Regulatory Affairs Team — Operating Procedures

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1. Team Overview

The Regulatory Affairs Team manages all regulatory submissions, FDA interactions, international registrations, and compliance with medical device regulations worldwide.

2. Team Leadership

Role	Name	Contact
VP Regulatory Affairs	Dr. Robert Kim	rkim@acmemeddevices.com
Director, FDA Submissions	Catherine Wu	cwu@acmemeddevices.com
Director, International	Hans Mueller	hmueller@acmemeddevices.com
Regulatory Specialist	Priya Sharma	psharma@acmemeddevices.com

3. Mandatory Rules

3.1 FDA Submissions

- 510(k) submissions require VP RA signature before filing
- ALL clinical data must be verified by Clinical Affairs before inclusion
- Predicate device strategy must be approved by VP RA before development starts
- NO device may be marketed in US without 510(k) clearance or approved exemption

3.2 Post-Market Requirements

- MDR (Medical Device Report) evaluation within 5 days of complaint receipt
- 30-day MDR deadline for death/serious injury — NO EXTENSIONS
- Annual registration and device listing updates by December 31
- Field Safety Corrective Actions: notify FDA within 10 working days

3.3 Labeling Changes

- ANY labeling change requires RA review before implementation
- IFU changes may trigger new 510(k) — always consult RA first
- UDI compliance required for all Class II devices

4. Required Approvals

Action	Approver	Form
510(k) submission	VP RA + VP Product	ACME-510K-001
EU MDR technical file	VP RA + Notified Body	ACME-MDR-001
Label change	VP RA	ACME-LBL-001
Recall classification	VP RA + QA Director + Legal	ACME-RCL-001

5. Legal Gray Areas & Escalation

5.1 Substantial Equivalence Questions

If uncertain whether a device modification affects substantial equivalence: Document the change. Prepare SE analysis. If ANY doubt, file Letter to File or Pre-Sub meeting request with FDA. Err on the side of caution — marketing non-cleared device is a federal offense.

5.2 International Registration Shortcuts

Some distributors may suggest 'faster' registration pathways abroad. NEVER allow device distribution without proper country registration. Even 'CE mark equivalents' require verification. Escalate unusual requests to VP RA.

6. Key Regulatory References

- 21 CFR Part 807 — Establishment Registration and Device Listing
- 21 CFR Part 814 — Premarket Approval
- 21 CFR Part 820 — Quality System Regulation
- EU MDR 2017/745 — Medical Device Regulation
- FDA CDRH website: fda.gov/medical-devices