



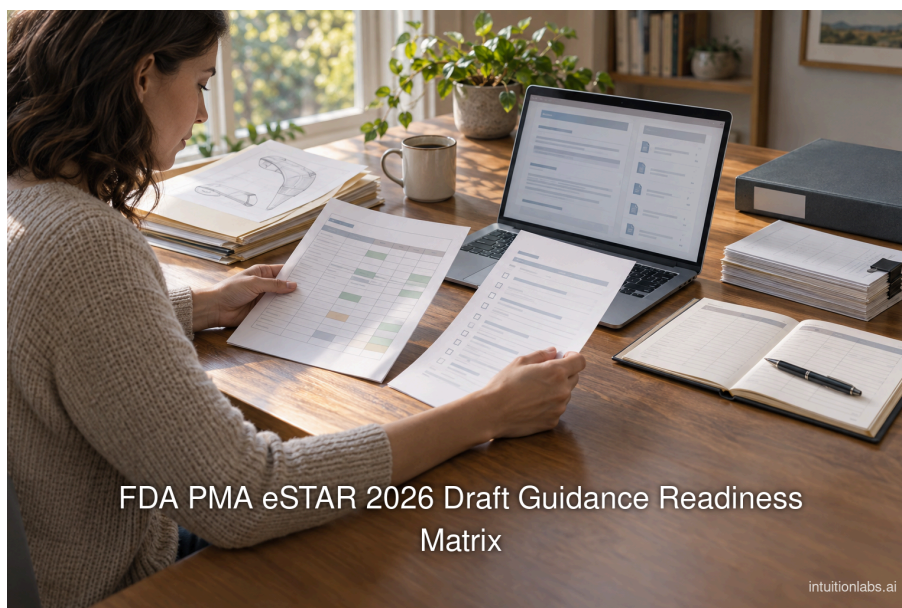
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FDA PMA eSTAR 2026 Draft Guidance Readiness Matrix

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Executive Summary

As of **September 29, 2026**, FDA's PMA-specific eSTAR guidance is a **draft that is not for implementation**. Current FDA instructions allow voluntary eSTAR use for designated Original PMAs and supplements, while covered 510(k) and De Novo submissions follow separate mandatory eSTAR rules. (www.federalregister.gov) (www.fda.gov) The PMA draft names Original PMAs, Panel-Track, 180-Day, Real-Time, and 30-Day Notice/135-Day supplements. (www.govinfo.gov) It proposes a transition of **at least one year after final guidance**, but no mandatory PMA calendar date has been set. (www.fda.gov) The priority comment date is **November 17, 2026**. (www.federalregister.gov)

The central decision is whether to pilot a supported PMA type now while preserving the ability to change course when FDA finalizes the standard, timetable, and exceptions. The future electronic-format requirement is linked by statute to a date specified in final guidance. (www.govinfo.gov) The draft anticipates a **15-calendar-day** technical screen after the appropriate fee is paid and describes a **360-day** response window following a technical deficiency. (www.fda.gov) These are proposed screening and response intervals, not a present-day deadline for PMA eSTAR adoption. The separate general eSTAR FAQ has its own hold language, so an internal procedure should use the applicable FDA communication for a particular submission.

A readiness program should classify each work item, record CDRH or CBER routing, and control the exact downloaded PDF template. The approved RIM/DMS source package, attachment manifest, single-writer publishing step, and acknowledged PDF are the evidence needed to reproduce a submission and its responses. Veeva's documented source-version lock is one example of how a system can prevent source drift; it is not a regulatory software requirement. (regulatory.veevavault.help)

The report supplies a current-versus-proposed matrix, a PMA-type routing matrix, and a source-to-template map. A **30/60/90-day** plan starts with portfolio classification, moves to controlled authoring and attachment tests, and ends with a measured voluntary pilot. The key test is whether the organization can reproduce the exact file it submitted and explain each conditional answer, omission, and source version. PMA regulations already require separate nonclinical and clinical sections and a justification for omitted nonapplicable information. (www.ecfr.gov) Neither agency workload totals nor template file limits establish an eSTAR adoption rate or a sponsor return on investment.

