



How to Use UX to Streamline Medical Device Product Cycles

Presented by Don Goetz - Manager of User Experience Milton Yarberry - Director of Medical Programs

Integrated Computer Solutions Inc.





MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.





GO Premarket Quality Management Software

GROW Postmarket Quality Management Software

GURU QA/RA Medical Device Expert Services "Greenlight Guru Software is the handrail for Medical Device Development and Documentation"

"My QMS is world class"



About ICS

- Founded in 1987, 120 employees
- HQ in Boston, offices in the Bay Area and Ottawa
- We provide:
 - UX design services
 - UI development
 - Custom software development services
 - ISO 13485-compliant development process
 - Linux and QNX platform and board support
 - Full end-to-end product realization
 - Qt training
- Our UX First approach means products we design are developed on time and on budget
- We deliver 70+ projects annually for global brands





Boston UX

- User experience (UX) design to help you with your IEC 62366 compliant process
- Offering a full suite of user experience services:
 - Product vision and direction
 - o UX design
 - Visual & motion design
 - Voice integration design
 - Usability research and testing





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About Us

- Don Goetz
 - Manager of User Experience, Boston UX/ICS
- Milton Yarberry
 - Director of Medical Programs, ICS



Agenda

- What is UX Design?
- Our UX Design Process
- Regulated Design
- Reducing Development Cycles
- Q&A

What is User Experience and UX Design?

• User Experience

- "User experience" encompasses all aspects of the end-user's interaction with the company, its services, and its products. (Nielsen Norman Group)
- User Experience Design
 - User experience (UX) design is the process design teams use to create products that provide meaningful and relevant experiences to users. (Interaction Design Foundation)





Our UX Design Process









Key Process Points

- This is an inclusive and iterative process
 - Stakeholders should be involved throughout the entire exercise
 - This allows the designers to lean on their expertise when needed, while also keeping them in the loop and informed
- This may look like a linear process, but it's not
 - Our process usually uses an agile development process
 - It does also work in the waterfall model, if a client prefers
 - Different sections of an application are designed and developed concurrently



• Patient Health Home Monitoring System





Poll Question

I am happy with my organization's UX design process?

- Agree
- Disagree
- We do not have a UX Design Process





Discover

- Laying the foundation for the project
- Includes
 - Project alignment
 - Domain immersion
 - Market research
 - Requirements gathering
 - Regulator standards being followed (HE 75, IEC 62366)
 - Hardware specification (Touch vs. Multi-Touch, etc.)
- Potential deliverables
 - UX Design plan



Understand

- Gathering project information and translating it into actionable design goals
- Feedback from the SMEs, stakeholders and actual users are critical
- This phase sets the stage for the rest of the project
 - This is where you layout all of the initial requirements for the project





Understand

- Tasks include determining:
 - Who the users are and what their use environments are
 - What tasks are to be performed
 - What are the functional requirements
 - What are the technical limitations
 - What the initial information architecture will be



Understand

- Potential Deliverables
 - User research report
 - Formal definition of objectives and project success
 - Exploratory screen designs
 - Potential visual design directions
 - Delivery schedule
 - \circ User personas
 - Use cases/user stories
 - Initial information architecture



Design

- This is where the work that most people think of as "design" gets done
- This is an iterative process
 - Many design revisions may be needed
 - May need to return to the Understanding Phase to get more information for the design





Design

• Tasks include:

- Sketching and critiquing ideas
- Establishing system workflows
- Low-fidelity wireframing
- Prototyping design solutions
- Hi-fidelity mockups
- Creating design patterns and styles



Design

- Potential deliverables:
 - Final information architecture
 - Workflow diagrams
 - Wireframes
 - Mockup prototype
 - Hi-fidelity mockups



Evaluate

- Testing designs and analyzing results
- Iterative process
 - The results of this phase can lead to significant changes
 - You may need to return to the Understanding or Design phase to make these changes





Evaluate

• Tasks include:

- Usability assessments
- Contextual inquiry
- Heuristic review
- Put in more if we have them

• Deliverables

- User testing summary
- Changes that need to be made in the next design iteration



Deliver/Support

- Set up development for success
- Tasks include
 - Handoff of elements needed by the dev team
 - QA of developed screens
- Potential Deliverables
 - Design system
 - Visual specifications
 - Interaction specifications
 - Asset package
 - Build-ready components
 - QA buglist



Our UX Design Process









Poll Question

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What do you find most challenging relative to UX Design?

- Management buy-in
- Lack of internal resources
- Finding designers that understand medical device development





Regulatory UX - User Related Errors

- History of medical device use related errors
 - Relatively recent 1995 "use error" is coined (MD+DI)
 - Good old days
 - "Made a mistake", "lapse of attention", "mental slip", "stupid brain"
 - Human error or lapse, implying a user's accountability, isolated event
 - Use vs. User
 - Use Error user interface designs that contribute to users making errors
 - User Error attributed to the user, implying the user's accountability (slips, lapses, mistakes)
 - More precisely, Use Error:
 - "an act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user" (per ISO 14971, IEC 62366) → pretty broad!
 - "use errors are the direct result of poor user interface design" (IEC 62366, Annex A) → points the finger!

User Related Errors 2

• Tie in to "Safe and Effective"

- "Safe and effective use of a medical device means that users do not make errors that lead to injury and they achieve the desired medical treatment. If safe and effective use is not achieved, use error has occurred. Why and how use error occurs is a <u>human factors</u> concern" (FDA Glossary of Medical Devices)
- Use Error fixes: *Training? Labeling?*
- User Errors are not allocatable
- Use Errors *need to be fixed*



HF/UX Standards

 EC 62366:2007 Medical Devices - Application of usability engineering to medical devices 		2015 IEC 62366:2015 IEC breaks standard into two parts. Part 1: Application of usability engineering to medical devices.
	• 2011 FDA Draft Guidance FDA Publishes "Applying Human Factors and Usability Engineering to Medical Devices"	2016 FDA Final Guidance

HF/UX Rationale

- USERS AND ENVIRONMENTS Identify and analyze intended users and expected use scenarios and use environments
- HAZARDS AND CONSEQUENCES Identify and explore potential device use- related hazards and risks, and their potential clinical consequences
- IMPLEMENT CONTROLS Explore different design alternatives





Regulatory Usability vs. User Experience

– Human Factors

Applying knowledge of human abilities/limitations to device design



UOUP for Legacy UI (IEC 62366)

SOUP = Software Of Unknown Provenance

UOUP = SOUP on a UI = UI without IEC 62366

- 1) Perform full usability processes on all parts of the UI (5.1-5.9), or
- 2) Post-market analysis and report, or
- 3) Rationale to not apply usability procedures to legacy UI

Using UX to Feed Regulatory Development



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Using UX to Feed Development





How UX Design Streamlines Development





32

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Poll Question

What areas, separate from UX, would improve the development cycles at your company?

- Rapid prototyping tools
- Collaboration processes
- Code generation tools
- QMS process improvement
- Other











Thanks for Attending!



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