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How Human Factors is a key component of your product risk management process and why regulatory agencies are paying attention

27-October-2021

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Assistant Professor, Pathway for Patient Health

Agenda

01 **Human Factors Background**

Overview

02 **What are regulatory bodies asking for**

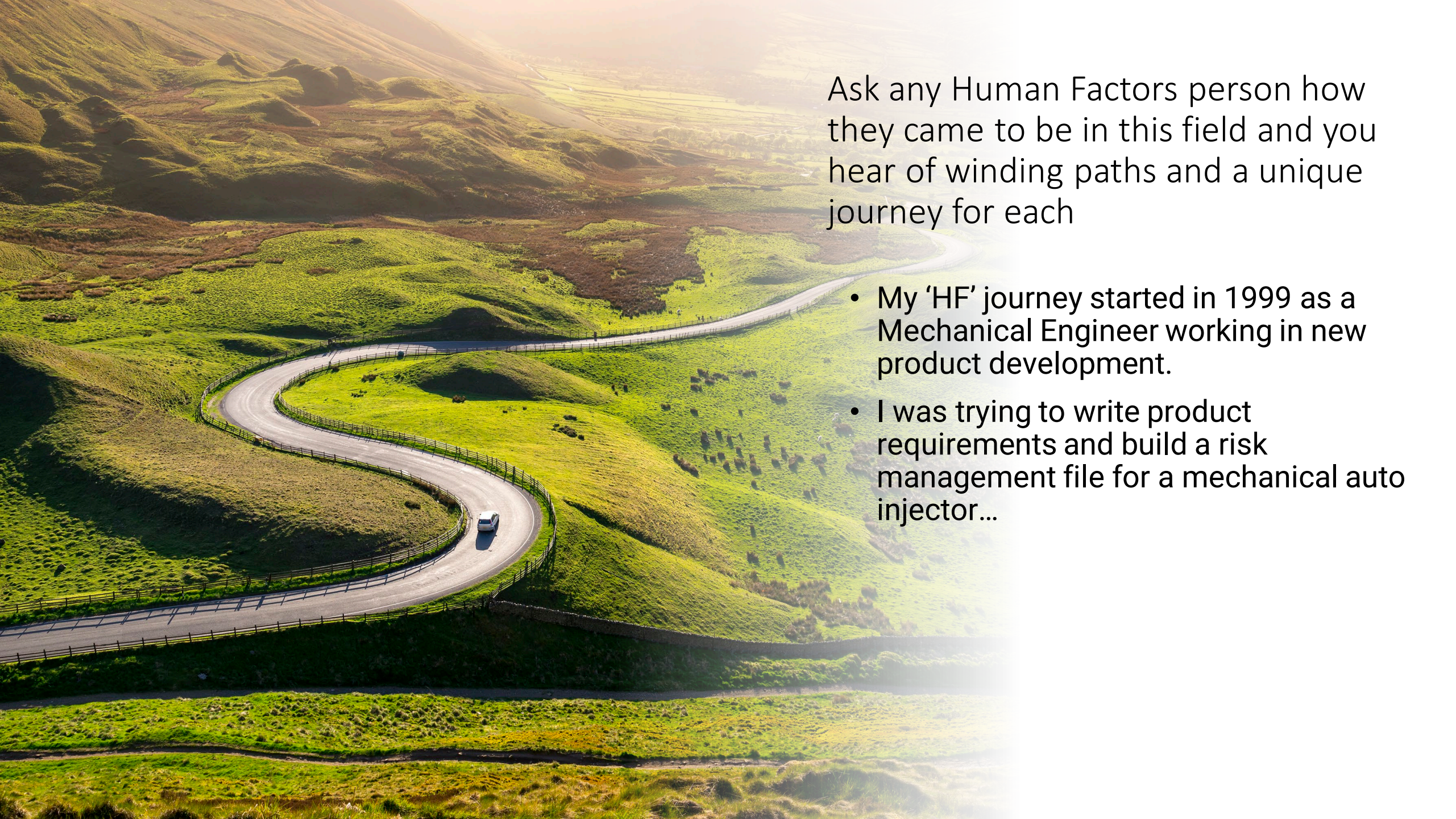
Submission requirements for human factors

03 **HF in development processes**

Risk management, design controls, software development

04 **Thank you**

Let’s keep in touch



Ask any Human Factors person how they came to be in this field and you hear of winding paths and a unique journey for each

- My ‘HF’ journey started in 1999 as a Mechanical Engineer working in new product development.
- I was trying to write product requirements and build a risk management file for a mechanical auto injector…

