Start strong in European *MedTech.*

The Vigilo guide for Regulatory Affairs, Quality and Clinical professionals. Set up in ten minutes, read regulatory news with confidence and assess roles like an insider.

10 min
to set up Vigilo so relevant roles and updates come to you

5
dates to tell apart in any EU regulation

7
signals to read in any MedTech job advert

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WELCOME

Your field moves fast. This guide keeps you ahead.

Regulatory Affairs, Quality and Clinical work in European MedTech sits where EU law, constant guidance updates and a cross-border hiring market meet. Here are the essentials in one place.

WHAT YOU WILL BE ABLE TO DO

Set up

PAGES 3 AND 4

Get the right roles and updates delivered, without checking job sites every day.

Decode

PAGES 5 AND 9

Tell a proposal from an obligation, and a publication date from an application date.

Move

PAGES 6 TO 8

See where you could go next, read adverts like an insider and apply with evidence.

CHOOSE YOUR PATH

Looking for a role now	Set up alerts and matches, then sharpen how you read adverts and apply.	p. 3 · 7 · 8
New to MedTech regulation	Learn to read regulatory news, then explore the career map and the glossary.	p. 5 · 6 · 9
Experienced and short on time	Ten-minute set-up, then keep the sources and glossary to hand.	p. 3 · 4 · 9

WHY YOU CAN RELY ON VIGILO

Primary sources first

Every regulatory item links to the regulator, the legal text or the original publisher.

Always up to date

Sources checked every weekday. Roles re-checked the morning we share them.

Close to the industry

In direct contact with companies and industry organisations across Europe.

Specialists only

Only Regulatory Affairs, Quality and Clinical in MedTech. Free for candidates.

YOUR MOVE Turn to page 3 and complete the set-up now. It takes less than ten minutes.

SET UP ONCE

Five steps. Then the roles come to you.

9

MINUTES IN TOTAL

1 Get the Tuesday briefing

1 MIN

One email a week: selected regulatory developments, each with its source and what to check, then verified open roles.

Already subscribed? Tick it off.

☐

2 Create your free account

2 MIN

Sign up on vigilomedtech.com with an email link, a password, Google or LinkedIn.

Your account lets you save roles and see your Job matches.

☐

3 Complete your profile

3 MIN

Add your function, experience and preferences. Vigilo uses your profile to rank live roles on your personal Job matches page. Tick “Email me jobs that match my profile” for a weekly email of up to ten matches.

No new matches that week means no email.

☐

4 Set a job alert

2 MIN

Choose your function, location and remote preference. You get a weekly digest, only when new roles match.

Confirm from the email you receive. Change or stop it from any digest.

☐

5 Follow Vigilo on LinkedIn

1 MIN

Short carousels from Monday to Thursday: open roles, the number of the week, a scenario and a mini tutorial.

linkedin.com/company/vigilo-medtech-jobs

☐

JOB ALERTS OR JOB MATCHES? USE BOTH: THEY CATCH DIFFERENT ROLES

	Job alert	Job matches
BASED ON	The filters you choose: function, location, remote	Your profile
YOU RECEIVE	A weekly digest	A weekly email with up to ten roles
SENT ONLY WHEN	New roles match your filters	There are new matches for you
BEST FOR	A precise search you already know	Roles you would not think to search for
SWITCH ON	Step 4, then confirm by email	Step 3, then tick the box

YOUR MOVE When your first Tuesday briefing arrives, move it to your main inbox and add the sender to your contacts.

A FIXED RHYTHM

One format a day. Each one does one job.

4

DAYS A WEEK
ZURICH TIME

Mon

09:00 · LinkedIn

Open roles

Up to five verified roles. If fewer meet the bar, we post fewer.

Tue

09:00 · LinkedIn

Number of the week

One figure with its unit, geography, year and source.

09:30 · Email

The Tuesday briefing

Developments, what to check and verified roles. Built to read in minutes.

Wed

09:00 · LinkedIn

Story or scenario

A documented public case, or a scenario clearly labelled as illustrative.

