
Masterclass
starts in
3 mins
YOUR MEDICAL DEVICE FASTER TO THE US MARKET
SECRETS FOR A SUCCESSFUL 510(K) SUBMISSION
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by Mieke Janssen

Welcome

Your US market entry starts here

- MedTech innovators
- For start-up & scale-up leaders, R&D, regulatory, product and commercial managers

ready to **unlock** the US market

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About . . .

Mieke Janssen

- In quality and regulatory since 2007
- Former regulatory lead at top Belgian medtech innovator
- Independent consultant since 2020

- Supported 50+ 510(k) submissions
- Innovative medical devices which were not 510(k) cleared before
- Strategic bridge between R&D, commercial and FDA

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About . . .

Bart Leekens

- Coach – Lead Trainer –
- Lead Auditor Medical Devices
- Quality and Regulatory Compliance
- Healthcare (Medical Devices)

- Quality Management Systems and Quality System Regulations
- EU Regulations and Guidance for medical devices – FDA Quality System Regulation – Good Distribution Practice
- International Standards related to Management Systems
- Internal, supplier and subcontractor audits
- Facilitating certification and surveillance audits

FDA Clearance is more than a legal box to check

Not only a legal **obligation**, but strategic market **advantage** if you approach it well

Learn to approach it **smart**, not just compliant

Why most innovators struggle

You've built something that matters.

- groundbreaking devices often stall in the FDA maze
- lack of clarity = hesitation
- delay, outsource too soon, or get lost in complexity

The result?

- Lost time.
- Lost budget.
- Missed opportunity.

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Walk away with strategic clarity

WHAT YOU WILL LEARN TODAY

- 8 core insights from 20 years of **experience**
- 6 **essential** steps to speed and success
- a proven **bonus** tool
- access to a private session for **tailored** advice

Imagine this ...

What if your device got cleared in 5 months?

What would that mean for your product launch?

Your roadmap? Your investor pitch?

What would that unlock for your team?

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Common obstacles

BARRIERS YOU CAN BEAT

- No predicate that exactly matches → there always is a path
- Company does not have US presence → doesn’t stop your clearance
- Struggling to explain your innovation to reviewers? You’re not alone - it’s solvable
- Don’t know where to start? You will know after today

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Engage with us

This is not a lecture - it’s your opportunity

- Use the Q&A
- Take notes
- Ask what you are really wondering
- Share your reflections
- The more you engage, the more you gain

Eye - openers

Game changing insights from real-world experience

- 8 actionable **insights** that challenge your thinking on the 510(K) process
- Designed to shift both your **strategy** and **mindset** on FDA clearance

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Eye-opener 1:

Regulatory = starting point for your commercial strategy

START WITH REGULATORY, BUILD FOR SUCCESS

- Begin with **claims** and shape your product accordingly
- Regulatory isn't just about compliance, it is the foundation for your **market positioning**

REGULATORY SHAPES YOUR COMMERCIAL STORY

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Eye-opener 2:

The FDA reads words, not minds nor passion

CLARITY OVER EMOTION

- **FDA reviewers** rely solely on the clarity and structure of your submission file - not your passion or intentions
- Your file must **speak for itself**: **clarity** and **structure** are key

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Eye-opener 3:

Clear positioning = fewer questions

PRECISION AVOIDS BACK-AND-FORTH

- less fluff = less friction
- a **precise** submission leads to fewer follow-up questions and faster approval

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Eye-opener 4:

Choosing the right predicate device is key

FIND YOUR CLOSEST MATCH

- Choose a **predicate device** that closely mirrors your product
- **Don’t aim for a 100% match** - differences are acceptable & must be clearly explained
- The predicate device sets the stage for your **regulatory strategy** and approach

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Eye-opener 5:

Data is key - Structure is power

TRUST COMES FROM CONSISTENCY AND CLARITY

- Coherent data = FDA reviewer trust
- Think in terms of **consistency**, **traceability**, and **clarity** to build confidence in your submission

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Eye-opener 6:

Naming risks builds trust

ACKNOWLEDGE RISKS, GAIN CREDIBILITY

- Ignoring risks undermines your **credibility** with the FDA
- Being **transparant** and showing **control** over risks builds confidence with reviewers

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Eye-opener 7:
Reviewer time is limited