My Background

A brief snapshot of my experience

1998 — Mechanical Engineer, Systems Engineer

2008 — Design Assurance Engineer

2011 — Quality Engineering, R&D Manager, PDP

2015 — HF Team Lead & Reviewer

2021 — President, Assistant Professor

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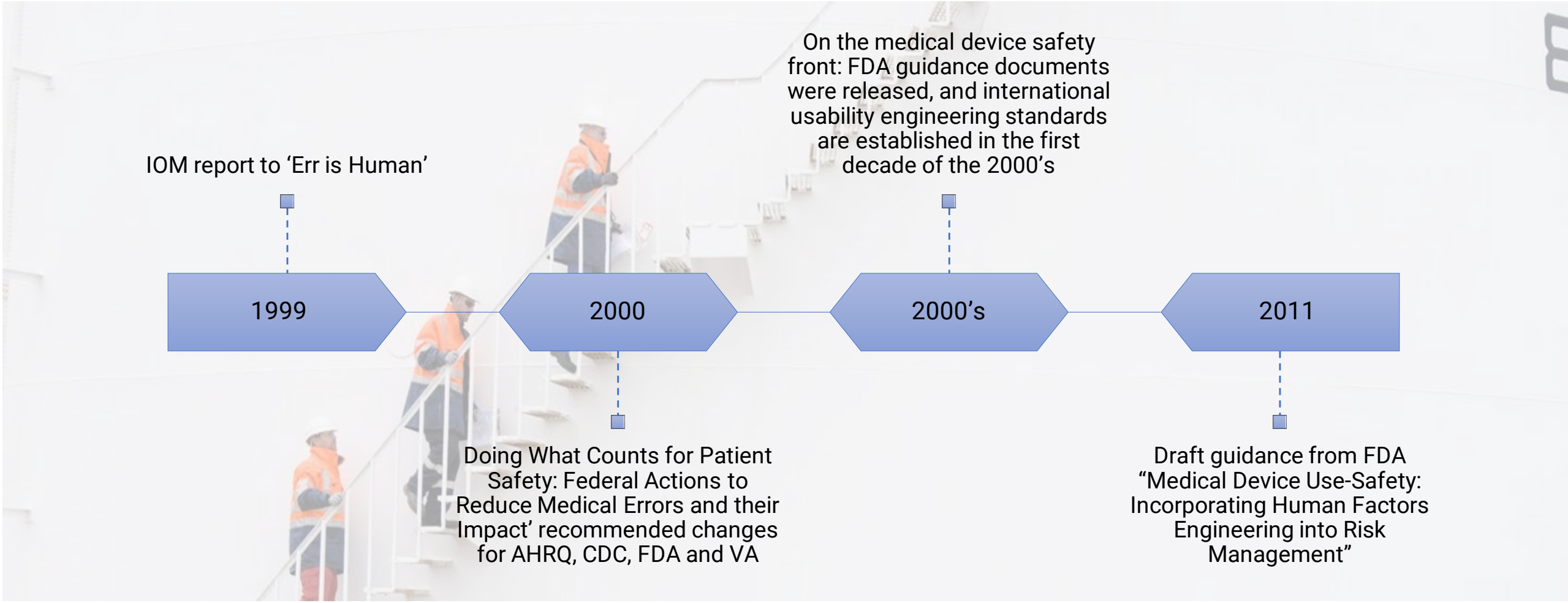
Pathway for Patient Health

