **Planned Modifications (Description of Changes):** The PCCP must *describe each planned change* to the device or its software function (www.ketryx.com). This includes a clear, itemized list of all modifications the manufacturer anticipates making under the plan. For example, if the device uses machine learning, the PCCP should specify what aspects of the ML model will change (new training data, altered algorithm parameters, additional output categories, etc.). Each listed change should

include a justification of *why* it is included. FDA guidance advises: “To ensure an efficient review, FDA recommends that a PCCP include only a limited number of modifications that are specific, and that can be verified and validated.” (FDA guidance, Section VI) In other words, the manufacturer should not propose open-ended or vague changes, but rather a bounded set of specific updates. Changes that cannot be readily tested or are overly complex should be excluded from the PCCP and handled separately. This focus makes the review manageable and ensures each planned change is clearly understood and feasible to validate.

- **Modification Protocol:** For each proposed change, the PCCP must detail *how* the modification will be implemented and verified (www.ketryx.com) (orthogonal.io). This includes the technical approach, development methods, and any verification/validation (V&V) activities. For example, if a learning model will be retrained periodically, the protocol should describe the data collection process, model versioning, performance testing, and criteria that must be met. The protocol might indicate whether changes will be applied automatically or require manual updates, and whether modifications will be uniform across all units of the device. Essentially, this section spells out the *procedure* for executing the changes in a controlled manner. FDA expects manufacturers to integrate these processes into their quality systems, with well-defined test methods. As one industry analysis notes, a strong PCCP will clearly outline verification/validation steps for each planned update (orthogonal.io), so that FDA can be confident the post-change device will meet requirements.
- **Impact Assessment:** A key part of the PCCP is a *risk/benefit analysis* of the planned changes (www.ketryx.com) (orthogonal.io). This involves evaluating how each modification could affect device safety and effectiveness, and what mitigation strategies will be used. For example, retraining an AI model could risk “model drift” or unintended bias; the PCCP should identify these risks and describe controls (such as ongoing performance monitoring or thresholds that trigger rollbacks). Similarly, changes to sensor calibration or decision thresholds should include analysis of potential over/under-sensitivity and plans to validate normal operation. The impact assessment should quantify how the device’s outputs might change and confirm that all results remain clinically acceptable. The plan may also address labeling updates or user training needed as the device evolves. In sum, the PCCP must demonstrate a thorough understanding of the effects of the planned changes. FDA explicitly suggests documenting both the evaluation of benefits and risks and plans to mitigate risks (www.ketryx.com). Underlying all this is the requirement (in FD&C 515C) that the manufacturer demonstrate the device “will remain safe and effective” after applying the changes (www.boleary.com).

This structure – changes, protocol, assessment – is often summarized as the **three core components** of a PCCP. The guidance itself groups these under sections like “Description of Modifications,” “Modification Protocol,” and “Impact Assessment.” FDA commentary and industry summaries confirm this triadic structure (www.ketryx.com) (www.ketryx.com). The table below illustrates how these fit together:

PCCP Section	Content (examples)
Description of Modifications	Itemized list of each planned change. Justification for each. Any changes to inputs, outputs, algorithms, etc. (FDA advises limiting to clearly defined, verifiable changes) (www.ketryx.com).

PCCP Section	Content (examples)
<i>Modification Protocol</i>	Procedures and methods for developing, testing, and implementing the changes. Verification/validation plans for new software versions. Description of data, controls, and rollout processes. Clear V&V to demonstrate each new version meets specs (www.ketryx.com) (orthogonal.io).
<i>Impact Assessment</i>	Evaluation of how each change affects safety and effectiveness. Risk analysis (hazard ID, risk controls) and plans to mitigate them. Benefit analysis (e.g. performance improvement). Plans for labeling updates, monitoring, or user notification if needed (www.ketryx.com) (orthogonal.io).

Table 2. Key components of a PCCP, per FDA guidance (www.ketryx.com) (www.ketryx.com).

Besides these core sections, a robust PCCP should integrate with the manufacturer's quality systems. For instance, it may reference standard operating procedures for change control, or commit to post-market surveillance provisions specific to the changed functionality. FDA's statute and guidance also highlight that labeling may need updates as the device changes, and that certain "notices" must be filed if specified conditions occur (www.boleary.com). In practice, successful PCCPs are those that leave no question about *what* will happen to the device and *how* safety is ensured at each step, while confining the plan to a finite, carefully chosen set of changes.

Regulatory Submission Process and Manufacturer Implications

Including a PCCP in a Submission

A PCCP is submitted as part of a device's marketing submission: a 510(k), De Novo classification request, or PMA. FDA reviews the device and the proposed plan. The resulting marketing authorization is 510(k) clearance, a granted De Novo request, or PMA approval, depending on the pathway ([FDA guidance](#)).

- **Changes within the PCCP:** Modifications implemented consistently with the authorized plan can proceed without additional marketing submissions for each modification.
- **Changes outside the PCCP:** Evaluate each modification under the applicable statutory and regulatory requirements and FDA's device-modification guidance. Being outside the plan does not by itself establish that a submission is required ([FDA guidance, Section V.D](#)).

