Within healthcare the scope of Human Factors extends to:

- Medical devices
- Combination product delivery devices
  - Pen injectors
  - Prefilled Syringes
  - Patches, etc.
- In Vitro Diagnostics Devices
- Device Software
Combination Product Examples

• Prefilled Syringes
• Pen injectors or autoinjectors
• Pharmaceutical Aerosol delivery devices/Inhalation devices
• Transdermal delivery systems/Patches
• Drug packaged with delivery device
Prefilled Syringes US Requirements

• Prefilled syringes historically classified as container closure systems and thus followed Drug GMP

• Now confirmed as a **Combination Product** from 21 CFR Part 3 & 4
  – Requires Design Controls under 21 CFR Part 820.30

• Requires Design Validation

What is Design Validation?
Design Validation

- *Design validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s).

User Needs
Intended Uses

Design Validation is not just Human Factors!
Regulatory Requirements

Design Validation… Global market requirement for Devices

- US – 21 CFR Part 820:30
- Rest of World - ISO 13485

Validation Methods

- Human Factors studies (FDA guidance's & ISO 62366)
- Bench top testing
- Clinical evaluation
- User/market feedback

Successful Validation

Outcome

Redesign
HF Standards/Guidance

- ANSI/AAMI HE75:2009 Human Factors Engineering – Design of Medical Devices
- FDA CDRH Draft Guidance for Industry
  - Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (18 July 2000) superseded by:
  - Applying Human Factors and Usability Engineering to Medical Devices (February 2016)
  - Human Factors Studies and Related Clinical Study Considerations in Combination Product Design And Development (February 2016) - DRAFT

- US and rest of world requirements are the same except US expect summative HF studies ratification by FDA before execution of protocol
Human Factors Definition

is “…the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations.…”

(ANSI/AAMI HE75:2009, Introduction)

It’s a marriage of psychology and science & engineering!
Usability Definition

- is the “characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction”

*(ISO/IE 62366:2007, Definition 3.17)*

**Human Factors and Usability terminology interchangeable!**
What is Human Factors?

• Is it a certificate?
• Is it just performing a study to comply?
• Can I introduce it after my product is developed?

The answer to all these is NO!

• Human Factors is about designing the right product for its intended users in the intended environment

Human Factors is not an end point; it’s a process!
Human Factors Inputs and Outputs

**Use Environment**
- Light, noise
- Distraction
- Motion/Vibration
- Workload

**User**
- Knowledge
- Abilities
- Expectations
- Limitations

**Device**
- Instructions for Use
- Training Material
- Device Complexity
- User Interface

**Scope**
- Doctors prescription
- Pharmacy
- Transport
- Use by Patient/Caregiver/HCP
- Disposal

**Outcome**
- Safe & Effective
- Unsafe or Ineffective
Hierarchy of Variables

Groups Responsible

Ind. Design / Marketing

ID / HF Engineering

Eng’g. / HF Eng’g.

Emotion
Preference
Usability
Effectiveness
Safety

Adapted from Hancock, Pepe & Murphy (2005), *Ergonomics in Design*, 13 (1), 8-14
Product Development Overview

**INPUTS**
- Drug Product
- Device Concept Research
- User Requirements Specification (URS)

**OUTPUTS**
- Combination Product
- Instructions For Use (IFU)
- Training Device (if appl.)
- Training Material
- Product & Device Labels
- Packaging
- Design History File / Technical File

**Design Control**

**Human Factors**

**Risk Management**

**Manufacturing**

**Clinical & Human Factors Studies**

**REGULATORY SUBMISSION DOCUMENTATION**

**On Market**
User Research is critical

Consider human factors early in development

Cost of Change

Concept Development process timeline Filing / Launch
Formative and Summative Studies

Formative studies – contribute to leaps in design maturity and IFU development

Summative study – validates the design for regulatory filing
Formative Studies

Design Inputs

HF Documentation

Mature Design
Summative Study
Design Freedom

100% Formative Study 100% Formative Study 100% Formative Study 100% Final Formative Study

Design Freedom

Device Hardware

Instructions for Use (IFU)

Development process timeline

Concept

Filing / Launch
Human Factors Engineering: Inputs

- User requirements research
- Ethnography / emersion studies
- Use scenarios / preconceptions
- Lifestyles / trends / personas /regimes
- Competitive benchmarking
- Technology benchmarking
- Brand landscape / opportunities
- Literature / best practices

Research | Design development | Launch | Post Launch

HF Engineering

Design/Engineering

Pfizer

Devices Centre of Excellence
Human Factors Engineering: Early formative

• Early stage formative usability studies
• Design refinement
• Early IFU design/wording
• Discovering options
Human Factors Engineering: Late formative

- Late stage formative usability studies
- Choosing options
- IFU refinement

- Packaging
- Branding
- Video and online support
- Training and support
- Training aids / Peripherals

Design / Engineering

HF Engineering

Research | Design development | Post Launch

Launch | Filing
Human Factors Engineering: Validation

• Human Factors pre-clinical validation (using clinically representative product)
• Human Factors summative (using commercially representative product)
Human Factors does not end at Filing!

