HIGH UNCERTAINTY

Emergency Research Protocol

When You Need an Answer NOW — A 5-Step Crisis Workflow

aruntastic.
GEO & AI Search Mastery

HIGH UNCERTAINTY

What's Inside

Section 1: The 5-Step Crisis Workflow

When Panic Sets In, Follow These Steps

Tight deadlines create anxiety. This workflow gives you a reliable process for those "need it yesterday" moments. Instead of spiraling through random searches, follow this structured approach.

KEY PRINCIPLE

Speed comes from structure, not shortcuts. A systematic approach is actually faster than panicked searching.

1. **Step 1: Define the Exact Question**
   Write down the specific regulatory question in one sentence. "What are the Notified Body requirements for integral DDC?" is searchable. "Need DDC info" is not.

2. **Step 2: Check the Primary Source First**
   Go directly to the relevant regulation (MDR, IVDR) article. Do not start with Google or secondary sources.

3. **Step 3: Check for Guidance Documents**
   Search the MDCG guidance library and EMA Q&A documents for clarification on your specific question.

4. **Step 4: Document What You Found**
   Record the source, date, and relevant excerpts. This creates your audit trail and prevents re-searching.

5. **Step 5: Verify Currency**
   Check the document date and look for any superseding documents before finalizing your answer.

TIME SAVER

Bookmark the EMA Q&A index page and MDCG guidance library. These two pages answer 80% of urgent questions.

Section 2: Document Hierarchy Quick-Reference

Which Document Takes Priority?

When documents conflict or overlap, follow this hierarchy to determine which source has authority.

PRIORITY	DOCUMENT TYPE	AUTHORITY LEVEL
1 (Highest)	EU Regulation (MDR 2017/745, IVDR)	Legal binding
2	EU Directives (2001/83/EC)	Legal binding
3	EMA Guidelines (CHMP/QWP)	Regulatory expectation
4	MDCG Guidance Documents	Harmonized interpretation
5	EMA Q&A Documents	Clarification/interpretation
6 (Lowest)	Industry guidance, consultants	Reference only

CRITICAL RULE

Never cite lower-tier documents when a higher-tier document addresses the same question. If MDR Article 117 answers your question, cite that — not an MDCG interpretation.

Drug-Device Combination Specific Hierarchy

- MDR Article 117 and Annex I Chapter III — Primary legal requirements
- EMA Guideline on quality requirements for DDC (EMA/CHMP/QWP/BWP/259165/2019) — Detailed quality guidance
- EMA Q&A for applicants regarding DDC (EMA/37991/2019) — Practical clarifications
- MDCG 2022-5 — Borderline classification guidance

Section 3: Confidence Verification Checklist

Do You Have Enough to Proceed?

Use this checklist before finalizing your research. If you can check all boxes, you have sufficient confidence to proceed.

- [ ] I can cite a specific article, annex, or section number
- [ ] The document I am citing is the current version (check date)
- [ ] I checked for any Q&A or guidance that clarifies this requirement
- [ ] I searched for any amendments or corrigenda to the regulation
- [ ] I can explain WHY this requirement applies to my specific situation
- [ ] I have recorded my research path (sources checked, dates, conclusions)

When 6/6 Is Not Possible

Sometimes you cannot achieve full confidence. In these cases:

- Document what you found AND what gaps remain
- Note the regulatory risk level if your interpretation is wrong
- Escalate to a senior colleague or external expert (see Section 4)
- Include appropriate caveats in your advice ("Based on current guidance...")

> **DOCUMENTATION HABIT**
>
> Save your research in a dated folder structure: YYYY-MM-DD_Topic_Name. Future you will thank past you.

Section 4: When to Escalate

Decision Framework for Seeking Expert Help

Knowing when to escalate is a professional skill, not a weakness. Use this framework to make confident escalation decisions.

Escalate Immediately If:

- [ ] The question involves novel products with no precedent
- [ ] Contradictory guidance exists between EMA and MDCG documents
- [ ] The regulatory consequence of being wrong is severe (CRL, rejection)
- [ ] You have spent 2+ hours without finding a clear answer
- [ ] The question requires interpretation of multiple overlapping regulations

Before You Escalate, Prepare:

- The specific question in one sentence
- What sources you already checked
- What you found (including partial answers)
- Why you are uncertain (conflicting info, gap in guidance, etc.)

Arun Nagarathanam

Building tools for regulatory professionals who need certainty, not guesswork.

aruntastic.com/regulatory
linkedin.com/in/arun-nagarathanam/