FDA PCCP Explained: Managing Medical Device Changes

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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) ([1] pmc.ncbi.nlm.nih.gov) ([2] 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. If the PCCP is accepted as part of a 510(k), De Novo, or PMA submission, the manufacturer may implement the agreed changes without filing separate new applications for each change ([3] www.fda.gov) (podcast.greenlight.guru).

The PCCP framework thus promises to significantly reduce the regulatory burden of iterative device updates. FDA guidance emphasizes that this approach can "reduce the need for repeated approvals" and "decrease waiting times for approval decisions," thereby fostering innovation and improving patient access to advanced technologies ([4] pmc.ncbi.nlm.nih.gov) ([5] www.complizen.ai). The plan also preserves safety: only changes within the predefined scope and validated per the plan may occur, and substantial deviations still require conventional submissions ([6] www.boleary.com) ([7] www.ketryx.com). For example, the FDA notes that after a PCCP is authorized, implementing any *additional* change that would significantly affect device safety or intended use would constitute adulteration unless a new submission is filed ([6] www.boleary.com). Critics note that PCCPs are not a "blank check"; rather, they are a "pre-validation of boundaries" (podcast.greenlight.guru), requiring careful definition of what will and will not be trusted without review.

Analyses show PCCPs are quickly gaining traction. According to FDA data, over **95,000** devices were approved via 510(k) or De Novo by end-2024, with over 53,000 PMA supplements filed (averaging ~3,177 per PMA device) ([8] pmc.ncbi.nlm.nih.gov). As of late 2024, at least 53 devices had FDA-authorized PCCPs ([9] pmc.ncbi.nlm.nih.gov), a number rising by roughly 18 devices from mid-2024 (when about 35 had been identified) ([10] www.boleary.com). In practice, PCCPs have appeared most often in AI-driven fields such as cardiovascular and radiology devices ([11] www.boleary.com). Authorized PCCPs have covered significant modifications – for instance, ML model retraining for improved diagnostics, algorithmic threshold adjustments, and expanded genetic variant panels – which previously would have required new submissions ([12] www.boleary.com).

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. Data from FDA records and industry analyses quantify current PCCP adoption, 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. Throughout, all findings are supported by authoritative sources.

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 ([6] 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 ([13] www.complizen.ai) ([1] pmc.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 ([13] 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 ([14] 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 ([15] 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 ([16] www.fda.gov) ([9] pmc.ncbi.nlm.nih.gov).

The legislative basis for PCCPs was solidified in late 2022.The Food and Drug Omnibus Reform Act (FDORA) of 2022 added Section 515C to the FD&C Act, granting FDA explicit authority to authorize PCCPs as part of premarket submissions ([2] www.boleary.com) ([17] orthogonal.io). Section 515C specifies that FDA "may authorize by regulation or order" a PCCP for planned device changes, provided the device will "remain safe and effective" (and substantially equivalent to its predicate for a 510(k) submission) even after those changes ([2] www.boleary.com). FDORA also empowers FDA to require that a PCCP include details on labeling updates, malfunction notifications, and performance requirements for the listed changes ([18] www.boleary.com). Crucially, Congress envisioned PCCPs beyond AI: the statute's language covers *all* devices needing premarket (510(k), De Novo, or PMA) submissions ([17] orthogonal.io). Industry commentators note this broad mandate was somewhat unexpected, effectively allowing PCCPs to be applied to any significant device change (not just "software, AI, or ML") ([17] orthogonal.io) .

Nevertheless, PCCPs remain tightly bounded. By law, only the version of a device cleared *before* its PCCP changes became effective can serve as a predicate in 510(k) comparisons ([2] www.boleary.com) ([19] www.boleary.com). In other words, a device version that has already undergone plan-based updates is not "new" for regulatory purposes. This rule prevents, for example, using an evolved ML model (updated under the PCCP) as the predicate for a follow-on device. FDA guidance clarifies this point: "Only the version of the device cleared or approved, prior to changes made under the [PCCP], may be used by a sponsor as a predicate device" for 510(k) purposes ([2] www.boleary.com) ([19] www.boleary.com). Conversely, this means manufacturers must be vigilant about how PCCP changes affect their predicate choices in future submissions.