The PCCP mechanism supports iterative improvement while maintaining safety and effectiveness. The exemption depends on consistent implementation of the authorized modifications and protocol.

Effects on Predicate Device Strategy

PCCP changes affect future 510(k) comparisons. Initially, the subject device must be compared with the predicate version cleared or approved before changes under the PCCP. FDA guidance adds an important exception: once a device incorporating those changes receives a subsequent 510(k) clearance, it can serve as an eligible predicate ([FDA guidance, Sections V.B and V.F](#)).

Manufacturers should track which modifications were implemented under a PCCP and which device versions received subsequent clearance. This avoids treating a PCCP-modified version as either automatically eligible or permanently excluded.

Quality System and Risk Management

Implementing a PCCP requires close integration with a firm's Quality Management System (QMS). FDA's Quality Management System Regulation (QMSR) became effective February 2, 2026 and incorporates ISO 13485:2016. Current design and development requirements are addressed through 21 CFR 820.7 and 820.10, including the applicability provisions in 820.10(c). The former 21 CFR 820.30 design-control framework is historical ([FDA QMSR](#); [FDA design and development module](#)). Each planned modification should follow the PCCP's description and protocol. Risk management processes under ISO 14971 (or equivalent) should be applied to each planned change. The impact assessment should address hazards and mitigations for the changed device.

Industry experts emphasize that cross-functional collaboration is critical. Regulatory, engineering, and quality teams must work together to draft a credible plan. The plan should be part of the device dossier and also reflected in the design and development file. As one MedTech consultant put it, companies “must align regulatory teams with engineering and quality assurance to ensure compliance without slowing down AI development” ([orthogonal.io](#)). That includes not only technical V&V, but also changes to labeling and training materials.

The design and development file should include or reference records demonstrating conformity to design and development requirements, including changes ([FDA design and development module](#)).

Data and Early Adoption by Industry

Historical public-record searches can identify examples of devices with PCCPs, but should not be treated as an official FDA adoption census or a measured adoption rate. O'Leary's published table describes search results as of about August 1, 2024 ([independent device search](#)). O'Leary instructs readers to treat the results as estimates; false inclusions and omissions are possible. This article does not infer an adoption rate from the snapshots.

For genomic tests, FDA's 2017 fact sheet describes a narrower historical policy: after authorization of a tumor-profiling NGS test, additional variants of the same type may be reported within existing analytically validated genes, for claims consistent with the clinical criteria in the original submission, without an additional FDA submission. This is not an allowance to add new genes without review ([FDA fact sheet](#)).

PCCPs provide a mechanism for implementing planned modifications without separate submissions when those modifications are implemented consistently with an authorized plan. That mechanism establishes a potential efficiency benefit; it does not measure reductions in filing volume, review time, or cost ([FDA guidance](#)).

Case Studies and Real-World Examples

To illustrate PCCP use, consider hypothetical scenarios and a historical FDA policy:

- **Autonomous Blood Pressure Monitor (Example Scenario):** A company markets a wearable cuffless blood pressure monitor that uses an AI model. Before the device hits the market, the manufacturer has identified future improvements: for instance, retraining the model with data from hypertensive and

hypotensive patient populations, and slightly adjusting alert thresholds for high blood pressure. Under a PCCP, the company includes these changes in its 510(k). The PCCP describes each planned retraining cycle and validation plan, and specifies monitor reading adjustments (e.g. increasing the alert setpoint from 140 to 145 mmHg in certain subgroups). The FDA reviews and clears the monitor *and* the PCCP. Later, as new data arrives, the company updates its model per the plan. Each time, it performs the pre-agreed performance tests (accuracy studies, bias checks, etc.). Because these steps adhere to the PCCP, the updates are implemented immediately without a new 510(k). If at some point the company wants to add an entirely new feature (say, a blood glucose estimation), that change falls outside the PCCP and must be assessed under the applicable submission requirements.

- **RadPathAI Imaging System (Illustrative Case):** RadPathAI develops an MRI image analysis software for detecting tumors. In this hypothetical scenario, FDA grants the De Novo classification request and includes a PCCP that allows the model to be retrained annually with new imaging data, as long as the updated accuracy improves or remains at least equivalent to the authorized level. The PCCP also permits adjusting confidence threshold parameters by up to $\pm 5\%$ for calibration. After authorization, RadPathAI collects new labeled images and retrains its model according to the protocol in the PCCP. They verify the new model against a held-out test set. Since all changes conform to the PCCP, RadPathAI does not submit a new application – it documents the changes in its quality system and follows the authorized plan. These assumed permissions and performance results are illustrative, rather than evidence of an actual authorization or clinical benefit.
- **Tumor-Profiling NGS Tests (Historical Policy):** FDA's 2017 fact sheet names the OncoPrint Dx Target Test. Its general tumor-profiling policy permits reporting additional variants of the same type within existing analytically validated genes, for claims consistent with the original submission's clinical criteria, without an additional FDA submission. It does not authorize adding new genes without review or establish a device-specific PCCP authorization for the named tests ([FDA fact sheet](#)). Gene additions must be assessed under the applicable submission requirements ([FDA guidance](#)).
- **Orthopedic AI (Conceptual):** Consider an FDA-cleared system that plans custom 3D-printed implants using AI. While not explicitly documented yet, PCCPs could theoretically be used in non-software domains. For example, an implant planning software might have a PCCP allowing iterative refinement of biomechanical models or personalization algorithms as more patient outcome data becomes available. (This is a hypothetical use case, not evidence of an authorized implant-related PCCP.) For such devices, anticipated updates that do not change intended use – e.g. better predictive analytics or expanded anatomical variations – could be prenegotiated via PCCP.

