

# AI for Medical Device Quality Professionals

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# The Work Week Problem

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- Three months ago, I was clocking **55+ hour weeks** and drowning in **endless documentation**. Balancing kid obligations, family time and building a business. Meanwhile, my LinkedIn feed was full of AI success stories, and I felt like I was still waiting on the platform while everyone else had already boarded the train.
- After 20 years in regulatory and quality, I thought I'd seen it all. But the real challenge wasn't technical complexity—it was **the sheer volume of documentation needed to keep startups moving toward FDA submissions**.
- **Design requirements took days. Risk management files ate up entire weeks. SOPs, protocols, and CAPAs consumed precious time that should have gone to strategy.** I finally got curious—and scared enough of being left behind—that I decided to try AI.

# Why the FDA Is Already Ahead of Us

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While many of us debated whether AI was safe for regulatory work, the FDA jumped in back in 2023. They're already using AI for 510(k) reviews, spotting inconsistencies faster than we ever could.



They're running pattern recognition across clinical data, automating risk assessments, and analyzing quality systems with deeper insight than traditional reviews.



Here's the reality: the FDA now spots submission gaps before we even know they exist. This isn't about replacing us—it's about not getting outpaced by our own regulators.

# My 3 Month Learning Curve

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**Month 1:** I treated AI like a fancy Google. My prompts were basic, and the results were generic and textbook-like. Better than nothing, but far from client-ready.

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**Month 2:** Enter YouTube University. Tina Huang and Futurepedia completely shifted my prompting approach. I learned to provide role, context, examples, and constraints. Suddenly, AI gave me usable drafts tailored for startups.

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**Month 3:** Claude Projects changed the game. Dedicated projects held my style, templates, and client needs. But I also learned the hard way about AI hallucinations—like OSHA regulations that didn't exist—and about usage limits cutting me off mid-project. Now I fact-check everything and manage sessions more intentionally.

PS – I also have adjusted my settings on all the tools so my data is not used to train the model.

# My Personal AI Toolkit

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## Claude Pro:

Go-to for complex, long documents & submissions.  
Matches my writing style and carries context well.

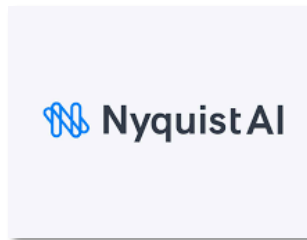


**Perplexity Pro:** Shortcut for regulatory research & updates.  
Hours of database digging reduced to minutes.



## ChatGPT Plus:

Quick Q&A partner for brainstorming, graphics, slide generation & backup when other tools hit limits.



## Nyquist AI:

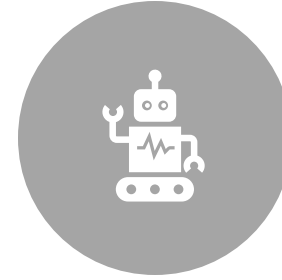
Specialized tool for predicate mapping & competitive intelligence—weeks of research done instantly.

➡ **Implementation Strategy:** Start with your biggest time sink, master one tool, then layer workflows and train your team.

# Where AI Shines (and Where It Doesn't)



AI DRAFTS INSTRUCTIONS FOR USE IN HOURS INSTEAD OF DAYS, STRUCTURES DESIGN REQUIREMENTS IN A DAY INSTEAD OF WEEKS, AND GENERATES CAPA REPORT FORMATS THAT CONSISTENTLY HOLD UP IN AUDITS.



BUT THERE ARE LIMITS. AI CANNOT—AND SHOULD NOT—REPLACE STRATEGIC DECISIONS, RISK JUDGMENT, OR CLIENT RELATIONSHIP MANAGEMENT. THOSE ARE MY NON-NEGOTIABLES.



AI IS A MULTIPLIER. IT SCALES EXPERTISE YOU CAN'T AFFORD TO HIRE, MAKING A SMALL TEAM PERFORM LIKE A LARGER ONE WITHOUT THE OVERHEAD.

# Personally Tested 3-Step Prompt System



1

**Step 1: Structure every prompt with role, instruction, context, examples, constraints, and output format.**

This gives AI the foundation it needs to be useful.



2

**Step 2: Run a reality check**

Ask: What assumptions were made? What would be impossible for a 10-person team? Then refine outputs for clarity, efficiency, and regulatory realism.



3

**Step 3: Save your wins.**

Reverse engineer prompts from the best outputs and build your own prompt library. That library becomes your AI playbook, cutting time and boosting consistency.

# Prompt Example: Design Requirements

- ✓ **Prompt:** Generate design requirements matrix for a mitral valve replacement.
- 👤 **Role:** Regulatory consultant for startup Medtech companies.
- 📋 **Instruction:** Develop compliant design requirements aligned to FDA and ISO standards.
- 👥 **Context:** Audience: Leadership team and design control file | Background: Startup with limited resources, preparing first FDA submission | Purpose: Compliant but efficient requirements | Tone: Professional and pragmatic
- ∞ **Constraints:** No ambiguous wording; realistic for startup budgets.
- 📄 **Output Format:** Matrix identical to FDA-approved examples.
- 🔨 **Result:** Cuts 1–2 weeks of drafting into 2 days with compliance-ready content.



# Refine

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## Evaluate

What assumptions did you make in this response

What might be missing based on the prompt

Is there anything that feels mismatched with the goal

Steel man the opposing view

## Iterate

Now rewrite this to be more concise

Add a bit of humor

Try a more emotional tone

Give me 3 variations with different pacing

## Optimize

Cut any unnecessary words

Make the instruction as clear as possible

Turn background info into tighter context

Ask the model how to optimize

# What not to Automate

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AI should **never** handle final strategy calls, CAPA root cause analysis, or client-specific risk assessments.

These demand professional judgment and carry too much weight for companies to gamble on.

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**The rule:** Let AI handle documentation structure and formatting.

You handle strategy, nuance, and decisions that shape funding and approval timelines.

# Next Steps

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**This week:** Sign up for Claude Pro, test my 3-step system on your biggest time sink, and track your time savings.

**This month:** Build your first 5 prompts for routine tasks, share your wins, and calculate ROI.

**This quarter:** Implement one full AI workflow & train others on what works. Start thinking strategically instead of drowning in documents.

**Bottom line:** AI amplifies expertise—it doesn't replace it. Use it to deliver safer, faster, smarter quality outcomes



Questions?