Chapter 7 Template: Team Competence Gap Analysis

Subtract to Ship: MDR Certification, Chapter 7: Team & Competences*

Instructions

Map your team against MDR-required roles. For each role, assess actual competence (not CVs, not job titles). If you cannot verify competence through specific questions and evidence, mark the gap. This exercise takes 1-2 hours and prevents months of wasted engagement with under-qualified team members.

Part 1: Role-by-Role Assessment

Person Responsible for Regulatory Compliance (PRRC), MDR Article 15

Field	Your Answer
Name of current PRRC (or "none")	
Internal or external?	
Qualification path: (a) Degree + 1 year RA/QMS experience, or (b) 4 years RA/QMS experience?	
Evidence: Degree certificate?	Yes No N/A
Evidence: Employment records proving regulatory experience?	Yes No
Can this person explain your conformity assessment procedure in specific terms?	Yes No
Status:	Covered Gap

Risk Manager, EN ISO 14971

Field	Your Answer
Name of risk manager (or "none")	
Formal training in EN ISO 14971?	Yes No
Has built a risk management file before?	Yes No
Can walk through a risk analysis for your device type?	Yes No
Status:	Covered Gap

Clinical Investigator (if applicable)

Field	Your Answer
Is clinical investigation part of your conformity route?	Yes No
Name of clinical affairs lead (or "none")	
GCP training certificate?	Yes No
Experience with clinical investigation design?	Yes No
Understanding of Article 62 requirements?	Yes No
Status:	Covered Gap Not needed

Quality Management Representative, EN ISO 13485

Field	Your Answer
Name of QM representative (or "none")	
Formally appointed by management?	Yes No
Understands EN ISO 13485 requirements?	Yes No
Can explain the QMS without reading from the procedure manual?	Yes No
Status:	Covered Gap

Software Developer (if applicable), EN 62304

Field	Your Answer
Does your device include software?	Yes No
Name of software lead (or "none")	
Training in EN 62304?	Yes No
Experience with documented software lifecycle?	Yes No
Status:	Covered Gap Not needed

Biocompatibility Expert (if applicable), EN ISO 10993

Field	Your Answer
Does your device contact the body?	Yes No
Name of biocompatibility lead (or "none")	
Knowledge of EN ISO 10993 series?	Yes No
Status:	Covered Gap Not needed

Part 2: Gap Closing Strategy

For each gap identified above, choose a strategy:

Role	Gap Description	Strategy	Timeline	Estimated Cost
		Train Hire Outsource		EUR _
		Train Hire Outsource		EUR _
		Train Hire Outsource		EUR _
		Train Hire Outsource		EUR _

Priority Assignment

Based on your device class and conformity route:

Priority	Class I (no NB)	Class IIa+ (NB required)	Class IIb/III (clinical)
PRRC	Critical	Critical	Critical
Risk Manager	Important	Critical	Critical
Clinical Investigator	Usually not needed	Evaluate	Critical
QM Representative	Critical	Critical	Critical

Part 3: Competence Verification Questions

Use these to verify claimed competence. Ask the person directly.

For the PRRC: - "Walk me through the conformity assessment procedure for our device." - "What does Article 15 require for your role?" - "How would you ensure timely reporting of a serious incident?"

For the Risk Manager: - "Walk me through how you would build a risk management file for our device." - "What is the difference between risk estimation and risk evaluation?" - "How do you determine whether a residual risk is acceptable?"

For the QM Representative: - "Walk me through your last management review." - "How does our document control process work?" - "What triggers a CAPA in our system?"

If the person cannot answer confidently and specifically, that is a gap, regardless of their job title or CV.

Part 4: Build-Up Timeline

Period	Actions	Cost Estimate
Months 1-3	External PRRC. CEO as QM rep (with training). One team member starts EN ISO 14971 training.	EUR 7,000-19,000
Months 4-9	Risk management competence develops. QMS build with external support + knowledge transfer.	EUR 15,000-30,000
Months 10-18	Clinical investigation competence (if needed). Evaluate internal PRRC transition.	Depends on class

Part 5: The Outsourcing Trap Check

- [ ] Every outsourcing contract includes a knowledge transfer component
- [ ] Someone internal can explain every outsourced deliverable
- [ ] If the consultant left tomorrow, we could maintain the QMS ourselves
- [ ] We are not dependent on a single external person for all regulatory knowledge

If any box is unchecked: you have a dependency, not a strategy.

Summary

Assessment	Count
Roles fully covered	____ / 6
Gaps identified	____
Gaps with closing strategy	____

0 gaps: Verify once more. Overconfidence is as dangerous as ignorance.

1-2 gaps: Manageable. Build closing plan with timelines and budgets.

3+ gaps: You need a partner before spending on regulatory work.

Date completed:

_

Completed by:

_