Thu

09:00 · LinkedIn

Mini tutorial

One narrow task in three to five steps, with jurisdiction and references.

EVERY WEEK Your job alert digest and your Job matches email, only when there is something new for you.

WHAT VIGILO DOES

A direct route to the right roles

→ Lists Regulatory Affairs, Quality and Clinical roles in MedTech, IVD and medical software across Europe.

→ Sends you to the original listing to apply, usually on the employer's own site.

→ Explains what changed in regulation, for whom, and what to check.

WHAT "VERIFIED" MEANS FOR THE ROLES WE SHARE ON MONDAY AND TUESDAY

Live

Checked on the original listing the morning we publish.

Direct

Apply opens the original listing, never a copy.

In scope

Regulatory Affairs, Quality or Clinical, in MedTech, IVD or medical software.

Labelled

Paid placements are always marked as such.

YOUR MOVE Pick the one format most useful for your job this month and read it every week. Consistency beats volume.

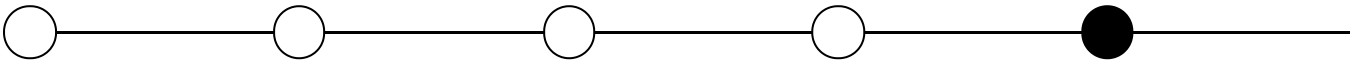
A SKILL THAT PAYS OFF

Know which date you are looking at.

5

DATES IN THE LIFE OF A REGULATION

TOOL 1 · THE LIFE OF AN EU REGULATION, WITH THE MDR AS EXAMPLE



Proposal

The Commission proposes a text. Nothing applies yet.

2012

Adoption

Parliament and Council agree the final text.

April 2017

Publication

The text appears in the Official Journal.

5 May 2017

Entry into force

The law exists; obligations may still be deferred.

25 May 2017

Application

The obligations actually apply.

26 May 2021*

* After a one-year postponement. Four years separate entry into force from application: quoting the wrong one changes the story.

TOOL 2 · LEGAL WEIGHT, FROM BINDING TO CLAIM

Regulations and national law	
Implementing and delegated acts	
Harmonised standards	Voluntary; presumption of conformity
MDCG guidance	Not legally binding, widely followed
Proposals	And consultations. Not law yet
Company claims	Check independently

ANATOMY OF A VIGILO UPDATE

PROPOSAL | EU

1. EU: what changed, in plain words
2. **Key date:** named as publication, entry into force or application.
3. **Who it affects:** role and economic operator.
4. **What to check:** one practical next step.
5. **Source:** link to the primary page.

FIVE QUESTIONS TO ASK OF ANY REGULATORY HEADLINE

1 Where?

EU-wide, one member state, or outside the EU?

2 How binding?

Law, guidance, proposal or claim?

3 Which date?

Publication, entry into force or application?

4 Who?

Manufacturer, importer, representative, notified body?

5 Says who?

Can you open the primary source?

WORKED EXAMPLE · “EU EXTENDS MDR DEADLINES”, MARCH 2023

1	2	3	4	5
EU-wide, and the EEA	*Law: an amending Regulation*	*In force on publication, 20 March 2023*	*Manufacturers of certain legacy devices, under conditions*	*EUR-Lex: Regulation (EU) 2023/607*

YOUR MOVE

Before you forward the next regulatory headline to your team, answer the five questions above in one line each.

WHERE YOU ARE, WHERE YOU COULD GO

Three families. Many bridges.

Typical titles and standards in each family. Titles vary by company size and country, so read the responsibilities, not just the title.

Regulatory Affairs

Gets devices onto the market and keeps them there: strategy, technical documentation, submissions, authority contact.

Head or Director of RA	SENIOR
RA Manager · PRRC	LEAD
Senior RA Specialist	MID
RA Associate or Specialist	ENTRY

KNOW YOUR WAY AROUND

MDR · IVDR · MDCG guidance · EUDAMED · GSPR · UDI

Quality

Builds and runs the quality management system: audits, CAPA, complaints, suppliers, risk and design controls.