One Step at a Time

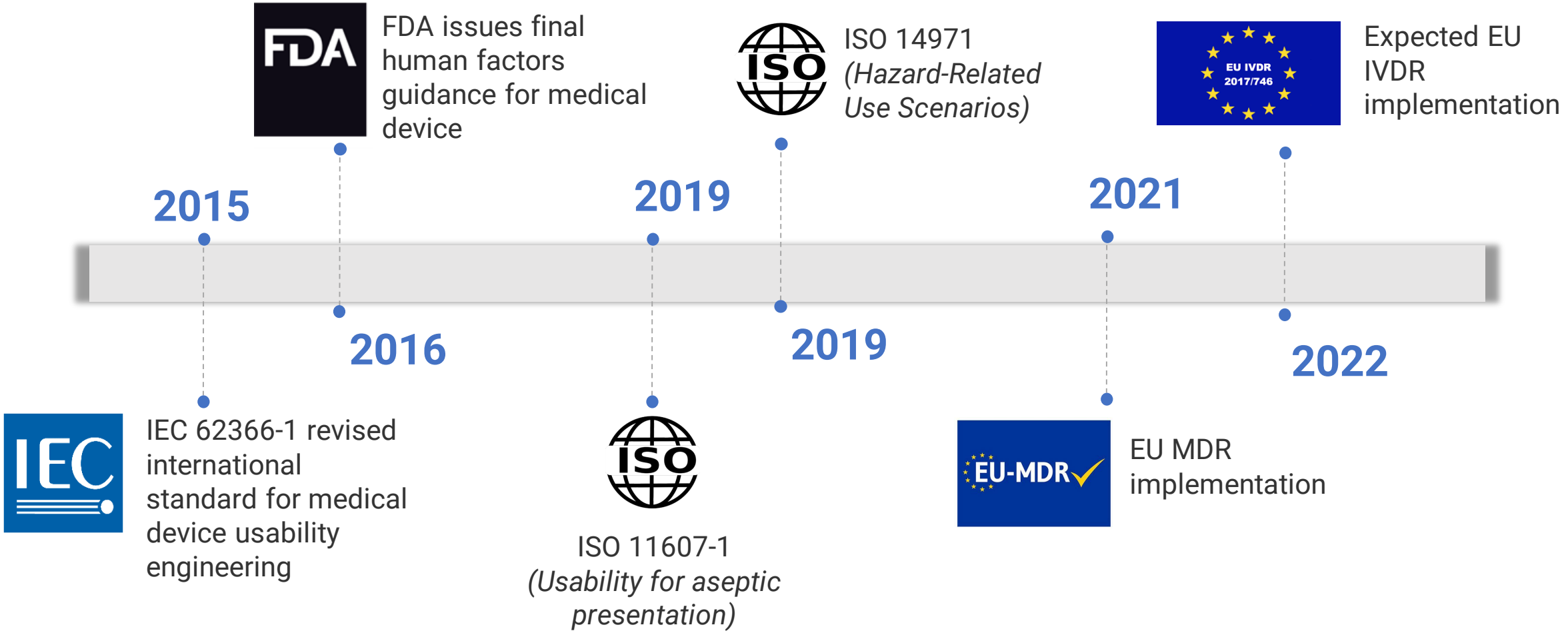
Recognition to Action



Making Healthcare Safe, The Story of the Patient Safety Movement, Leape, L, Springer 2021

Regulatory Landscape

Safe & Effective use: Human factors/Usability Engineering expectations



What is Human Factors?

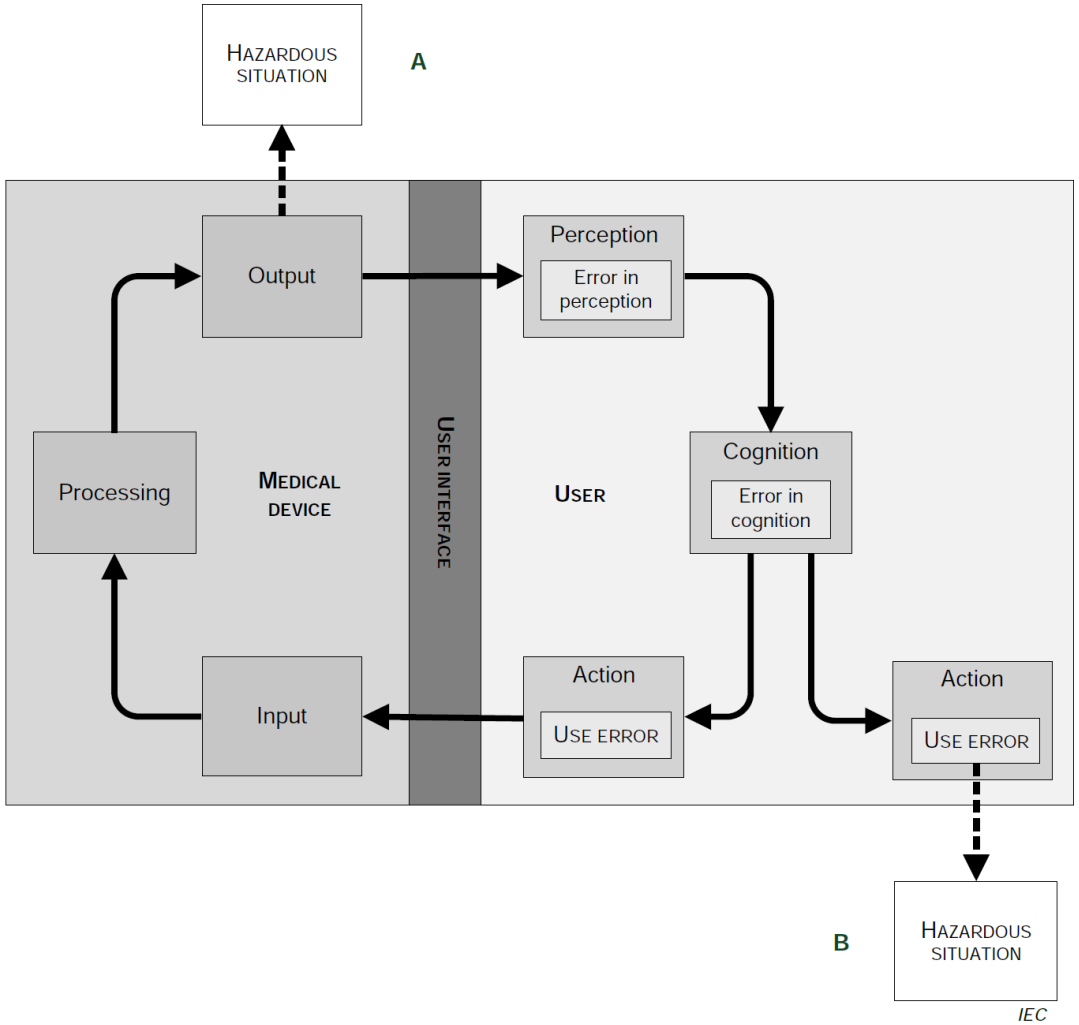
Usability Engineering / Human Factors Engineering

- Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of MEDICAL DEVICES (including software), systems and TASKS to achieve adequate USABILITY

- Note 1 to entry: Achieving adequate USABILITY can result in acceptable RISK related to use. (From IEC 62366-1:2015/Amd 1:2020)

Human Factors Engineering? Usability Engineering?