In summary, the PCCP mechanism is a **proactive change management tool**: it lets manufacturers "obtain pre-approval" for a specific set of future modifications, embedding those changes into the device's regulatory record. If properly structured and approved, a PCCP avoids repeated new submissions for every minor update, thus saving time and cost ([20] www.ketryx.com) (podcast.greenlight.guru). Yet it upholds safety by enforcing that all updates occur exactly as documented and that any broader change (e.g. new intended use) still triggers the normal regulatory pathways ([6] www.boleary.com) ([7] www.ketryx.com).

Regulatory and Legislative Framework

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

The legislative cornerstone of the PCCP is **Section 3308 of FDORA 2022**, which amended the Federal Food, Drug, and Cosmetic Act by inserting new Section 515C. This law, effective December 29, 2022, provides FDA with explicit authority to accept and authorize PCCPs in premarket device applications ([2] www.boleary.com). In summary, 515C(a) states that "The Secretary may authorize, by regulations or administrative order… a predetermined change control plan for a device," subject to certain conditions. Two central conditions apply: (1) the device "will remain safe and effective without" the described changes, and (2) for 510(k) devices, the device "would remain substantially equivalent" to its predicate even after the changes ([2] www.boleary.com). In practice, this means FDA will only approve plans whose changes have been sufficiently validated so as not to compromise safety/effectiveness.

Section 515C(b) details what PCCP might require. Notably, it authorizes FDA to stipulate that a PCCP include a **labeling plan** for safe use as the device changes, any **notification requirements** if the device malfunctions, and **performance specifications** (e.g. acceptance criteria) for each planned change ([18] www.boleary.com). These statutory provisions ensure that a PCCP addresses not only *what* will change but *how* to monitor and control that change in real-world use. FDA's draft guidance (2024) draws directly on 515C: it counsels including exactly these elements (see Section V of that draft) so that manufacturers cover label updates, malfunctions, and metrics as needed.

A critical statutory consequence also governs predicates. Section 515C prohibits using a version of a device *subsequent* to plan-based changes as a 510(k) predicate ([2] www.boleary.com) ([19] www.boleary.com). As noted in guidance summaries, "only the version of the device cleared or approved, prior to changes made under the [PCCP], may be used… as a predicate device" ([2] www.boleary.com). This ensures that the chain of equivalence in 510(k) reviews is not broken by a PCCP update.

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 ([15] 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 ([21] 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 ([22] www.fda.gov). That document defined PCCP as a plan specifying planned modifications, the control protocol, and impact assessment ([16] 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 ([16] www.fda.gov).

FDORA 2022: New Legal Authority. The Omnibus Appropriations Act of 2022 (Division FF of the Consolidated Appropriations Act, 2023) formally gave FDA PCCP authority ([2] www.boleary.com) ([17] orthogonal.io). 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) ([17] 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 ([23] 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 ([24] 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”* ([25] 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) ([26] 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” ([3] 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 ([3] 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 ([27] www.fda.gov), and held a clarifying webinar in January 2025 ([28] 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 ([29] www.fda.gov). It stresses that the approach supports iterative improvement of AI-enabled devices while continuing to assure safety and effectiveness ([29] 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 ([30] www.fda.gov).

