

Product Team — Operating Procedures

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1. Team Overview

The Product Team manages the full product lifecycle from concept through launch and post-market surveillance for all ACME medical devices.

2. Team Leadership

Role	Name	Contact
Chief Product Officer	Dr. Amanda Foster	afoster@acmemeddevices.com
Senior Product Manager (Cardio)	James Mitchell	jmittchell@acmemeddevices.com
Senior Product Manager (Ortho)	Rachel Green	rgreen@acmemeddevices.com
Product Analyst	Kevin Patel	kpatel@acmemeddevices.com

3. Mandatory Rules

3.1 Product Launch Gate Reviews

- Gate 1 (Concept): CPO + VP Engineering approval required
- Gate 2 (Design Freeze): Design Review Board must sign off
- Gate 3 (Verification): All V&V testing complete, QA Director approval
- Gate 4 (Validation): Clinical data reviewed, Regulatory submission ready
- Gate 5 (Launch): FDA clearance received, CEO final approval
- NO GATE MAY BE SKIPPED — documented waiver requires CEO + Legal

3.2 Design Control Requirements

- Design History File (DHF) must be current before any gate review
- Risk Management File per ISO 14971 required at every gate
- Traceability matrix linking requirements to verification required

3.3 Competitive Intelligence

- NEVER reverse engineer competitor devices without Legal approval
- NEVER use confidential competitor information from new hires
- All competitive analysis must be documented in approved CI database

4. Required Approvals

Action	Approver	Form
New product concept	CPO + CEO	ACME-NPC-001
Design change post-freeze	Design Review Board	ACME-DCR-002
Clinical study initiation	CPO + Medical Director + IRB	ACME-CLIN-001
Product discontinuation	CPO + CFO + Legal	ACME-EOL-001

5. Legal Gray Areas & Escalation

5.1 Predicate Device Selection

510(k) predicate selection is critical. If uncertain whether a predicate is appropriate, STOP and consult Regulatory Affairs (Dr. Robert Kim) before proceeding. Wrong predicate = FDA rejection or worse.

5.2 Clinical Data from Outside US

OUS clinical data may or may not be acceptable to FDA. Always consult Regulatory before including in submissions. EU MDR data requires specific gap analysis.

6. Key Interfaces

Department	Contact	Interaction
Regulatory Affairs	Dr. Robert Kim	FDA strategy, submissions
Engineering	VP Engineering	Design inputs, V&V
Clinical Affairs	Dr. Susan Park	Clinical studies, data
Marketing	CMO	Launch planning, messaging