PRODUCT MANAGEMENT AND PRODUCT OWNERSHIP FIELD GUIDE

Developing and Manufacturing Medical Devices

A practical guide for Product Managers and Product Owners

From unmet need and intended purpose to controlled delivery, market readiness and lifecycle value

General cross-market guidance | Edition 1.0 | August 2026

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How to use this guide

This guide explains how Product Managers and Product Owners contribute to developing, manufacturing, launching and sustaining medical devices and in vitro diagnostic medical devices. It is written for people who shape product direction, prioritise value, manage product backlogs, coordinate stakeholders and support lifecycle decisions. It connects commercial and user objectives to patient safety, clinical evidence, regulatory strategy, design controls and dependable delivery.

> **CORE MESSAGE** In a regulated medical-device organisation, product leadership is the disciplined management of value within safety, evidence and compliance boundaries. A feature is not ready merely because customers want it or a team can build it.

Scope and important limitations

- Apply current company procedures, approved governance and market-specific requirements to the actual product and jurisdiction.
- Clarify whether the organisation uses Product Manager and Product Owner as distinct roles or combines them; titles do not determine regulatory accountability.
- Do not make independent medical, regulatory, quality, risk-acceptance, cybersecurity or release decisions unless formally authorised and competent to do so.
- Distinguish medical devices, IVDs, accessories, services, consumer products and non-device software functions before applying product assumptions.
- Verify current legislation, standards, guidance, product classification and evidence expectations through qualified specialists.

1. Product leadership in a regulated environment

Product Managers and Product Owners connect needs, strategy and delivery. They help the organisation choose the right problem, define the value proposition, maintain priorities and make trade-offs visible while regulated functions ensure that safety, performance and conformity are demonstrated.

Distinguish the two perspectives

Role perspective	Typical emphasis
Product Manager	Market, clinical need, portfolio, positioning, business case, roadmap and lifecycle value.
Product Owner	Product goal, backlog, acceptance clarity, team decisions, increments and delivery flow.
Shared responsibility	Intended purpose alignment, stakeholder decisions, evidence-aware priorities and controlled change.

Respect formal accountability

Product leadership can propose priorities and recommend decisions, but designated Quality, Regulatory, Clinical, Engineering and management roles retain their controlled authorities. Governance should state who recommends, reviews, approves and implements each decision.

2. Understand the medical-device lifecycle

Medical-device value is created across the complete lifecycle, not only during development. Decisions taken during discovery affect verification, manufacturing, regulatory approval, customer support and post-market obligations.

Product contribution by phase

Lifecycle phase	Product leadership contribution
Discovery	Need, users, care pathway, opportunity, alternatives and strategic fit.
Definition	Intended purpose, claims, target profile, business case and evidence strategy.
Development	Priorities, requirement intent, trade-offs, stakeholder alignment and decision cadence.
Transfer and launch	Readiness, positioning, training, supply, service and controlled claims.
Post-market	Feedback, complaints, signals, adoption, improvements and roadmap updates.

Lifecycle phase	Product leadership contribution
Retirement	Transition, support, records, communications and remaining obligations.

Optimise the whole system

Accelerating one team can delay the product if clinical evidence, supplier qualification, verification, labelling or regulatory work cannot support the same release. Product plans should represent the full value stream.

3. Medical-device regulatory and quality foundations

The intended purpose, risk and market determine which regulatory pathways and quality controls apply. Product leaders need working knowledge of the framework so that commercial assumptions do not conflict with conformity obligations.

Know the practical foundations

- ISO 13485 provides a widely used quality-management framework for medical-device organisations.
- ISO 14971 provides the lifecycle process for managing medical-device risks.
- The EU MDR and IVDR regulate market access and lifecycle obligations for medical devices and IVDs in the European Union.
- The US FDA Quality Management System Regulation became effective on 2 February 2026 and incorporates ISO 13485:2016 by reference, subject to US legal provisions.
- Product-specific standards, common specifications and guidance may materially affect design, evidence, labelling and manufacturing plans.

