



## De-Risking Your Use-Related Risk Analysis: Human Factors guidelines for Regulatory Compliance

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Core Human Factors, A Rimkus Company, uses research to help companies improve products at any point in the design life cycle, from conceptualization through post-market troubleshooting. We offer research services, participant recruitment, and Institutional Review Board (IRB) reviews.

Our niche is health care, and we can align our efforts with clients' human factors and ergonomic (HFE) programs. We specialize in human factors testing for medical devices, drug delivery devices, and healthcare systems. We have helped hundreds of products successfully navigate Food and Drug Administration (FDA) review and gain CE marks.

# The Human Factors deliverable FDA Flags Most Often

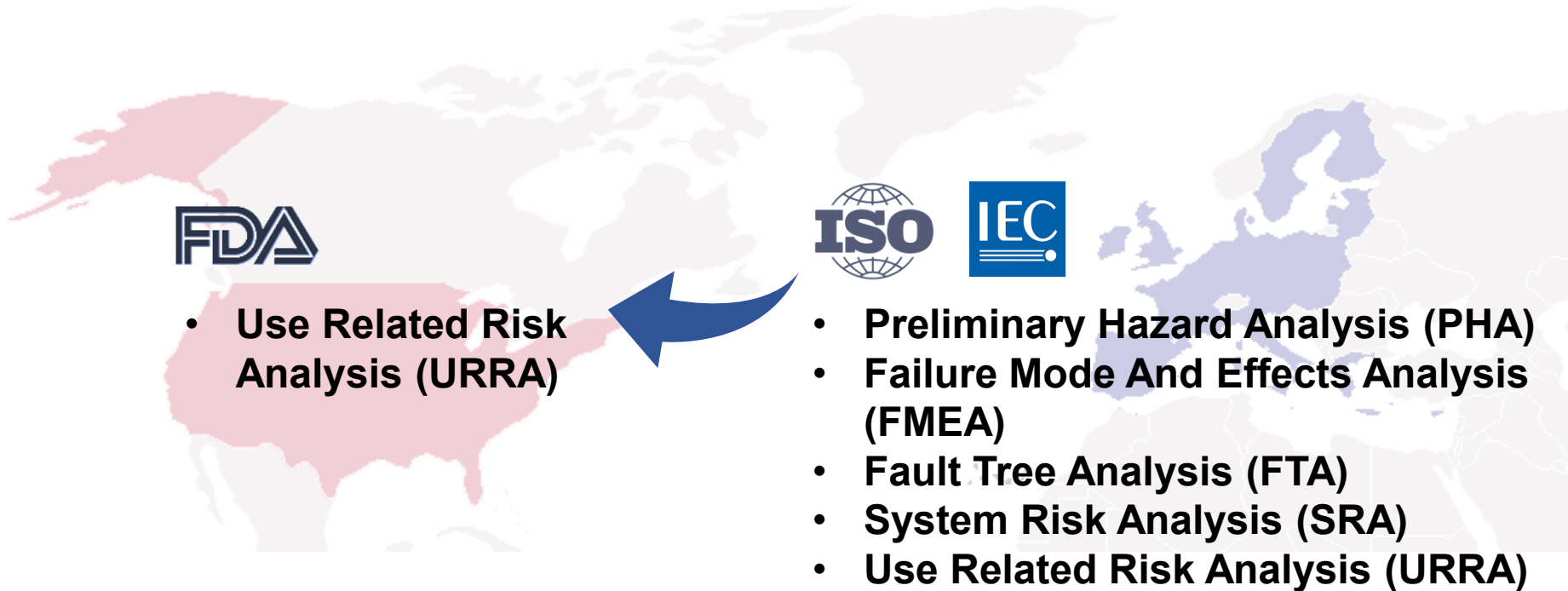
## Review Statistics 2019



No.	Deficiency	Percentage
1	Preliminary use-related risk analyses and evaluation (URRA): not available, unacceptable, incomplete	31.3%
2	Test results: acceptance rates, goal approach, no subjective interview data, incomplete data analyses	17.3%
3	Improper testing methodology: no critical tasks and use scenarios	13.2%
4	Number and sample test participants, combined distinct users, not all distinct users evaluated.	8.5%
5	No Human factors report/data submitted for review	8.3%
6	Test environment and conditions of use not representative	7.2%
7	Human factors testing conducted outside USA no justification	6.2%
8	Human factors report based on the requirements ANSI/AAMI/IEC 62366-1:2015	4.9%
9	Training provided to test participants and how it corresponded to real-world training levels	3.1%

