
HUMAN FACTORS & USABILITY

MedTech Usability Prep Kit

Avoid the top 5 failures that kill
FDA submissions

A practical workbook from ClariMed's human factors
and usability experts. Five failure patterns, and the
audits that catch them early.



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DISCLAIMER

This workbook is 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 rheumatoid arthritis. It had the potential to let patients with limited hand mobility 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, and every failed device follows the same path.

THE PATTERN THAT COSTS MILLIONS

- 1 Engineers design for ideal users in ideal conditions
- 2 Late-stage studies reveal fundamental problems
- 3 Changes can cost many times what they would have earlier
- 4 FDA rejects the submission and 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: \$2–5M redesign, 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
Improve your odds of first-time approval

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

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

CASE IN POINT

\$2M

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 a 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 or experienced
- ✗ Non-realistic training: more or less than what real users would receive

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

Gloves worn

Never

Sometimes

Always

Time pressure

Low

Moderate

High

Interruptions

Rare

Occasional

Frequent

QUICK COST CALCULATOR

Illustrative ranges: cost to fix user issues found

Concept phase

\$10–50K

\$ _____

Design phase

\$100–500K

\$ _____

After tooling

\$1–3M

\$ _____

After launch

\$5–20M+

\$ _____

Your current phase _____

Your risk exposure \$ _____

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 a 24-month development cycle

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

Starting HF at month 12 means most key design decisions are already locked in.

COMMON PITFALLS, AND WHY THEY FAIL

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

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 | ☐ Screen layouts / information architecture |
| ☐ Physical control placement | ☐ Color coding / visual design |
| ☐ Alarms and alerts | ☐ Labels and symbols |
| ☐ Instructions / training | ☐ Nothing, all locked |

Count your checkmarks (excluding “Nothing, all locked”)

0–2

High risk of validation failure

3–5

Moderate flexibility remains

6–8

Well-positioned for success

The three-round formula

An illustrative human factors investment model. Actual costs vary by program scope and device type.

01**Concept**

Low-fidelity, non-functional
"dummy" prototype

COST

\$15–25K

SAVES

\$2M+ in architecture
changes

02**Design**

Working prototype

COST

\$35–50K

SAVES

\$500K in tooling
changes

03**Pre-validation**

Final device

COST

\$60–85K

SAVES

A 6-month FDA delay

TOTAL INVESTMENT

\$110–160K

POTENTIAL SAVINGS

\$2.5M+

and six months of schedule

Three modest, well-timed rounds cost less than one late redesign, and they buy the one thing a redesign can't: time on the market.

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.

REALITY CHECK

The emergency room at 3 AM

Here's what your device might actually face.

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

Your usability lab setup missed all of that.

COMMON PITFALLS

- ✗ Perfect lighting when users work in shadows
- ✗ Silence when real use is noisy and full of distractions
- ✗ Unlimited time when seconds matter
- ✗ Expert observers coaching participants
- ✗ One task at a time when users multitask

Environmental reality check

For each factor, describe your test environment and the real one, then rate the gap risk.

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"

is a validation failure risk. Close the gap in your protocol before you close the study.



Next: can you simulate the chaos?

Turn the page for the simulation checklist and the real cost of testing in perfect conditions.

Page 11 →

The simulation checklist

For your next test, mark everything you can realistically 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 the following. Illustrative examples based on industry experience, not formal data.

- Unforeseen use problems, and 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?

Answer honestly.



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.

THE TRAINING DECAY CURVE

ILLUSTRATIVE RETENTION RANGES AFTER A SINGLE TRAINING SESSION



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

The honest training audit

For each task, mark the outcome without training, the risk level, and how many minutes of training you currently require.

TASK	WITHOUT TRAINING	TRAINING TIME	RISK LEVEL
Initial setup	☐ Success ☐ Fail	 min	☐ H ☐ M ☐ L
Basic operation	☐ Success ☐ Fail	 min	☐ H ☐ M ☐ L
Emergency response	☐ Success ☐ Fail	 min	☐ H ☐ M ☐ L
Maintenance	☐ Success ☐ Fail	 min	☐ H ☐ M ☐ L
Troubleshooting	☐ Success ☐ Fail	 min	☐ H ☐ M ☐ L

Any "Fail"

without training warrants scrutiny. FDA prefers design fixes over training fixes.

Design fixes vs. training fixes

List each issue found in testing, then mark which fixes are possible.

ISSUE

DESIGN

LABELING

TRAINING

FDA PREFERS

☐☐☐

Design

☐☐☐

Design

☐☐☐

Design

☐☐☐

Design

THE FDA HIERARCHY

Design out problems

>

Guard against them

>

Warn about them

>

Train for them

THE TRAINING COST TRUTH

Real cost 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?



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 URRAs 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 all of these

USA	FDA guidance recommends 15 participants per user group
Europe	Local language requirements
UK	UKCA route post-Brexit; CE marking still accepted for limited periods
Canada	Bilingual labeling
Japan	Cultural use patterns matter

Missing any of these can significantly extend your timeline for that market.

COMMON PITFALLS

- ✗ English-only testing for a global device
- ✗ US-only participants for worldwide sales
- ✗ Ignoring cultural differences in device use
- ✗ A sequential market approach instead of parallel
- ✗ Assuming FDA approval works everywhere

Market priority matrix

Estimate revenue potential per market, circle the regulatory path, and mark whether you're ready today.

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
_____	\$ _____	_____	☐ Yes ☐ No

TOTAL ADDRESSABLE
MARKET

\$ _____

MARKETS YOU'RE
READY FOR

REVENUE LEFT BEHIND

\$ _____

Harmonization quick check

Can you answer “yes” to each of these today?

- ☐ Design works for all target markets
- ☐ Testing includes global user populations
- ☐ IFU translated and validated for each market
- ☐ Cultural use patterns considered
- ☐ Local regulatory requirements mapped
- ☐ A single protocol covers all regions

Fewer than four “yes” answers means sequential launches.

THE TIME & COST IMPACT

Illustrative ranges. Actual results vary by program.

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

10–25×

YOUR 7-POINT ASSESSMENT

Take 3 minutes. Save 3 years.

Rate each area honestly. Strong scores 2 points, adequate 1, weak 0.

AREA	STRONG · 2	ADEQUATE · 1	WEAK · 0
1 User populations defined	☐	☐	☐
2 Use environments mapped	☐	☐	☐
3 Risk analysis complete	☐	☐	☐
4 Known-use problems reviewed	☐	☐	☐
5 Formative evaluation with representative intended users	☐	☐	☐
6 Global requirements addressed	☐	☐	☐
7 Validation protocol ready	☐	☐	☐
YOUR TOTAL SCORE			/ 14

WHAT YOUR SCORE MEANS

12-14

Ready for submission

8-11

Gaps to address

4-7

Significant risk

0-3

High rejection probability

If you scored below 8, you need expert help now.

Every month of delay costs you market share and revenue.

The 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

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.

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

Anmarie 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 reviewer expectations shift, with deep experience across the CDER and CDRH communities.
Jenny Collinson	Bridges global regulatory requirements (US, EU, China, Japan) and development team realities, building HFE processes that work from concept to launch.
Jessica Parry, C. ErgHF	Guides EU and 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.



Clarifying the pathway for usable medical products.

Contact us to discuss how we can advance your medical device development efforts together.

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