Introduction and Background

The U.S. Food and Drug Administration (FDA) issued a premarket approval (PMA) specific electronic Submission Template and Resource (eSTAR) draft on September 18, 2026. The document is explicitly **draft guidance, not for implementation**. It concerns designated applications and supplements reviewed by both the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The practical decision for a PMA program is whether to use eSTAR voluntarily now, and which publishing controls can be built without treating a future requirement as if it already applies. The Federal Register likewise describes the draft as neither final nor currently implementable. (www.federalregister.gov)

The distinction matters because FDA already requires eSTAR for covered **510(k)** premarket notifications and **De Novo** requests, while it still lists designated PMA types under **voluntary** use. (www.fda.gov) The legal basis for a later PMA electronic-format requirement is different from the current operating status: the amended statute refers to a date specified in final guidance. (www.govinfo.gov) The draft says final guidance will set electronic-format standards, a timetable, and waiver or exemption criteria. No mandatory PMA date should be inferred from the issue date of the draft or from the separate 510(k) and De Novo milestones.

This report is an operating guide for regulatory operations leaders, PMA program managers, submission publishers, quality teams, and regulatory information management (RIM) and document management system (DMS) owners. It treats eSTAR as a generated submission artifact whose source files, decisions, and approvals remain traceable. IntuitionLabs describes its services across regulatory and quality workflows and Veeva application integration; that is an adjacent advisory perspective on submission controls, not an eSTAR product claim. (intuitionlabs.ai) (intuitionlabs.ai) The analysis below separates confirmed present-state instructions, draft proposals, and suggested internal controls.

Key Changes

A PMA-specific path from voluntary use to a future requirement

FDA's September document is a PMA-specific step toward an electronic template standard, not a final mandate. The draft lists **Original PMAs, Panel-Track, 180-Day, Real-Time, and 30-Day Notice/135-Day** supplements. (www.govinfo.gov) (www.govinfo.gov) FDA's current eSTAR page identifies the same broad voluntary PMA family. The draft expressly excludes PMA Modules and Modular Shells. (www.fda.gov) This distinction should be coded into the submission inventory before a team decides whether a pending amendment or supplement belongs in an eSTAR pilot.

The draft proposes a transition of **at least one year after final guidance** before the designated PMA electronic submissions become required. (www.fda.gov) That is an interval, not a calendar deadline. The operative date, format standard, and detailed exceptions depend on a final document that FDA has not yet issued. (www.govinfo.gov) The Federal Register notice invites comments by **November 17, 2026** for consideration during drafting, while FDA states that guidance comments can be submitted at any time. (www.federalregister.gov) Organizations should assign someone to monitor docket **FDA-2026-D-9429** and maintain a dated decision log, especially if a final version changes scope or timing. (www.federalregister.gov)

Potentially binding elements and proposed exceptions

The draft distinguishes the future standards, timetable, and waiver or exemption criteria that would have binding effect on finalization from other guidance recommendations. The statute's final-guidance trigger explains why an internal policy must not say that PMA eSTAR is mandatory today. (www.govinfo.gov) In the draft, FDA says it has not identified circumstances that generally justify a waiver for designated PMA submissions. (www.fda.gov) That is a proposed position. It is not a reason to erase a case-specific escalation path from a future procedure.

The proposed exemption list includes interactive review responses and several amendments or administrative communications. It also identifies correspondence or legal-entity changes and other post-decision or withdrawal communications. A practical decision tree begins by determining the application type, then whether the item is a new designated submission or a response or exempt communication, then the reviewing center and transmission route. Each branch should record the source paragraph and date used, because the final guidance may revise the list. The specific exception used should be visible in the submission record rather than embedded in an email.

Screening shifts the preflight burden

FDA proposes virus scanning and **technical screening** for PMA eSTAR submissions. The draft anticipates screening within **15 calendar days** after receipt, with the appropriate user fee paid before that screening begins. (www.fda.gov) An eSTAR with a technical deficiency could be held while the applicant supplies information; the draft describes a **360-day** response window before FDA considers the submission withdrawn. (www.fda.gov) Original PMAs and Panel-Track supplements that pass the technical screen still undergo filing review; eSTAR is not an assurance of substantive completeness.