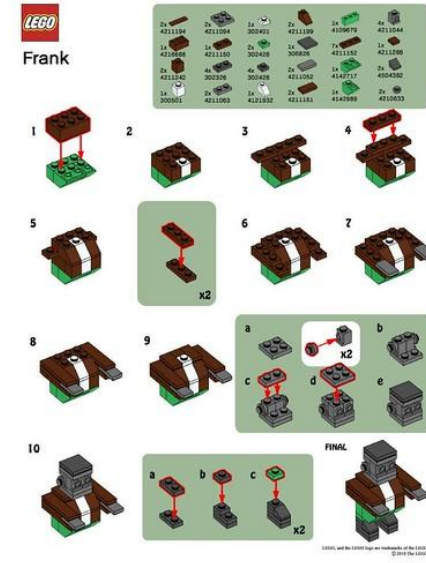


# Bridging EU to US regulations



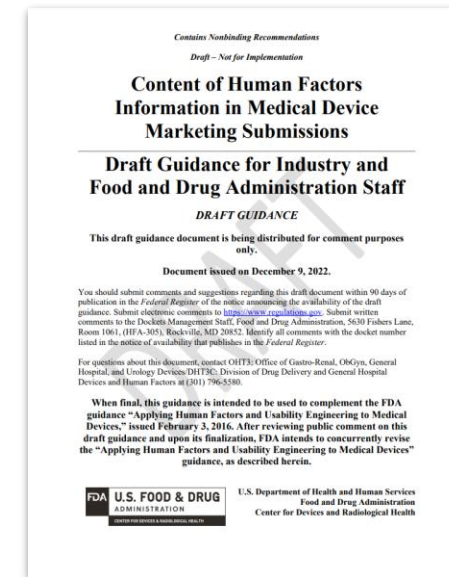
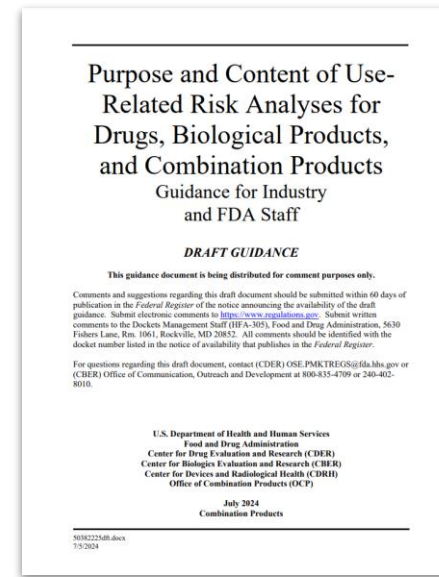
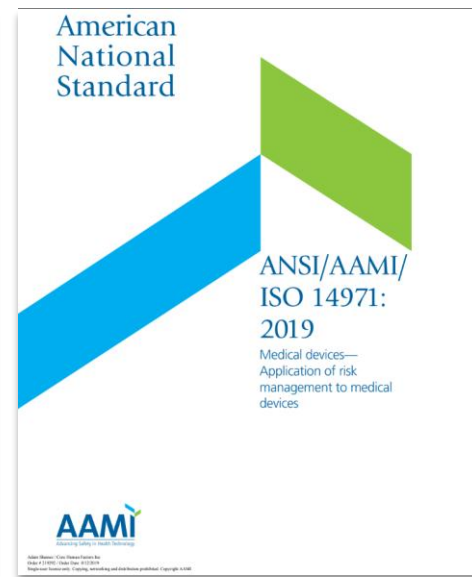
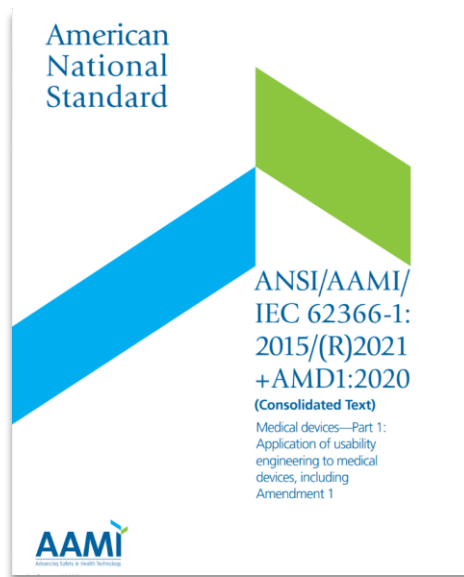
# What is a Use Related Risk Analysis (URRA)?