Does my product need to change?

- Market surveillance
- Patient focus groups
- Complaints

HF Engineering

Research  Design development  Post Launch

Launch

Filing
Further considerations

• Human Factors Studies are typically simulation only
  – Actual use HF studies only requested if use cannot be simulated

• Gather usability feedback from clinical use
  – FDA may ask for this to bolster the usability story

• Real use human factors data typically only anticipated during development. e.g. injection into skin (tolerability etc)

• Clinical usability data relies typically relies on subject (not moderator) and is secondary to HF study data

• FDA expect human factors data or similar to determine potential use issues when on market!
Managing Use Risks

• Must comply with ISO 14971
• Identification typically through User task Analysis (UTA)
• Analysis and evaluation typically through UFMEA
• Risks categorised as:
  – Anticipated
  – Unanticipated
  – Deliberate misuse (out of scope)

Key to understand safety critical tasks and associated risks
Do I require Human Factors?

- The product sponsor must determine based upon:
  - Use related risks
  - Environment of use
  - User population

- May utilize clinical usability feedback or user feedback data from similar marketed products
- FDA recommend talking to them early to ratify approach
- FDA typically want to see the risk assessment

Determine though risk assessment
When HF Studies are required

• Combination products used outside the healthcare environment or by laypersons
  – E.g. home use products or products for self-administration by patients or lay-caregivers

• Combination products that have a device constituent part which HF data should be submitted
Prefilled syringes requiring HF studies

Prefilled syringes with staked needle and needle guard:

- Used by HCP’s in an acute setting
- Used by Patients with neuromuscular disorder or visual impairment
- Where a unique differentiation is required to prevent med errors
- Which is used with various tubing, connectors, pumps and other device constituents in a high risk setting
Examples where HF is not required

A Prefilled syringe:

- Used exclusively by Healthcare Providers (HCP’s)
- That has precedence in a healthcare environment
- Design does not contain novel features
- Lay users whereby use is commonly used and well understood
  - however a good justification is required in this instance
Common use issues with prefilled syringes

- Needle sticks/recapping needles
- Incorrect injection technique
  - Angle of insertion/incorrect injection depth
- High plunger rod force (high viscosity drugs)
- Inappropriate grip
  - E.g. finger grip, plunger rod design or label design and position
- Label obscuring the medicine
- Text size on labelling too small/difficult to read
  - E.g. branding prominence over critical information such as expiration date

Key lessons

Design for user population and Understand/manage risks
User Training or Not?

• Depends on complexity of product
• If training is recommended ensure that a trained and untrained cohort of the user population is included in the summative HF study
  – Non-trained required unless the sponsor can prove that all intended users will be trained before product use
Human Factors Submission

- Design Validation data/conclusions within CTD section 3.2.P.2. and/or 5.3.5.4
- Include Human Factors Engineering Report
- Append HF Summative study report
- If Human Factors is not required:
  - Design Validation data/conclusions should include the usability risk assessment or summary concluding no HF was required

What is a Human Factors Engineering Report?
Human Factors Engineering Report

• HFER is the story of the device usability development
• HFER sections include:
  – Conclusion
  – Intended device users, uses, use environments and training
  – Device user interface
  – Summary of known use problems
  – User task selection, characterization and prioritization
  – Summary of formative evaluations
  – Validation testing
Human Factors Report Conclusion

• Conclude on use error & close calls on critical tasks

• Justify acceptability of findings through
  – Subjective feedback
  – Known problems with similar marketed products
  – Study artefacts including participant nerves
  – If they read the labelling or not

• Provide a risk benefits analysis
  – Could the risk be reduced further?

• Is the product safe and effective?
Conclusions

• Human Factors/Usability is not an ‘add on’
  – Consider intended users early in the development process

• Regulatory Agencies want product sponsor to:
  – Understand and document all user/device interface risks
  – Safety critical risks are identified
  – Reduce use related risks as far as possible
    • Design
    • Labelling
    • Controls (manufacturing controls, user training etc.)
  – Determine if HF data is required for submission

• Don’t forget Design Validation data is always required even if HF data is not!
Thank You