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WHITE PAPER

Creating an FDA-Ready Moderator's Script for Your Human Factors Validation Study

By Margarita Cajina, Senior Human Factors Engineer, and Anthony Andre, PhD, CPE, Founding Director, Interface Analysis Associates LLC



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Table of Contents

Click a topic to jump to that section.

Introduction 3

What is a Moderator's Script? 4

FDA Guidance 4

What is Required to Develop the Script? 5

Intended Users 5

Use Environments 5

Training 5

Product Labeling 5

Coding the IFU to Develop Scenarios 5

URRA 6

How to Construct a Validation Script 7

Constructing the Validation Script 7

When and Why to Create Multiple Scripts 7

The Script Format and Layout 9

The Script Sections 10

Order of Main Script Sections 10

How to Script the Performance Section: Intros and Prompts 11

How to Script the Knowledge Task Section 13

How to Script the Debriefs 14

How to Script the Subjective Section 15

Helpful Tips 15

Using the Script to Create the Data Log 16

Formative vs. Validation Scripts 17

Winning Strategies 18

Conclusion 18

About the Authors 19

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Introduction

The moderator's guide, or script, for a human factors (HF) validation study is informed by FDA guidance, study-specific protocol requirements, FDA feedback, and established user research best practices.

The focus of this paper is on validation scripts, with a brief explanation of the differences between validation and formative scripts. Following these recommendations and best practices should result in an FDA compliant moderator's script that is also an efficient and useful tool for study execution.

Key Insights

- The study script should support the test team in clearly identifying what they are observing, measuring, or tracking while also being traceable back to the Instructions for Use (IFU) and Use-Related Risk Assessment (URRA).
- The FDA requires realistic test conditions, independent natural device interaction, scenarios and tasks organized in a logical order, and a definition of success or failure for each task.
- Remember that the script writer and moderator may not be the same person. Make sure that the script is clear and communicates exactly what is needed to run the session.

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What is a Moderator's Script?

Validation protocols for the FDA, whether for combination drug products or medical devices, contain two main sections. The first half centers around product information, intended use, users, and use environments along with a synopsis of the history of the HF program. The second half centers on the proposed methodology of the HF validation study, and within that methodology, the moderator's script becomes the central focus of the FDA.

The moderator's script provides a detailed view of the planned discourse between moderator and participant, revealing study tasks and metrics.

FDA Guidance

HF guidance from the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) provides some direction on developing the moderator's script, but few of the guidance comments are direct and explicit to development of the script.

The statements are more abstract, so inference is required for script construction. Practical experience with the FDA and script feedback fill in a more complete picture and support development of a useful template that relies on the instructions for use (IFU) and use-related risk analysis (URRA) as its main inputs.

Script-related guidance from the FDA provides several stipulations:

- All critical tasks must be performed during the test.
- Test conditions are sufficiently realistic to represent actual conditions of use.
- Allow for independent and natural use, without moderator interference or instruction on what or how to use.
- Use of "think aloud" or verbal protocol is prohibited.
- Tasks that logically occur in sequence when using the device can be grouped into use scenarios.
- Knowledge tasks should be open-ended and neutrally worded.
- Accept participant responses and comments without judgement.
- Prior to testing, define user performance that represents success for each task.

The moderator's script does more than conform to FDA guidance and reviewer comments. When designed correctly, it enables and facilitates the following:

- Development of the data log.
- A reminder of the room setup, supplies needed, and reset instructions.
- The moderator's ability to detect use errors and close calls during the session in real time.
- The moderator's ability to execute the protocol in a consistent and unbiased manner.
- Allows test team members to follow along and cross check.

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What is Required to Develop the Script?

Multiple components are required to develop a successful moderator's script. This paper explores individual elements, including intended users, use environments, training, product labeling, coding scenarios, and the URRA, along with the reasoning behind their inclusion.

Intended Users

Clarity regarding the intended users of the product allows for use of appropriate language and scenarios for those users in the script. It is important to note that multiple user groups may result in multiple scripts when they are responsible for performing different tasks.

For example, healthcare providers (HCPs) and lay users often perform different tasks and use different language, terminology, and workflows. Pediatric users, whether alone or part of dyads, might require a separate introduction. Rescue products may require a unique approach to the script.

Use Environments

The script must be representative of real-world conditions because the space and surroundings affect how a user interacts with a product. Whether the use environment is a doctor's office, home use, or public setting, that information is used to make the scenario more realistic. Lighting conditions, noise, contextual elements, or distractions should be added as necessary to replicate the actual use environment.

