Manufacturing Team — Operating Procedures

Document ID: ACME-MFG-001 | Classification: Internal Use Only

1. Team Overview

The Manufacturing Team produces all ACME medical devices under FDA 21 CFR Part 820 Quality System Regulation and ISO 13485:2016 requirements at our San Jose, CA facility.

2. Team Leadership

Role	Name	Contact
VP Manufacturing	William Torres	wtorres@acmemeddevices.com
Quality Assurance Director	Dr. Linda Chang	lchang@acmemeddevices.com
Production Manager	Michael Brown	mbrown@acmemeddevices.com
Supply Chain Manager	Karen White	kwhite@acmemeddevices.com

3. Mandatory Rules

3.1 Device History Record (DHR)

- Every device MUST have complete DHR before release
- DHR must include: lot numbers, component traceability, test results, operator IDs
- Missing DHR data = STOP SHIPMENT until resolved
- DHR falsification = immediate termination and FDA notification

3.2 Non-Conformance Handling

- ALL non-conformances must be documented in NCR system within 4 hours
- Critical NC (patient safety risk): Production line HALT, notify QA Director immediately
- Major NC: Quarantine affected lot, 24-hour resolution deadline
- Minor NC: Document and resolve within 5 business days

3.3 Cleanroom Protocols

- Class 7 cleanroom: Full gowning required, no exceptions
- Particle counts logged every 4 hours during production
- Unauthorized entry = security incident report + retraining

4. Required Approvals

Action	Approver	Form
Process change (any)	QA Director + VP Mfg	ACME-CHG-001
Supplier change	QA Director + Supply Chain	ACME-SUP-002
Deviation from spec	QA Director	ACME-DEV-003
Batch release	QA Manager (min)	ACME-REL-001

5. Legal Gray Areas & Escalation

5.1 Component Substitution

If approved supplier cannot deliver and alternative is proposed: NEVER substitute without engineering evaluation and QA approval. Even 'equivalent' parts require Form ACME-SUB-001 and may trigger FDA notification.

5.2 Customer Complaints About Product

If complaint suggests potential device malfunction: Escalate to QA Director within 2 hours. Do NOT destroy or modify the returned unit. MDR (Medical Device Report) evaluation required within 5 days per 21 CFR 803.

6. Regulatory References

- 21 CFR Part 820 — Quality System Regulation
- 21 CFR Part 803 — Medical Device Reporting
- ISO 13485:2016 — Medical Device QMS
- California Medical Device Manufacturing License #MFG-2024-0892