REGULATORY AFFAIRS FIELD GUIDE

Developing and Manufacturing Medical Devices

A practical guide for regulatory affairs teams

From intended purpose and market strategy to defensible submissions, compliant labelling and controlled lifecycle obligations

General cross-market guidance | Edition 1.0 | August 2026

Table of Contents

How to use this guide

This guide explains how regulatory affairs managers, specialists and associates shape the development, manufacture, market authorisation and lifecycle maintenance of medical devices. It covers regulatory strategy, intended purpose, classification, jurisdictional pathways, technical documentation, essential evidence, labelling, registrations, submissions, authority interactions, change assessment, vigilance and post-market obligations. It addresses medical devices, in vitro diagnostic devices, connected products and software where the relevant regulatory frameworks apply.

CORE MESSAGE Regulatory affairs turns the product's intended purpose, risks, evidence and commercial ambitions into a coherent, defensible route to market and maintains that position throughout the device lifecycle.

Scope and important limitations

- Start with the legal manufacturer, intended purpose, medical claims, product boundary, target markets and device classification.
- Confirm the current version and applicability of legislation, standards, regulatory guidance and jurisdiction-specific administrative requirements.
- Distinguish regulatory obligations from company preferences, guidance, harmonised standards, recognised consensus standards and contractual requirements.
- Coordinate with quality, clinical, engineering, risk management, cybersecurity, manufacturing and commercial teams from the beginning of development.
- Avoid assuming that authorisation, certification, classification or evidence in one market automatically applies in another.

1. The role of regulatory affairs in medical-device development

Regulatory affairs interprets requirements, defines the route to market, guides evidence planning and maintains the manufacturer's regulatory position. The function is most effective when it shapes early decisions rather than attempting to assemble a submission after design, claims and evidence have already diverged.

Core regulatory responsibilities

Responsibility	Practical outcome
Strategy	An approved market, classification, pathway and evidence approach aligned with the product and business plan.
Interpretation	Applicable legislation, standards and guidance are translated into actionable requirements.
Evidence integration	Risk, design, verification, clinical, usability and manufacturing evidence support a consistent argument.
Submission and authorisation	Applications, technical documentation and authority responses are complete and controlled.
Lifecycle compliance	Registrations, claims, changes, vigilance and post-market obligations remain current.

Maintain accountability with the manufacturer

Consultants, authorised representatives, notified bodies, importers and distributors play defined roles, but the manufacturer remains responsible for the device and its regulatory evidence. Regulatory affairs must make ownership, authority and contractual responsibilities explicit.

2. Intended purpose, claims and regulatory product boundary

The intended purpose determines whether the product is regulated, how it may be classified, which risks and evidence matter and what can be communicated commercially. It should specify the medical purpose, patient or specimen population, intended user, environment, operating principle and important limitations.

Create one controlled product definition

- Define indications, intended population, user group, use environment, duration and relevant clinical workflow.
- Identify accessories, consumables, reagents, software, cloud services, networks and external-system dependencies.
- Distinguish the regulated medical function from general wellness, administrative or supporting functions.

- Ensure product claims, instructions, clinical evidence, risk management and verification use the same definition.
- Assess proposed new users, indications, integrations or claims before they enter marketing materials or development commitments.

Avoid accidental claims and regulatory scope expansion

Website wording, sales demonstrations, training, user-interface text and investor materials can imply medical claims. A statement that appears commercially harmless may alter classification, evidence needs or off-label promotion risk. Regulatory review should cover all customer-facing claims, not only the formal instructions for use.

3. Building a regulatory strategy

A regulatory strategy translates product and business decisions into market-specific pathways, evidence requirements, responsibilities, milestones and lifecycle obligations. It should be documented early, reviewed at defined gates and updated when the product, market or regulatory environment changes.

Essential elements of a strategy

- Legal manufacturer, intended purpose, product family, variants, accessories and software boundaries.
- Target markets, launch sequence, classification assumptions and proposed conformity or submission pathways.
- Applicable legislation, standards, guidance, common specifications and recognised or harmonised references.
- Quality-system, design-control, risk, clinical, usability, cybersecurity and manufacturing evidence needs.
- Notified-body, competent-authority, FDA or other regulator engagement and administrative dependencies.
- Timelines, resource assumptions, change-control consequences and post-market commitments.