- USABILITY
  - characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT
  - Note 1 to entry: All aspects of USABILITY, including EFFECTIVENESS, EFFICIENCY and USER satisfaction, can either increase or decrease SAFETY.
- USER INTERFACE
  - means by which the USER and the MEDICAL DEVICE interact
  - Note 1 to entry: ACCOMPANYING DOCUMENTATION is considered part of the MEDICAL DEVICE AND ITS USER INTERFACE.
  - Note 2 to entry: USER INTERFACE includes all the elements of the MEDICAL DEVICE with which the USER interacts including the physical aspects of the MEDICAL DEVICE as well as visual, auditory, tactile displays and is not limited to a software interface. Note 3 to entry: For the purposes of this standard, a system of MEDICAL DEVICES can be treated as a single USER INTERFACE.
- **Bottom line: The goal is to optimize the user interface to ensure safe and effective use**

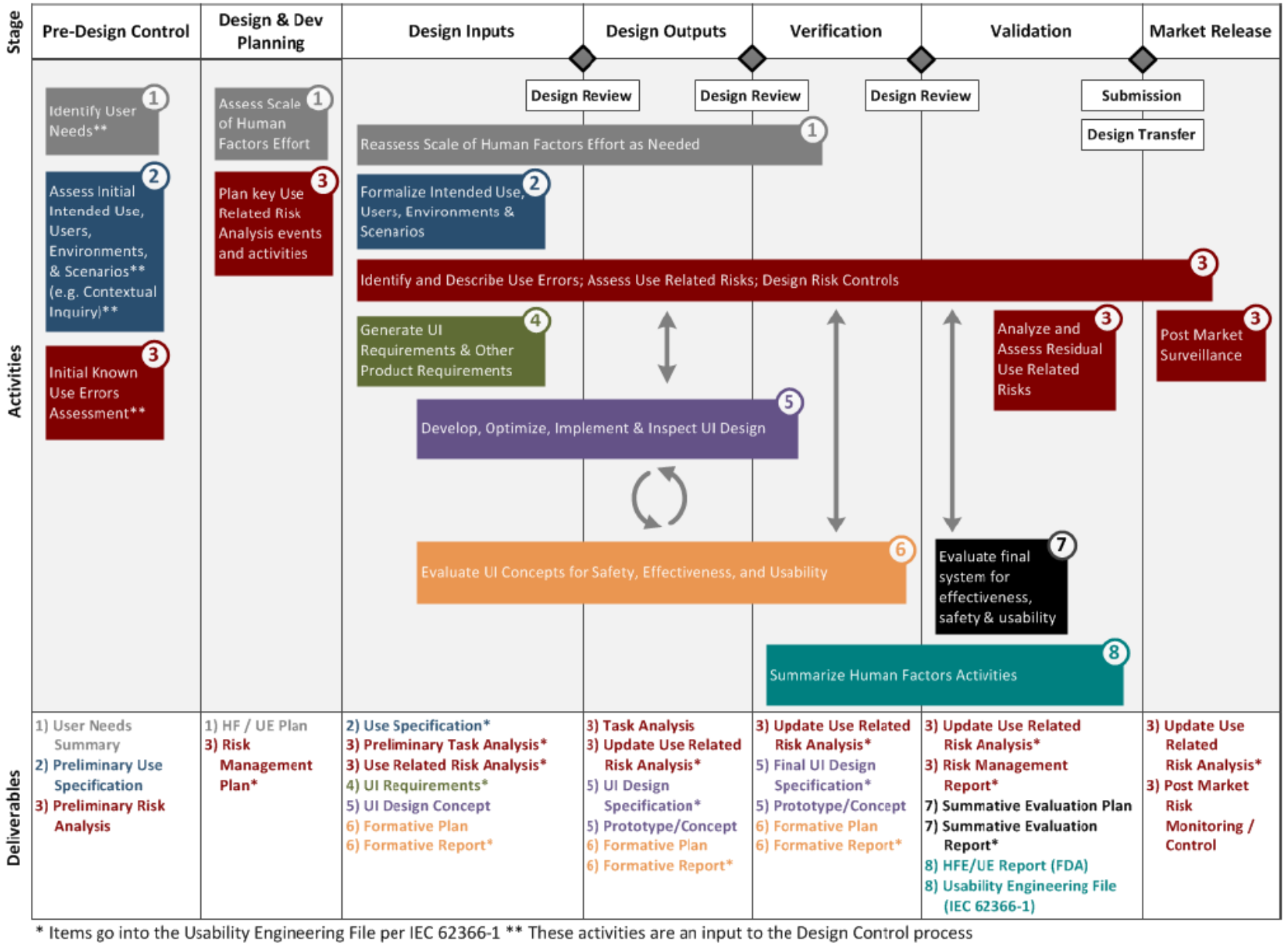


(From IEC 62366-1:2015/Amd 1:2020)

How Does This Translate to the Manufacturer?

Regulations and Product Lifecycle

- Quality management systems – 21 CFR 820 and ISO 13485:2016
  - Human Factors in Product Development Process
  - Integration into the Risk Management Process (ISO 14971:2019)
  - Integration with the Software Development Lifecycle (IEC 62304:2016)
- Both the 2016 FDA Human Factors Guidance and IEC 62366-1:2015 establish a lifecycle process to design in usability, assessing and maintaining use related safety.