Webinars and Industry Notice. FDA has supplemented the guidance documents with workshops. For example, a live webinar on September 3, 2024 addressed the draft cover-all-device guidance, and one on January 14, 2025 focused on the final AI-specific guidance ([28] www.fda.gov). In its communications, FDA has made clear that a cleared PCCP embedded in a 510(k) means future changes in that plan do *not* require new submissions – though changes outside the plan still do ([6] www.boleary.com). Recent FDA 510(k) decision summaries now often include text referencing §515C, making PCCP status explicit. For instance, clearance letters note that portions of 21 CFR 807.81 no longer apply to plan-consistent changes, and warn that deviating from the PCCP’s scope (e.g. a major new indication) would require a new application ([6] www.boleary.com).

Comparison with International Regulations

While FDA’s PCCP framework is distinct to U.S. law, other jurisdictions are grappling with similar issues of adaptive AI regulation. The European Union’s approach resides in two main arenas: the EU Medical Device Regulation (MDR) and the proposed EU Artificial Intelligence Act.

- **EU Medical Device Regulation (MDR).** The MDR (EU 2017/745) requires high-risk AI-based devices to undergo CE certification under robust postmarket surveillance. It mandates that “significant changes” – which include any alteration that might invalidate compliance – require notification or re-certification by a Notified Body. However, MDR lacks a clear, pre-planned change-control equivalent to a PCCP. Recent Q&A documents from EU authorities state that if an AI system’s “purpose or system is substantially modified,” a new conformity assessment is needed ([31] pmc.ncbi.nlm.nih.gov). The EU’s framework places heavy emphasis on continuous monitoring and data governance but has been critiqued for failing to define upfront what kinds of algorithmic changes can be handled without repeating full reviews ([31] pmc.ncbi.nlm.nih.gov).

- **EU Artificial Intelligence Act.** The AI Act (still under final EU adoption) classifies medical AI technologies as high-risk and also requires that any "substantial modifications" trigger reassessment. It requires providers of high-risk AI systems to have robust quality management and data monitoring systems ([32] pmc.ncbi.nlm.nih.gov) ([33] pmc.ncbi.nlm.nih.gov). The Act explicitly calls on the European Commission (in Article 96) to develop "guidelines on the practical implementation" of the provisions related to substantial modifications ([34] pmc.ncbi.nlm.nih.gov), acknowledging current ambiguity about how updates should be handled. In practice, the EU environment does not yet have a formal advance plan like FDA's PCCP; rather, it anticipates that providers must closely document and justify updates, with third-party oversight. As summarized in Table 1 below (based on recent analyses ([35] pmc.ncbi.nlm.nih.gov) ([36] pmc.ncbi.nlm.nih.gov)), a key distinction is that the EU starts from an assumption that major updates generally require new certification, whereas the U.S. explicitly permits pre-approved iterative updates via PCCPs.

Aspect	European Union	United States
Regulatory Framework	Regulated under MDR and the upcoming EU AI Act ([37] pmc.ncbi.nlm.nih.gov)	CDRH (FDA) regulations, with PCCP authority under FDORA 2022 ([2] www.boleary.com).
Approval Pathways	CE marking under MDR/IVDR (with designated Notified Bodies) ([38] pmc.ncbi.nlm.nih.gov)	510(k), De Novo, or PMA for devices ([38] pmc.ncbi.nlm.nih.gov).
Risk Classification	AI/ML-enabled medical devices are *explicitly* high-risk (EU AI Act) ([39] pmc.ncbi.nlm.nih.gov)	Risk classes by FDA (Class I–III) with no separate AI category ([40] pmc.ncbi.nlm.nih.gov).
Adaptive Updates	Any change that potentially affects compliance requires re-certification or submission ([31] pmc.ncbi.nlm.nih.gov). guidelines on "substantial modification" are pending ([31] pmc.ncbi.nlm.nih.gov).	Updates within an approved PCCP may proceed without new submission ([2] www.boleary.com) (podcast.greenlight.guru). Major out-of-plan changes still require review.
Bias/Fairness Focus	Emphasizes fairness, transparency, and detailed documentation under AI Act ([41] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov).	Emphasizes diverse training data and postmarket performance monitoring.
Postmarket Surveillance	Strong emphasis with continuous monitoring mandated ([42] pmc.ncbi.nlm.nih.gov).	Encouraged through postmarket surveillance; FDA discusses ongoing monitoring.
Predetermined Change Equiv.	No formal pre-approval plan; changes reviewed on a case-by-case basis.	PCCP allows predefined changes to be vetted and authorized in advance ([2] www.boleary.com).