Challenge business assumptions early

A low-risk classification, predicate availability, exemption, equivalence claim or reliance route is an assumption until supported by evidence. Regulatory affairs should identify uncertainty, request specialist input and prevent unsupported assumptions from becoming fixed programme commitments.

4. Medical-device and IVD classification

Classification determines the level of regulatory control, conformity assessment, review and evidence. Rules differ by jurisdiction and depend on intended purpose, invasiveness, duration, anatomical contact, diagnostic significance, software function and other product-specific factors.

Document a defensible classification rationale

- Identify the applicable legislation, classification rule, definitions and relevant guidance.
- Explain the intended use, operating principle, patient or specimen population and context of use.
- Assess software functions, accessories, reusable instruments, combination-product issues and borderline characteristics.
- Compare alternative rules and justify why the selected classification is appropriate.
- Reassess classification when claims, indication, technology, user, duration or intended market changes.

Do not transfer classification between markets automatically

An EU classification, US product code or UK classification may inform discussion but does not replace a jurisdiction-specific rationale. Even where risk concepts overlap, legal definitions, special controls, predicate logic and conformity routes can differ materially.

5. European Union MDR and IVDR foundations

Regulation (EU) 2017/745 governs medical devices; Regulation (EU) 2017/746 governs in vitro diagnostic medical devices. These frameworks establish manufacturer obligations, classification, conformity assessment, general safety and performance requirements, technical documentation, clinical or performance evaluation, post-market surveillance and vigilance.

Plan the European conformity pathway

- Identify the applicable regulation, classification, conformity-assessment annex and notified-body involvement.
- Define legal manufacturer, authorised representative where relevant, importer and distributor obligations.

- Establish the applicable general safety and performance requirements and supporting evidence.
- Prepare technical documentation, declaration of conformity, labelling, UDI and registration arrangements.
- Integrate clinical or performance evaluation, post-market surveillance, vigilance and periodic reporting.

Treat transition and legacy provisions as controlled decisions

Transitional provisions, certificate validity, significant-change restrictions and legacy-device status are fact-specific and time-sensitive. Regulatory affairs should verify the current legal position, preserve documentary evidence and avoid using general transition summaries as authorisation for a specific product.

6. United States regulatory foundations

The US Food and Drug Administration regulates medical devices using classification, general controls, special controls and premarket pathways appropriate to risk. The FDA Quality Management System Regulation became effective on 2 February 2026 and incorporates ISO 13485:2016 by reference together with additional US requirements.

Identify the correct US pathway

Pathway	General regulatory purpose
Exempt device	Certain lower-risk devices may be exempt from premarket notification while remaining subject to applicable controls.
510(k)	Demonstrates substantial equivalence to a legally marketed predicate device, supported by appropriate evidence.
De Novo	Provides risk-based classification for a novel device without a suitable legally marketed predicate where controls can provide assurance.
Premarket approval	Provides scientific and regulatory review for devices requiring approval, generally associated with higher-risk Class III products.
Investigational use	May require an investigational-device exemption or other controls depending on the proposed clinical investigation.

Separate clearance, approval and authorisation language

A 510(k) device is cleared, not approved. A PMA device is approved. A De Novo request results in classification and marketing authorisation. Regulatory affairs should ensure that labelling, commercial language, public statements and internal reporting use terminology appropriate to the actual pathway.

7. Great Britain, Northern Ireland and other markets

The UK framework continues to evolve, and Great Britain and Northern Ireland may have different applicable arrangements. Other markets, including Switzerland, Canada, Australia, Japan and countries using reliance or recognition mechanisms, have their own registration, representation, labelling and evidence requirements.

Maintain market-specific intelligence

- Confirm the current UK legislation, MHRA guidance, acceptance arrangements, post-market rules and registration requirements.
- Identify whether Great Britain, Northern Ireland or both are in scope.
- Check local authorised-representative, importer, language, UDI, certificate and documentation requirements.
- Assess whether reliance on another regulator's authorisation is available and what conditions apply.
- Maintain a change-watch process because roadmaps and proposed reforms are not the same as enacted obligations.

Design a global core with local adaptations

A common evidence package can support multiple markets when the intended purpose, configuration and acceptance criteria are compatible. Regulatory affairs should identify where local rules require additional evidence, translated information, different administrative records or alternative claims.