Use experts early

A late classification or regulatory-pathway correction can invalidate the business case and schedule. Regulatory and Quality partners should participate before commitments are made.

4. Unmet need, users and clinical context

A strong product opportunity begins with a well-evidenced problem in a real care pathway. Product discovery should consider patients, carers, healthcare professionals, laboratories, service staff, purchasers and other affected people.

Frame the need before the solution

- Describe the clinical or operational problem, who experiences it and its frequency and consequence.
- Map the current pathway, workarounds, delays, failure points and available alternatives.
- Separate stated preferences from observed behaviour and clinically meaningful need.
- Identify health inequities, access barriers and underserved populations that the design may affect.
- Quantify the value of improvement without inventing precision unsupported by data.
- Record assumptions and the evidence needed to confirm or reject them.

Avoid solution-first discovery

A technically attractive concept can search for a problem and create unsupported claims. Discovery should be capable of stopping or substantially changing the concept.

5. Intended purpose, indications and claims

Intended purpose is a foundational product decision. It influences whether the product is a medical device, its classification, applicable evidence, users, labelling, risk analysis and market route.

Define the complete proposition

- Medical purpose and clinical role: screening, diagnosis, monitoring, prediction, prognosis or treatment as applicable.
- Target population, indications, contraindications and relevant subgroups.
- Intended users, use environments, workflows, specimen or anatomical context and duration.
- Core function, expected clinical or performance outcome and relevant comparator.
- Accessories, connected services, required consumables and external dependencies.
- Claims that are specific, measurable and supported by the planned evidence.

Control the claims baseline

The approved claims baseline should align product requirements, clinical plans, risk documents, regulatory submissions, labelling, sales material and training. Product leaders should prevent informal claim expansion.

6. Product strategy and target product profile

The target product profile converts opportunity into a controlled strategic hypothesis. It describes the desired product and the minimum acceptable characteristics needed to justify continued investment.

Create a decision-ready profile

- Intended purpose, users, population, environment and workflow.
- Clinical, technical, usability and service outcomes.
- Safety, cybersecurity, privacy, reliability and interoperability expectations.
- Regulatory pathway, evidence concept and market sequence.
- Manufacturing scale, cost, supply, sustainability and support assumptions.
- Minimum, target and aspirational values with rationale and decision dates.

Keep aspiration separate from commitment

A target profile may include ambition, while released claims and requirements require evidence and approval. The document should show which statements are hypotheses and which are controlled commitments.

7. Stakeholders and voice of the customer

Medical-device products serve interconnected stakeholders whose needs can conflict. Product leadership should make these conflicts explicit and avoid treating the purchaser as the only customer.

Build a representative stakeholder map

- Patients, carers and people affected by false, delayed or missed results.
- Healthcare professionals, laboratory staff, technicians and service personnel.
- Healthcare organisations, procurement, payers and reimbursement bodies.
- Regulators, notified bodies, ethics committees and competent authorities.
- Distributors, suppliers, partners and digital-platform operators.
- Internal functions responsible for quality, safety, evidence, manufacture and support.

Use ethically obtained insight

Research involving patients, health information or clinical settings may require consent, privacy controls, ethics review or clinical oversight. “Customer discovery” does not exempt the activity from applicable controls.

8. Classification, regulatory pathways and market sequence

Classification and regulatory strategy shape evidence, cost, timing and change flexibility. The same product may face different classifications, claims or procedural routes across markets.

Ask the questions that change the plan

- Is each product function a medical device, IVD, accessory or non-device function?
- Which risk class, product code, classification rule or special control applies?
- Is there a predicate, established technology or novel regulatory question?
- What clinical, performance, usability and technical evidence will be required?
- Which economic operator, sponsor, legal manufacturer and market responsibilities apply?
- What market order best balances learning, evidence reuse, revenue and operational readiness?

Do not publish dates before resolving critical uncertainty

A roadmap date is not credible when classification, evidence, manufacturing capacity or authority interaction remains a material unknown. Communicate ranges and decision gates instead.

9. Business case and portfolio decisions

The business case should integrate patient and customer value with development, evidence, regulatory, manufacturing and lifecycle costs. It should expose uncertainty rather than hide it behind a single net-present-value figure.