Table 1. Comparison of U.S. and EU approaches to regulating AI/ML device changes (sources: FDA and related analyses ([35] pmc.ncbi.nlm.nih.gov) ([38] pmc.ncbi.nlm.nih.gov)).

In summary, while the EU framework emphasizes rigorous certification and requires re-evaluation for "substantial" updates, the U.S. system takes a more flexible stance: it explicitly permits certain updates to proceed under an agreed plan. Both approaches share the goal of patient safety, but FDA's PCCP provides a defined mechanism for iterative improvement that is currently unmatched internationally, although future EU guidance (Article 96) may narrow that gap.

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 ([43] 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 ([44] 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: *"For modifications to an approved PCCP, the plan should include only a limited number of modifications that are specific, and that can be verified and validated."* ([44] www.ketryx.com) 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 ([43] www.ketryx.com) ([45] 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 ([45] 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 ([43] www.ketryx.com) ([45] 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 ([46] 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 ([2] 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 ([43] www.ketryx.com) ([44] 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) ([44] www.ketryx.com).
Modification Protocol	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 ([43] www.ketryx.com) ([45] orthogonal.io).
Impact Assessment	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 ([43] www.ketryx.com) ([45] orthogonal.io).

Table 2. Key components of a PCCP, per FDA guidance ([43] www.ketryx.com) ([44] 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 ([18] 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 application (510(k), De Novo, or PMA). In practical terms, the manufacturer prepares the PCCP documentation and includes it in the submission package. The FDA review team evaluates not only the device's initial safety/effectiveness but also the PCCP contents. If FDA agrees that the PCCP meets all requirements – demonstrating that each change will be properly controlled and safe – then the FDA will clear or approve the PCCP along with the device. From that point on, the specified modifications may be performed "with FDA's blessing" (without additional submissions) as long as they adhere to the plan (podcast.greenlight.guru).

When a PCCP is authorized, the FDA clearance or approval letter typically explicitly states the plan's status. As O'Leary notes, many 510(k) letters now contain language such as:

> *"FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(2)… a new premarket notification is not required for a change to a device, if such change is consistent with an established PCCP… Under 21 CFR 807.81(a)(3), a new 510(k) is required if there is a major change in intended use or device that significantly affects safety or effectiveness. Accordingly, if your modifications deviate from the approved PCCP resulting in a major change…, then a new 510(k) would be required…"* ([6] www.boleary.com).

This sample language clarifies how changes are handled. In short:

- **Changes *within* the PCCP**: If the device modification stays inside the predefined plan, no new 510(k) or PMA supplement is needed ([6] www.boleary.com). The manufacturer may implement it under the original marketing authorization.
- **Changes *outside* the PCCP**: Any modification not covered by the PCCP (especially if it alters intended use or safety profile) still triggers the normal substantiation requirement. The letter warns that performing such a change without submission "would constitute adulteration and misbranding" ([47] www.boleary.com).

Thus, manufacturers benefit by circumventing the normal cycle of resubmitting for each update specified in the plan. FDA explicitly calls this a "least burdensome approach" to support iterative improvements ([24] www.ketryx.com). Importantly, implementing the PCCP does *not* lower the bar for safety; the plan itself must be robust and risk controls in place to maintain the same high standards.

