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Predetermined Change Control Plans (PCCPs)

A Comprehensive Readiness Checklist for AI-Enabled Medical Device Manufacturers

Based on FDA Final Guidance (December 2024) and FDORA Section 515C Statutory Framework

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Data-Driven Evaluation • Digital Health Modernization • AI-Enabled Solutions

About This Checklist

The FDA's final guidance on Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (December 2024, updated August 2025) establishes the framework for pre-authorizing future modifications to AI/ML-enabled medical devices without requiring separate marketing submissions for each change.

This regulatory innovation—rooted in Section 515C of the FD&C; Act, added by the Food and Drug Omnibus Reform Act (FDORA) of 2022—allows manufacturers to prospectively specify planned modifications, validation methodologies, and impact assessments as part of their initial 510(k), De Novo, or PMA submissions.

This checklist is designed for MedTech executives, regulatory affairs professionals, quality engineers, and AI/ML development teams preparing to develop or include a PCCP in a marketing submission. Use it to systematically assess your organization's readiness across every dimension of PCCP development and compliance.

> A PCCP includes three core components: (1) Description of Modifications — what changes will be made; (2) Modification Protocol — how changes will be developed, validated, and implemented; and (3) Impact Assessment — the evaluation of benefits and risks. Each modification described in the PCCP must maintain the device's intended use and provide reasonable assurance of continued safety and effectiveness.

PCCP at a Glance

Dimension	Details
Statutory Authority	Section 515C of the FD&C; Act, added by FDORA 2022 (Pub. L. No. 117-328)
FDA Guidance	Final Guidance issued December 4, 2024; updated August 18, 2025
Eligible Pathways	510(k) Premarket Notification, De Novo Classification, PMA Application
Eligible Devices	AI-enabled medical devices, SaMD with AI functionality, device-led combination products with AI-DSF components
Core Components	Description of Modifications, Modification Protocol, Impact Assessment
Key Benefit	Implement pre-authorized AI/ML modifications without separate marketing submissions for each change
International Alignment	FDA collaborates with Health Canada and UK MHRA on harmonized PCCP guiding principles

1. Strategic Readiness Assessment

Eligibility Determination

- [ ] Confirm the device includes one or more AI-enabled device software functions (AI-DSFs)
- [ ] Verify the device is eligible for 510(k), De Novo, or PMA submission pathway
- [ ] Assess whether planned modifications would otherwise require separate marketing submissions
- [ ] Evaluate if device-led combination products contain AI-DSF components requiring PCCP coverage

Scope Definition

- [ ] Define explicit boundaries of planned modifications (in-scope vs. out-of-scope)
- [ ] Confirm all planned modifications remain within the device's authorized intended use
- [ ] Limit the PCCP to a focused, manageable number of specific modifications that can be verified and validated
- [ ] Document whether modifications will be automatic (software-deployed) or manual (human intervention required)
- [ ] Specify if modifications will be uniform across all devices or vary by clinical site or patient characteristics

FDA Engagement Planning

- [ ] Schedule a Q-Submission (Pre-Submission) meeting with FDA to validate the proposed PCCP approach
- [ ] Prepare responses to anticipated FDA questions about modification scope and boundaries
- [ ] Identify the appropriate FDA review division with purview over the AI-DSF
- [ ] Develop a communication plan for ongoing FDA interaction during PCCP implementation

> FDA Recommendation: Manufacturers are strongly encouraged to leverage the Q-Submission Program for obtaining FDA feedback on a proposed PCCP prior to submitting the marketing application. Early engagement reduces review friction and improves authorization outcomes.

2. Description of Modifications

Modification Specification

- [ ] Itemize each planned modification to the AI-DSF with specific, clear descriptions
- [ ] Describe the current state (pre-modification) and expected post-modification state of the device
- [ ] Quantify expected performance changes with statistical bounds (e.g., sensitivity ±5%, specificity target >95%)
- [ ] Specify types of modifications: algorithm parameter adjustments, training data updates, model retraining, threshold changes
- [ ] Document changes to device outputs, alerts, recommendations, or clinical decision support logic

Implementation Approach

- [ ] Describe the deployment mechanism: automatic software update, manual update, or hybrid approach
- [ ] Define rollback procedures for modifications that fail to meet acceptance criteria
- [ ] Specify user notification requirements for each modification type

- [ ] Document parallel monitoring periods (e.g., 30-day performance observation post-deployment)

Intended Use Preservation

- [ ] Confirm that no modification alters the device's indications for use
- [ ] Demonstrate that each modification maintains substantial equivalence (510(k)) or safety/effectiveness (PMA/De Novo)
- [ ] Document the rationale linking each modification to improved device performance within authorized scope

> FDA Guidance: The PCCP should include only a limited number of modifications that are specific, and that can be verified and validated. Overly complex modifications, lack of specificity, or insufficient testing methods may impact PCCP authorization.