Include the complete cost and value picture

- Addressable population, adoption pathway, pricing, reimbursement and sales-cycle assumptions.
- Development, verification, clinical, regulatory, tooling, validation and launch costs.

- Cost of goods, yield, logistics, service, vigilance, cybersecurity and sustaining engineering.
- Competitive response, patent or freedom-to-operate considerations and product lifetime.
- Probability-weighted scenarios, sensitivity analysis and stop conditions.
- Strategic value, platform reuse and opportunity cost relative to other investments.

Revisit the case at gates

Discovery findings, technical feasibility, authority feedback, supplier quotations and clinical results should update the business case. Sunk cost is not evidence that the product should continue.

10. Requirements, acceptance criteria and traceability

Product leaders help translate needs and value into clear, testable expectations. They should describe the problem and outcome without prescribing an implementation unnecessarily.

Create useful requirements input

- Link user and stakeholder needs to intended purpose and clinical context.
- State measurable outcomes, conditions, boundaries and acceptance criteria.
- Identify regulatory, risk-control, usability, interoperability and service requirements.
- Resolve ambiguous words such as easy, fast, intuitive, robust and seamless.
- Maintain traceability through system requirements, design outputs, verification and validation.
- Control changes to acceptance criteria after results become known.

Separate requirement levels

A roadmap outcome, user need, system requirement, software story and verification criterion serve different purposes. Product artefacts should not collapse them into one untraceable backlog item.

11. Risk management and product trade-offs

Product trade-offs must account for patient and user harm, not only cost and schedule. Product leaders contribute use context, foreseeable behaviour, benefit expectations and business decisions to the formal risk process.

Participate constructively in risk management

- Describe users, environments, workflows, misuse, off-label pressures and foreseeable abnormal situations.
- Ensure serious harms and diagnostic or treatment consequences remain visible in prioritisation.
- Support risk-control requirements and avoid removing controls solely to simplify the experience.
- Consider whether a new feature, market or user group creates new hazards or changes exposure.
- Keep benefit claims consistent with the benefit-risk conclusion.
- Escalate unresolved safety uncertainty to the authorised decision-maker.

Do not prioritise risk controls by popularity

A control needed for acceptable residual risk cannot be deferred simply because it is invisible to customers. Its necessity and implementation should be decided through the controlled risk process.

12. Clinical and performance evidence

Evidence must support the intended purpose, claims and benefit-risk position. Product leaders should understand the evidence strategy well enough to avoid promising outcomes that the planned studies cannot establish.

Connect claims to evidence

- Map each clinical or performance claim to the supporting data source and acceptance criterion.
- Understand study population, comparator, endpoints, sample size, duration and important limitations.
- Distinguish feasibility, usability, analytical, clinical-performance and clinical-outcome evidence.
- Include post-market clinical or performance follow-up where uncertainty remains.
- Plan product configuration and supply so study evidence represents the intended commercial device.
- Communicate evidence limitations accurately to commercial and customer-facing teams.

Protect study integrity

Product interest must not influence participant protection, endpoint definitions, data handling or selective reporting. Clinical and Medical Affairs and statistical roles require appropriate independence.

13. Usability and human factors

Usability engineering addresses whether intended users can use the device safely and effectively in realistic conditions. Product discovery and usability engineering should exchange insight while retaining their distinct purposes.

Bring product insight into usability work

- Identify users, goals, tasks, environments, constraints and critical interactions.
- Represent differences in training, capability, language, stress and accessibility.
- Include installation, maintenance, cleaning, troubleshooting and disposal where relevant.
- Treat labelling, training, alarms and accessories as parts of the user experience.
- Prioritise use-related risk controls before convenience-only refinements.
- Ensure final validation uses a production-equivalent interface and representative participants.

Do not confuse preference testing with validation

A favourable product interview does not demonstrate safe and effective use. Formative and summative human-factors activities have defined evidence purposes.

14. Software, cybersecurity, privacy and data

Connected and software-enabled devices create continuing obligations for secure development, privacy, updates, monitoring and service availability. Product roadmaps must budget for these capabilities throughout the supported life.