- Part of an overall risk management framework
- Focused on steps for use as its organizing principle (Task Analysis)
- Cyclical, living document
- Start it as part of development, update to reflect the final product, and keep it up to date throughout the product's life cycle

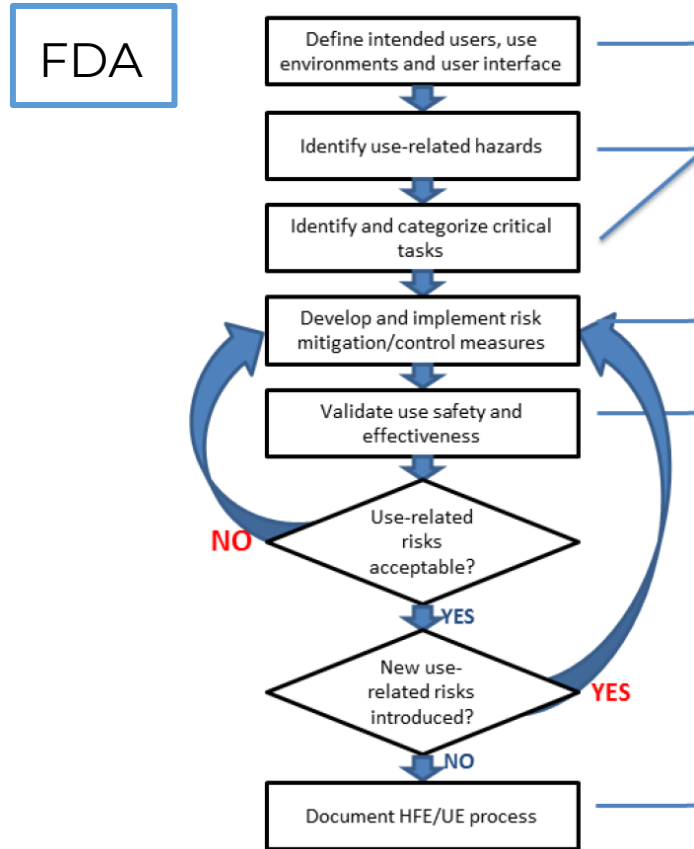


# Use-Related Risk Analysis (URRA)- Why?

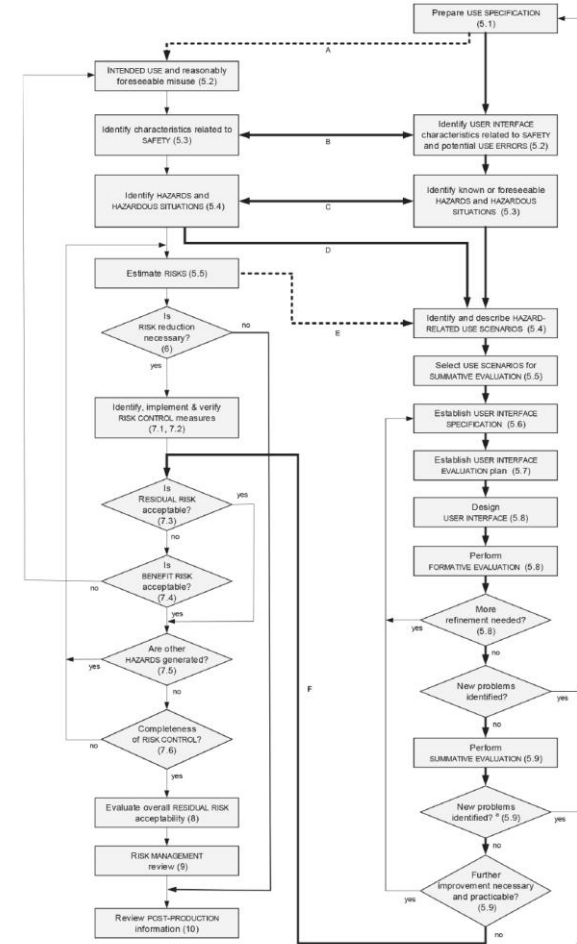
- Determines IF you need to submit a Human Factors Validation Study to FDA
- Determines what you need to test in a Human Factors Validation Study for an FDA submission