* Items go into the Usability Engineering File per IEC 62366-1 ** These activities are an input to the Design Control process

This is NOT a test, well… this is not ONLY a test

AAMI TIR59:2017
Integrating human factors into design controls

Regulatory Interaction

What does this look like?

- FDA CDRH, CDER, CBER
  - Pre-market review of data
  - Specific application type requests (generics, Rx-OTC, EUA for COVID diagnostics)
  - Audits/inspections
- NB - Conformity assessments

When is this data requested and is Validation data needed?

- As necessitated by use-related risk

→→→

How does this play out?

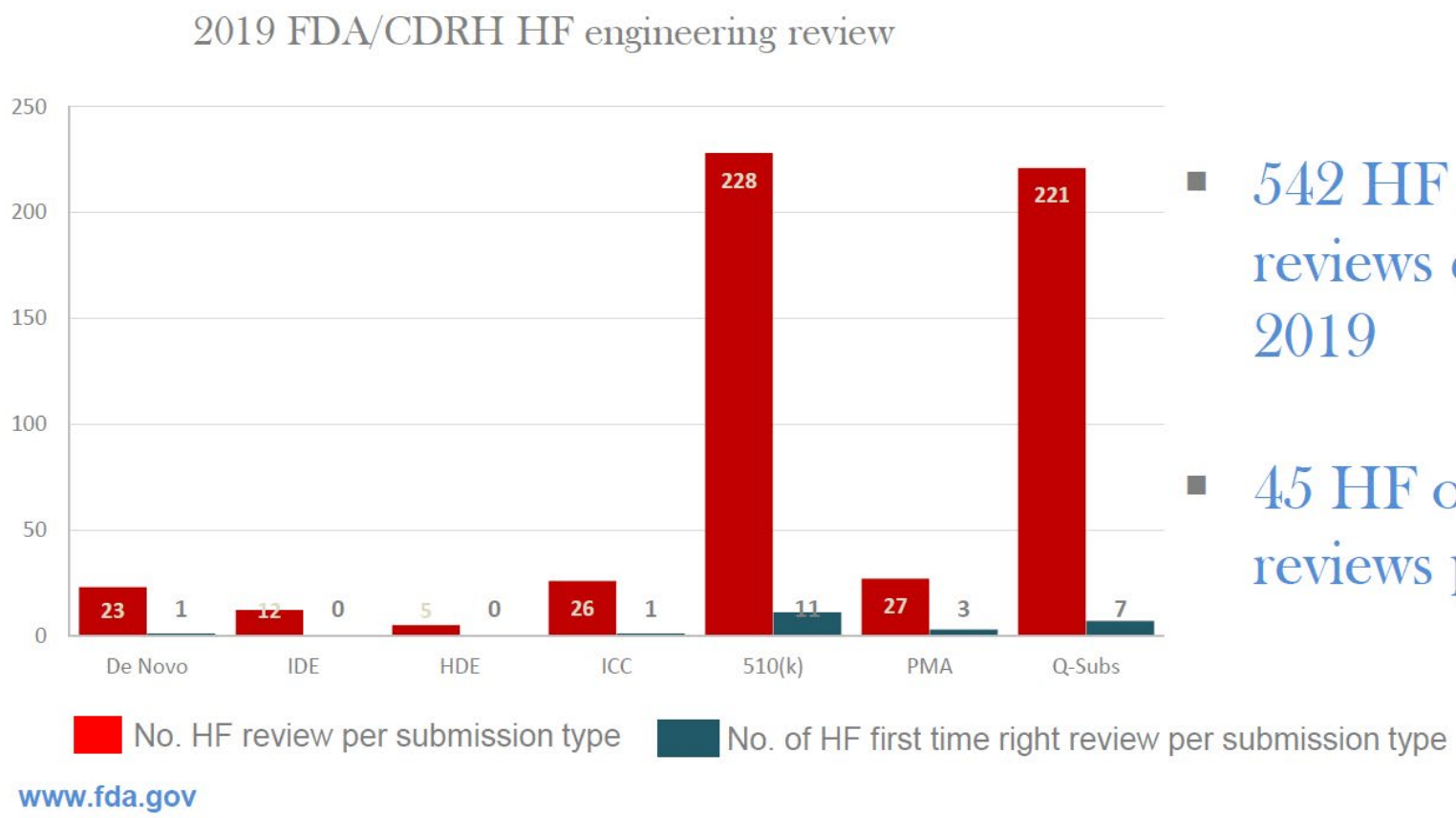
"CDRH believes that for those devices where an analysis of risk indicates that users performing tasks incorrectly or failing to perform tasks **could result in serious harm**, manufacturers should submit human factors data in premarket submissions"

FDA: combination product user interface should be assessed in HF studies "to ensure that **use-related hazards** associated with the product are eliminated or mitigated to **reduce patient adverse events and medication errors attributable to use-related errors**."

