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Product Development for Medical, Life Sciences and Consumer Health

Usability Testing for FDA Validation

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Topics

- Why is usability testing required for FDA validation?
- How is validation testing different from other testing?
- Conducting the test (infusion pump example)
- Preparing the FDA report
- Case study: Drug delivery device
- Relevant standards and regulations

Why is usability testing required?

Why is usability testing required?

Testing for ease and accuracy of use is the **only way to ensure** that users can **safely and effectively** operate, install, and maintain devices.

This process **culminates in full testing** of a model embodying all the user-interface characteristics for both hardware and software of a fully functioning device.

-- from the FDA (1996), *Do It By Design*

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US: Quality System Regulation 21 CFR 820

Subpart C - Design Controls

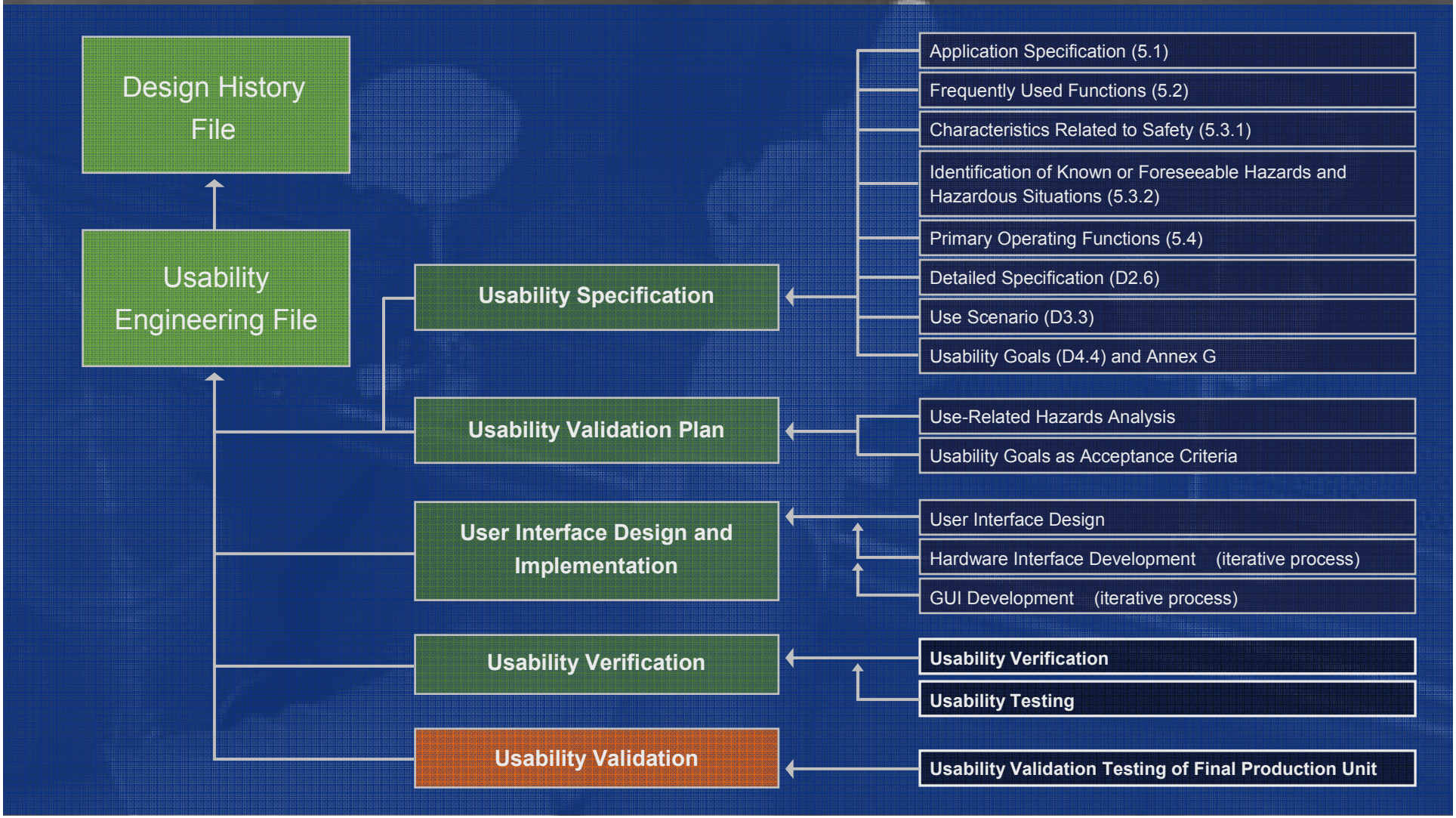
The need for human factors techniques or data in the design process is implicit in paragraphs c, f, and g of Section 820.30.

(g) Design validation: "Design validation shall ensure that devices conform to defined user needs and intended uses, and shall include testing of production units under actual or simulated use conditions."