3. Modification Protocol

Data Management Practices

- [ ] Establish training data collection and validation protocols with documented quality criteria
- [ ] Define data quality assessment and bias evaluation methods for new training datasets
- [ ] Implement dataset versioning and change documentation procedures
- [ ] Specify data sources, inclusion/exclusion criteria, and representativeness requirements
- [ ] Document performance monitoring data collection and analysis plans

Re-Training Practices

- [ ] Define triggers for model retraining (time-based, data drift detection, performance threshold breach)
- [ ] Specify re-training methodology, including hyperparameter selection and model architecture constraints
- [ ] Document safeguards against catastrophic forgetting or unintended performance degradation
- [ ] Establish model version control and traceability from training data through deployment

Performance Evaluation (Verification & Validation)

- [ ] Define pre-deployment testing protocols with quantified, pre-specified acceptance criteria
- [ ] Specify holdout test datasets with confirmed ground truth for independent validation
- [ ] Establish clinical validation methods for real-world performance verification
- [ ] Define statistical analysis methods, sample sizes, and confidence interval requirements
- [ ] Include failure detection mechanisms and automated performance alert thresholds
- [ ] Specify acceptance criteria for each modification type described in the PCCP

Update Procedures

- [ ] Document deployment scheduling, rollout sequencing, and phased implementation plans
- [ ] Define change authorization and approval workflows within the QMS
- [ ] Specify user notification, training, and communication requirements for each update
- [ ] Establish documentation and audit trail maintenance procedures for every modification
- [ ] Define post-deployment real-world performance monitoring duration and metrics

> Key Requirement: Four components are required in the Modification Protocol and must be traceable to the Description of Modifications: (1) Data management practices, (2) Re-training practices, (3) Performance evaluation, and (4) Update procedures.

4. Impact Assessment

Safety Impact Analysis

- [ ] Evaluate potential for false positive/negative results and their clinical consequences
- [ ] Assess changes to diagnostic accuracy and impact on treatment decisions
- [ ] Document risk mitigation measures for modification failures or unexpected behavior
- [ ] Analyze patient safety implications including worst-case performance scenarios

Clinical Effectiveness Assessment

- [ ] Quantify expected improvements to patient outcomes and diagnostic performance
- [ ] Provide performance metrics with statistical confidence intervals
- [ ] Evaluate clinical workflow integration impact for healthcare providers
- [ ] Document long-term monitoring and assessment procedures for sustained effectiveness

Benefit–Risk Analysis

- [ ] Conduct risk assessment using ISO 14971 methodology for each planned modification
- [ ] Quantify benefits with clinical outcome improvements and population-level impact estimates
- [ ] Document risk mitigation strategies and control measures for identified hazards
- [ ] Evaluate interdependencies among modifications and cumulative impact of all changes
- [ ] Compare modified vs. unmodified device versions with quantified benefit-risk differential

Stakeholder Impact

- [ ] Assess healthcare provider training and workflow modification requirements
- [ ] Define patient communication plans for device updates and performance changes
- [ ] Evaluate integration impact on healthcare IT systems and interoperability
- [ ] Document regulatory reporting and notification procedures for implemented modifications

> The Impact Assessment must demonstrate that activities in the Modification Protocol maintain device safety and effectiveness, including an evaluation of social harm risks and strategies to mitigate identified hazards.

5. Quality Management System Integration

Design Controls (21 CFR 820.30 / QMSR)

- [ ] Integrate PCCP modification procedures into existing design control framework
- [ ] Establish design review checkpoints specific to PCCP-authorized modifications
- [ ] Document traceability between design inputs, outputs, verification, and validation for each modification
- [ ] Ensure PCCP procedures comply with the new QMSR (effective February 2026), aligned with ISO 13485:2016

Risk Management

- [ ] Update the risk management file (ISO 14971) to include PCCP modification scenarios
- [ ] Establish risk acceptance criteria specific to AI-DSF modifications
- [ ] Define residual risk review and monitoring procedures for implemented changes
- [ ] Integrate PCCP risk management with post-market surveillance activities

CAPA Integration

- [ ] Establish CAPA procedures specific to PCCP modification failures
- [ ] Define corrective action triggers when modifications exceed acceptance criteria bounds
- [ ] Document preventive action protocols for systemic modification issues
- [ ] Link CAPA findings to PCCP scope evaluation and potential boundary adjustments

Records and Audit Readiness

- [ ] Maintain all records that would otherwise be generated and submitted to FDA for each modification
- [ ] Ensure recordkeeping is consistent with 21 CFR Part 820 requirements and QMS standards
- [ ] Establish an audit trail for every modification decision, implementation, and outcome
- [ ] Prepare documentation packages suitable for FDA inspection and audit review