FDA's broader eSTAR program page separately describes a technical-screening hold of **up to 180 days** for certain irrelevant attachments or inaccurate answers. (www.fda.gov) These statements appear in different contexts and should not be collapsed into one universal PMA response deadline. Program procedures should cite the applicable communication from FDA for each submission and re-check the final PMA guidance before setting a binding internal clock. (www.federalregister.gov) The operating control is to make the eSTAR status, eligibility answers, attachment inventory, and paid-fee evidence part of the preflight packet.

Current and Proposed Requirement Matrix

Table 1 separates the live operating baseline from the draft proposal. The proposed column is a planning input, not current law.

Control question	Current baseline as of September 29, 2026	Draft PMA proposal and readiness action
Is eSTAR mandatory?	Covered 510(k) and De Novo submissions use eSTAR unless exempted; designated PMAs can use it voluntarily. (www.fda.gov)	A final PMA guidance would set the effective timetable. Register a final-guidance watch and do not assign a mandatory date now.
What is in scope?	FDA lists Original PMAs and specified Panel-Track, Real-Time, 180-Day, and 30-Day Notice/135-Day supplements for voluntary use.	The draft designates those types and excludes Modules and Modular Shells. Code each active work item by type. (www.govinfo.gov) (www.govinfo.gov)

Control question	Current baseline as of September 29, 2026	Draft PMA proposal and readiness action
Which template?	FDA's current page lists nIVD and IVD eSTAR Version 7.1 . (www.fda.gov)	Record the exact downloaded template and its major and minor version at project start; check FDA's page again at release.
Which route?	CDRH-led premarket types may use the CDRH Portal, subject to upload constraints.	The draft identifies FDA's electronic portal for CDRH and the Electronic Submissions Gateway for CBER. Route selection belongs in the preflight signoff.
Which exceptions?	PMA eSTAR use remains voluntary for the designated set.	Track the proposed exemption categories and lack of a general waiver category, then compare them with final text.
What acceptance check?	The CDRH Portal will not accept an eSTAR marked incomplete.	Expect virus and technical screening under the proposal; verify answers, files, and fees before dispatch.

The matrix should be owned as a controlled decision record. It is especially useful when a program spans centers or has multiple supplement types: a general instruction to “use the latest eSTAR” does not decide eligibility, route, or whether a response should preserve an acknowledged version. FDA's eCopy status table still classifies other PMA submission types separately, so a type absent from the draft list should not be silently swept into the future mandate.

Designated PMA Types and Filing Routes

The application type is the first classification control. A supplement is required before a covered change affecting an approved device, while the regulation limits the supplement to information needed to support that change. (www.ecfr.gov) (www.ecfr.gov) Its separate change section must identify each requested change and explain the reason. (www.ecfr.gov) The regulation already calls for electronic-format PMA supplements, which is distinct from a future eSTAR template mandate. (www.ecfr.gov) Under the current regulation, the PMA application contains separate nonclinical and clinical sections; if information does not apply, the applicant may identify and justify the omission. (www.ecfr.gov) (www.ecfr.gov) Those obligations are content obligations independent of the PDF template. eSTAR's guided questions display only sections relevant to earlier answers, which makes answer governance important: an incorrect branch can hide a requested section from the working view. The source dossier should therefore keep a complete requirement map even when the dynamic PDF does not display every possible heading. (www.imdrf.org)

Table 2 is a routing matrix for the designated types, with controls that matter during a voluntary pilot and after any final timetable.

Submission family	eSTAR status and center	Operational control
Original PMA	In the voluntary PMA set for CDRH or CBER.	Confirm application number, evidence index, user-fee receipt, center route, and filing-review readiness.
Panel-Track supplement	In the designated set for either reviewing center. (www.govinfo.gov)	Treat major change evidence and review chronology as a distinct content plan; do not reuse the original-PMA packet without reconciliation. (www.ecfr.gov)