These examples illustrate how PCCPs can be tailored to diverse device types. Across cases, the common theme is **planning ahead**: manufacturers identify likely improvements (algorithm retraining, performance tuning within the authorized scope) and incorporate them into a submitted plan. By doing so, they forge a clear path for safe innovation.

Data Analysis and Industry Insights

Scope of Adoption: Historical independent searches of public FDA records provide examples of PCCP use. O’Leary’s table is explicitly a search snapshot dated about August 1, 2024; it is not an official FDA adoption count ([independent search](#)). O’Leary instructs readers to treat the results as estimates. This article does not infer a measured adoption rate from the snapshots.

Regulatory Efficiency: FDA’s guidance establishes that modifications implemented consistently with an authorized PCCP can avoid separate marketing submissions. This mechanism can offer efficiency benefits, but the evidence cited here does not quantify reductions in filings, review time, or costs ([FDA guidance](#)).

Planning Considerations: FDA recommends a limited number of specific modifications that can be verified and validated, supported by an implementation protocol and impact assessment ([FDA guidance](#)).

Orthogonal (a regulatory consulting firm) published a whitepaper in 2023 highlighting that PCCPs are especially useful for Class II SaMD devices. They note that by authorizing PCCPs, FDA can make “the significant insignificant” – i.e. allow meaningful changes under a controlled umbrella ([orthogonal.io](#)). Orthogonal and MedSec experts held workshops suggesting that *beyond* AI/ML, companies could responsibly expand PCCPs to cover other software changes (e.g. device workflow tools) as long as risks are managed.

PCCPs require early planning across regulatory, quality, and engineering teams. Changes outside the authorized plan still need assessment under the applicable modification rules ([FDA guidance](#)).

International Harmonization and Future Directions

Adaptive AI devices raise common lifecycle-management questions across jurisdictions. FDA’s PCCP approach is not internationally unique: Health Canada permits changes consistent with an authorized MLMD PCCP without a significant-change licence amendment application, subject to other amendment requirements and post-market oversight ([Health Canada guidance](#)).

The International Medical Device Regulators Forum published its final **Good machine learning practice for medical device development: Guiding principles**, IMDRF/AIML WG/N88 FINAL:2025. Its principles apply across the medical-device lifecycle ([IMDRF document record](#); [final document](#)).

For the EU, Article 43(4) and Annex IV 2(f) of the enacted AI Act provide a mechanism for predetermined, technically documented changes to qualifying continuously learning high-risk systems. Global manufacturers should assess each jurisdiction’s applicable framework and implementation dates, including separate MDR/IVDR change obligations ([AI Act](#)).

Conclusion

FDA’s Predetermined Change Control Plan supports planned device modifications through advance review of a defined change scope, implementation methods, and impact assessment. Changes implemented consistently with an authorized PCCP can proceed without separate marketing submissions for each modification. This offers a potential efficiency benefit, rather than evidence of measured reductions in filings, time, or cost ([FDA guidance](#)).

Manufacturers should define verifiable changes, integrate the plan with their quality system, and assess out-of-plan changes under the ordinary modification requirements. FDA's AI-specific final guidance and general-device draft provide recommendations for this work ([AI-specific guidance](#); [general-device draft](#)). International planning should account for Health Canada's PCCP pathway and the EU AI Act's predetermined-learning-change provision rather than assume that FDA's approach is internationally exclusive ([Health Canada](#); [AI Act](#)).

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://pmc.ncbi.nlm.nih.gov/articles/PMC12577744/>
2. <https://www.boleary.com/blog/posts/202408-pccp/>
3. <https://www.fda.gov/media/166704/download>
4. <https://www.complizen.ai/post/fda-ai-machine-learning-medical-devices-review-2025>
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6. https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles?trk=public_post_comment-text
7. <https://www.govinfo.gov/content/pkg/USCODE-2023-title21/pdf/USCODE-2023-title21-chap9-subchapV-partA-sec360e-4.pdf>
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THE PUBLISHER

About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore [AI enablement](#), [pharma and biotech software development](#), [data engineering and BI](#), and [Veeva services](#). [Contact IntuitionLabs](#) to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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