8. General safety and performance requirements

For EU MDR and IVDR products, the general safety and performance requirements establish device-specific obligations concerning safety, risk, performance, materials, infection, information and product characteristics. Regulatory affairs should ensure that each applicable requirement is addressed by objective evidence.

Build an evidence-backed GSPR checklist

- Identify applicable requirements and document clear justification for non-applicable items.
- Link each requirement to standards, specifications, risk controls, reports, validation or labelling evidence.
- Use controlled document identifiers, versions and product configurations.
- Identify gaps, incomplete studies, unverified claims and conflicting evidence.
- Reassess the checklist after design, intended-purpose, standards or market changes.

Do not confuse a checklist with conformity evidence

The checklist is a navigation and rationale tool. An unsupported statement that a requirement is met does not establish conformity. A reviewer should be able to follow each important claim to the underlying approved evidence.

9. Standards, harmonisation and recognised consensus standards

Standards can provide methods and technical expectations that support compliance, but their legal effect depends on jurisdiction, edition, scope, amendments and recognition or harmonisation status. Regulatory affairs should distinguish mandatory legal obligations from voluntary standards and guidance.

Maintain a controlled standards assessment

- Identify standards relevant to quality, risk, software, usability, electrical safety, cybersecurity, biological safety and product-specific functions.
- Record the edition, amendments, jurisdictional status and applicability to the actual device.
- Check the scope and limitations of harmonisation or FDA recognition before relying on presumed conformity or declarations.
- Assess gaps where the device uses a newer edition, alternative method or non-harmonised standard.
- Monitor withdrawal, amendment, replacement and changes in state of the art.

Use product-family terminology accurately

Essential performance belongs to applicable IEC 60601 medical-electrical-equipment contexts. Primary functions are used in relevant ISO 11608 injection-system contexts.

These terms should not be applied generically to every important function without confirming that the underlying standard applies.

10. Quality-system and design-control evidence

Regulatory submissions depend on controlled development and manufacturing evidence. Regulatory affairs should understand how the quality system, design history, risk management and technical documentation relate, while avoiding duplication of records solely for submission convenience.

Review quality-system readiness

- Confirm the approved quality-system scope, legal manufacturer, sites, suppliers and outsourced activities.
- Assess design and development planning, document control, competence, risk and change management.
- Review verification, validation, design transfer, production controls and release evidence.
- Identify open audit findings, CAPAs, supplier concerns and nonconformities relevant to market readiness.
- Map market-specific requirements, including the FDA QMSR and EU manufacturer obligations.

Protect the distinction between design records and technical documentation

The design file records development activity and decisions. Technical documentation presents the evidence needed to demonstrate conformity for a defined product. These bodies of evidence overlap, but their purpose, structure, audience and maintenance requirements are not identical.

11. Technical documentation structure and control

Technical documentation should describe the device, intended purpose, design, manufacture, risk controls, applicable requirements, verification, validation, clinical or performance evidence, labelling and lifecycle arrangements. It must remain coherent for the actual marketed configuration.

Organise the core evidence set

Evidence area	Typical regulatory question
Device description	What is the product, how does it work and which configurations or accessories are covered?
Design and manufacture	How is the product designed, produced, controlled and released?
Requirements and conformity	Which legal and technical requirements apply, and where is supporting evidence located?
Risk management	What can cause harm, how is risk controlled and why is overall residual risk acceptable?
Verification and validation	What evidence demonstrates that the defined configuration meets requirements and intended use?
Clinical or performance evidence	Are the medical benefits, diagnostic performance and claims supported?
Labelling and lifecycle	Are instructions, registrations, post-market surveillance and change controls appropriate?

Maintain configuration and version discipline

A technical file is unreliable if its reports describe different hardware, software, materials, manufacturing processes or intended use. Regulatory affairs should reconcile versions, approvals and configuration differences before submission or notified-body review.

12. Risk management and benefit-risk consistency

The regulatory argument depends on a credible product-risk analysis and an evidence-based overall benefit-risk conclusion. Regulatory affairs should ensure that risk conclusions are consistent with intended purpose, clinical or performance evidence, usability, labelling, cybersecurity and post-market experience.