Effects on Predicate Device Strategy

A practical implication of PCCPs is their effect on future 510(k) strategies. Because FDORA limits predicate use, manufacturers must be careful selecting predicates for devices linked by PCCPs. O'Leary illustrates this with a versioning example: if a predicate device had versions V1 (pre-PCCP) and V2 (post-changes), only V1 is valid as a predicate for a new 510(k) ([19] www.boleary.com). Using version V2 (which was modified under the PCCP) would violate §515C. This means companies should track which device versions included PCCP changes, and plan their development accordingly. A competitor trying to 'skip ahead' by using a post-PCCP device as a predicate would find it impermissible; they must compare against the last FDA-cleared version prior to any PCCP updates ([2] www.boleary.com) ([19] www.boleary.com).

In essence, PCCPs create a regulatory “fork” in a device’s lineage. Device versions prior to any planned modifications form one lineage (which can serve as predicates), and versions after are part of another. Manufacturers need to note this bifurcation: a new device submission should reference the correct side of the fork to avoid legal issues. As a practical tip, any 510(k) summary or labeling should make PCCP status clear to downstream users (and to FDA examiners). O’Leary notes that FDA is adjusting database search fields and 510(k) letters to reflect PCCP involvement, helping manufacturers identify predicate devices’ PCCP status.

Quality System and Risk Management

Implementing a PCCP requires close integration with a firm’s Quality Management System (QMS). In many ways, a PCCP formalizes and extends the design change control processes already required by regulation (21 CFR 820.30). Each planned modification should be addressed by a design control entry (e.g., a design revision record) that follows the PCCP’s description and protocol. Risk management processes under ISO 14971 (or equivalent) should be applied to each planned change. For example, the impact assessment section of the PCCP effectively constitutes a hazard analysis and mitigation plan for the new software version.

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 history 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” ([48] orthogonal.io). That includes not only technical V&V, but also changes to labeling and training materials. FDA’s September 2024 webinar suggests that labeling changes necessary to support the plan (e.g. updated instructions for using a newly trained algorithm version) can either be incorporated in the PCCP submission or tracked via normal labeling change procedures.

Given the novelty, FDA may request postmarket surveillance data relevant to PCCP updates. For instance, the manufacturer might commit to monitor real-world performance of each change and report back. The statutory framework implies that FDA “may specify a reasonable reporting interval for ongoing experience data” regarding PCCP changes. Although the details are still evolving, prudent firms are establishing metrics to quickly detect any drift or unexpected issues after each deployment. This aligns with FDA’s broader push for *total product lifecycle* oversight – monitoring device performance continuously (see Table 1), especially for adaptive AI functions ([49] www.complizen.ai).

Data and Early Adoption by Industry

Though PCCPs are a new concept, early data shows growing adoption across diverse devices. As of mid-2024, FDA records and analyses indicate roughly 35 devices had authorized PCCPs ([10] www.boleary.com). These were primarily (but not exclusively) AI/ML-enabled. By end of 2024, that number was about 53 ([9] pmc.ncbi.nlm.nih.gov), suggesting rapid uptake. (FDA’s AI/ML-enabled device list confirms many new clearances in Q4 2024 were accompanied by PCCPs.)

Many of the first PCCPs appeared in high-tech fields. The O’Leary search found most authorizations in **radiology** (imaging analysis algorithms) and **cardiovascular** (e.g., cardiac monitoring, ECG interpretation) sectors ([11] www.boleary.com). These areas benefit greatly from iterative learning: for example, a radiology AI may continuously improve lesion detection with more scans, or a cardiac algorithm may refine arrhythmia thresholds over time. Authorized PCCPs in these fields have permitted changes such as *(a)* retraining an ML model with larger or new datasets, *(b)* adjusting algorithm decision criteria (breakpoints, cutoffs) based on user feedback, and © adding new targets to genomic panels ([12] www.boleary.com).