# How Risk Analyses Compare



14971



62366



# Where do we start?



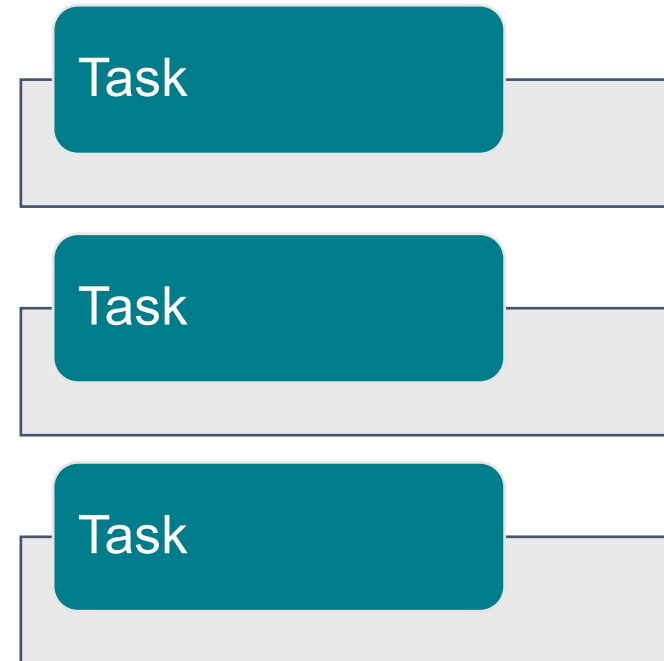
# Example URRA columns

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures (BD: By Design PM: Protective Measure IFS: Information for Safety)	Validation Method



# Task Analysis

- Task based
- Organized by use scenarios and tasks, not by hazard



# Example URRRA

## Epinephrine Autoinjector

1. Open Package and remove device
2. Pull off cap
3. Inject into outer thigh
4. Hold 10 seconds



# Risk Analysis: Task Analysis (possible interactions)

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector							
2.4	Administering a dose	Push in needle end until it clicks							



# Potential Use Error Identification

- What can go wrong at each step **from the user's perspective**, (not what things in the device might fail)
- **Reasonably foreseeable.** Doesn't matter if they may have made more than one error to get there, the question is it realistic.

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube						
2.4	Administering a dose	Push in needle end until it clicks	Pushes too lightly (no click)						



# Risk Analysis: Potential use errors

- Sources of known use related errors:
  - Formative
  - Previous version
  - Predicate devices (MAUDE database)
  - Social media