Review the regulatory quality of risk evidence

- Confirm the risk-management policy, plan, product scope, intended use and acceptability criteria.

- Assess whether relevant hazards, use errors, failure conditions and reasonably foreseeable misuse are covered.
- Trace selected controls to approved requirements and objective verification evidence.
- Check residual-risk disclosure against instructions, contraindications, warnings and clinical documentation.
- Ensure overall residual-risk and benefit-risk conclusions reflect current evidence and market requirements.

Avoid unsupported benefit-risk claims

Claims that benefits outweigh risks must be supported by appropriate medical or diagnostic evidence. A general statement of commercial usefulness, a green risk matrix or an unverified feature list is insufficient.

13. Clinical evaluation and clinical evidence

Clinical evaluation establishes whether clinical evidence supports the intended purpose, safety, clinical performance and benefit-risk position of a medical device. The depth and form of evidence depend on the product, claims, novelty, risk, equivalent-device assumptions and applicable law.

Coordinate clinical and regulatory planning

- Align clinical questions, intended population, comparators, endpoints and claims with the regulatory strategy.
- Assess the suitability of literature, existing clinical data, equivalent-device evidence and clinical investigations.
- Ensure evaluation methods and conclusions are scientifically defensible and appropriately approved.
- Connect undesirable side-effects, contraindications and residual risk to labelling and risk management.
- Define post-market clinical follow-up where required and link findings to lifecycle updates.

Challenge equivalence carefully

Equivalence is not established by similar appearance or intended use alone. The applicable legal and scientific criteria, access to data and relevance of differences must be assessed before relying on another device’s evidence.

14. IVD performance evaluation

For in vitro diagnostic devices, performance evaluation connects scientific validity, analytical performance and clinical performance to the intended purpose. The assessment should reflect specimen type, analyte, population, operating environment, users and the consequences of incorrect results.

Review the IVD evidence model

- Confirm intended purpose, analyte or marker, specimen type, target population and clinical role.
- Assess scientific validity and the relationship between the measured marker and the relevant condition.
- Review analytical performance characteristics such as accuracy, precision, sensitivity, specificity and interference where applicable.
- Assess clinical performance, cut-offs, workflow, comparator methods and intended-use settings.
- Connect performance limitations, false results and use conditions to risk, labelling and post-market monitoring.

Keep analyser, reagent and software boundaries explicit

An IVD system may include an analyser, reagents, calibration materials, controls, software and external information systems. Regulatory affairs should define which elements are regulated together, which claims apply to each component and how changes affect the system evidence.

15. Verification, validation and submission-ready evidence

Verification demonstrates fulfilment of specified requirements. Validation demonstrates suitability for intended use. Regulatory affairs should confirm that evidence supports the submitted product, claimed performance, risk controls and applicable standards.

Challenge evidence before it enters a submission

- Identify the tested article, hardware revision, software version, consumables and manufacturing state.
- Confirm approved methods, sample rationale, environmental conditions and acceptance criteria.
- Review deviations, failed results, retests, exclusions and limitations.

- Assess whether external laboratory reports, modelling or historical data remain applicable.
- Trace critical performance, claims and risk controls to the underlying approved evidence.

Prevent configuration drift

A submission can become internally inconsistent when engineering updates software, manufacturing changes a supplier or marketing expands claims after studies are complete. Regulatory affairs should maintain a defined evidence baseline and assess every proposed change against it.

16. Software, digital health and cybersecurity submissions

Software may be a component of a medical device, a device in its own right, or a supporting service. Regulatory affairs should determine the regulated boundary, safety impact, lifecycle evidence, cybersecurity obligations, interoperability claims and post-market maintenance expectations.

Define the software evidence package

- Document intended software functions, architecture, interfaces, data flows and external dependencies.
- Assess applicable software safety classification, development lifecycle, verification and unresolved anomalies.
- Define cybersecurity risk assessment, threat modelling, security controls and verification evidence.
- Maintain software-component transparency, vulnerability monitoring and secure update arrangements.
- Assess clinical impact of service outage, incorrect data, software change and compromised connectivity.

Plan for lifecycle change before launch

Connected devices require a controlled approach to patches, third-party components, cloud changes and vulnerability response. Regulatory affairs should define when changes require notification, new evidence, submission or altered labelling instead of treating cybersecurity maintenance as outside regulatory control.