Human factors relevance: Design validation should be used to demonstrate that the potential for use error that can lead to patient injury has been minimized. **The regulation requires testing the device under actual or simulated use conditions.** Realistic use conditions, therefore, should be carried out by test participants who represent a range of typical intended users in terms of their ability to acquire information from, manipulate, and maintain the device and understand the accompanying labeling.

From the FDA -- *"Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation"*

ISO: 62366 Usability Engineering Process



How is validation testing different?

This is the **most important** HFE report that the FDA reviews

Iterative, formative usability testing is already done

It should **tie back to**:

- User profiles
- FMEA
- Usability goals

It must validate the **safety and usability** of the device

Conducting the validation test

Designing the test

Select & recruit **participants**

Select **tasks or features** to be tested

Select measures

Prepare the test materials

Handle **logistics** & preparation

Run a pilot test

Example

What are some **user profiles** for a test of an infusion pump?

Example

What are some **user profiles** for a test of an infusion pump?

- Nurses – specify
- Physicians – specify
- Others?

How many participants?

No specific number required by the FDA

Sample size should be larger than for formative tests

Consider the impact of potential **use errors**

Consider the **variability** of patient population

Ron Kaye of the FDA[1]:

> "Upwards of 25 participants [per user group] seems about right…Rarely does small sample size arise as FDA's primary reason for viewing a particular summative human factors test as unsatisfactory. Rather it is that the selected user tasks exclude some of the critical ones, the participants do not effectively represent the user population, the performance measurements are not germane, or there is no clear link between the test results and safety."

[1] "Usability Testing: Validating User Interface Design," by Michael Wiklund, Medical Device & Diagnostic Industry, 2007.

Selecting tasks

Primary operating functions (POFs)

Subset - frequently performed functions

Address a **safety concern**

Performed under stress

Redesigned after previous testing

Illustrate error recovery

Example

What are some **tasks** you might test on an infusion pump?

Example

What are some **tasks** you might test on an infusion pump?

- Turn on the pump
- Set it up for drug administration by keying in the flow rate and volume-to-be-infused parameters
- Install the administration set
- Perform primary and secondary infusion
- Change parameters
- React to an emergency
- Set alarms
- Silence alarms

Selecting measures

Objective measures

- Measures of performance
- Observable

Subjective measures

- Ratings, opinions, comments

Base these on your **usability goals**

Which ones can be quantified?

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Example

What are some **measures** you might use when testing an infusion pump?

Example

What are some **measures** you might use when testing an infusion pump?

- Task times
- Number of errors
- Types of errors
- Completed tasks (%)
- Usability ratings
- Failure to react to alarms
- Satisfaction with control layout

Conducting the sessions

Where to conduct the test?

How long should sessions take?

Who should **moderate**?

Should participants **think aloud**?

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Conducting the sessions

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Who should **moderate**?

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Typical outline:

Introduction & informed consent

Pre-test questionnaire

User performs tasks

- Objective & subjective data collected

Post-test interview and ratings

Preparing the FDA report

Analyzing the data

Analyze **quantitative** data

- Calculate descriptive stats

Analyze **qualitative** data

- Moderator's & observers' notes
- Questionnaires & rating sheets
- Pre- and post-test interview results

Identify **usability issues**

Identify any residual **safety risks**

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Examples of usability issues

Nurses **can't figure out** how to insert tubing in an infusion pump

Lab technicians load disposables into the wrong drawer

Nurses **incorrectly program** parameters in a patient monitor

Patients misinterpret the LEDs on a ventricular assist device

Surgeons experience **pinch points** with a hand-held instrument

Acceptance criteria

What constitutes a **successful task outcome**?

It is difficult to establish a criterion for pass-fail rates

90%? 95%? 99%?

Each error/failure must be carefully analyzed – does it place the user or patient at risk?

Example:

For this study, at least 28 of the 30 subjects must have registered a "success" for a particular scenario for the design to pass usability validation. The design must also score an average of 4.0 or higher on a 5-point scale in order to pass usability validation.

Report format

There is no prescribed format

Tie it back to the FMEA

Was usability **validated** or not?

Are additional design changes needed?