Define the digital product responsibly

- Identify device software functions, cloud services, mobile applications, data flows and external platforms.
- Define data purpose, minimisation, retention, access, localisation and individual-rights needs.

- Prioritise security architecture, authentication, updateability, logging and vulnerability response.
- Plan software support, third-party components, end-of-support and customer communications.
- Assess algorithm, model or data changes for safety, performance, bias and regulatory impact.
- Treat uptime, recovery and degraded operation according to patient and workflow consequence.

Do not sell the future security roadmap as a current control

Risk acceptability and market readiness depend on implemented and verified controls. Planned backlog items are not evidence that a current vulnerability is controlled.

15. Architecture, interfaces and product ecosystem

Medical devices operate within systems of people, accessories, networks, consumables, services and external equipment. Product definition should cover the ecosystem and boundaries, not only the headline device.

Control ecosystem assumptions

- Define supported accessories, consumables, mobile devices, browsers, networks and operating systems.
- Clarify interoperability, data formats, timing, units, alarms and failure behaviour.
- Assign ownership for external interfaces and third-party platform changes.
- Identify installation, calibration, maintenance, cleaning and disposal dependencies.
- Define compatibility claims and how they will be verified and maintained.
- Plan how customers will recognise unsupported configurations.

Make boundaries visible

A component outside the regulatory device boundary can still be essential to safe operation. Commercial bundles, contracts, instructions and technical architecture should describe the same system reality.

16. Design reviews and decision gates

Design reviews and governance gates create structured opportunities to assess whether the product remains safe, feasible, valuable and ready for the next commitment. They should enable decisions rather than ceremonial approval.

Prepare a balanced gate case

- State the decision sought, scope, options and accountable approver.
- Summarise needs, intended purpose, claims, requirements and unresolved changes.
- Present risk, clinical, regulatory, technical, manufacturing and supplier status.
- Update schedule, cost, resources, business case and material uncertainty.
- Show objective entry and exit evidence, deviations and conditions.
- Record continue, modify, pause or stop decisions with owners and due dates.

Expose negative evidence

A product gate is not a sales presentation. Unfavourable results, weak assumptions and dissenting specialist views are decision-critical information.

17. Verification, validation and evidence readiness

Verification asks whether specified requirements were fulfilled; validation asks whether the resulting device fulfils user needs and intended use. Product leaders help protect scope, configuration and acceptance clarity.

Support a credible evidence programme

- Ensure requirements and acceptance criteria are stable enough for planned verification.
- Identify production-equivalent units, software versions, accessories and use conditions.
- Provide representative users, workflows and scenarios for validation.
- Protect independence and prevent informal reinterpretation of failed criteria.
- Track anomalies, deviations, retesting and residual impact on claims or launch.
- Confirm that all evidence required for release and submission is complete and approved.

Treat failure as information

A failed test may reveal a design, requirement, method or manufacturing issue. Product pressure should not convert a failure into acceptance without a documented, technically justified resolution.

18. Suppliers, procurement and external partners

Supplier choices can determine product quality, evidence access, change control, availability and long-term cost. Product roadmaps should consider supplier lifecycle and contractual control before dependency becomes irreversible.

Include supplier realities in product decisions

- Define technical, quality, regulatory, capacity, service and evidence expectations.
- Identify sole-source items, obsolescence, geopolitical exposure and substitution constraints.
- Ensure the organisation can obtain change notifications and investigate failures.
- Address software licences, cloud service levels, data processing and exit rights.
- Plan qualification, incoming controls, process validation and production ramp.
- Include supplier change lead time in roadmap and lifecycle planning.

Avoid price-only selection

A cheaper component or service may increase verification, regulatory, support or continuity cost. Total lifecycle risk and value should drive the decision.

19. Industrialisation, manufacturing and supply readiness

A verified design must be reproducibly manufactured, tested, released and supplied. Product success depends on process capability, yield, capacity, packaging, logistics and service arrangements.