17. Usability, labelling and information supplied by the manufacturer

Instructions, labels, symbols, training and user-interface information are part of the regulatory evidence. They communicate intended purpose, limitations, warnings, contraindications, safe use, installation, service and other information required for the actual user and market.

Review labelling as a controlled evidence set

- Confirm consistency with the approved intended purpose, classification, claims and product configuration.
- Include required identifiers, manufacturer details, UDI, warnings, storage conditions and disposal instructions where applicable.
- Check language, accessibility, readability, symbols, regional requirements and electronic-instructions conditions.
- Connect safety information to the risk file and verify user understanding where relevant.
- Control websites, packaging, marketing materials and training content alongside formal labels and instructions.

Avoid information-only risk-control assumptions

A warning does not automatically demonstrate that a user can recognise a hazard and respond effectively. Regulatory affairs should confirm that user-mediated controls are supported by the usability evidence and that safer design options were assessed where required.

18. UDI, registrations and EUDAMED

Unique device identification and registration improve traceability and support regulatory oversight. The European Commission states that four EUDAMED modules became mandatory on 28 May 2026: actor registration, UDI/device registration, notified bodies and certificates, and market surveillance.

Control identification and registration data

- Identify the legal manufacturer, economic operators, device family, Basic UDI-DI where applicable and device identifiers.
- Maintain accurate product names, intended purpose, risk class, certificates, packaging levels and market status.

- Ensure UDI information is consistent across labels, databases, technical documentation and distribution systems.
- Verify applicable EUDAMED module obligations and the timing or status of modules not yet mandatory.
- Define ownership for changes, certificate updates, discontinued devices and registration corrections.

Avoid treating registration as market authorisation

Database entry or an assigned identifier does not by itself demonstrate conformity, notified-body certification or FDA clearance. Registration is an administrative obligation that must be supported by the underlying regulatory status.

19. Notified bodies, authorised representatives and economic operators

European conformity assessment often involves a notified body, while non-EU manufacturers may require an authorised representative. Importers and distributors have defined obligations that must be reflected in contracts, information flow and lifecycle responsibilities.

Manage external regulatory relationships

- Confirm notified-body designation, scope, capacity, contract and expected technical-documentation review.
- Define authorised-representative mandate, access to documentation and incident communication.
- Clarify importer and distributor checks, traceability, complaints and field-action responsibilities.
- Plan certificate maintenance, surveillance, significant changes and authority communications.
- Maintain clear ownership of submissions, responses, evidence requests and final manufacturer decisions.

20. Submission planning and dossier assembly

A successful submission is a structured regulatory argument, not a collection of available documents. The dossier should explain the product, claims, pathway, risks, evidence and outstanding limitations in a form appropriate to the reviewer and jurisdiction.

Create a controlled submission plan

1. **Confirm the regulatory question.** Define the market, pathway, intended purpose, classification and requested decision.
2. **Define the evidence baseline.** Identify the approved configuration, claims, standards, reports and quality-system status.
3. **Map requirements to evidence.** Link each dossier section and applicable requirement to an approved source.
4. **Review completeness and consistency.** Resolve conflicting versions, missing studies, unsupported claims and open anomalies.
5. **Approve and submit.** Obtain appropriate technical, quality, clinical and management approvals and retain submission records.
6. **Manage review and lifecycle impact.** Coordinate questions, changes, commitments, authorisation conditions and post-market obligations.

Use an evidence-gap register

A gap register should identify the missing item, regulatory significance, owner, delivery date, dependency and proposed mitigation. It helps distinguish a manageable formatting issue from an absence of safety, clinical, risk-control or manufacturing evidence.

21. FDA 510(k), De Novo and PMA strategy

US pathway selection should be based on device classification, intended use, technology, predicate availability, regulatory history and the evidence needed to support safety and effectiveness. A superficially similar product does not automatically provide a suitable predicate.

Questions that determine pathway suitability

- Is there a legally marketed predicate with an appropriate intended use and relevant technological characteristics?
- Do differences raise new questions of safety or effectiveness?
- Can general and special controls provide reasonable assurance for a novel device without a suitable predicate?
- Does the device fall into a category that requires premarket approval or another specific route?
- Which non-clinical, clinical, usability, cybersecurity and software evidence does the proposed pathway require?