Submission family	eSTAR status and center	Operational control
180-Day supplement	In the designated set. (www.govinfo.gov)	Validate change description, testing references, attachments, and route against the approved PMA baseline. (www.ecfr.gov)
Real-Time supplement	In the designated set. (www.govinfo.gov)	Maintain the agreed interaction record and check that the chosen eSTAR answers match the change category.
30-Day Notice/135-Day supplement	In the designated set. (www.govinfo.gov)	Record the notice classification and the applicable fee before using the template. (www.ecfr.gov)
PMA Module or Modular Shell	Expressly outside the draft's designated set.	Keep on the applicable non-eSTAR publishing route unless FDA later changes scope. (www.federalregister.gov)

The table is a classification aid, not a substitute for a regulatory-pathway decision. A **30-Day Notice** concerns manufacturing procedure or method changes and must describe the change and supporting information; an inadequate notice can move to a **135-Day supplement** review. (www.ecfr.gov) (www.ecfr.gov) Changes that do not affect safety or effectiveness can instead be reported in a periodic report under the regulation. (www.ecfr.gov) This taxonomy must be resolved before a template is chosen. For CDRH, the Portal permits upload of CDRH-led premarket types, but its official correspondent or designated delegates control progress tracking. For CBER, the draft points to the Electronic Submissions Gateway; a CDRH Portal procedure should not be copied over without a center-specific transmission check. The currently published CDRH Portal page also permits an electronic submission to be mailed to the Document Control Center when size limits prevent portal transmission. That is a transport contingency, not a blanket eSTAR-format waiver.

Implementation Considerations and Process Changes

Keep authoritative content outside the dynamic PDF

A controlled RIM or DMS should hold approved source content, its versions, owners, evidence lineage, and signoffs. The eSTAR file is the assembled regulatory output. This distinction matters because FDA describes eSTAR as an **interactive PDF** and says its displayed sections change with applicant answers. The source system should retain a content plan that names the eSTAR destination, source document identifier, approved version, rendition used, attachment name, and reviewer. A separate immutable manifest can list each attached file and its hash at release; this is an internal control proposal, not an FDA-prescribed field. A locked source version can help make that manifest reproducible. (regulatory.veevavault.help)

Table 3 gives a compact source-to-template map. It is intentionally generic because the live PDF prompts are conditional and can change with template version. The International Medical Device Regulators Forum (IMDRF) table of contents provides a useful independent organizing reference for device description and submission organization, but it does not replace the FDA eSTAR prompts. (www.imdrf.org) (www.imdrf.org)

Source content in RIM/DMS	eSTAR destination or decision	Release evidence
Cover correspondence, applicant and device identifiers	Administrative and application-identification prompts	Approved source version, data-field reconciliation, correspondence approval. (regulatory.veevavault.help)

Source content in RIM/DMS	eSTAR destination or decision	Release evidence
Device description, intended use, configuration	Device and product sections displayed by the chosen answers	Source-to-field map; IMDRF device-description heading can help index the source package. (www.imdrf.org)
Nonclinical and clinical evidence	Applicable study and performance sections	Study list, approved report versions, omissions with written justification where appropriate. (www.ecfr.gov)
Manufacturing and quality information	Conditional manufacturing and quality prompts	Approved source files, quality review, and regulated-record retention controls. (www.ecfr.gov)
Change rationale for a supplement	Supplement-specific prompts and supporting files	Cross-reference to approved PMA baseline and change-control record.
PDFs and other permitted evidence files	Embedded attachment controls	Filename, type, size, opening test, and final manifest. (pdfa.org)

The IMDRF assembly guide also recommends filenames that present related files in their intended sequence, a useful manifest convention when a source dossier has multiple reports. (www.imdrf.org) The map makes the approval boundary visible. Veeva's regulatory publishing documentation, for example, describes links from published documents back to source documents and lifecycle states such as publishing review. (regulatory.veevavault.help) Its content-plan guidance documents locking an item to a specific document version, a useful example of how a system can prevent silent source drift. (regulatory.veevavault.help) The particular software is optional; the control objective is to identify what was approved and what was actually placed in eSTAR. Veeva also warns that publishing a fillable regulatory PDF from a viewable rendition may flatten it, a reason to test the source-to-output path before relying on a generated copy. (regulatory.veevavault.help) In any system, quality approval and regulatory release should be separate recorded decisions. (regulatory.veevavault.help)