ONE SHOT TO IMPRESS

- You only have one chance to make a strong first impression
- Reviewers have limited time - make every page count to avoid endless back-and-forths

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Eye-opener 8:

Documentation without a system = future problem

YOUR DOCUMENTATION MUST LIVE INSIDE YOUR QMS

- documentation created only to satisfy the reviewer is fragile
- important to think format so that it supports your process and QMS
- a strong QMS ensures structure, traceability and future-proof compliance

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Summary of eye openers

SUMMARY OF KEY INSIGHTS

- Regulatory is your commercial starting point
- Clear communication is essential
- Strategic claims drive product design
- Choose your predicate carefully
- Data must be structured for clarity
- Acknowledge risks to build trust
- Reviewer time is limited
- Maintain documentation as part of your QMS

Reflection

REFLECTION AND NEXT STEPS

Use the chat to share your thoughts

- Which insight resonated most with you today?
- What will you implement first to improve your 510(k) strategy?

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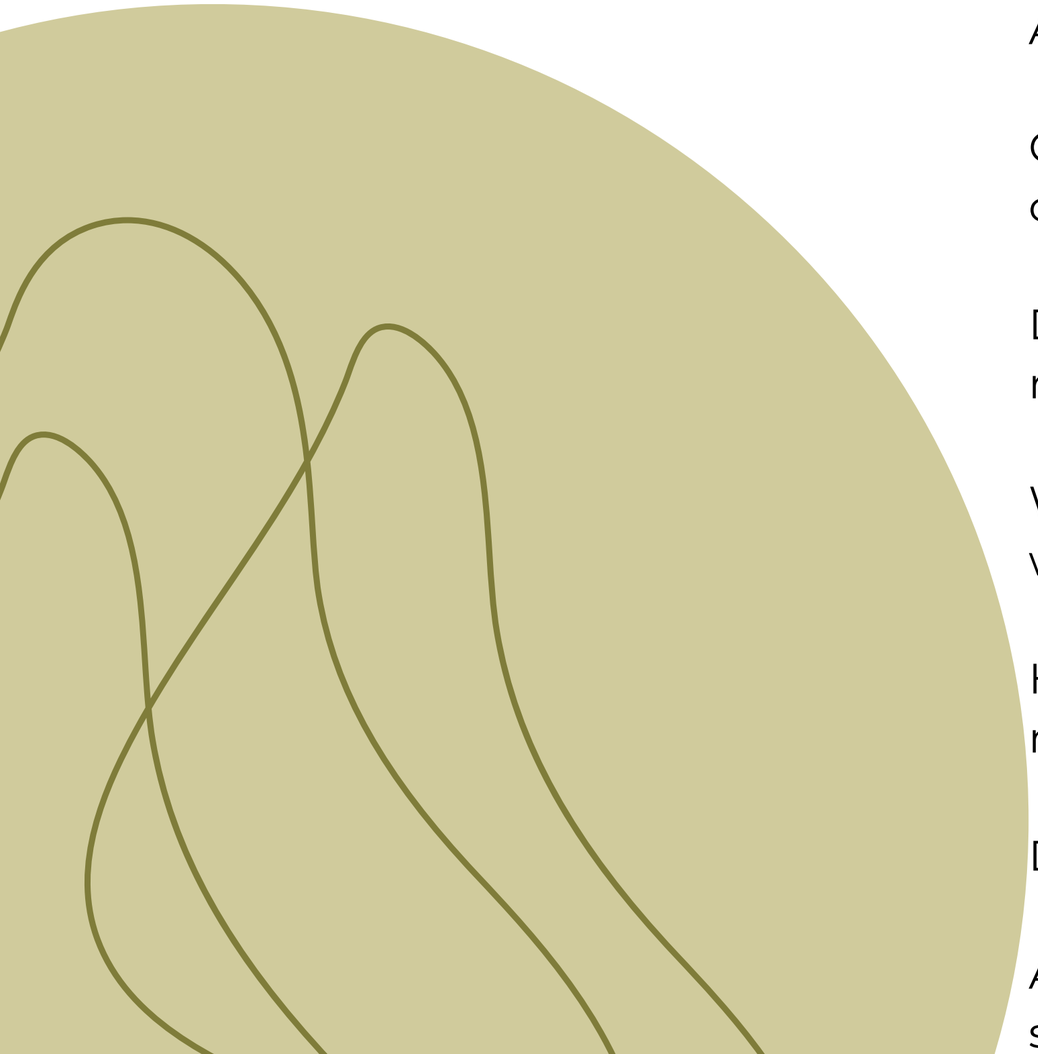
Ready to take action?