- Would early FDA interaction reduce uncertainty about the product, claims or evidence plan?

Avoid predicate-driven design distortion

A predicate comparison should support a credible substantial-equivalence argument, not force misleading claims or conceal significant technological differences. If the intended purpose or risk profile diverges materially, the appropriate strategy may require a different pathway.

22. Regulator interactions and deficiency responses

Questions from a notified body or regulator should be treated as requests for a clear, evidence-based explanation. Effective responses connect the question to the actual product, requirement, analysis and approved evidence without introducing inconsistent claims or unreviewed changes.

Coordinate a controlled response process

- Record the exact request, due date, owner, affected market and required decision.
- Identify source evidence and the technical or clinical experts needed to interpret it.
- Resolve conflicting documents, configuration differences and unsupported assumptions before responding.
- Answer the actual question directly and identify the controlled supporting attachment.
- Assess whether the response changes claims, risk conclusions, labelling or existing authorisations.

Do not manufacture evidence to meet a deadline

If evidence is missing, state the gap, propose an appropriate study or clarification and negotiate the response plan where permitted. Backdating, rewriting historical results or presenting assumptions as completed evidence creates a more serious regulatory problem than acknowledging a genuine deficiency.

23. Regulatory change assessment and lifecycle maintenance

Design, software, material, supplier, manufacturing, intended-purpose and labelling changes may affect existing approvals or certificates. Regulatory affairs should be involved before implementation to determine whether notification, prior approval, submission, new testing or updated technical documentation is required.

Apply a jurisdiction-specific change assessment

- Identify affected markets, authorisations, certificates, product versions and claims.
- Assess the change against intended use, classification, risk controls, clinical evidence and technological characteristics.
- Determine required verification, validation, process revalidation and usability or biological evidence.
- Check notified-body significant-change rules, FDA submission guidance and other local requirements.
- Update registrations, UDI data, labels, technical documentation and customer communication where appropriate.

Control cumulative change

Several individually minor modifications can collectively alter the product's risk, performance or regulatory identity. Maintain configuration history and periodically assess the cumulative effect instead of evaluating each change in isolation.

24. Post-market surveillance, vigilance and field actions

Regulatory obligations continue after the product is placed on the market. Post-market surveillance collects and evaluates real-world information; vigilance addresses reportable serious incidents and field safety corrective actions; periodic reporting may be required according to device type, risk and jurisdiction.

Integrate lifecycle information

- Collect complaints, service data, production trends, literature, comparable-device incidents and cybersecurity information.
- Assess reportability, timelines, competent authorities and market-specific communication requirements.
- Connect findings to risk management, clinical or performance evaluation, CAPA and design change.
- Maintain post-market surveillance plans, periodic reports and follow-up activities as applicable.
- Coordinate field actions, customer communication, traceability and effectiveness checks across affected markets.

Escalate safety signals promptly

Commercial sensitivity, incomplete investigation or uncertainty over responsibility should not delay appropriate safety escalation. Regulatory affairs should work with quality, clinical, risk and management teams to document decisions, preserve evidence and meet applicable reporting obligations.

25. Advertising, promotion and commercial communications

Promotional materials must remain consistent with the approved intended purpose, authorised claims, evidence and local restrictions. Regulatory affairs should establish a practical review process covering brochures, websites, presentations, demonstrations, training and digital content.

Control promotional claims

- Verify that performance, clinical, comparative and compatibility statements are supported.
- Avoid claims that imply unapproved indications, patient populations or use environments.
- Use the correct regulatory status, such as cleared, approved or CE marked, without exaggeration.
- Ensure warnings, limitations and contraindications are not contradicted or omitted where relevant.
- Assess translations, distributor materials and customer-generated proposals before publication.

Make review workable for commercial teams

Provide approved claim libraries, examples, escalation criteria and clear turnaround expectations. Effective regulatory control should help commercial teams communicate accurately and confidently without forcing every minor wording change into an unnecessary executive review.

26. Regulatory intelligence and horizon scanning

Regulations, harmonised standards, guidance, databases and authority expectations change over time. Regulatory affairs should maintain an organised intelligence process that evaluates relevance and drives action rather than collecting newsletters without impact assessment.