Govern the dynamic PDF and its attachments

FDA says concurrent coauthoring of the eSTAR dynamic PDF is **not supported**. Team members using shared storage must work sequentially; FDA suggests a static PDF for parallel comments and markup. (www.fda.gov) A workable cycle is: check out the eSTAR to one publisher, import or enter approved content, add attachments, run a local completeness check, circulate a static review copy, reconcile comments in the source system, and then return one controlled working eSTAR for final edits. A version-history log can show the handoffs. (learn.microsoft.com) Microsoft documents document-library checkout as an exclusive-editing control and version history as a record of who changed a file. (support.microsoft.com) (learn.microsoft.com) Its guidance also says version-history limits should fit recovery objectives, which argues for a deliberate retention setting on the working eSTAR library. (learn.microsoft.com)

FDA instructs users to save eSTAR locally because browsers cannot open its dynamic PDF. Its current page recommends Acrobat Pro and identifies minimum versions of PDF-XChange Editor and Foxit PDF Reader; Acrobat Reader can open the file but cannot save edits or add attachments. (www.fda.gov) Tool qualification should test exactly the operations the submission needs: conditional fields, attachment insertion, saving,

reopening, and any signatures. Adobe's web Fill and Sign documentation separately warns that dynamic XFA PDFs are unsupported there; that document is not evidence that every eSTAR file is XFA, but it reinforces the need to test the actual FDA template in the chosen desktop tool. (helpx.adobe.com)

FDA caps attachment names at **124 characters** and says zip attachments are rejected, while Word, Excel, MP4, and PDF materials may be accepted. Attachment controls should also test file size before the final build: the current FDA page gives **1 GB per attachment and 4 GB per entire eSTAR** for CDRH Portal transmission, and **100 GB** for CBER Electronic Submission Gateway submissions. (www.fda.gov) (www.fda.gov) A separate FDA ESG NextGen table lists a **200 GB** threshold for the CBER PMA submission type; the pages have different labels and do not reconcile the two figures, so large-file plans should confirm the applicable route and limit before release. (www.fda.gov) Adobe notes that embedded attachments move with a PDF when the file moves. (helpx.adobe.com) The PDF Association notes that creators may store embedded file streams differently and that an EmbeddedFiles index does not require unique filenames; an attachment manifest should therefore use source IDs as well as displayed names. (pdfa.org) (pdfa.org) This helps explain why the complete assembled PDF, not just its source folder, must be archived and reopened for a release check. PDF/A-3 permits embedded attachments as an archival format, but the submission copy should be the FDA-supported eSTAR artifact rather than a converted archive rendition. (pdfa.org)

Exporting and importing eSTAR XML does **not** carry attachments, according to FDA. (www.fda.gov) A version migration therefore requires a fresh attachment manifest comparison and a file-open test. Electronic signatures also need sequencing: FDA instructs users to remove a signature before changing attachments, and Adobe states that saving a digitally signed PDF invalidates the signature. (helpx.adobe.com) A publisher should sign only after content and attachment freeze, then preserve the released file and evidence of transmission. (helpx.adobe.com) (regulatory.veevavault.help)

Version governance and response handling

FDA identifies **major and minor** eSTAR updates and says a prior major version may sometimes remain usable when its changes do not affect the device. Minor updates do not typically generate information requests solely because of those minor changes. The decision to remain on an older version should nevertheless be documented against the current FDA change log, the device's relevant sections, and the projected submission date. A version number without the exact downloaded file is insufficient for reconstruction.

After FDA acknowledges an original eSTAR submission, FDA says the submission is **grandfathered** to that eSTAR version for responses. (www.fda.gov) The response should modify the original eSTAR; unaffected sections and attachments should remain unchanged. The operational decision tree is: before acknowledgment, assess whether a current template is needed; after acknowledgment, retrieve the exact acknowledged file and maintain its version for that response; if any migration is separately needed, rebuild the attachment set because XML does not include it. This is why a RIM/DMS record should preserve both the approved source package and the exact transmitted dynamic PDF. (learn.microsoft.com)

The regulated-record environment can support this traceability. **21 CFR 11.10** addresses system validation, record protection, and secure time-stamped audit trails for covered electronic record systems. (www.ecfr.gov) (www.ecfr.gov) Current **21 CFR 820.10** references a quality management system compliant with applicable ISO 13485 requirements; ISO describes that standard as medical-device-specific.