IEC 62366-1: select the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION. The MANUFACTURER shall select:– all HAZARD-RELATED USE SCENARIOS; – **a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM** …

Analysis of HF Submissions & First-time Success

URRA Impacts on CDRH clearance or approval

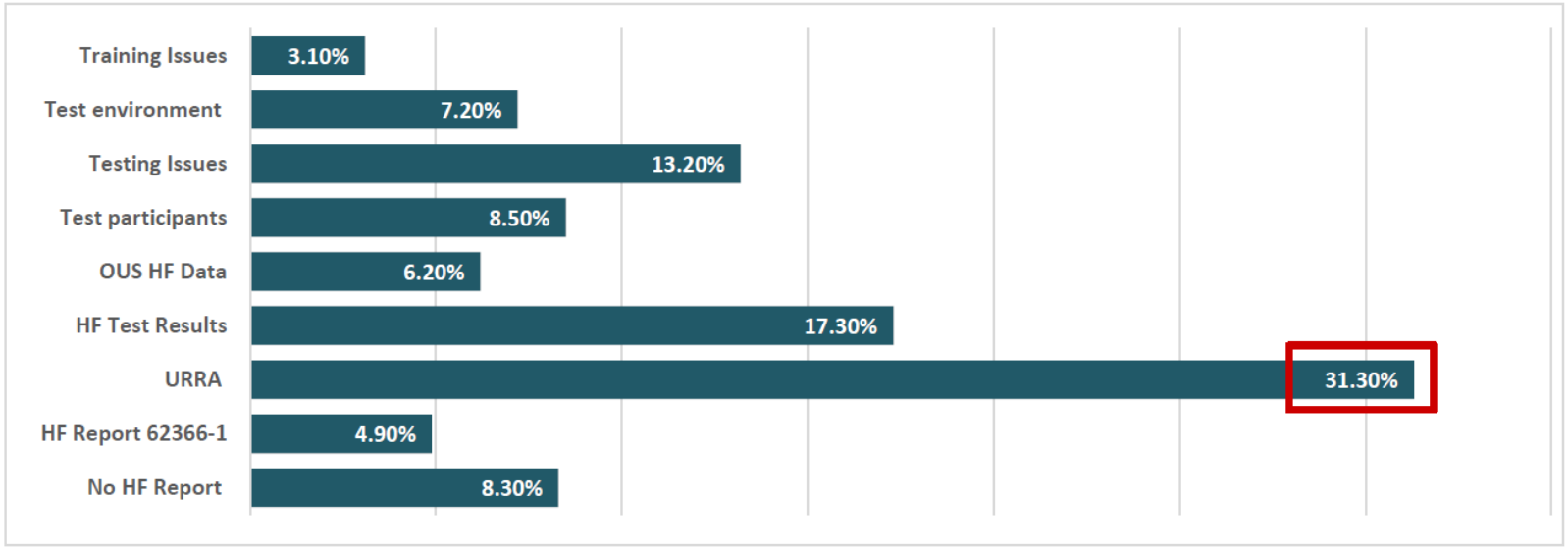


- 542 HF engineering reviews completed in 2019
- 45 HF on average reviews per month

Wiyor, H.D. (October 22, 2020). *Risk Assessment of Medical Products in Human Factors Submissions with a Focus on EU countries.* MHFN Webinar

HF Submission Deficiencies

URRA Impacts on CDRH clearance or approval



- Affects 80% of HF deficiencies generated
- 1 in every 5 HF submission impacted by URRA (US)
- 1 in every 3 HF submission is impacted by URRA (OUS)

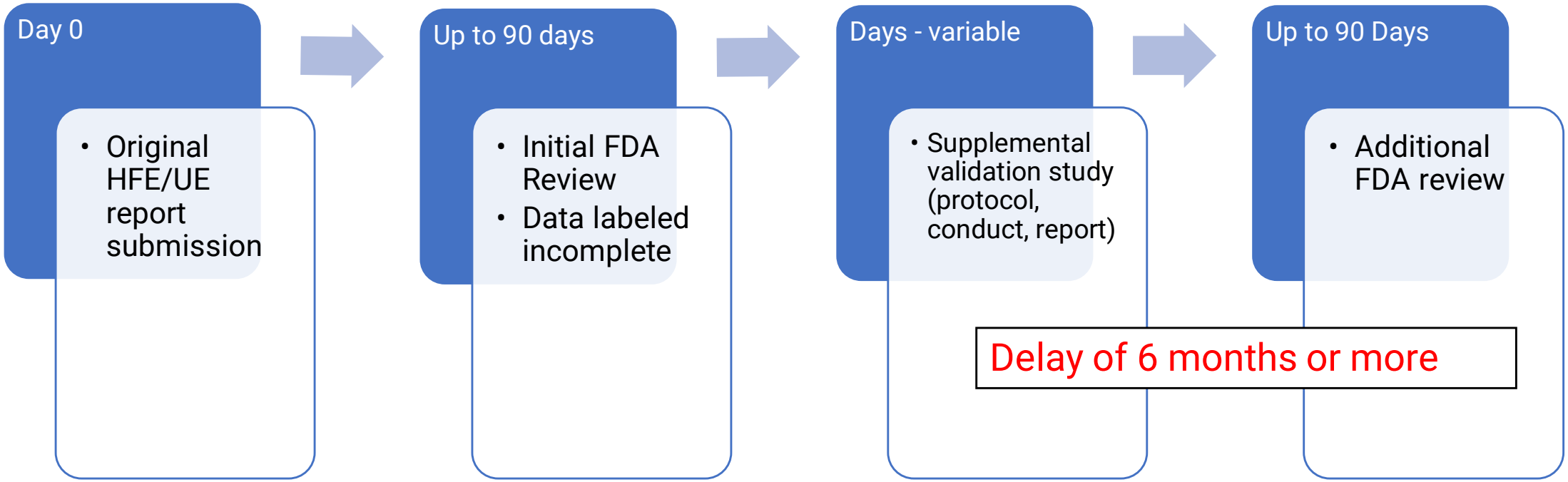
www.fda.gov

Wiyor, H.D. (October 22, 2020). *Risk Assessment of Medical Products in Human Factors Submissions with a Focus on EU countries.* MHFN Webinar