Operate an actionable intelligence process

- Monitor primary sources from regulators, the European Commission, standards organisations and notified bodies.
- Assess relevance to current products, markets, pending submissions and development programmes.
- Assign ownership, deadlines and affected procedures, documents, training or product evidence.
- Distinguish enacted law from consultation, draft guidance, proposed timelines and informal opinion.
- Escalate changes that may affect certification, classification, registrations, post-market duties or supply continuity.

Use the 2026 regulatory environment accurately

As of August 2026, the FDA QMSR is effective and the first four EUDAMED modules are mandatory. The UK framework continues to develop through legislation and guidance. Future proposals should not be described as already binding unless their enacted status and effective date are confirmed.

27. Regulatory metrics, reviews and recurring failures

Regulatory metrics should reveal decision readiness, evidence risk, authority dependencies and lifecycle exposure. Counting submitted documents without assessing their quality can conceal serious classification, clinical or technical gaps.

Track indicators that support decisions

- Status of classification rationales, regulatory strategies, intended-purpose approvals and market pathways.
- Coverage of GSPRs, evidence gaps, critical studies, risk-control verification and claim support.
- Submission milestones, authority questions, certificate expiry, registration accuracy and change assessments.
- Post-market reporting timeliness, field-action status and emerging safety or cybersecurity signals.
- Regulatory intelligence actions, standards transitions and market-specific lifecycle obligations.

Recognise common regulatory failure patterns

Failure pattern	More effective response
Regulatory affairs joins after design freeze.	Integrate classification, pathway, claims and evidence planning into early development.
Intended purpose differs between documents.	Maintain one controlled product definition across clinical, risk, labelling and submissions.
A GSPR matrix contains unsupported statements.	Link each applicable requirement to current, approved objective evidence.
A predicate is assumed rather than justified.	Evaluate intended use, technology, regulatory history and safety questions explicitly.
Software or cloud changes bypass RA.	Include connected-system changes in market-specific regulatory impact assessment.
Registrations are treated as approval.	Maintain clear separation between administrative entries and actual authorisation status.
Post-market duties are left to operations alone.	Connect complaints, vigilance, risk, CAPA, clinical evidence and market communication.

Questions to ask at every development milestone

- Do we know exactly which product, intended purpose, claims, configuration and markets are in scope?
- Is classification and the proposed route to market supported by current, jurisdiction-specific evidence?
- Can every important claim, risk control and applicable regulatory requirement be traced to objective evidence?
- Are software, suppliers, manufacturing, labelling and clinical evidence consistent with the submitted configuration?
- Do proposed changes, complaints or new guidance affect existing authorisations or lifecycle obligations?
- Would a notified body or regulator understand and accept the evidence argument without retrospective reconstruction?

PRACTICAL RULE A defensible regulatory position connects the approved intended purpose, correct market pathway, current requirements, representative evidence and controlled lifecycle decisions for the actual product placed on the market.

Appendix A. Regulatory deliverables by development phase

Development phase	Representative regulatory deliverables
Concept and feasibility	Intended-purpose draft, initial classification, target markets, regulatory assumptions and pathway options.
Design inputs	Regulatory strategy, standards assessment, GSPR plan, evidence requirements and claim review.
Architecture and development	Updated classification, device description, technical-documentation structure and cross-functional evidence review.
Verification and validation	Submission evidence map, GSPR updates, clinical or performance alignment and configuration review.
Transfer and submission	Approved technical documentation, dossier, labelling, UDI, registrations and authority engagement.
Authorisation and release	Certificates or decisions, declarations, market release controls and lifecycle commitments.
Post-market and change	Vigilance, periodic reporting, change assessments, registration updates and regulatory intelligence actions.

Appendix B. Essential regulatory review checklist

Review area	Minimum question
Intended purpose	Are medical purpose, population, users, environment and claims clearly defined and consistent?
Classification	Is the classification rationale current, jurisdiction-specific and approved?
Market pathway	Is the conformity or submission route correct for the actual product and claims?
Requirements	Are applicable legislation, GSPRs, standards and guidance identified and mapped?
Evidence	Do risk, verification, clinical, usability, software and manufacturing records support the submitted configuration?