Head or VP of Quality	SENIOR
QMS or Quality Manager	LEAD
Supplier Quality · CAPA lead	MID
Quality Engineer	ENTRY

KNOW YOUR WAY AROUND

ISO 13485 · ISO 14971 · IEC 62304 · IEC 62366-1 · ISO 19011

Clinical

Generates and evaluates clinical evidence: investigations, clinical evaluation, performance studies, follow-up.

Head of Clinical Affairs	SENIOR
Clinical Affairs Manager	LEAD
Senior CRA · Clinical Evaluation	MID
CRA · Clinical Specialist	ENTRY

KNOW YOUR WAY AROUND

ISO 14155 · ISO 20916 (IVD) · CER · PMCF · SSCP

BRIDGES: HYBRID ROLES WHERE TWO FAMILIES MEET

Post-market surveillance

Quality data meets clinical and regulatory reporting: PMS plans, PSURs, vigilance.

Clinical evaluation

Clinical evidence written for regulatory review.

Software and AI devices

RA and Quality with IEC 62304 and cybersecurity.

Notified bodies

Reviewer and auditor roles that value industry experience.

SKILLS THAT TRAVEL ACROSS ALL THREE FAMILIES

Risk management thinking · Clear technical writing · Audit and inspection readiness · Reading legal text precisely · Working across functions · Data and evidence literacy

A role to know: the PRRC

Article 15 of the MDR and of the IVDR requires manufacturers to have a Person Responsible for Regulatory Compliance; micro and small firms may rely on an external one. The route in: a relevant degree plus one year in regulatory affairs or quality management for devices, or four years' experience in those fields.

YOUR MOVE

Mark where you are and the next step you want. Then set a job alert for that title, not your current one.

READ BETWEEN THE LINES

Every line of an advert tells you something.

7
SIGNALS TO READ

ILLUSTRATIVE EXAMPLE · NOT A REAL VACANCY

Regulatory Affairs Specialist

Device manufacturer · EU-based · Hybrid

YOUR ROLE

1. Maintain technical documentation for Class IIb devices under the MDR
2. Prepare notified body submissions and answer deficiency questions
3. Manage EUDAMED and UDI registrations
4. Act as deputy PRRC

YOUR PROFILE

5. 3+ years in RA for medical devices
6. Working knowledge of ISO 13485 and ISO 14971
7. Fluent English; a second EU language is an advantage

NOT IN THE ADVERT, SO ASK

— Salary range and on-site days

— Team size and who you report to

— Which notified body they work with

In EU countries, the Pay Transparency Directive (EU) 2023/970 gives applicants a right to pay information before the interview, once transposed into national law.

1. **Class and regulation**
   Higher classes mean deeper documentation and more notified body contact. Match it to the classes you have worked on.
2. **Notified body contact**
   Have one concrete example ready: a review you led or a deficiency you closed.
3. **EUDAMED and UDI**
   Data-heavy, deadline-driven work. Ask how far their registrations have progressed.
4. **Deputy PRRC**
   Check you meet the Article 15 route. It is a step towards the PRRC role itself.
5. **Years of experience**
   Often a guide, not a wall. Strong, relevant evidence can outweigh a missing year.
6. **Named standards**
   Mirror them in your CV with what you did, not just the number.
7. **Language**
   “An advantage” is not “required”. Be honest about your level.

SAME TITLE, DIFFERENT JOB: WHO IS HIRING CHANGES THE WORK

Manufacturer	Consultancy	Notified body	Start-up	Representative or importer
Owns the technical documentation. Depth on one portfolio over time.	Many clients and devices. Breadth, pace and deadlines set by others.	Reviews other companies’ files and audits their systems. Strict independence rules.	Often the first RA or Quality hire. You build the system and the strategy.	EU duties on behalf of non-EU manufacturers: authorised representative, importer, distributor.

GREEN FLAGS

+	Named regulation, device class and target markets
+	A clear reporting line and team size
+	A salary range and a realistic list of must-haves

WORTH A QUESTION

?	A long list of standards with no context
?	RA, Quality, Clinical and PRRC duties in one junior role
?	No word on which products or markets you will cover

YOUR MOVE Take the last role you saved and annotate it with these seven signals before deciding whether to apply.