Are your starting to see a way forward?

Can you see how strategy-led regulatory helps your commercial success?

Do you believe clarity in structure will reduce reviewer pushback?

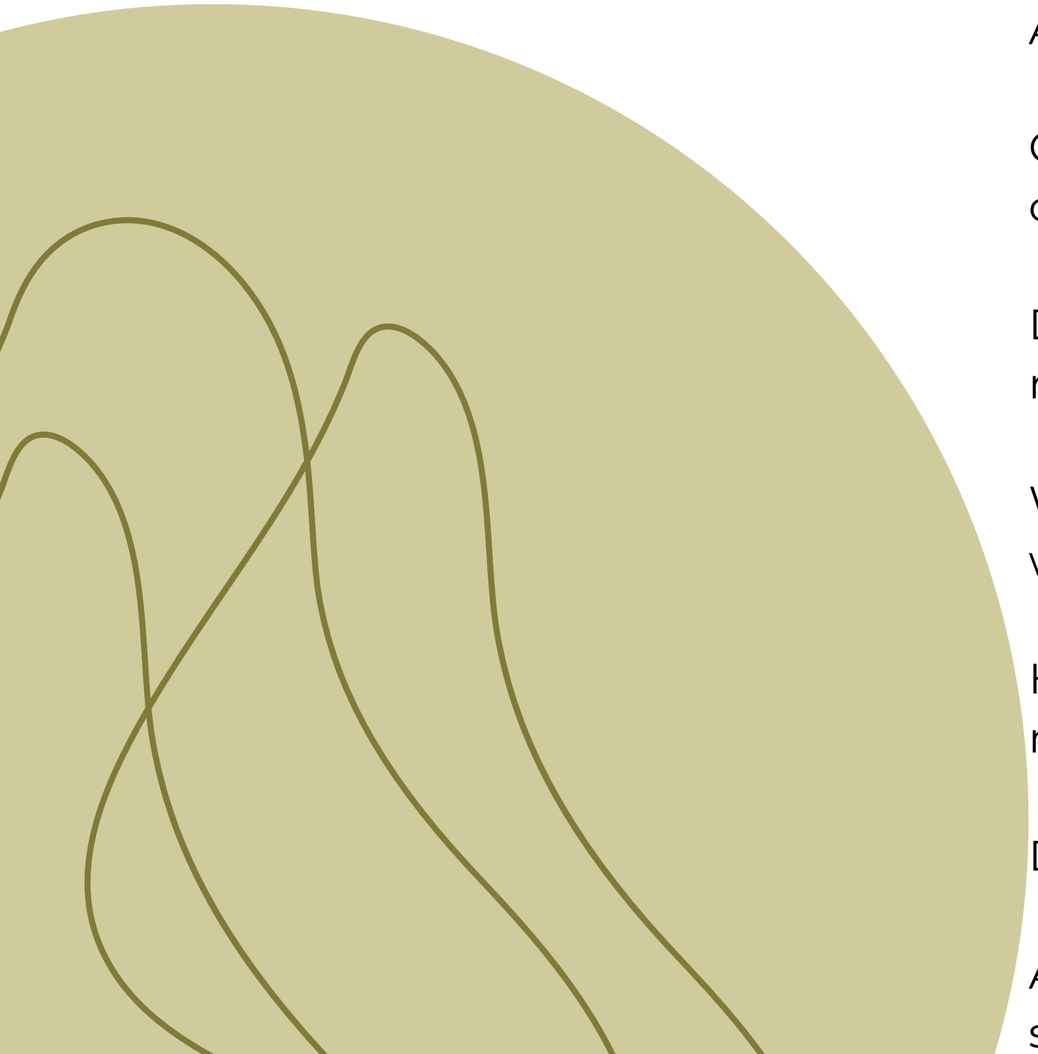
Would you like to feel more in control when dealing with the FDA?

How valuable is it to cut 6 months off your go-to-market?

Do you want to know exactly what to do next?