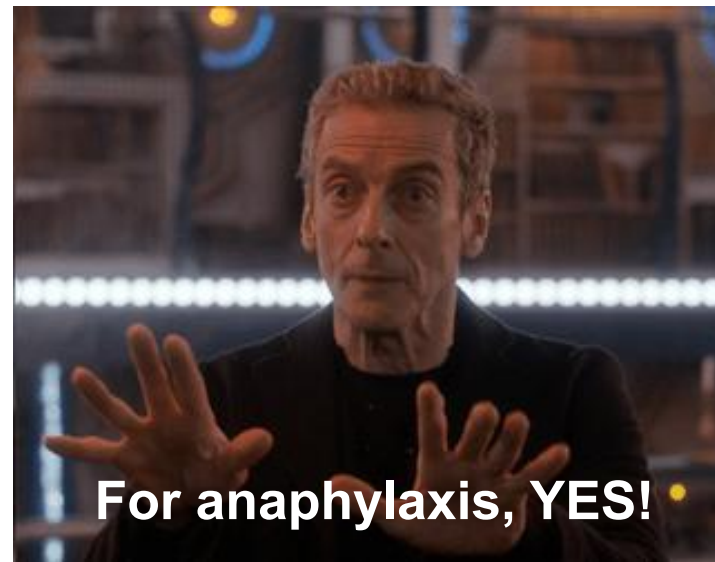
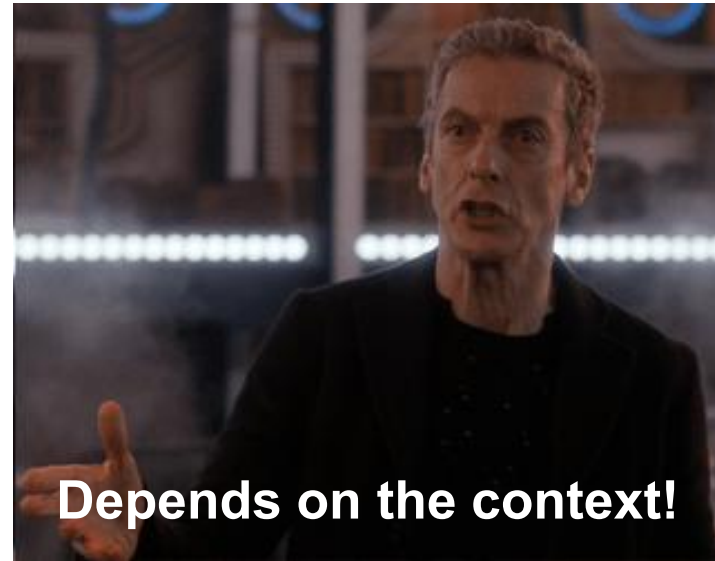
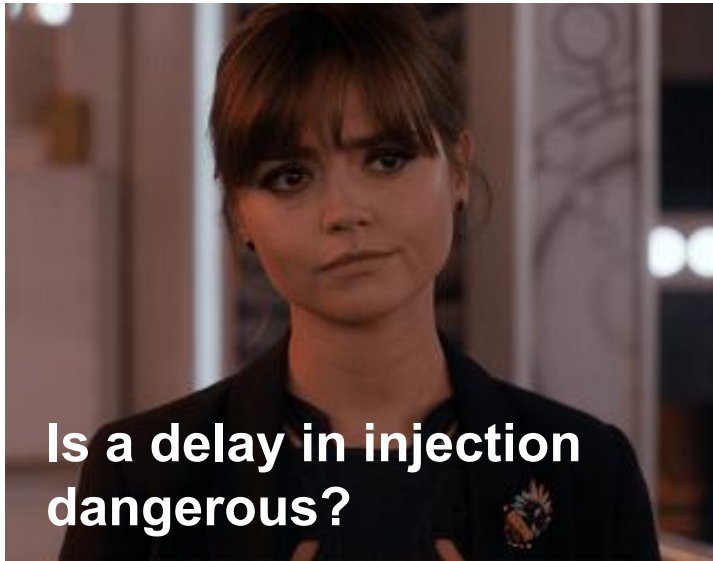


# Hazard Identification

- What hazard does this potential use error create?

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube	Delay of dose					
2.4	Administering a dose	Push in needle end until it clicks	Pushes too lightly (no click)	No dose					





# Harm and Severity Identification

- What could happen to the patient/user if that hazard occurs?
- What is the clinical harm?

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube	Delay of dose	Severe anaphylaxis, Airway compromise, Death	5			
2.4	Administering a dose	Push in needle end until it clicks	Pushes too lightly (no click)	No dose	Severe anaphylaxis, Airway compromise, Death	5			



# Risk Estimation (Severity)

- What is the harm level?
- Can use your own severity scale, many companies use this one from 24971

Common terms	Possible description	Severity level
Negligible	Inconvenience or temporary discomfort	1
Minor	Results in temporary injury or impairment not requiring professional medical intervention	2
Serious	Results in injury or impairment requiring professional medical intervention	3
Critical	Results in permanent impairment or life-threatening injury	4
Catastrophic	Results in patient death	5



