1. Purpose/Scope:

This training video will cover the setup of the URRA Work Instruction and the essential steps for integrating it into your Quality Management System. Topics include managing naming conventions and tracking revision changes.

It will also explore how to define a use error and address the variations in how different organizations interpret the term “Use Error.”

The video will provide an overview of the PC/A Cycle, its significance in Human Factors Engineering, and its role in creating and maintaining a URRA. Additionally, there will be a brief explanation of the difference between Harm and Clinical Harm and how this distinction impacts the management of your URRA. We will discuss the importance of having a 'pre-sub meeting' with the FDA before design validation for Human Factors Engineering.

An in-depth explanation and example of each column in a URRA will be provided, as we fill in sample rows for a fictional device. The timestamps below serve as a helpful video table of contents.

2. Time Stamps

Time	Description
00:00	Introduction
00:21	Document Header
03:07	Section 1. Purpose and Scope
07:37	Section 2. Document Approval, Section 3. Revision History
08:49	Section 4. References
11:38	Section 5. Definitions
13:55	Use-Related Risk Analysis Introduction
19:27	URRA Column 1. Use-Related Risk Analysis Task #
21:33	URRA Column 2. User Task
27:02	URRA Column 3. Possible Use Error(s)
32:28	URRA Column 4. Potential Hazards and Clinical Harm
38:42	URRA Column 5. Severity of Harm
42:46	URRA Column 6. Critical Task (Y/N)
44:37	URRA Column 7. Risk Mitigation Measure(s)
47:33	URRA Column 8. Validation Method for Effectiveness of Risk Mitigation Measure