FDA Consideration

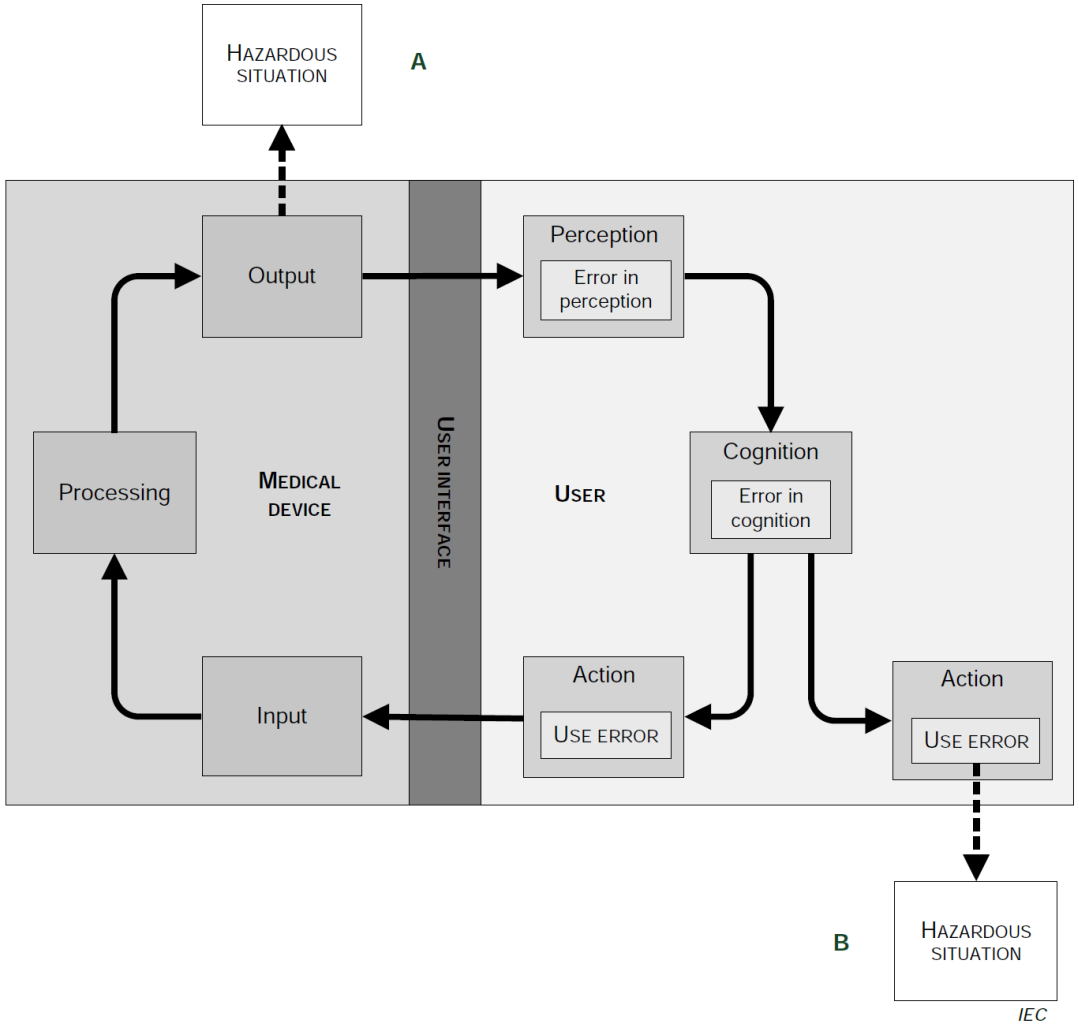
90% of first time FDA submissions are labeled incomplete

Consider the cost in time and budget for a delayed or incomplete submission



Data output of Human Factors Studies

- The MANUFACTURER shall analyze the data of the SUMMATIVE EVALUATION and
  - shall identify all USE ERRORS and use difficulties that occurred.
  - If a USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION, the root cause of any such USE ERROR or use difficulty shall be determined.
  - The root causes should be determined based on methods including observations of USER performance as well as subjective comments from the USER.
- Are further improvements necessary?
  - If so rinse and repeat; If not-
    - document why improvement is not necessary or not practicable;
    - identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and
    - evaluate the RESIDUAL RISK according to ISO 14971:2019, 7.3