6. Labeling and Transparency Requirements

Device Labeling

- [ ] Disclose that the device contains a machine learning model in device labeling
- [ ] Indicate that the device has an authorized PCCP in the labeling materials
- [ ] Summarize implemented changes and supporting data in updated labeling as modifications are deployed
- [ ] Satisfy all applicable FDA labeling requirements (21 CFR Part 801) for AI-enabled devices

Healthcare Provider Communication

- [ ] Develop notification protocols for healthcare providers when modifications are implemented
- [ ] Provide performance comparison data (pre- vs. post-modification) in accessible format
- [ ] Establish channels for healthcare provider feedback on modification impact
- [ ] Maintain up-to-date instructions for use reflecting current device capabilities

7. Post-Market Implementation

Performance Monitoring

- [ ] Implement continuous performance monitoring with statistical process control methods
- [ ] Compare real-world effectiveness against pre-market validation benchmarks
- [ ] Monitor for adverse events specific to AI-DSF modifications
- [ ] Collect and analyze user feedback on modification performance and clinical impact

Compliance Maintenance

- [ ] Conduct regular assessments of modification protocol effectiveness
- [ ] Evaluate whether implemented modifications remain within authorized PCCP scope
- [ ] Identify modifications that may exceed PCCP boundaries and require new marketing submissions
- [ ] Update PCCP documentation when scope or methodology changes are needed (PCCP modification requires new submission)

Reporting and Surveillance

- [ ] Submit regular performance reports to FDA with modification effectiveness data as required
- [ ] Integrate PCCP monitoring with Medical Device Reporting (MDR) requirements
- [ ] Maintain post-market surveillance plans aligned with PCCP modification scope
- [ ] Document version control and maintenance records for the authorized PCCP

> PCCP Maintenance: If a manufacturer needs to modify a previously authorized PCCP itself — not just implement the pre-authorized device modifications — a new marketing submission is required to amend the PCCP scope, methodology, or modification boundaries.

8. Regulatory Pathway-Specific Considerations

510(k) Submissions

- [ ] Incorporate PCCP as a clearly identified section within the 510(k) submission package
- [ ] Demonstrate that each planned modification maintains substantial equivalence to the predicate device
- [ ] Consider Special 510(k) pathway alignment for future PCCP scope modifications

De Novo Requests

- [ ] Incorporate PCCP requirements into the proposed special controls framework
- [ ] Demonstrate how the modification protocol supports novel device classification
- [ ] Establish precedent for future 510(k) submissions referencing the PCCP approach

PMA Applications

- [ ] Include PCCP within the PMA with comprehensive safety and effectiveness data for each modification
- [ ] Address heightened scrutiny for high-risk, life-sustaining, life-supporting, or implantable devices with AI-DSFs
- [ ] Prepare for potential post-market study commitments for long-term modification effectiveness assessment

International Alignment

- [ ] Evaluate Health Canada and UK MHRA harmonized PCCP guiding principles for global submissions
- [ ] Consider EU AI Act requirements for high-risk AI systems, including conformity assessment
- [ ] Align with relevant ISO standards: IEC 62304 (software lifecycle), ISO/IEC 23053 (AI risk framework)

Key References

FDA, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions," Final Guidance, December 2024 (Updated August 2025). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence

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FDA Webinar: Final Guidance on PCCP for AI-Enabled Device Software Functions, January 14, 2025. https://www.fda.gov/medical-devices/cdrh-new-news-and-updates/webinar-final-guidance-marketing-submission-recommendations-predetermined-change-control-plan

> Disclaimer: This checklist is provided for informational and planning purposes only. It does not constitute legal or regulatory advice. Organizations should consult with qualified regulatory affairs professionals and legal counsel to ensure full compliance with FDA requirements and applicable regulations. The regulatory landscape for AI-enabled medical devices continues to evolve; always refer to the most current FDA guidance documents.

About CAHIR Solutions

CAHIR Solutions is a Tampa-based consulting and technology firm founded in 2024 that specializes in data-driven evaluation, digital health modernization, and AI-enabled solutions. The company partners with health systems, agencies, and MedTech innovators to scale technology-enabled care models that improve clinical outcomes, patient experience, and operational performance through advanced analytics, interoperability, and value-based care-aligned strategies.

CAHIR's multidisciplinary team integrates program evaluation, informatics, and governance to support sustainable, high-quality care delivery. The firm's core competencies span healthcare regulation and compliance (FDA, CMMC, GSA), MedTech industry dynamics and scaling, health equity and health disparities reduction, data analytics and performance measurement, and organizational governance and risk management.

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