ClariMed

MedTech Usability PREP KIT

Avoid the Top 5 Failures That Kill FDA Submissions

A practical workbook from ClariMed's human factors and usability experts

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Disclaimer
This course and the accompanying workbook are provided for general educational purposes. The information reflects current best practices in human factors and usability engineering, but it is not intended as regulatory, compliance, or legal advice. Each organization is responsible for applying its own professional judgment and quality system to ensure conformity with applicable requirements.

The Billion-Dollar Blind Spot

A pharmaceutical giant spent billions developing a revolutionary drug, in an injection device, for the treatment of rheumatoid arthritis. It had the potential to enable patients with limited hand mobility to self-medicate at home instead of traveling to hospitals.

One problem: The patients couldn't open the package.

> *The pharma company had spent billions developing this life-changing drug. But, the patients could not open the packaging to get to the drug. The packaging of the drug delivery device was an afterthought.*
>
> **— Annmarie Nicolson, ClariMed**

This isn't rare. It happens frequently.

The Pattern That Costs Millions. Every failed device follows the same path:

1. Engineers design for ideal users in ideal conditions
2. Late-stage studies reveal fundamental problems
3. Changes now cost up to 100x what they would have earlier
4. FDA reject submission & launch is delayed
5. Competitors launch first

Your Two Choices

Option A: The Expensive Path

- Treat human factors as paperwork
- Test with users at the end
- Budget for rejection and redesign
- Risk a costly product recall

Cost: up to $2-5M redesign cost, 6-12 month delay

Option B: The Smart Path

- Deeply understand your users early
- Evaluate low-cost prototypes first
- Iterate, design, iterate
- Fix problems before they’re costly
- Pass regulatory review the first time

Investment: $200-500K HF cost, on-time launch

Failure #1

Speaking with the Wrong People

❗ The Core Challenge

Your advisory board loves the device. Your clinical experts approve. Your internal team successfully completes every task. None of that matters if real users can't operate it at 3 AM during an emergency.

> *If you're designing for home health, you need people who live in that context... not just trained professionals in a lab setting.*
>
> **— Wendy Sledge, ClariMed**

💸 The $2M Example

A ventilator company tested their device with respiratory therapists from a teaching hospital. The FDA rejected it—the device was actually intended for home health aides with high school education. When retested with the correct users, critical errors emerged, forcing a complete redesign.

Common Pitfalls

❌ **Using "super users"** who know your device too well
❌ **Evaluating with employees** who want you to succeed
❌ **Recruiting from advisory boards** who helped design it
❌ **Selecting participants** who are too educated/experienced
❌ **Non-realistic training** - more or less than what real users would receive

WORKBOOK: Define Your Users

User Population Checklist

Primary Users

- ☐ Job title(s): _____
- ☐ Education level: _____ ☐ Years of experience typical: _____
- ☐ Certification(s) required?: _____ ☐ Age range: _____

Accurate User Group Identification

Is there variation in tasks, responsibilities or workflow for your product? _____

Are the tasks these users perform institution, state, or country policy dependent? _____

Use Conditions That Matter

Lighting:	☐ Bright	☐ Variable	☐ Dark
Noise level:	☐ Quiet	☐ Moderate	☐ Loud or chaotic
Gloves worn:	☐ Never	☐ Sometimes	☐ Always
Time pressure:	☐ Low	☐ Moderate	☐ High
Interruptions:	☐ Rare	☐ Occasional	☐ Frequent

💰 Quick Cost Calculator

Cost to fix user issues found (illustrative ranges):

Concept phase:	$10-50K	$_____
Design phase:	$100-500K	$_____
After tooling:	$1-3M	$_____
After launch:	$5-20M + brand damage	$_____

Your current phase: _____ **Your risk exposure:** $_____

Failure #2

Starting After Design Freeze

❗ The Core Challenge

“We'll add human factors for the FDA submission" might be the most expensive sentence in medical device development. By design freeze, you've already made every key decision. A Human Factors evaluation now only reveals problems you can't afford to fix.

