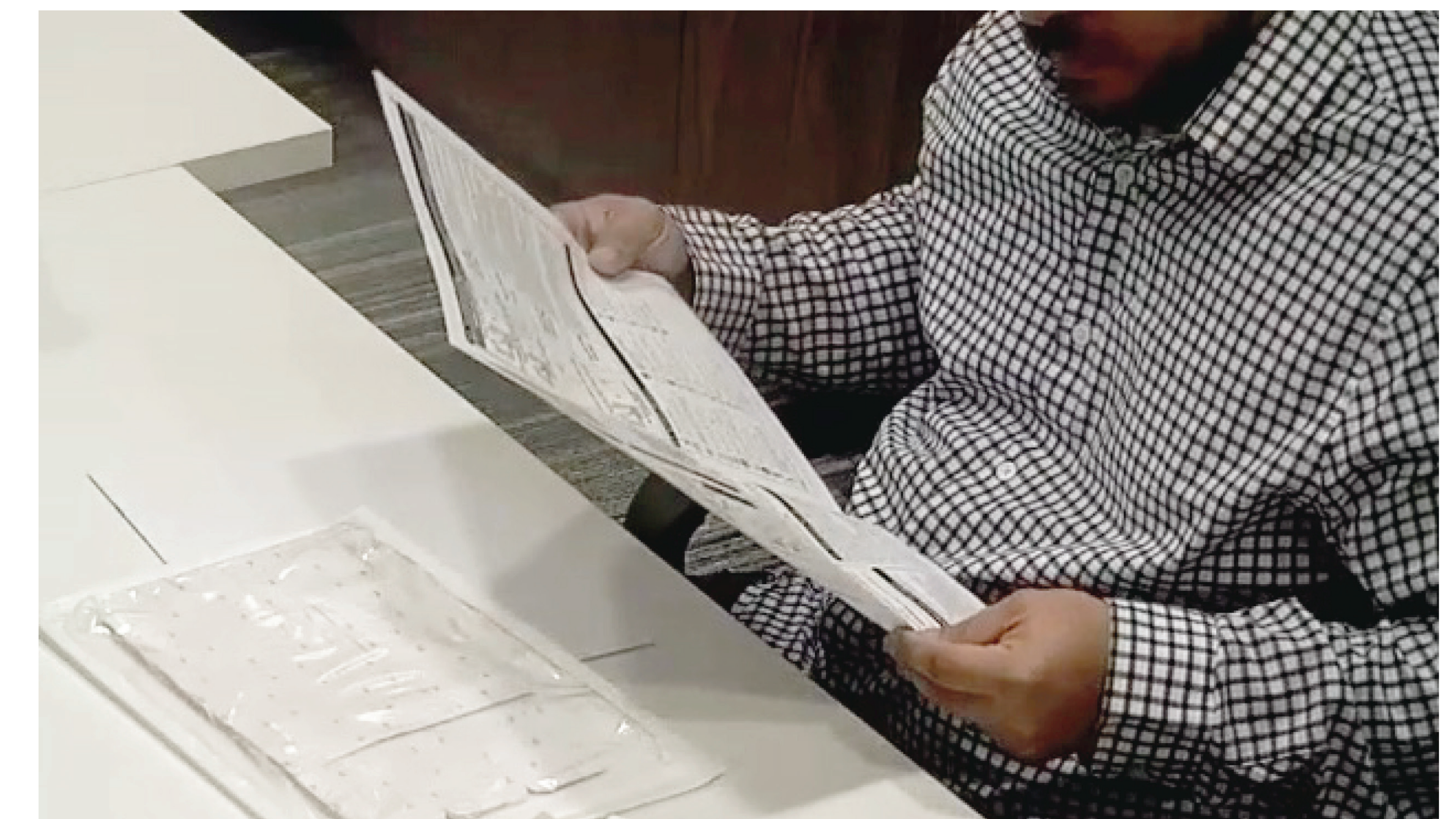


## Why do I need to validate my IFU

- FDA includes Instructions for Use (IFU) as part of the product labeling
- Labelling is considered part of the device User Interface (UI)
- The IFU can also be a risk control measure
- The need to validate the IFU is based on its use as a risk control measure
  - If IFU (or other labeling) is used as a primary risk control measure for a particular hazard, that risk control must be validated
  - Information for safety (labeling) is the least effective form of risk control
    - If possible, other, stronger risk control measures should be employed

## How do I validate my IFU

- Ideally, **IFU should be** developed early in the program and **evaluated as part of formative studies** prior to validation
  - Like any other part of the UI
- Preferred method - System Validation
  - Evaluate the IFU **as part of a simulated use evaluation of the entire system**
    - Participants would use the IFU as needed to assist when completing validation tasks
  - This is the most realistic way to validate the IFU
  - May still need to evaluate specific risk controls in the IFU as knowledge-based questions for things you can't observe or can't simulate safely
- Dedicated IFU Validation Studies
  - Specifically validating the content in the IFU, vs. general knowledge from training, experience, or other sources
  - Specifically instruct users to **locate content** and then **demonstrate comprehension** of material
  - This does not demonstrate the effectiveness of the risk control as part of the system
    - In other words, would users actually use the IFU if needed (look something up in the IFU for assistance using the device)



Participant taking part in an IFU Validation Study

## Challenges of Dedicated IFU Validation Studies

- Is dedicated IFU Validation "realistic"
  - Can the IFU really be a risk control when we know that in many cases, users either don't have access or time to read the IFU, or just choose not to read them
- How do you handle case where users aren't able to locate content, but are able to comprehend content when directed to it
  - In real life, if they can't find the content, how can the risk control be effective?
- How to ask IFU Validation Questions
  - Try to avoid using the exact wording you are asking users to locate
  - Can result in obscure, awkwardly worded, or too general questions, and can introduce bias



## Recommendations / Next Steps

- First, need to make IFU's more usable and accessible
  - Clear, concise information in a format that allows users to quickly locate information
  - Overcome long term bias due to poor quality IFU's
- Plan ahead
  - Develop your IFU early in the product development process
  - Evaluate / Optimize your IFU during one or more formative evaluations
  - Iterative process just like the rest of your UI
- Validate your IFU as part of the simulated use Summative Validation

