HIGH CONFIDENCE

Knowledge Transfer Template

Document Your Expertise So Others Can Learn From It

aruntastic.
GEO & AI Search Mastery

HIGH CONFIDENCE

What's Inside

1. **Documentation Template**
   Capture institutional knowledge
2. **Onboarding Checklist**
   Get new team members up to speed
3. **Process Map Template**
   Visual workflows for complex research
4. **"How I Found It" Format**
   Share your research journey

Section 1: Documentation Template

Capture What's In Your Head

Your expertise is valuable — but only if others can access it. This template helps you document institutional knowledge in a format that others can actually use.

THE PROBLEM

Most regulatory knowledge lives in experts' heads and email archives. When that person leaves or is unavailable, the knowledge is effectively lost.

Topic Documentation Template

TEMPLATE

Regulatory Topic Knowledge Base Entry

- Topic: [e.g., "DDC Notified Body Requirements"]
- Last Updated: [Date]
- Primary Sources: [List of regulations/guidelines]
- Key Requirements: [Bullet summary]
- Common Questions: [FAQs with answers]
- Pitfalls to Avoid: [Common mistakes]
- Related Topics: [Cross-references]
- Contact for Questions: [Name/email]

Example: DDC Classification Entry

KNOWLEDGE BASE ENTRY

```
Topic: Drug-Device Combination Classification
Last Updated: 2025-01-15
Primary Sources:
- MDR Article 117
- EMA DDC Q&A Rev.6
- MDCG 2022-5

Key Requirements:
- Integral DDC: Device is not reusable, CE marking via
 Notified Body opinion route
- Non-integral: Device marketed separately, full CE marking
- Borderline: Use MDCG 2022-5 decision tree

Common Questions:
 Q: Pre-filled syringe for my drug - integral or non-integral?
 A: Usually integral. Check EMA Q&A Section 3.2 for criteria.

Pitfalls:
- Don't assume pre-filled = always integral
- Check if device has its own Instructions for Use
```

START SMALL

Don't try to document everything at once. Pick your top 5 most-asked questions and document those first.

Section 2: Onboarding Checklist

Get New Team Members Up to Speed

A structured onboarding checklist reduces the time to competency for new regulatory professionals and ensures consistent training.

Week 1: Foundations

- [ ] Access to EMA website and EUR-Lex set up
- [ ] Introduction to internal knowledge base / SharePoint
- [ ] Overview of company's product portfolio
- [ ] Assigned mentor for questions
- [ ] Read: Company's regulatory strategy document

Week 2: Core Regulations

- [ ] Read MDR overview (focus on scope, Article 1-2)
- [ ] Understand classification rules (Annex VIII)
- [ ] Review Directive 2001/83/EC basics (if pharma)
- [ ] Shadow a senior colleague on a real task
- [ ] Complete first guided research exercise

Week 3-4: Specialty Areas

- [ ] Deep dive into team's specialty (DDC, IVD, etc.)
- [ ] Review 3 recent submissions as examples
- [ ] Complete first independent research task (supervised)
- [ ] Set up personal RSS feeds and monitoring
- [ ] End of month: Knowledge check conversation with mentor

Section 3: Process Map Template

Visual Workflows for Complex Research

Some regulatory questions require a decision tree to answer. Documenting these as visual process maps makes them reusable and trainable.

WHY VISUAL?

A decision tree that takes 10 minutes to explain verbally can be understood in 30 seconds as a diagram.

Process Map Structure

- Start node: The initial question or trigger
- Decision diamonds: Yes/No questions that branch the path
- Process boxes: Actions to take at each step
- End nodes: Final answers or outcomes
- Annotations: Source references for each decision point

Example: DDC Pathway Decision Tree

STEP	QUESTION	IF YES	IF NO
1	Is the device integral to the drug?	Go to Step 2	Non-integral DDC (separate CE)
2	Is the device already CE marked?	Use existing CE	Go to Step 3
3	Class I device?	Self-declaration	Notified Body opinion
4	Class IIa/IIb/III?	NB opinion required	Review classification

TOOL TIP

Use draw.io (free) or Lucidchart for process maps. Export as PNG and embed in your knowledge base.

Section 4: "How I Found It" Format

Share Your Research Journey

The most valuable knowledge transfer isn't just the answer — it's how you found the answer. This format teaches others your research process.

"How I Found It" Template

TEMPLATE

Research Journey Documentation

- Question Asked: [Original question]
- First Place I Looked: [And what I found/didn't find]
- What Led Me to the Answer: [Search terms, cross-references]
- Dead Ends: [What didn't work and why]
- Final Answer: [With source citation]
- Time Spent: [Realistic estimate]
- What I'd Do Differently: [Lessons learned]

Example

RESEARCH JOURNEY

```
Question: "Does our pre-filled syringe need a separate
Instructions for Use under MDR?"

First Look: MDR Annex I, Chapter III (device requirements)
- Found general IFU requirements but not DDC-specific

Dead End: Searched MDCG documents for "IFU" + "combination"
- Got irrelevant results about software

Breakthrough: EMA DDC Q&A, searched "instructions"
- Found Q3.8 addressing exactly this question

Final Answer: "Yes, if the device component has specific
handling/storage requirements beyond the drug's SmPC"
- Source: EMA/37991/2019 Rev.6, Section 3.8

Time: 45 minutes
Lesson: Start with EMA Q&A for DDC questions, not MDCG
```

Arun Nagarathanam

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

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