Plan launch supply as part of the product

- Define forecast ranges, ramp assumptions, lead times and capacity constraints.
- Confirm design transfer, work instructions, training, process validation and inspection readiness.
- Review yield, scrap, rework, test time, calibration and release constraints.
- Include packaging, sterilisation, shelf life, transport and storage where applicable.

- Plan traceability, unique device identification, distribution and field-return pathways.
- Define shortage allocation and communication rules that protect patients and compliance.

Separate pilot success from scalable production

Hand-built or intensively inspected units may not represent routine production. Launch decisions should use evidence from the controlled manufacturing state.

20. Labelling, training and launch readiness

Labelling and training communicate the approved product, intended use, limitations and safe operation. Launch material should be based on controlled evidence and the authorised market configuration.

Use a cross-functional readiness checklist

- Regulatory clearance or certification and market-specific registrations.
- Approved labelling, translations, claims, promotional review and medical information.
- Manufacturing capacity, released inventory, distribution and traceability.
- Customer training, installation, service, complaint and vigilance processes.
- Cybersecurity monitoring, update, incident and support arrangements.
- Launch metrics, escalation, field-feedback and corrective-action pathways.

Control the launch promise

Roadmap features, research uses and future indications should not be presented as available product capability. Commercial claims must match the approved device and evidence.

21. Market access, reimbursement and adoption

Regulatory market access permits supply; it does not guarantee reimbursement, procurement, workflow adoption or health-system value. These pathways should influence evidence and product strategy early.

Understand adoption barriers

- Clinical guideline position and professional acceptance.
- Reimbursement coding, coverage, payment and health-technology assessment.

- Capital, consumable, training, integration and workflow costs.
- Procurement evidence, tender requirements and environmental criteria.
- Installation, service, data integration and change-management effort.
- Patient access, equity, digital literacy and continuity of care.

Do not confuse willingness to try with willingness to adopt

Pilot enthusiasm may not survive budget, procurement, IT, evidence or workflow review. Adoption assumptions should be tested with the full decision network.

22. Product Owner practices in regulated development

Agile delivery can operate within medical-device design controls when product work, evidence and approvals remain traceable. The backlog should express product intent without becoming the only controlled record.

Maintain a compliant, usable backlog

- Link backlog items to approved needs, requirements, risks, anomalies and change records.
- Include evidence, documentation, cybersecurity, quality and regulatory work—not only visible features.
- Define acceptance criteria that can be objectively reviewed and tested.
- Preserve required review and approval outside informal team ceremonies.
- Control baseline and configuration relationships across increments and releases.
- Keep discovery hypotheses distinct from approved product requirements.

Avoid “agile” as an exemption

Iteration does not remove the need for planning, risk management, architecture, verification, validation or records. It changes how work is organised and evidence is accumulated.

23. Prioritisation, backlog and definition of done

Prioritisation should combine value, safety, evidence, dependency, uncertainty and delay cost. A regulated definition of done extends beyond code or design completion.

Use a multi-factor priority view

- Patient and user safety, including mandatory risk controls.

- Regulatory, clinical and quality evidence dependencies.
- Customer outcome and strategic value.
- Technical, supplier and manufacturing risk reduction.
- Time criticality, obsolescence and external commitments.
- Effort, opportunity cost and effect on other lifecycle obligations.

Define done at the right level

For a release, “done” may require approved requirements, risk updates, verification, validation, labelling, cybersecurity evidence, manufacturing readiness, traceability and authorised release—not merely accepted stories.

24. Roadmaps, release planning and controlled change

A medical-device roadmap should communicate outcomes, assumptions, evidence and decision points. Changes must be assessed for impact on the complete approved product, not only the modified component.

Manage change deliberately

- Describe the proposed change, rationale, affected configuration and intended markets.
- Assess impact on intended purpose, claims, classification, risks and clinical evidence.
- Assess requirements, architecture, verification, usability, cybersecurity and data.
- Assess suppliers, manufacturing, process validation, labelling, service and installed base.
- Determine regulatory notification, submission or approval requirements before implementation.
- Plan transition, compatibility, inventory, training, communication and post-release monitoring.