# Criticality (Yes or No)

- A Critical task for medical devices or combination products is defined as:
  - FDA: “A user task which, if performed incorrectly or not performed at all, would or could cause **(serious)** harm to the patient or user, where harm is defined to include compromised medical care.” (FDA Guidance: Applying human factors and usability engineering to medical devices. (2016)), FDA Guidance: Application of Human Factors Engineering Principles for Combination Products: Questions and Answers (September 2023)
  - 62366: A TASK in a HAZARD-RELATED USE SCENARIO, in which a USE ERROR can lead to significant HARM, can be thought of as a 'critical task' (IEC 62366-1:2015+AMD:2020)

Common terms	Possible description	Severity level
Negligible	Inconvenience or temporary discomfort	1
Minor	Results in temporary injury or impairment not requiring professional medical intervention	2
Serious	Results in injury or impairment requiring professional medical intervention	3
Critical	Results in permanent impairment or life-threatening injury	4
Catastrophic	Results in patient death	5

Critical tasks are commonly those assigned a severity of 3 or above or those that could lead to compromised medical care

# Risk Estimation (criticality)

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube	Delay of dose	Severe anaphylaxis, Airway compromise, Death	5	Yes		
2.4	Administering a dose	Push in needle end until it clicks	Pushes too lightly (no click)	No dose	Severe anaphylaxis, Airway compromise, Death	5	Yes		



# What about probability?

- Risk=Probability x Severity
- Probability is hard to determine
- Sample sizes are small
- Focus on severity instead

## 5.5 Risk estimation

For each identified *hazardous situation*, the manufacturer shall estimate the associated risk(s) using available information or data. For *hazardous situations* for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in *risk evaluation* and *risk control*. The results of these activities shall be recorded in the *risk management file*.

ISO 14971

In the absence of any data on the probability of occurrence of harm, it is not possible to reach any risk estimate, and it is usually necessary to evaluate the risk on the basis of the nature of the harm alone. If

ISO 24971

As part of their design controls<sup>1</sup>, manufacturers conduct a risk analysis that includes the risks associated with device use and the measures implemented to reduce those risks. ANSI/AAMI/ISO 14971, *Medical Devices – Application of risk management to medical devices*, defines risk as the combination of the probability of occurrence of harm and the severity of the potential harm<sup>2</sup>. However, because probability is very difficult to determine for use errors and in fact many use errors cannot be anticipated until device use is simulated and observed, the severity of the potential harm is more meaningful for determining the need to eliminate (design out) or reduce resulting harm. If the results of

FDA Guidance *Applying human factors and usability engineering to medical devices*. (2016))

# Risk Mitigation Measures

- What measures were taken to mitigate or reduce the risk.
- Must include references to all contraindications, warnings, and cautions



Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures (BD, PM, IFS)	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube	Delay of dose	Severe anaphylaxis, Airway compromise, Death	5	Yes	BD: Designed with a lip to help with top removal	
2.4	Administering a dose	Push in needle end until it clicks	Pushes too lightly (no click)	No dose	Severe anaphylaxis, Airway compromise, Death	5	Yes	BD: Tactile and auditory feedback (feeling and hearing the click) IFS: IFU states to listen for 'click'	

# Risk Control Measures (Mitigations)

- Another requirement of both ISO 14971 and the FDA Guidance is to include Risk Control Measures (mitigations)
  - 14971 and the FDA classifies these into three categories:



Inherent Safety  
by design



Protective measures  
(device or manufacturing)



Information for safety, and  
user training

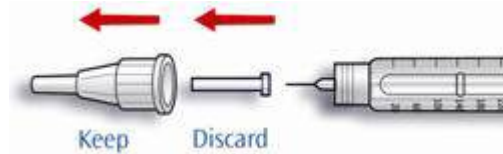
# Risk Control Measures

- What measures were taken to mitigate/control or reduce the risk?

Before and after use outer shield covers needle



Inherent Safety by design



Protective measures (device or manufacturing)



**Do not recap the Needle**

Information for safety, and user training

# Validation Method

- How will I test the efficacy of my mitigations?

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures (BD, PM, IFS)	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube	Delay of dose	Severe anaphylaxis, Airway compromise, Death	5	Yes	BD: Designed with a lip to help with top removal	HF Validation Study: Observation Task P1
2.4	Administering a dose	Push in needle end until it clicks	Pushes too lightly (no click)	No dose	Severe anaphylaxis, Airway compromise, Death	5	Yes	BD: Tactile and auditory feedback (feeling and hearing the click) IFS: IFU states to listen for 'click'	HF Validation Study: Observation Task P3



# Validation Method

- What if this were a monthly preventative migraine medication?