Are you someone who takes the lead - or waits and sees?

Ready to take action?



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Yes

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6 Steps towards a successful 510(k) submission

STEP 1: COMMERCIAL STRATEGY AND PRODUCT POSITIONING

- Define product's intended use
- Claims
- Performance characteristics (what does your product do, also: what does it NOT do)

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6 Steps towards a successful 510(k) submission

STEP 2: SELECT PREDICATE DEVICE & BUILD COMPARISON

- Use the substantial equivalence flowchart to build your comparison
- Identify device similarities
- Identify device differences & demonstrate why differences do not raise NEW issues of safety and effectiveness - demonstrate trust and control

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6 Steps towards a successful 510(k) submission

STEP 3: LINK CLAIMS, RISKS AND V&V

Map your device performance claims and risks against verification and validation data available to demonstrate a coherent and controlled story

- every performance claim must be backed by V&V data
- every risk must be supported by V&V data to demonstrate its acceptability

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6 Steps towards a successful 510(k) submission

STEP 4: PROACTIVELY IDENTIFY POTENTIAL CONCERNS

- Proactively include answer to potential concerns
- In case you do not have the answer (yet) or estimated cost is high: let FDA come back to you specifying what they want to see
  - opt for submitting a pre-submission before your actual 510(k) submission

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6 Steps towards a successful 510(k) submission

STEP 5: COMPOSE YOUR SUBMISSION FILE

- to the point
- smart
- structured
- formulate the conclusions you want your reviewer to make

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6 Steps towards a successful 510(k) submission

STEP 6: INSTALL A US FDA COMPLIANT QMS, BE PREPARED FOR QMSR

QSR = Quality System Regulation

- the existing FDA regulation found in **21 CFR Part 820**.
- contains the requirements (i.e. the “law”) for medical device manufacturers’ Quality Systems

QMSR = Quality Management System Regulation

- the **revised/updated regulation** which will replace the QSR (i.e. Part 820) starting **February 2, 2026**.
- incorporates ISO 13485:2016 by reference and aligns U.S. device QMS requirements more closely with international standards.

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QMSR: KEY DIFFERENCES AND IMPACT

• legal status / timing	• Enforceable regulatory framework from Feb 2, 2026
• terminology / structure	• Terminology and structure aligned with ISO 13485:2016
• incorporation of ISO standard	• ISO 13485:2016 by reference
• provisions	• General (A) and Supplemental (B) provisions
• scope/record access	• Removes or limits exemption for certain records
• risk/lifecycle	• Pushes for integrated risk-based thinking
• inspection method	• QSIT replaced by new inspection process

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Bonus 1

SPECIAL OFFER FOR PARTICIPANTS OF THE MASTERCLASS

Free, private ExploRAtion call:
“Full speed to a successful US adventure”

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What’s included?

- one-on-one deep dive
- Review your current approach
- spot efficiency wins
- discuss strategy and next steps

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What you get

- clarity
- confidence
- direction
- regained control

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INTERESTED TO LEARN MORE?

BOOK YOUR EXPLORATION CALL NOW!

WHAT IF I HAVE NO FDA EXPERIENCE AT ALL?

I guide manufacturers of innovative medical devices through the process so that they can proceed **fast** and **efficient**, with the knowledge of an expert and meanwhile **learn** during the process

DO I HAVE TO DO IT ALONE?

- No, I coach and walk with you step by step
- as the device expert, you will be providing input specific to the device
- Get support to create format and structure
- Get support to build regulatory strategy, predicate comparison and structuring verification and validation data

Introducing ‘510(k) accelerator’

INVEST ONCE. BUILD EXPERTISE FOREVER.

- 6 month group training program for medtech innovators entering the US market
- learn the full regulatory strategy behind a successfull 510(k)
- option to develop your **510(k) strategy** or your **full submission file** with me
- repeatable frameworks, templates and guidance you can use for every future device
- open for 5 participants

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your shortcut to clarity, confidence and long-term capability

Bonus

SPECIAL OFFER FOR PARTICIPANTS OF THE MASTERCLASS

510k preparation checklist

What it solves

- link your message to real evidence
- align commercial story with technical part of the submission

provided by e-mail to all attendees
after the masterclass

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What we have covered

- 8 insights to shift your mind and strategy on US market clearance
- 6 steps for a successful 510(k) submission
- 1 bonus 510(k) preparation checklist
- opportunity for free one-on-one deep dive

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Questions?