Keep dates conditional

External roadmaps should distinguish committed, planned and exploratory items. Internal plans should show the evidence and approvals on which each date depends.

25. Post-market surveillance, complaints and vigilance

Post-market information tests product assumptions in real use. Product leaders should ensure that commercial feedback and usage data enter controlled quality and safety pathways when appropriate.

Connect feedback to action

- Recognise and promptly route complaints, adverse events and potential reportable incidents.
- Review trends by product, version, lot, market, user group and use context.
- Compare complaints with service, cybersecurity, clinical, literature and sales information.
- Support signal assessment, CAPA, field action and labelling decisions with product context.
- Update priorities when new evidence changes benefit, risk, usability or adoption assumptions.
- Ensure customer communication is timely, accurate and approved.

Do not filter inconvenient feedback

Commercial teams may hear weak signals first. Informal categorisation must not prevent a possible complaint or safety event from reaching the responsible function.

26. Product metrics and learning

Metrics should show whether the product creates safe, sustained value and whether the lifecycle system responds effectively. Usage or revenue alone can hide poor outcomes, access barriers or safety concerns.

Use a balanced measurement set

- Clinical or performance outcomes and relevant safety indicators.
- Successful task completion, use errors, support burden and training effectiveness.
- Reliability, availability, service, complaint and return rates.
- Adoption, retention, workflow effect, access and customer value.
- Manufacturing yield, supply continuity and cost of quality.
- Evidence gaps, CAPA ageing, cybersecurity response and roadmap debt.

Define metrics before observing results

Predefined definitions, denominators, data provenance and review thresholds reduce the temptation to select flattering measures after launch.

27. Governance, communication and decision records

Good product governance makes authority, evidence and decisions visible without creating unnecessary bureaucracy. Communication should use a common product baseline across executives, teams and external partners.

Maintain decision quality

- State the decision, options, evidence, assumptions, uncertainty and recommendation.
- Identify required specialist reviews and the accountable approver.
- Record dissent, conditions, actions, owners and due dates.
- Link the decision to affected requirements, risks, claims, plans and configurations.
- Communicate changes to everyone who relies on the superseded decision.
- Review whether expected outcomes occurred and capture lessons.

Use one source of truth carefully

A product system may link controlled documents, requirements, backlog and dashboards, but it should not silently overwrite approved records or obscure the authoritative source.

28. Audit readiness, support and end of life

Product lifecycle responsibility continues through support, change, discontinuation and record retention. A credible product organisation can reconstruct why decisions were made and how customers were protected.

Prepare for inspection and continuity

- Trace intended purpose, claims and needs through evidence and released configuration.
- Retain product decisions, approvals, changes, deviations and unresolved commitments.
- Maintain supported configurations, service capability, spare parts and security updates.

- Plan last production, inventory, customer transition and regulatory notifications.
- Continue complaint, vigilance and safety obligations for the required period.
- Preserve records and knowledge when teams, suppliers or systems change.

Retirement is a product decision

End of sale, end of service and end of regulatory responsibility are different events. Plans should address patient dependency, installed products, data access and alternatives.

A practical product decision sequence

Use this sequence for a new product, major feature, new indication, market expansion or significant change. Adapt the depth to risk and the governing procedure.

1. **Frame the opportunity.** Define the unmet need, stakeholders, care pathway, proposed value and strategic fit.
2. **Establish the regulated proposition.** Define intended purpose, claims, product boundary, classification and target markets.
3. **Map evidence and constraints.** Identify clinical, risk, usability, technical, supplier, manufacturing and commercial evidence needs.
4. **Compare options.** Assess benefits, risks, cost, timing, uncertainty, dependencies and opportunity cost.
5. **Decide and control.** Record the approved direction, requirements, acceptance criteria, conditions and accountable owners.
6. **Deliver and learn.** Verify, validate, launch under control, monitor real-world outcomes and revisit assumptions.

Appendix A. Product leadership deliverables by lifecycle stage

Stage	Typical product leadership deliverables
Discovery	Need statement, stakeholder map, care pathway, opportunity hypothesis and discovery evidence.
Definition	Intended-purpose input, target product profile, claims baseline, business case and product strategy.
Planning	Roadmap, decision gates, evidence dependencies, release concept and governance model.