Training

The FDA expects the study to evaluate use of the product under the same training conditions that users will experience in the real world. Most validation studies do not involve training unless such training can be proven as guaranteed to be provided to users. Whether or not participants receive training influences how participants are prepared before unaided use and whether errors can be attributed to the product versus inadequate training.

When training is involved, there should be a dedicated training script separate from the validation study script. Training decay, the timing between user training and product use in testing, is typically a minimum of one hour. The training itself should also be evaluated through a final subjective question at the end of the validation study script to allow participants who received the training to assess its effectiveness.

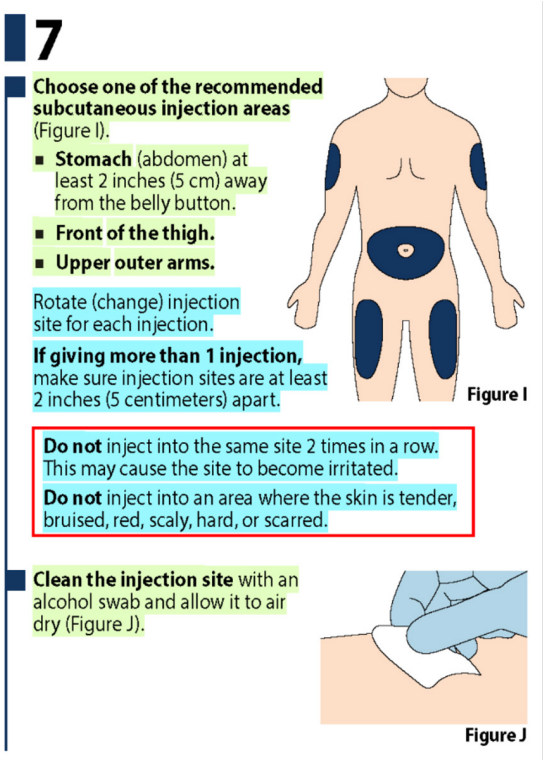
Product Labeling

The product labeling includes the IFU and any additional components that the user will have access to when using the product, such as a quick guide, the labeling on the package (both primary and secondary), or the labeling on the device. Labeling used in the study should be the final intend-to-market product labeling because it contains the information that users will rely on to use the product in the real world. The IFU is the most direct source for construction of the script, but all labeling sources may contribute to performance or knowledge tasks in the script.

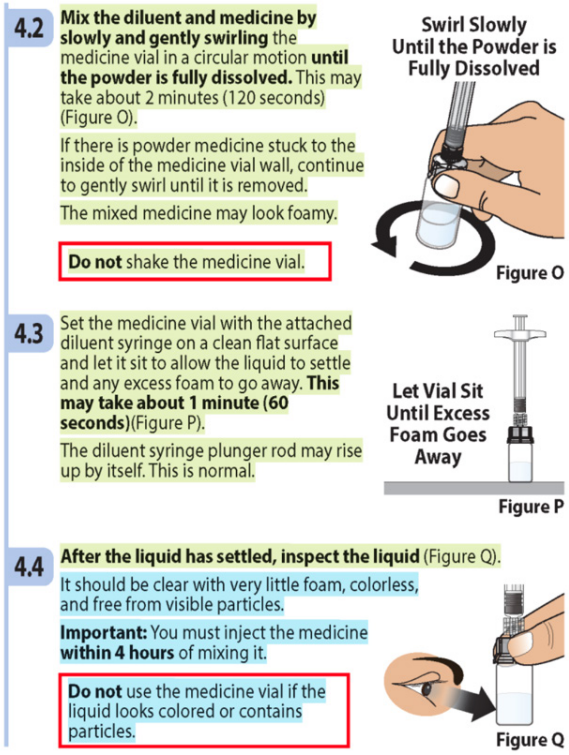
Coding the IFU to Develop Scenarios

Task coding is determined by whether the task can be realistically performed and observed during simulated use. Actions or information that cannot be demonstrated during the simulated use part of the study should be tested via knowledge tasks.

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Example 1



Example 2

Some tasks or information require performance of one part of the task while also demonstrating understanding of a condition or decision that cannot or will not occur during simulated use. The visual examples above show performance/observation tasks highlighted in green and knowledge tasks highlighted in blue.

The first example shows step 7 of an IFU. Choosing and cleaning an injection site are observable tasks—during the study, the participant should choose one of the recommended injection sites by placing the injection pad over that part of their body and clean the injection site (pad) with an alcohol swab. However, the items in blue cannot be easily observed. Participants only perform one injection, so rotating the injection site or choosing sites at least two inches apart for multiple injections will not occur during the study. Knowledge task questions ensure that participants understand the information presented in the instructions but are not observable during simulated use..

