

GROWING CONFIDENCE

Update Monitoring System

Stay Ahead of Regulatory Changes Proactively

What's Inside

1

RSS/Email Alerts Setup Guide

Automated notifications for EMA updates

2

Key EMA Pages to Monitor

Direct links to the sources that matter

3

Quarterly Review Calendar

Systematic review cadence

4

Change Impact Assessment Template

Evaluate what updates mean for you

Section 1: RSS/Email Alerts Setup Guide

Never Miss an Update Again

The most common source of regulatory uncertainty is not knowing about guidance changes. Setting up automated alerts takes 15 minutes and saves hours of manual checking.

THE PROBLEM

EMA publishes updates without notifying anyone directly. Documents are revised, Q&As are updated, new guidance is issued — all silently.

EMA RSS Feeds Setup

- 1 Step 1: Get an RSS Reader**
Use Feedly (feedly.com) — free tier is sufficient. Create an account.
- 2 Step 2: Add EMA News Feed**
In Feedly, click "+" and paste: <https://www.ema.europa.eu/en/rss/news>
- 3 Step 3: Add EMA Guidelines Feed**
Add: <https://www.ema.europa.eu/en/rss/human-regulatory-documents>
- 4 Step 4: Set Up Daily Digest**
In Feedly settings, enable daily email digest for your regulatory folder.

European Commission Alerts

- EC MDCG Documents: No RSS available — set calendar reminder for monthly check
- EUR-Lex: Subscribe to alerts for MDR (2017/745) and IVDR (2017/746)
- Official Journal: Subscribe to health/devices category for new legislation

FILTER NOISE

Create folders in your RSS reader: "Must Read" for your specific topics, "Scan Weekly" for broader regulatory news.

Section 2: Key EMA Pages to Monitor

Bookmark These Pages

Not all EMA pages have RSS feeds. For these critical pages, bookmark and check monthly.

Essential Bookmarks for DDC Professionals

PAGE	URL	CHECK FREQUENCY
EMA DDC Q&A	ema.europa.eu > Q&A drug-device	Monthly
Human Medicines Guidelines	ema.europa.eu > Scientific guidelines	Monthly
MDCG Guidance Library	ec.europa.eu > MDCG documents	Monthly
EMA News	ema.europa.eu > News	Weekly (or RSS)

Secondary Monitoring

- NBOG Best Practice Guides (nbog.eu)
- CMDh guidance documents (hma.eu/cmdh)
- MHRA guidance (UK divergence monitoring)
- FDA guidance (if US market is relevant)

PRO TIP

Save bookmarks in a dedicated browser folder called "Regulatory Monthly Check". Open all tabs at once on the first Monday of each month.

Section 3: Quarterly Review Calendar

Systematic Review Cadence

Beyond monitoring for new publications, schedule quarterly reviews of the guidance documents you rely on most frequently.

Quarterly Review Schedule Template

QUARTER	FOCUS AREA	KEY DOCUMENTS TO RE-CHECK
Q1 (Jan-Mar)	Classification & Borderline	MDCG 2022-5, MDCG 2021-24
Q2 (Apr-Jun)	Clinical Evidence	MDCG 2020-6, EMA clinical guidelines
Q3 (Jul-Sep)	Technical Documentation	MDCG 2019-9, Annex II/III requirements
Q4 (Oct-Dec)	DDC Specific	EMA DDC Guideline, EMA Q&A, Article 117

What to Check During Quarterly Review

- Document is still current version (no Rev.X+1)
- No new Q&A addressing my common questions
- No amendments to underlying regulation
- Internal procedures still align with current guidance
- Training materials reference current documents

CALENDAR TIP

Block 2 hours on the first Friday of each quarter for this review. Treat it as non-negotiable compliance time.

Section 4: Change Impact Assessment Template

Evaluate What Updates Mean for You

When you discover a guidance change, use this template to assess its impact on your work.

TEMPLATE
Change Impact Assessment

- Document Changed: [Name, version, date]
- What Changed: [Summary of key differences]
- Affected Products/Projects: [List]
- Impact Level: Critical / Significant / Minor / None
- Action Required: [Specific steps needed]
- Deadline: [When action must be completed]
- Owner: [Who is responsible]

Impact Level Definitions

LEVEL	DEFINITION	RESPONSE TIME
Critical	Affects ongoing submissions or approved products	Immediate
Significant	Requires procedure updates before next submission	30 days
Minor	Informational, no procedure changes needed	Note and file
None	Not relevant to current portfolio	No action

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