> *With rapid iterative methodologies, you conduct quick usability evaluations on low-to-mid-fidelity prototypes. This approach integrates user feedback seamlessly into development sprints.*
>
> **— Annmarie Nicolson, ClariMed**

⏳ **The Timeline Reality:** A device with 24-month development cycle

- **Months 1-6:** Concept development (HF should start here)
- **Months 6-12:** Design development
- **Months 12-18:** Detailed design (Most companies start HF here)
- **Months 18-24:** Verification & Validation (Too late for changes)

Starting HF at month 12 means you've already locked in 50% of your risk.

Common Pitfalls

❌ **"Our interface is intuitive"** - Says who?
❌ **"We'll fix it with training"** - FDA knows better: least reliable, and least consistent mitigation method
❌ **"It's similar to predicate"** - Similar isn't identical
❌ **"Clinical trials went well"** - Different from usability, clinical trials cover much of typical use, and don’t evaluate all high-risk tasks
❌ **"We'll test at validation"** - Validation isn't testing, it’s a confirmation of safety and efficacy

WORKBOOK: Your HF Timeline Audit

Where Are You Now?

Development Stage

- [ ] Concept (0-20% complete) — Perfect timing
- [ ] Early design (20-40%) — Good timing
- [ ] Detailed design (40-60%) — Getting risky
- [ ] Design freeze (60-80%) — Expensive fixes only
- [ ] Preparing validation (80-100%) — High stakes mode

What You Can Still Change

At your current stage, mark what's still changeable:

- [ ] Core functionality/workflow
- [ ] Physical control placement
- [ ] Alarms and alerts
- [ ] Instructions/training
- [ ] Screen layouts/information architecture
- [ ] Color coding/visual design
- [ ] Labels and symbols
- [ ] Nothing - all locked

Count your checkmarks: _____

0-2 checks: High risk of validation failure
3-5 checks: Moderate flexibility remains
6-8 checks: Well-positioned for success

WORKBOOK: Your HF Timeline Audit

🏆 The Three-Round Formula

(Illustrative human factors investment model — actual costs vary by program scope and device type)

Round 1: Concept (Low-Fidelity, "dummy"/non-functional prototype)

Cost: $15-25K **Saves:** $2M+ in architecture changes

Round 2: Design (Working prototype)

Cost: $35-50K **Saves:** $500K in tooling changes

Round 3: Pre-validation (Final device)

Cost: $60-85K **Saves:** 6-month FDA delay

Total investment: $110-160K Potential savings: $2.5M+ and 6 months

Failure #3

Perfect Lab Syndrome

❗ The Core Challenge

Your beautiful usability lab has perfect lighting, no distractions, and unlimited time. It represents exactly nowhere your device will actually be used. Real healthcare happens in chaos. If you're not conducting studies in chaos, you're not generating realistic data.

> ***Documentation has to stand on its own****... if someone else reads it without context, they should reach the same conclusions you did.*
>
> **— Kay Sim, ClariMed**

🚨 **The Emergency Room at 3 AM:** Here's what your device might actually face

- Nurse on hour 11 of 12-hour shift
- Three alarms sounding simultaneously
- Doctor yelling orders from next bed
- Overhead light broken two weeks ago
- Last training was six months ago on different model of device
- Patient's family asking questions
- Two minutes to complete setup

Your usability lab setup missed all of that.

Common Pitfalls

❌ **Perfect lighting** when users work in shadows
❌ **Silence** when real use is noisy, and there are distractions
❌ **Unlimited time** when seconds matter
❌ **Expert observers** coaching participants
❌ **One task at a time** when users multitask

WORKBOOK: Reality Test Your Testing

Environmental Reality Check

Your Testing Environment

Factor	*Your Test*	*Real World*	*Gap Risk*
Lighting	_____	_____	☐ H ☐ M ☐ L
Noise	_____	_____	☐ H ☐ M ☐ L
Interruptions	_____	_____	☐ H ☐ M ☐ L
Time constraints	_____	_____	☐ H ☐ M ☐ L
Concurrent tasks	_____	_____	☐ H ☐ M ☐ L
Physical position	_____	_____	☐ H ☐ M ☐ L

Any "H" = Validation failure risk

WORKBOOK: Reality Test Your Testing

The Simulation Checklist

For your next test, which can you simulate?