Review area	Minimum question
Labelling	Are identifiers, instructions, warnings, symbols and promotional claims accurate and controlled?
Administration	Are representatives, registrations, certificates, UDI and database entries appropriate?
Change	Are product, software, supplier and claim changes assessed before implementation?
Post-market	Are surveillance, vigilance, periodic reporting and field-action obligations understood and active?
Governance	Are decisions, responsibilities, authority communications and evidence baselines controlled?

Appendix C. Commonly relevant standards and frameworks

Confirm the current edition, scope, amendment status, recognition, harmonisation and market-specific applicability before relying on a reference.

Topic	Common reference	Regulatory relevance
Quality management	ISO 13485:2016; US 21 CFR Part 820 QMSR	Manufacturer quality-system requirements and design or production evidence.
Risk management	ISO 14971:2019; ISO/TR 24971:2020	Lifecycle risk controls, residual risk and benefit-risk evidence.
EU medical devices	Regulation (EU) 2017/745	Classification, conformity assessment, GSPRs, technical documentation and post-market obligations.
EU IVDs	Regulation (EU) 2017/746	IVD classification, performance evaluation, technical evidence and post-market obligations.
Software lifecycle	IEC 62304, applicable edition	Software development, safety classification, verification and maintenance evidence.
Usability	IEC 62366-1, applicable edition	Use-related risk, user-interface design and usability validation.

Topic	Common reference	Regulatory relevance
Cybersecurity	IEC 81001-5-1; FDA cybersecurity guidance	Secure product lifecycle, vulnerability management and premarket cybersecurity evidence.
Medical electrical equipment	IEC 60601 series, where applicable	Basic safety, electromagnetic compatibility and applicable essential performance.
Biological evaluation	ISO 10993-1:2025 and relevant parts	Biological safety and finished-device evaluation within risk management.
Manufacturer information	ISO 20417:2026; ISO 15223-1, as applicable	Information supplied by the manufacturer, labels and symbols.

Appendix D. Glossary

Term	Meaning in this guide
510(k)	A US premarket notification used to demonstrate substantial equivalence to a legally marketed predicate device.
Basic UDI-DI	A primary identifier used to group devices with the same intended purpose, risk class and essential design or manufacturing characteristics in the EU framework.
Classification	A regulatory determination of the product category and level of control required for a device.
Clinical evaluation	Assessment of clinical evidence supporting safety, clinical performance and benefit-risk.
De Novo	A US risk-based classification pathway for a novel device without an appropriate legally marketed predicate.
GSPR	General safety and performance requirement applicable under EU MDR or IVDR.
Intended purpose	The medical purpose and conditions of use specified by the manufacturer.
Performance evaluation	Assessment of scientific validity, analytical performance and clinical performance for an IVD.
PMA	Premarket approval, the FDA pathway for devices requiring scientific and regulatory approval.

Term	Meaning in this guide
Predicate	A legally marketed device used as the comparator in an appropriate US substantial-equivalence submission.
Regulatory strategy	The documented plan for classification, market pathway, evidence, timing and lifecycle obligations.
Technical documentation	The controlled evidence demonstrating the device's design, safety, performance and conformity.
UDI	Unique device identifier used to support product identification and traceability.
Vigilance	The assessment and reporting of specified serious incidents and related corrective actions.

Appendix E. Authoritative starting sources

- ISO — ISO 13485:2016, Medical devices quality management systems
- ISO — ISO 14971:2019, Application of risk management to medical devices
- ISO — ISO/TR 24971:2020, Guidance on the application of ISO 14971
- FDA — Quality Management System Regulation
- FDA — Overview of Device Regulation
- FDA — Premarket Notification 510(k)
- FDA — De Novo Classification Request
- FDA — Premarket Approval
- FDA — Cybersecurity in Medical Devices: Quality Management System Considerations
- European Union — Regulation (EU) 2017/745 on medical devices
- European Union — Regulation (EU) 2017/746 on in vitro diagnostic devices
- European Commission — EUDAMED overview and mandatory modules
- European Commission — UDI and device registration
- European Commission — MDCG endorsed documents and other guidance
- UK Government — Implementation of the future regulation of medical devices

CONTROLLED USE Consult current controlled legislation, standards and regulatory guidance. Classification, pathway, evidence, labelling and post-market obligations depend on the actual product, intended purpose, market and approved company processes.