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Tie it back to the FMEA

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Typical outline:

Purpose

Methodology

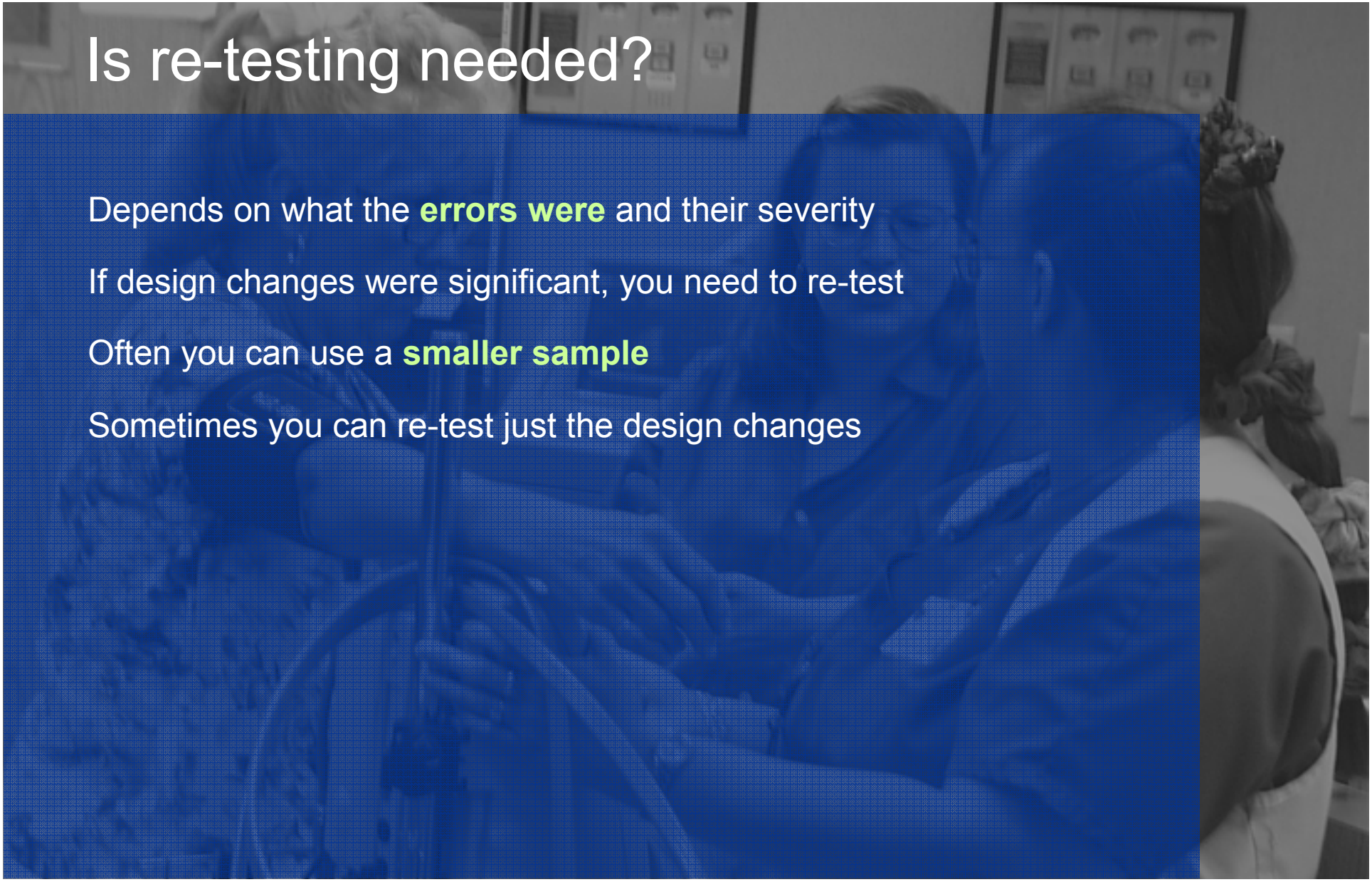
Data analysis

Task success rates

Errors and usability issues

Conclusions (pass/fail)

Is re-testing needed?



Depends on what the **errors were** and their severity

If design changes were significant, you need to re-test

Often you can use a **smaller sample**

Sometimes you can re-test just the design changes

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Case study: Drug delivery device

Client submitted for 510(k) clearance, but FDA required validation testing

- **User profiles:** Patients and health care professionals
- **Selected tasks:** All primary operating functions
- **Measures:** Objective and subjective, based on hazards analysis
- **Materials:** Two detailed moderator's scripts, training, IFUs
- **Test environment:** Market research facility
- **Data collection:** Real-time using carefully designed spreadsheets
- **Analysis:** Completed by client, reviewed by Farm
- **Results:** Showed hazards had been addressed, no new issues

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Final thoughts

Usability testing should be **iterative** during the design process

Validation testing is **required** for CE Mark & FDA

Validation testing must include **safety-critical** tasks

Validation testing must be done with **actual users** in **actual or simulated** environments

Standards & regulations

FDA Quality System Regulations

21 CFR 820.30, Subpart C

Design Controls, paragraphs c, f, and g

ANSI/AAMI HE74:2001

Human Factors Design Process for Medical Devices

ANSI/AAMI HE75:2009

Human Factors Engineering – Design of Medical Devices

ISO/IEC 62366:2008

Application of Usability Engineering to Medical Devices

Do It By Design (FDA, 1996)

An Introduction to Human Factors in Medical Devices

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