- [ ] Dim lighting conditions
- [ ] Gloved hands/additional PPE
- [ ] Background noise/alarms
- [ ] True, not idealized positioning
- [ ] Interruption scenarios
- [ ] Stressed/tired users
- [ ] Time constraints
- [ ] Competing priorities

Quick Reality Check

Testing in perfect conditions when your device will be used in chaos often leads to:
(Illustrative examples — trends based on industry experience, not formal data)

- *Unforeseen Use Problems, & major failures in Validation testing*
- *Far lower FDA acceptance rates*
- *Higher post-market failure risk*
- *More customer complaints and corrective actions*
- *Longer training requirements and onboarding times*
- *Loss of trust in your brand*

Worth the risk to save $50K on realistic testing?

Failure #4

The Training Excuse

❗ The Core Challenge

"We'll address that with training" is the engineering equivalent of "The check is in the mail." FDA knows training degrades. Users skip it. New staff miss it. Stressed people forget it. If your device needs extensive training to be safe, it's not safe.

> *Final reports need to clearly address residual use-related risk... whether you've mitigated it, documented a rationale, or made further changes.*
>
> **— Kay Sim, ClariMed**

📚 The Training Decay Curve: *(illustrative ranges)*

Day 1 after training: 100% retention
Week 1: 80% retention
Month 1: 60% retention
Month 6: 30% retention
Emergency situation: 10% retention

Your design must work at 10%, not just at 100%.

Common Pitfalls

❌ **Complex workflows** requiring memorization
❌ **Non-intuitive controls** needing explanation
❌ **Critical steps** that are easy to skip
❌ **Warnings buried** in manuals
❌ **Assuming users will read** instructions

WORKBOOK: Training Reality Assessment

The Honest Training Audit

Your Current Training Requirements

Task	*Training Needed*	*Without Training*	*Risk Level*
Initial setup	_____ minutes	☐ Success ☐ Fail	☐ H ☐ M ☐ L
Basic operation	_____ minutes	☐ Success ☐ Fail	☐ H ☐ M ☐ L
Emergency response	_____ minutes	☐ Success ☐ Fail	☐ H ☐ M ☐ L
Maintenance	_____ minutes	☐ Success ☐ Fail	☐ H ☐ M ☐ L
Troubleshooting	_____ minutes	☐ Success ☐ Fail	☐ H ☐ M ☐ L

Any "Fail" without training = FDA red flag

WORKBOOK: Training Reality Assessment

Design vs. Training Fixes

For each issue found in testing:

Issue	*Design Fix*	*Labeling Fix*	*Training Fix*	*FDA Preference*
_____	☐ Possible	☐ Possible	☐ Possible	Design
_____	☐ Possible	☐ Possible	☐ Possible	Design
_____	☐ Possible	☐ Possible	☐ Possible	Design
_____	☐ Possible	☐ Possible	☐ Possible	Design

FDA Rule: Design out problems > Guard against them > Warn about them > Train for them

The Training Cost Truth

Real training costs per facility: *(illustrative ranges)*

- *Initial training session: $5,000-10,000*
- *Annual refreshers: $2,500-5,000*
- *New staff onboarding: $500-1,000/person*
- *Documentation/certification: $1,000-2,500*

10 customers × 5 years = $250,000-500,000

Could you invest that in better design instead?

Failure #5

Single Market Tunnel Vision

❗ The Core Challenge

Design for FDA. Pass FDA. Discover your device needs major changes for Europe. Redesign. Retest. Resubmit. Watch competitors eat your lunch globally. Smart companies design for global, test strategically, and prepare to submit everywhere.

We map URRA outputs directly to risk files and design control inputs so nothing falls through the cracks.

— Jessica Parry, ClariMed

🌍 The Global Reality: *Your device probably needs to work in*

- **USA:** FDA's 15-person minimum
- **Europe:** Local language requirements
- **UK:** Separate UKCA marking post-Brexit
- **Canada:** Bilingual labeling
- **Japan:** Cultural use patterns matter

Missing any of these doubles your timeline for that market.

