

Chapter 14 Template: Post-Market Surveillance System Setup

Subtract to Ship: MDR Certification, Chapter 14: Post-Market Surveillance

Instructions

Design your PMS system during development, not after launch. PMS is the only regulatory obligation that also functions as free market research. The system should be operational before your first device reaches a customer. This template covers the five components of a lean PMS setup.

Component 1: Complaint Management Process

Intake Channels

Channel	Active?	Responsible Person
Email (dedicated address)	☐ Yes ☐ No	
Phone	☐ Yes ☐ No	
Web form	☐ Yes ☐ No	
Distributor reports	☐ Yes ☐ No ☐ N/A	
Field service reports	☐ Yes ☐ No ☐ N/A	

Complaint Log Template

Field	Description
Complaint ID	Auto-generated sequential number
Date received	
Device identifier (UDI / serial / lot)	
Reporter (name, role, institution)	
Description of event	
Patient impact (none / minor / serious / death)	
Severity assessment	
Vigilance report required? (Y/N)	
Root cause analysis	

Field	Description
Corrective action	
Follow-up actions	
Date closed	

Escalation Criteria and Timelines

Event Type	Assessment Timeline	Reporting Timeline
Serious public health threat	Within 24 hours	Immediately, at latest 2 days (Article 87(4))
Death or unanticipated serious deterioration in state of health	Within 24 hours	Immediately, at latest 10 days (Article 87(5))
Serious incident (other)	Within 48 hours	Immediately after establishing the causal relationship (or that it is reasonably possible), at latest 15 days (Article 87(3))
Non-serious complaint	Within 5 business days	No external report required
Trend signal detected	Within 5 business days	Per Article 88

Component 2: PMS Plan (Article 84 / Annex III Section 1)

PMS Plan Outline

Section	Content	Status
1. Scope	Device description, intended purpose, device class	☐ Draft ☐ Done
2. Data sources	Complaints, usage data, literature, clinical outcomes, registries	☐ Draft ☐ Done
3. Collection methods	How each data source is gathered	☐ Draft ☐ Done
4. Analysis procedures	How data is reviewed and patterns detected	☐ Draft ☐ Done
5. Reporting format	PMS Report (Class I) or PSUR (Class IIa+)	☐ Draft ☐ Done

Section	Content	Status
6. Responsibilities	Who does what	☐ Draft ☐ Done
7. Review frequency	How often PMS data is reviewed	☐ Draft ☐ Done
8. Trend detection method	Baseline, threshold, statistical approach	☐ Draft ☐ Done

Component 3: PMCF Plan (Annex XIV Part B)

PMCF Activity	Frequency	Responsibility	Status
User surveys / questionnaires	Every ___ months		☐ Planned
Systematic literature review	Every ___ months		☐ Planned
Application studies (if applicable)			☐ Planned ☐ N/A
Registry participation (if applicable)			☐ Planned ☐ N/A
Review and update of PMCF plan	Annually		☐ Planned

PMCF Survey Template (adapt to your device)

1. How frequently do you use the device? (daily / weekly / monthly / rarely)
2. Rate the device's clinical performance (1-5 scale)
3. Have you experienced any device malfunctions? (Y/N, describe)
4. Have any adverse events occurred during use? (Y/N, describe)
5. Rate overall satisfaction (1-5 scale)
6. What improvements would you suggest?

Component 4: Trend Detection Method (Article 88)

Define Your Baseline

Metric	Value	Source
Expected complaint rate per devices in use	___ per 1,000 devices	
Expected malfunction rate	___ per 1,000 devices	
Observation period for baseline	___ months	

Define Your Threshold

Signal	Threshold for Investigation	Statistical Method
Complaint rate increase	> ____% above baseline	
Malfunction rate increase	> ____% above baseline	
New adverse event type	Any occurrence	
Cluster of similar events	____ events in ____ days	

Document in PMS Plan

- ☐ Baseline is defined and documented
- ☐ Threshold is defined and documented
- ☐ Statistical method is defined and documented
- ☐ "We look at the data and see if anything seems off" is NOT our approach

Component 5: Reporting Rhythm

Device Class	Report Type	Frequency	Submitted To
Class I	PMS Report (Article 85)	Updated when necessary	Available to competent authority on request
Class IIa	PSUR (Article 86)	At least every 2 years	Available to NB and competent authority on request
Class IIb	PSUR (Article 86)	At least annually	Available to NB; submitted to NB for implantable devices
Class III	PSUR (Article 86)	At least annually	Submitted to NB via electronic system

Your device class: _____

Your reporting rhythm: _____

The Compliance Dividend: Same Data, Two Lenses

PMS Activity	Regulatory Purpose	Business Purpose
Complaint tracking	Vigilance reporting, safety monitoring	Product improvement roadmap
PMCF surveys	Clinical evidence update	Customer satisfaction data
Usage data analysis	Verify intended purpose alignment	Feature usage analytics
Literature review	State of the art monitoring	Competitive intelligence

PMS Activity	Regulatory Purpose	Business Purpose
Trend analysis	Article 88 reporting	Early warning system

Readiness Checklist

- ☐ PMS plan written and part of technical documentation
- ☐ Complaint management process defined with intake channels
- ☐ PMCF plan written with specific activities and timelines
- ☐ Trend detection method defined (baseline + threshold + statistical approach)
- ☐ Reporting rhythm matches device class
- ☐ PMS data flows into QMS (CAPA, risk management, clinical evaluation)

Date completed: _____

Completed by: _____

This worksheet is part of the Subtract to Ship: MDR Certification playbook by Felix Lenhard and Tibor Zechmeister. It does not replace professional regulatory advice.