Chapter 19 Template: Regulatory Partner Evaluation Scorecard

Subtract to Ship: MDR Certification, Chapter 19: Saving Resources with the Right Measures

Instructions

Evaluate potential regulatory partners against five criteria. All five must pass, not three out of five, not four. A partner who scores perfectly on qualifications but does not understand startup constraints will give you advice you cannot afford to follow. Score each candidate honestly. This evaluation takes 30 minutes per candidate and can save six figures.

Part 1: Five Partner Criteria Scorecard

Candidate: _____

#	Criterion	Score (0-10)	Evidence / Notes
1	**Emotional Fit**, Can I be honest with this person? Can they be honest with me? Will they deliver hard truths I need to hear?	/10	
2	**Technology Understanding**, Do they understand my technology well enough to ask intelligent questions? Can they identify regulatory risks specific to my tech type?	/10	
3	**Shared Vision**, Do they understand what I am optimising for (speed, IP, investors, international)? Will they push back when priorities conflict with reality?	/10	
4	**Startup Dynamics**, Do they understand limited budgets, small teams, compressed timelines? Or do they give advice designed for a 50,000-person company?	/10	
5	**Proven Qualifications**, Have they actually guided companies through MDR certification? Multiple companies? Different device classes? Can they name them?	/10	
	TOTAL	**/50**	

Scoring Guide

Score per Criterion	Interpretation
8-10	Strong fit on this criterion
5-7	Acceptable, but watch for gaps

Score per Criterion	Interpretation
Below 5	Have an honest conversation about this criterion
Below 3	This partnership may cost more than it saves

Part 2: Qualification Verification Questions

Ask these directly. A qualified partner answers with specifics.

Question	Their Answer
How many companies have you guided through MDR certification?	
What device classes have you worked with?	
Which Notified Bodies have you worked with?	
What was the average timeline from start to CE marking?	
What went wrong in a recent project, and how did you handle it?	
Can you provide references from companies you have guided?	

If answers are vague ("many clients," "extensive experience") without names, numbers, or timelines: that is a presentation, not a track record.

Part 3: Red Flag Check

Red Flag	Present?
"We handle everything." (One-stop-shop claim, signals breadth without depth)	☐ Yes ☐ No
"This will be easy." (Nothing about MDR is easy. Minimising = inexperienced or dishonest)	☐ Yes ☐ No
Cannot name specific companies they have guided to certification.	☐ Yes ☐ No
Never says "I don't know" or "we need a specialist for that."	☐ Yes ☐ No
Quotes a timeline under 12 months for Class IIa without knowing your device.	☐ Yes ☐ No
Proposes a generic approach before understanding your specific product.	☐ Yes ☐ No

Any red flag present: proceed with extreme caution or find another partner.

Part 4: Multi-Candidate Comparison

Criterion	Candidate 1: _____	Candidate 2: _____	Candidate 3: _____
Emotional Fit	/10	/10	/10

Criterion	Candidate 1: _____	Candidate 2: _____	Candidate 3: _____
Technology Understanding	/10	/10	/10
Shared Vision	/10	/10	/10
Startup Dynamics	/10	/10	/10
Proven Qualifications	/10	/10	/10
TOTAL	**/50**	**/50**	**/50**
Red flags?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Fee structure			
Availability			

Part 5: In-House vs. Outsource Decision

Activity	In-House or Outsource?	Rationale
Regulatory understanding (absorbing and owning knowledge)	**Always in-house**	Cannot outsource understanding
Quality management ownership	**Always in-house**	Must be lived, not just maintained
PRRC function	External first, internal ASAP	Article 15(2) allows external for small enterprises
Decision-making (you sign, you are responsible)	**Always in-house**	Article 19(3), manufacturer assumes responsibility
Specialised testing (biocompatibility, electrical)	**Outsource**	Temporary, specialised expertise
Clinical evaluation writing	**Outsource**	Specialised skill, may not need permanently
NB strategy and preparation	**Outsource**	Deep NB experience is valuable
Initial regulatory roadmap	**Outsource**	Highest-ROI consultation

Knowledge Transfer Check

For every outsourced activity:

- ☐ The contract includes a knowledge transfer component
- ☐ Someone internal can explain every outsourced deliverable
- ☐ If the consultant left tomorrow, we could maintain the work ourselves
- ☐ We are building internal competence, not permanent dependency

Part 6: The Economics of Getting Help Early

Scenario A: Partner from Month 1

Activity	Cost
Intended purpose, classification, conformity assessment procedure, NB selection	EUR 10,000-30,000
Building on correct foundation from the start	Included in regular development
Total additional cost	**EUR 10,000-30,000**

Scenario B: DIY, then fix with Partner in Month 12

Activity	Cost
Partner engagement (remediation pricing)	EUR 20,000-50,000
Rework of documentation built on wrong classification	EUR 30,000-80,000
Extended timeline (6-12 months additional) at burn rate	EUR _____
NB relationship starts with correction instead of confirmation	Incalculable
Total additional cost	**EUR 50,000-150,000+**

Scenario B costs 3-5x more than Scenario A. Always.

Part 7: Five Decisions Summary

Decision	Your Answer
1. Is my product actually a medical device? (Verified with expert)	☐ Yes ☐ No ☐ Not yet verified
2. What stays in-house vs. outsourced?	Defined: ☐ Yes ☐ No
3. When am I bringing in a partner?	☐ Now ☐ Month ____
4. Does my partner pass all five criteria?	☐ Yes ☐ No
5. Do I know what my partner does NOT know?	☐ Yes ☐ No

Selected partner: _____

Engagement start date: _____

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.