What do you still want to know?

Where do you feel unsure?

Link to free one-on-one session

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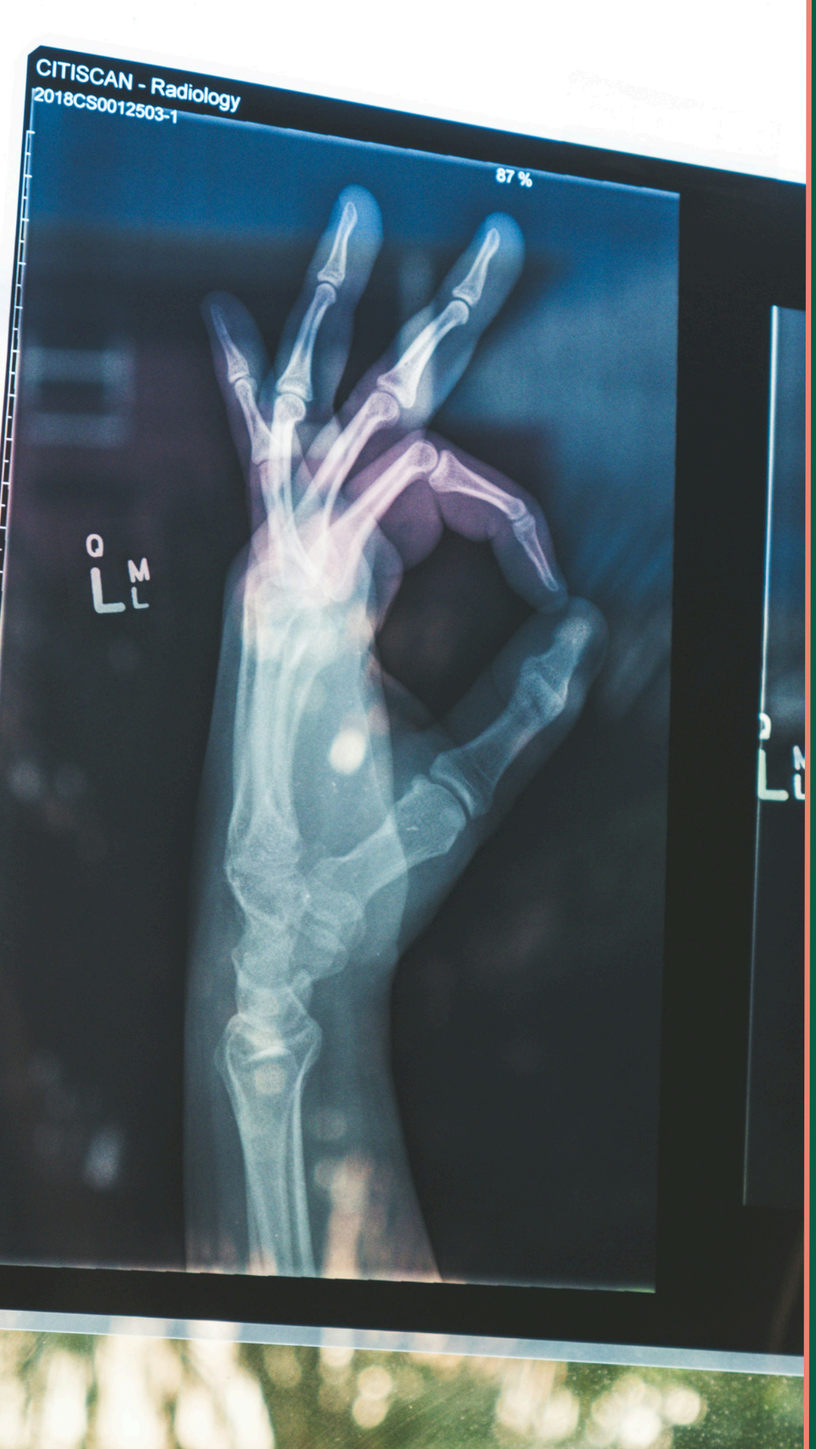

Thank you for your attention

“A SMART START IS FASTER THAN A BLIND SPRINT”