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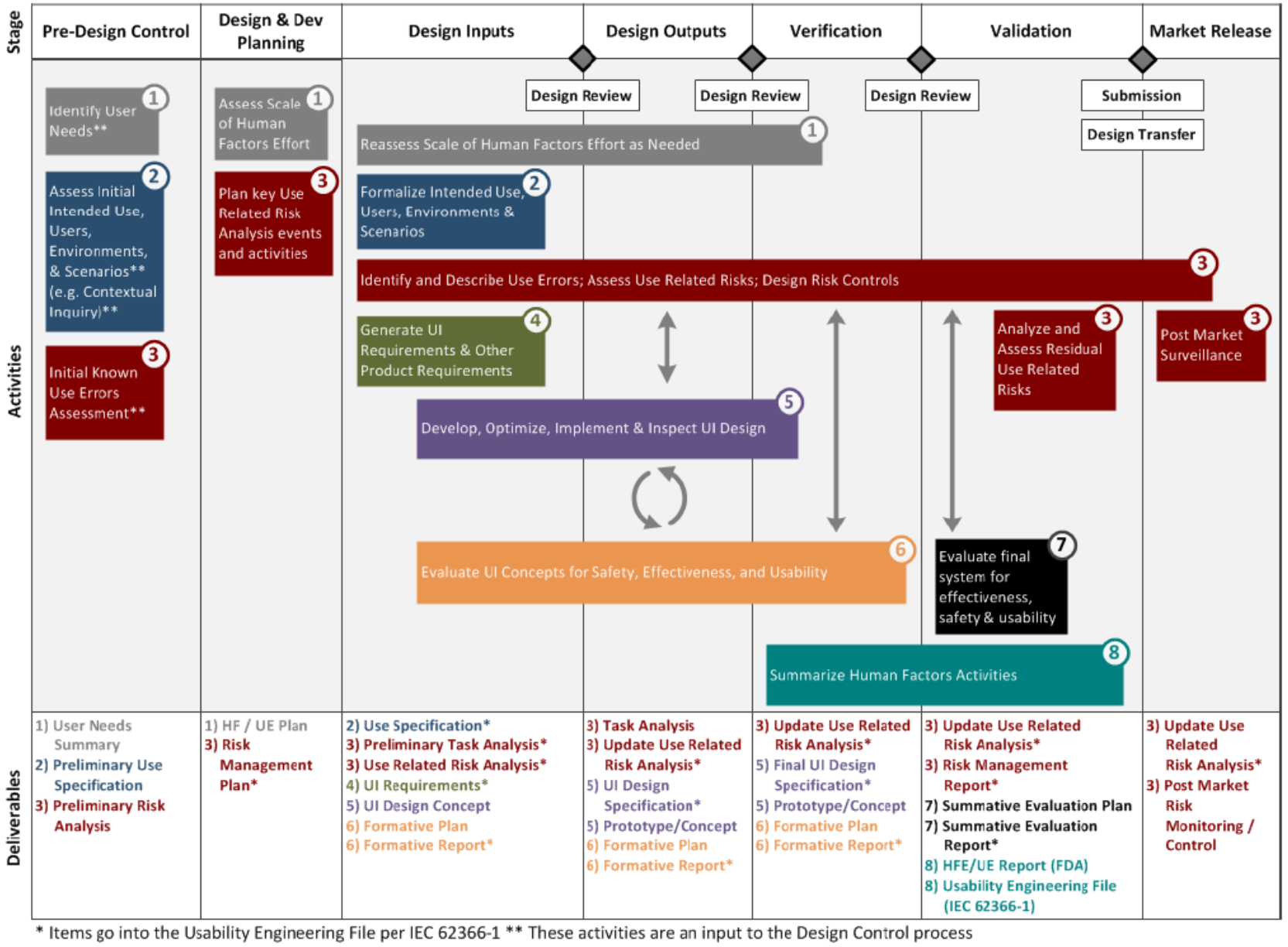

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AAMI TIR59:2017
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Human Factors

Outcomes

The goal: to optimize the user interface to ensure safe and effective use

- Activities start in concept development and progress with the Risk Management Process and Product Development Process
- Use-related risk assessment provides focus for the development activities around your user interface and provides a framework to manage post-market surveillance and change management
- Generates the data to support your regulatory submissions
- Improves your product and your user’s experience

Human Factors

Bottom Line

Bottom line: A Human Factors/Usability assessment will be done on your product. The decision is this:

- Do you drive it during development or
- Are your users doing it for you on the market?

Questions?

KEEP IN TOUCH

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Types of Human Factors Studies

Early formative studies

- Use a smaller sample size (5-8 users/user group)
- May evaluate focused aspects of the user interface rather than entire user interface
- May evaluate design alternatives and early concepts
- May evaluate user characteristics and preferences, environmental characteristics, etc. to inform design assumptions, device design or selection

Late-stage formative studies

- Use a smaller sample size (5-8 users/user group)
- Bring more aspects of user interface together to evaluate at one time – eventually testing entire user interface and approaching commercial design and validation study methodology
- Inform design of device, packaging, instructions, and/or training
- Build readiness to a successful validation

Summative (Validation) studies

- Use a larger sample size (minimum 15 users/user group)
- Assess the entire user interface with all defined user groups
- Uses the final commercial-ready design of the device or product user interface
- Demonstrates use related safety and effectiveness of the device or product user interface in the hands of the end users