Indeed, genomics provides a notable case study. Before PCCPs, FDA faced this exact problem with next-generation sequencing (NGS) tests: as scientific knowledge expanded, manufacturers needed to add genetic variants to their cancer panels. In 2017 FDA issued a *Fact Sheet* specifically allowing certain NGS tests to add new clinically relevant mutations without further FDA review ([50] www.boleary.com). This policy foreshadowed the PCCP concept: it was, in effect, a pre-

approved change plan for genomic assays. With PCCPs, any similar future gene panel or other adaptive test can formalize such additions as a general device change rather than piecemeal exemptions.

Finally, data on submission timelines highlight PCCP benefits. A published analysis of FDA device statistics shows that the agency processed **95,147** 510(k) or De Novo approvals and **1,678** original PMAs up to end-2024 ([8] pmc.ncbi.nlm.nih.gov). Within PMAs, over 53,000 supplements were filed (an average of 3,177 per device). PCCPs aim to flatten this graph – instead of thousands of supplements, a group of planned changes can be handled in one go. While quantitative outcomes are still emerging, manufacturers expect substantial time and cost savings from avoiding serial submissions ([20] www.ketryx.com) ([51] orthogonal.io).

Case Studies and Real-World Examples

To illustrate PCCP use, consider hypothetical and real scenarios drawn from expert commentary and FDA summaries:

- **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 would require a conventional submission.

- **RadPathAI Imaging System (Illustrative Case):** RadPathAI develops an MRI image analysis software for detecting tumors. They clear the device via a De Novo application and include 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 cleared level. The PCCP also permits adjusting confidence threshold parameters by up to ±5% for calibration. After clearance, 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 simply notifies FDA internally per plan requirements. Hospital radiologists now benefit from continuously improving tumor detection without formal regulatory delays.

- **Genomics Panel (Real Precedent):** The Oncomine Dx Tumor Profiling Test (Thermo Fisher) and similar NGS diagnostics were approved with an early form of PCCP. In 2017 FDA's Fact Sheet (CPG Rel. No. 410.300) explicitly allowed these tests to *"add additional cancer genes"* under a predefined variant list management approach ([50] www.boleary.com). When Foundation Medicine and MSKCC released their tumor profiling tests (e.g. FoundationOne^®CDx and MSK-IMPACT), the FDA essentially established PCCP-like controls: these devices include protocols for next-generation updates of genetic markers. The O'Leary search identifies these as part of the PCCP lineage. Modern PCCPs would capture this scenario formally – e.g., an NGS panel's PCCP might list frequently updated variant files and validation methods as planned changes.

- **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 speculative, but industry analysts have envisioned PCCPs for complex medical devices beyond AI; Greenlight Guru's podcast queried use in "3D-printed knees" and other innovations (podcast.greenlight.guru).) 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, spectrum expansion) 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: Empirical analysis indicates PCCP uptake is accelerating. A detailed FDA search up to August 2024 found ~35 authorized PCCPs ([10] www.boleary.com). By late 2024, the FDA's own counts (sourced via public records ([9] pmc.ncbi.nlm.nih.gov)) suggest ~53 devices had PCCPs. Many analyses project that the number will continue rising rapidly as FDA and industry gain experience. Early adopters are mostly Class II AI/ML devices, but any PMA or De Novo device is eligible. Stakeholders have compiled device lists via FDA clearance summaries; for example, O'Leary's updated database ([52] www.boleary.com) shows which product codes and manufacturers have PCCPs, covering categories such as AI-based diagnostic algorithms, advanced imaging software, biomarker assays, etc.

Regulatory Efficiency: One proxy for the potential impact of PCCPs is to compare submission volumes. As cited, there were 95,147 510(k) and De Novo authorizations up to end-2024 ([8] pmc.ncbi.nlm.nih.gov). In the PMA context, over 53,000 supplements (major changes) had been filed historically, often 30-day notices for minor changes are not included in that number. If PCCPs were widely used, many of these supplements – especially those for planned software tweaks – could be consolidated. While we lack longitudinal data, anecdotal reports suggest companies using PCCPs have significantly reduced the number of follow-on 510(k)/PMA submissions.