(www.ecfr.gov) (www.iso.org) NIST's general control catalog also groups audit, accountability, and configuration management as distinct control families; it is a design reference, not an FDA PMA template rule. (csrc.nist.gov) These requirements do not prescribe an eSTAR-specific software architecture. They support a controlled release history around a dynamic artifact that is edited sequentially.

Data Analysis and Evidence

The useful numbers are regulatory intervals, file constraints, and workload context, not an invented adoption rate. FDA's fiscal year **2025** MDUFA report records **90** combined original PMAs, product development protocols, Panel-Track supplements, and premarket reports, **215** 180-Day supplements, and **276** Real-Time supplements in its review workload table. (www.fda.gov) These are agency workload categories, not counts of eSTAR submissions; the first category is broader than the designated original-PMA type. FDA also labels the fiscal year 2025 performance figures preliminary. The figures indicate that supplement families represent material routing volume, but do not show the percentage of sponsors ready for eSTAR.

The draft's operational clock has three distinct components: a post-finalization transition, technical screening, and a deficiency-response window. These are not interchangeable service-level targets. The first concerns when a future requirement starts, the second FDA's anticipated screening interval, and the third a response window after a deficiency. Any internal workback plan should also include the existing application content and center-routing checks.

For a transition exposure worksheet, enter the organization's own counts: **O** active Original PMAs, **P** Panel-Track, **D** 180-Day, **R** Real-Time, **N** 30-Day Notice/135-Day, and **M** Modules or Modular Shells. Eligible pipeline candidates under the current draft are **E = O + P + D + R + N**; **M** is tracked separately because the draft excludes Modules and Modular Shells. (www.govinfo.gov) (www.govinfo.gov) Add a field for each candidate's reviewing center, current eSTAR version, acknowledgment status, expected filing date, and exemption branch. Then calculate **pilot coverage = voluntarily built eSTAR candidates / E**, with a zero-denominator case reported as not applicable. These are user-entered portfolio measures, not FDA adoption statistics.

Submission fees are a separate budget line from template readiness. FDA's fiscal year **2026** fee schedule listed a standard original-PMA fee of **\$579,272**, a Panel-Track fee of **\$463,418**, an 180-Day supplement fee of **\$86,891**, a Real-Time supplement fee of **\$40,549**, and a 30-Day Notice fee of **\$9,268**. (www.govinfo.gov) The published fiscal year **2027** schedule takes effect on **October 1, 2026**, after this article's publication anchor, and sets different amounts. (www.govinfo.gov) (www.govinfo.gov) Fee reductions or waivers under the user-fee program are distinct from the draft's proposed electronic-format waiver and exemption logic. No fee number should be used as a proxy for eSTAR publishing cost or benefit.

There is no verified public number in the fetched sources for PMA eSTAR adoption or sponsor preparation-time savings. A useful pilot measurement should therefore start at the organization level: hours to assemble the first controlled PDF, attachment reconciliation defects found before submission, tool errors, reviewer changes after static markup, and time to restore an acknowledged version for a response. The baseline and pilot should be compared by submission family, because a Real-Time supplement and an Original PMA have different content and review patterns. The regulation likewise limits supplement content to what supports the

change. (www.ecfr.gov) Veeva's documented source-version lock and Microsoft's version-history controls are examples of systems that can provide source-trace evidence, but they are not performance benchmarks. (regulatory.veevavault.help) (learn.microsoft.com)

Implications and Future Directions

A PMA organization can move voluntarily without betting on an unissued mandate. The first **30 days** should classify the active pipeline, assign a final-guidance monitor, record the current eSTAR version, and test a sample of dynamic-PDF operations in a controlled desktop environment. The next **30 days** should map source documents to conditional prompts, set a single-writer checkout rule, and rehearse attachment insertion and XML reimport. The following **30 days** should pilot a designated supplement or original PMA, retain the exact transmitted artifact, and measure preflight defects and response retrieval time. This **30/60/90-day** sequence is an internal readiness plan, not an FDA timetable.