Stage	Typical product leadership deliverables
Development	Prioritised requirements and backlog, decision records, acceptance clarity and stakeholder alignment.
Launch	Readiness assessment, approved positioning, training, supply, support and metric plan.
Post-market	Product review, feedback and trend input, roadmap updates and lifecycle business case.
Retirement	Transition plan, support dates, customer communication and residual-obligation tracking.

Appendix B. Essential Product Manager and Product Owner review checklist

Review area	Minimum question
Need	Is the problem evidenced in the real clinical or operational pathway?
Purpose and claims	Are intended purpose, users, population, environment and claims controlled and aligned?
Regulatory	Are classification, pathway, evidence and market assumptions confirmed by qualified specialists?
Safety	Are risk controls and unresolved safety uncertainty visible in priorities and decisions?
Evidence	Can planned verification, validation and clinical work support the promised outcomes?
Supply	Can the approved product be manufactured, released, serviced and supported at the planned scale?
Change	Has impact on the complete product, evidence, markets and installed base been assessed?
Launch	Are approvals, labelling, training, supply, support and monitoring ready together?
Post-market	Do feedback, complaints, signals and real-world outcomes update the roadmap?

Review area	Minimum question
Governance	Are decisions, dissent, assumptions, approvals, actions and authoritative records traceable?

Appendix C. Commonly relevant standards and frameworks

This is an orientation list. Confirm applicability, current editions and market-specific status through approved Quality and Regulatory processes.

Topic	Common reference	Product leadership relevance
Quality management	ISO 13485:2016; US 21 CFR Part 820 QMSR	Lifecycle controls, records, suppliers, production, CAPA and release.
Risk management	ISO 14971:2019; ISO/TR 24971:2020	Hazards, risk controls, benefit-risk, change and post-market information.
EU medical devices	Regulation (EU) 2017/745	Intended purpose, classification, evidence, labelling, PMS and market access.
EU IVDs	Regulation (EU) 2017/746	Intended purpose, classification, performance evidence, labelling and PMS.
Usability	IEC 62366-1, where applicable	Users, use environments, critical tasks and use-related risk.
Software lifecycle	IEC 62304, where applicable	Software planning, requirements, architecture, verification, maintenance and problems.
Product cybersecurity	IEC 81001-5-1; current FDA guidance	Secure lifecycle, updates, vulnerabilities and support commitments.
Clinical investigations	ISO 14155, where applicable	Ethical, scientifically sound clinical evidence for medical devices.
IVD studies	ISO 20916, where applicable	Clinical performance-study planning and conduct for IVDs.

Appendix D. Glossary

Term	Meaning in this guide
Backlog	Ordered work representing product outcomes, requirements, evidence, defects and lifecycle obligations.
Claim	A statement about intended purpose, safety, performance, benefit or product capability requiring support.
Design validation	Confirmation that the device fulfils user needs and intended use under defined conditions.
Design verification	Confirmation that specified requirements have been fulfilled.
Intended purpose	The use for which a device is intended according to supplied information and objective intent.
Product Owner	The role accountable for maximising product value and managing product backlog in the chosen delivery model.
Product Manager	The role shaping product strategy, market understanding, proposition, roadmap and lifecycle value.
Product requirement	A controlled statement of capability or constraint that the product must fulfil.
Target product profile	A strategic description of minimum, target and aspirational product characteristics.
Traceability	The ability to connect needs, risks, requirements, design, evidence, release and change.

Appendix E. Authoritative starting sources

- European Union — Regulation (EU) 2017/745 on medical devices
- European Union — Regulation (EU) 2017/746 on in vitro diagnostic medical devices
- European Commission — MDCG-endorsed guidance and other guidance
- FDA — How to Determine if Your Product is a Medical Device
- FDA — Classify Your Medical Device
- FDA — Quality Management System Regulation
- FDA — Device Advice: comprehensive regulatory assistance
- 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 ISO 14971