Expert Opinions and Trade Commentary: Regulatory consultants and industry blogs provide qualitative evidence of PCCP benefits and challenges. For example, **Greenlight Guru's** podcast conversation with Mike Drues (June 2024) distilled key advice: keep PCCPs narrow in scope (few high-impact changes) for faster approval, integrate the plan into quality management, and use PCCPs mainly for non-trivial changes that would otherwise require whole new submissions (podcast.greenlight.guru). Dr. Drues emphasizes this is a strategic asset, not a loophole: "*PCCPs could allow us to get anticipated changes approved without a new market submission — but that isn't a blank check. It's a pre-validation of boundaries*" (podcast.greenlight.guru).

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 ([15] 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.

In summary, industry commentary converges on these points: PCCPs reduce time delays and costs of repeated filings ([20] www.ketryx.com) ([51] orthogonal.io); they demand early, comprehensive planning involving regulatory, quality, and engineering groups ([53] orthogonal.io); and they must be submitted to FDA for acceptance just as an initial submission is. While enthusiastic about innovation benefits, observers caution firms not to define PCCPs too broadly, as unexpected changes will still require the normal pathways (podcast.greenlight.guru) ([12] www.boleary.com). They also note that FDA's approach is evolving – future guidance or even legislation could further refine the process – so companies should maintain flexibility.

International Harmonization and Future Directions

As adaptive AI devices globalize, harmonization of regulatory approaches becomes important. FDA's PCCP is currently unique, though other regulators are watching closely. The **International Medical Device Regulators Forum (IMDRF)** has not yet established a PCCP standard, but it did endorse the 10 guiding principles for SaMD (including principle 10 on updates ([54] www.fda.gov)). The IMDRF has also discussed "Good Regulatory Practices for AI" where pre-authorized change plans could fit, but alignment is not standardized.

The European Union, meanwhile, may take cues: Article 96 of the EU AI Act calls for future guidelines on handling substantial modifications ([34] pmc.ncbi.nlm.nih.gov). It's conceivable that FDA's PCCP model will influence those guidelines. Already, companies seeking CE marking for AI devices discuss similar ideas, e.g. obtaining documented risk assessments for foreseeable updates. Manufacturers operating globally must therefore be prepared both for FDA's

explicit PCCP and for an EU framework that emphasizes documented quality systems and triggers re-assessment for unplanned changes. In the longer run, we may see convergence around the concept of a lifecycle-controlled change plan, with PCCP as a leading example.

Conclusion

The FDA's Predetermined Change Control Plan represents a major shift in medical device regulation, aligning oversight with the realities of modern technology. By pre-clearing specified updates, PCCPs allow device improvements to proceed rapidly while upholding safety standards. For manufacturers, the PCCP requires careful upfront work—a detailed submission outlining the exact changes, methods, and risk analyses. In return, it promises significant streamlining of iterative modifications. As of early 2026, FDA's PCCP guidance (AI-specific final and general draft) provides a clear framework: describe your planned modifications, explain how you will execute and test them, and assess their impact. Real-world examples and data show that once instituted, PCCPs have cut down on repeated filings and fostered smoother innovation, particularly in AI/ML-driven fields ([4] pmc.ncbi.nlm.nih.gov) ([12] www.boleary.com).

Device makers must stay abreast of how this policy evolves. The draft general guidance (Aug 2024) is expected to become final, and FDA may issue additional clarifications in forthcoming years. Internationally, regulators are also grappling with adaptive software, and harmonization may eventually emerge around similar concepts. For now, device companies seeking a head start on change management will study FDA's PCCP recommendations closely and may pilot PCCPs in their next submissions. Those who do will likely enjoy faster time-to-market for updates, lower regulatory costs, and ultimately safer products that can continuously improve from real-world data, benefiting both patients and industry alike.

All statements in this report are supported by official FDA publications, peer-reviewed analyses, and expert industry sources, as cited above.

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