A release preflight can be short but evidence based:

- **Classification:** record PMA type, reviewing center, pathway decision, and draft or final guidance version used. (www.govinfo.gov)
- **Template:** record eSTAR family, version, download date, tool version, and a completed local open-save-reopen test. (support.microsoft.com)
- **Content:** reconcile conditional answers to the content plan and justify omitted PMA information where applicable.
- **Attachments:** compare the manifest to the PDF, open every file, test allowed formats, names, and size constraints. (pdfa.org) (helpx.adobe.com)
- **Submission:** confirm fee payment, eSTAR complete status, transmission route, and authorized correspondent or delegate.
- **Archive:** retain the approved source versions, final dynamic PDF, manifest, static review copy, signoff record, and transmission acknowledgment. (regulatory.veevavault.help) (www.ecfr.gov) (learn.microsoft.com)

NIST's audit and configuration-management categories provide a general cross-check for the record and version controls, without defining an eSTAR requirement. (csrc.nist.gov) Regulatory operations should own classification and final release; quality should approve the controlled record and exception process; the RIM/DMS owner should maintain source lineage and fit version retention to recovery needs; and IT should qualify the PDF tool and access model. (learn.microsoft.com) (www.ecfr.gov) A version-change trigger should reopen the mapping only when a new FDA template or final guidance changes a relevant prompt, allowed format, or scope. FDA's major/minor version distinction and acknowledgment grandfathering allow a more precise decision than an unconditional template swap.

The main external trigger is the final guidance. The present document remains a draft.

(www.federalregister.gov) It may alter designated types, timing, route, exceptions, and screening language. The organization's tracker should show each draft assumption next to the final paragraph that confirms or replaces it, with an effective date and an owner for procedure updates. The comment opportunity through **November 17, 2026** is also a chance to surface implementation questions about center-specific routes,

modular scope, and response handling. (www.federalregister.gov) (www.govinfo.gov) A program that can produce a reproducible eSTAR file and explain each source decision is prepared to adjust when the final text arrives.

Frequently Asked Questions (FAQs)

Is PMA eSTAR required in September 2026?

No. FDA describes designated PMA eSTAR use as voluntary, and the September 2026 document is a draft not for implementation. (www.federalregister.gov) A future mandatory timetable depends on final guidance, so the draft issue date is not an effective date.

Which PMA submissions should be inventoried first?

Inventory Original PMAs, Panel-Track, 180-Day, Real-Time, and 30-Day Notice/135-Day supplements, then record reviewing center and planned filing date. (www.govinfo.gov) (www.govinfo.gov) Keep Modules and Modular Shells as a separate category for the scope inventory.

What is the current PMA eSTAR version?

FDA's current page lists **Version 7.1** for both non-in vitro diagnostic and in vitro diagnostic eSTAR templates. (www.fda.gov) Record the actual downloaded file and re-check the page before release; FDA distinguishes major and minor updates.

Conclusion

As of publication, the correct PMA eSTAR decision is about controlled voluntary adoption and readiness for a future final timetable. FDA has identified a designated set of original applications and supplements, excluded Modules and Modular Shells from the draft, and proposed a post-finalization transition. It has not established a mandatory PMA calendar date.

The most valuable near-term work is operational: classify the pipeline, keep approved source content in a versioned RIM/DMS, test the dynamic PDF with a single-writer workflow, reconcile attachments, and preserve the exact acknowledged file for responses. FDA's own instructions on sequential editing, XML attachment loss, and version grandfathering make these controls relevant even while PMA eSTAR use remains voluntary.

A final-guidance watch should convert each proposed rule into a dated procedure only when FDA finalizes it. Until then, a measured pilot can reveal local publishing effort and defects without presenting the draft as law or claiming unmeasured industry-wide savings. The resulting control record will make both a voluntary submission and any later transition easier to audit and update.

Source links

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

1. <https://www.federalregister.gov/documents/2026/09/18/2026-19181/electronic-submission-template-for-medical-device-premarket-approval-applications-pmas-draft>

2. <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
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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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