Common Pitfalls

❌ **English-only testing** for global device
❌ **US-only participants** for worldwide sales
❌ **Ignoring cultural differences** in device use
❌ **Sequential market approach** vs. parallel
❌ **Assuming FDA approval** works everywhere

WORKBOOK: Global Market Planning

Market Priority Matrix

Market	*Revenue Potential*	*Regulatory Path*	*Ready?*
USA	$_____	☐ 510(k) ☐ De Novo ☐ PMA	☐ Yes ☐ No
EU	$_____	☐ CE Mark under MDR	☐ Yes ☐ No
UK	$_____	☐ UKCA Mark under MHRA	☐ Yes ☐ No
Canada	$_____	☐ Health Canada	☐ Yes ☐ No
Japan	$_____	☐ PMDA	☐ Yes ☐ No
Other: _____	$_____	☐ _____	☐ Yes ☐ No

Total addressable market: $_____

Markets you're ready for: _____

Revenue you're leaving behind: $_____

WORKBOOK: Global Market Planning

Harmonization Quick Check

Can you answer "Yes" to these?

- [ ] Design works for all target markets
- [ ] Testing includes global user populations
- [ ] IFU translated/validated for each market
- [ ] Cultural use patterns considered
- [ ] Local regulatory requirements mapped
- [ ] Single protocol covers all regions

If less than 4 "Yes" = Sequential launches required

The Time & Cost Impact

Parallel Global Launch:

- *Additional investment: $200-400K*
- *Time to global market: 12-18 months*
- *First-mover advantage: Priceless*

Sequential Launch:

- *Cost per market: $150-250K*
- *Time per market: 6-12 months*
- *Time to global market: 3-5 years*
- *Revenue lost to competitors: $10-50M*

ROI on global planning: 10-25x

Your 7-Point Assessment

Take 3 Minutes. Save 3 Years.

Rate each area honestly:

Area	Strong (2pts)	Adequate (1pt)	Weak (0pts)
1. User populations defined	☐	☐	☐
2. Use environments mapped	☐	☐	☐
3. Risk analysis complete	☐	☐	☐
4. Known-Use Problems Review	☐	☐	☐
5. Formative evaluation with representative end users	☐	☐	☐
6. Global requirements addressed	☐	☐	☐
7. Validation protocol ready	☐	☐	☐

What Your Score Means

12-14	8-11	4-7	0-3
Ready for submission	Gaps to address	Significant risk	High rejection probability

IF YOU SCORED BELOW 10
you need expert help now.

Every month of delay costs you market share and revenue

Free ClariMed 7-Point Usability Assessment includes:

- ✓ Gap analysis against FDA requirements
- ✓ Risk prioritization matrix
- ✓ Budget and timeline estimate
- ✓ Go/No-Go recommendation
- ✓ 30-minute expert consultation

Schedule Your Free Assessment

clarimed.com/assessment | assessments@clarimed.com | 1-800-CLARIMED

Assessment valued at $2,500. Free for qualified medical device companies.

About ClariMed

Why Teams Trust ClariMed

We're not academics teaching theory. We're practitioners who've guided hundreds of devices through FDA, EU MDR, and global submissions.

Our Unique Approach

Early Integration: We start where others won't—at the concept stage when changes cost pennies, not millions.
Global Perspective: With teams in the US and UK, we design once for worldwide success.
Real-World Evaluation: We test in chaos because that's where devices actually get used.

A few of the Team Members Behind Your Success

Annmarie Nicolson: Pioneered rapid iterative testing methods that catch problems when they're cheap to fix.

Denise Forkey: Navigates 25+ years of FDA submission complexities, adapting strategies as reviewers shift while maintaining deep connections across CDER and CDRH communities.

Jenny Collinson: Bridges the gap between global regulatory requirements (US, EU, China, Japan) and development team realities, building HFE processes that actually work from concept to launch.

Kay Sim: Ensures that HF fits seamlessly into your DHF, through traceability to Risk Management and Design Controls and that your submissions approach is what's best for your product.

Jessica Parry (C. ErgHF): Guides EU/UK submissions from our Leeds facility, ensuring global harmonization.

Wendy Sledge: Recruits real users who break devices in ways engineers never imagine.

Kelley Kendle, CEO: Drives the vision—human factors isn't paperwork, it's your competitive advantage.

About ClariMed

The Bottom Line

Every team faces a choice:

1. Hope your device is "intuitive enough."

Typical outcome: Higher risk of FDA rejection, costly redesigns, and months of delay.

OR

2. Know your device will pass.

Typical investment: 2–4% of your development budget in early human factors work.
Typical outcome: First-time approval, faster launch, stronger market position.

Ready to choose confidence over chance?

Start with our free 7-Point Assessment

No sales pitch. No obligation. Just clarity on where you stand and what you need.
clarimed.com/assessment