Risk ID	Use Scenario	User Task	Potential Use Error	Hazard	Clinical Harm	Severity	Critical Task (Yes/No)	Risk Mitigation Measures (BD, PM, IFS)	Validation Method
2.1	Open Package	Flip off top of tube and remove autoinjector	Difficulty opening tube	Delay of dose	Patient inconvenience, no harm	1	No	BD: Designed with a lip to help with top removal	N/A, not critical



# Human Factors (Usability) Study



# Takeaways

- One size fits all is possible, but should be task-based and look like a URRRA
- URRRA drives study design decisions, including whether you need a study
- HF Validation Studies are designed to test the risk mitigation measures
- URRRA should be kept up to date, as the product and its risks and risk mitigation measure evolve



# Where is Core?

## Main office and Testing labs: Bala Cynwyd, Pennsylvania



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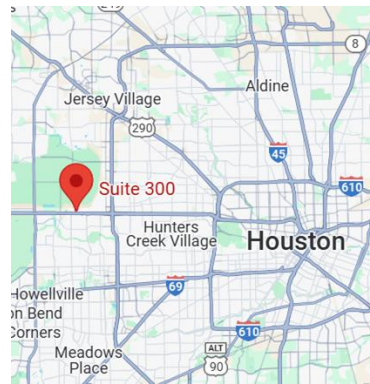


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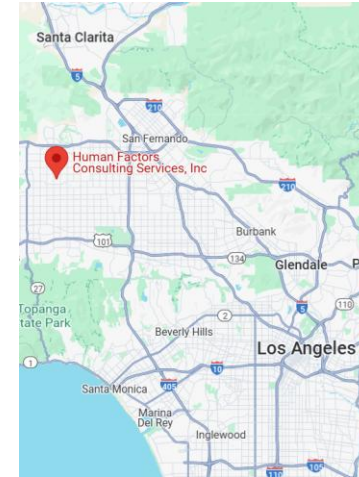
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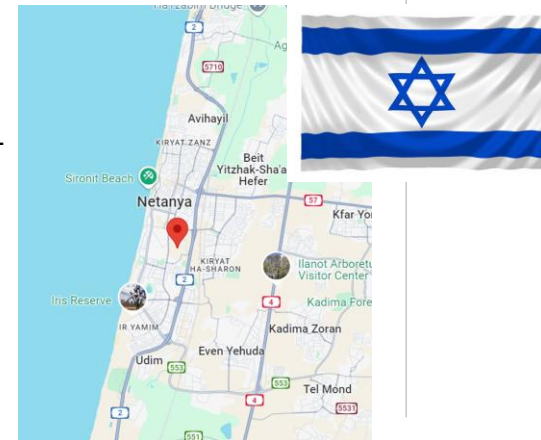


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# Our Team



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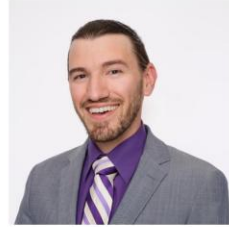
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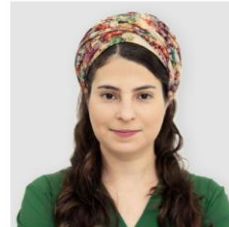
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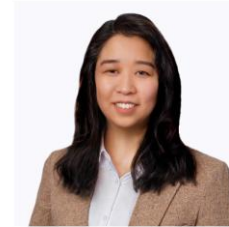
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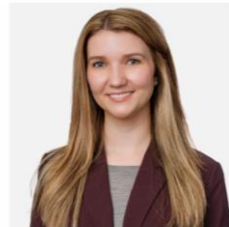
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Bert



Ernie



Suzie



Larry



Johnny & Friend

# What does Core do?

Support Medical Device and Pharmaceutical companies with their human factors and usability engineering programs



Task and use-related risk analysis



Regulatory Human Factors Strategy



Expert Review



Prepare Human Factors files for Notified Bodies



Instructions for Use Design



Human Factors Engineering Report for FDA Submission



Usability Testing

# Thank You! Visit our booth to ask questions

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