FROM READING TO APPLYING

Apply with evidence. Interview with questions.

BEFORE YOU CLICK APPLY

- ☐ **Match the framework**
  Same regulation, device type and class as your experience?
- ☐ **Use their words**
  Reuse the advert's standards and terms where they are true for you.
- ☐ **Check the basics**
  Location, on-site days, language, travel and contract type.
- ☐ **Show evidence**
  Audits hosted, files remediated, submissions led, studies monitored.
- ☐ **Know where you apply**
  On Vigilo, Apply opens the original listing.
- ☐ **Save and compare**
  Save the role in your account and decide with a clear head.

WRITE EVIDENCE, NOT DUTIES: A FOUR-PART LINE FOR YOUR CV

1 ACTION	2 SCOPE	3 FRAMEWORK	4 RESULT
What you did	On what	Under which rules	What changed
Led, wrote, closed, audited, trained	Device type, class, number of products	MDR, IVDR, ISO 13485, ISO 14155	Certificate kept, findings closed, study delivered

BEFORE Responsible for technical documentation.

AFTER Led[1] the MDR[3] technical documentation update for a Class IIb product family[2] and closed every notified body question in the first review round[4].

Illustrative wording. Use only what is true for you.

SIX QUESTIONS WORTH ASKING THEM

1. **Where is your portfolio in the MDR or IVDR transition?**
   Tells you whether the job is remediation, maintenance or new launches.
2. **Which notified body do you work with, and how are reviews going?**
   Signals workload and pressure in the coming year.
3. **Where do RA and Quality sit, and who is the PRRC?**
   Reveals influence, reporting lines and growth room.
4. **How do post-market data reach risk management and design?**
   Shows how mature the quality system really is.
5. **Which markets come next?**
   Markets outside the EU, such as the US, can reshape the role.
6. **What does success look like after six months?**
   Turns a vague role into a clear brief.

YOUR MOVE Before your next application, rewrite two CV lines with the four-part formula and pick two questions to ask.

GO TO THE SOURCE

The primary sources behind our updates

SOURCE	WATCH FOR	ADDRESS
European Commission	Announcements, MDCG guidance, EUDAMED news. Separate announcements from obligations.	health.ec.europa.eu/medical-devices-sector_en
EUR-Lex	The legal texts, consolidated versions and application dates.	eur-lex.europa.eu
MDCG guidance	Endorsed guidance documents. Not binding: check the version and what it replaces.	health.ec.europa.eu, MDCG guidance page
EUDAMED	The EU database: actors, devices, certificates and its roll-out status.	ec.europa.eu/tools/eudamed
Harmonised standards	The list published in the Official Journal that gives a presumption of conformity.	health.ec.europa.eu, harmonised standards page
Team-NB	The European association of notified bodies: positions and practice papers.	team-nb.org
MedTech Europe	Industry data. An association source: check the data year.	medtecheurope.org

GLOSSARY · THE ACRONYMS YOU WILL MEET MOST

AR
Authorised representative for non-EU manufacturers

CAPA
Corrective and preventive action

CE
EU conformity marking

CER
Clinical evaluation report

CS
Common specifications

EUDAMED
European database on medical devices

GSPR
General safety and performance requirements

IVD
In vitro diagnostic medical device

IVDR
In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

MDCG
Medical Device Coordination Group

MDR
Medical Devices Regulation (EU) 2017/745

NB
Notified body

NCA
National competent authority

PMCF
Post-market clinical follow-up

PMS
Post-market surveillance

PRRC
Person responsible for regulatory compliance

PSUR
Periodic safety update report

QMS
Quality management system

SRN
Single registration number in EUDAMED

SSCP
Summary of safety and clinical performance

UDI
Unique device identification

VIGILO

Relevant roles. Useful updates. Every Tuesday.

Start at **vigilomedtech.com**
Questions or feedback: contact@vigilomedtech.com

HIRING?

Put your next Regulatory Affairs, Quality or Clinical opportunity in front of the people it is meant for. Explore employer options at vigilomedtech.com.

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