The second example shows the steps for a product that must be reconstituted. Most tasks are observable, but a few are not. What the participant observes when inspecting the vial requires a knowledge task to verify.

URRA

The URRA is one of the most important inputs to development of the script. It identifies the use-related hazards, potential use errors, and critical tasks that the validation study must evaluate.

The FDA expects traceability between the tasks that are identified in the URRA and the validation script measures. The URRA should function like a blueprint for the validation script, with the evaluation method identified in the URRA directly informing how each task is tested in the validation script.

The three main columns from the URRA that are used to help develop the validation script are the Use Task Description, Description of Potential Use Errors, and Evaluation Method.

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How to Construct a Validation Script

The FDA requires realistic test conditions, independent natural device interaction, scenarios and tasks organized in a logical order, and a definition of success or failure for each task. Data collection must also include observational, knowledge task, and interview data, along with comprehensive debriefing.

Constructing the Validation Script

The study script's format and layout should support the test team in clearly identifying what they are observing, measuring, or tracking while also being traceable back to the IFU and URRA. The sections within the script are dependent on the product being evaluated because that is directly related to the procedures required for product use. However, the main sections below serve as a strong foundation:

- Supplies and Setup
- Introduction
- Performance Section (e.g., unaided use or unaided dose)
- Knowledge Task Section
- Debriefs
- Subjective Section

When and Why to Create Multiple Scripts

It is best to create separate scripts when a study contains multiple user groups with different tasks or use scenarios. For example, an HCP may be required to do setup and programming for a product, while a patient or caregiver may only ever be required to perform first time or daily use.

Multiple scripts also make the most sense in situations with a within-subjects design where you counterbalance the order that participants experience each condition. Having separate scripts allows the moderator to more easily follow multiple scripts in which tasks are presented in the correct order for each participant. Different training conditions (e.g., trained and untrained) is another scenario that requires separate scripts.

Separate scripts require more time and effort to develop, but they reduce moderator error while improving consistency across participants and traceability. Ultimately, it is also much easier for the FDA reviewer to evaluate each user group, ensuring that each group experienced the intended study conditions.

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The below example highlights scripts developed for two user groups who interact with the same system but perform different roles..

Nurses/technicians unpackage the components, prep the system, and move it into the sterile field (refer to Nurses/Technicians Script Example below). The surgeon then uses the system to perform the procedure (refer to the Surgeons Script Example below). The user groups have different scenarios, different tasks, and different measures so using separate scripts is the most appropriate choice.

Study Script (Session 2) – Nurses/Technicians

Supplies:	
• Product Kit • Introducer Sheath • Guidewire • Additional Preparation Syringes • Saline (minimum 50 mL)	• Contrast-saline mixture (minimum 50 mL) • Gloves • Quick Reference Guide and Instructions for Use • Patient Information Card

1. Introduction & Unaided Preparation

Task/Question	Observation/Measure
Moderator: Welcome, I am going to have you interact with the system that you were trained on earlier. We are going to imagine a scenario where your patient has already been prepped for their endovascular procedure, and you need to prepare the system for the surgeon. You should have everything that you need to perform the procedure here in this room. If there's anything that you need that you don't see here, please ask me for it.	
OBSERVATIONAL TASK: Please go ahead prepare the system for the surgeon. You can start whenever you are ready.	**Obtain Additional Supplies** __ Does not obtain introducer sheath __ Does not obtain guidewire __ Does not obtain additional preparation syringes __ Does not obtain saline __ Does not obtain contrast-saline **Open Product Kit Outside Sterile Field** __ Does not open Product Kit box __ Opens Product Kit within sterile field **Transfer Inner Tray into Sterile Field** __ Does not transfer inner tray into sterile field __ Does not use sterile technique to open outer tray and transfer inner tray into sterile field

Nurses/Technicians Script Example

Study Script (Session 2) – Surgeons

Supplies:	
• Prepared Product Kit • Introducer Sheath • Guidewire • Anatomical training model • Display screen for simulating fluoroscopic display	• Clock/Timer • Gloves • Quick Reference Guide • Instructions for Use • Patient Information Card • Additional Preparation Supplies

1. Introduction & Unaided Administration

Task/Question	Observation/Measure
Moderator: Welcome, I am going to have you interact with the system that you were trained on earlier. We are going to imagine a scenario where your patient has already been prepped for their endovascular procedure, and your team has already prepared the system. You should have everything that you need to perform the procedure here in this room. If there's anything that you need that you don't see here, please ask me for it.	
OBSERVATIONAL TASK: Please go ahead and treat your patient using the system. You can start whenever you are ready.	**Use fluoroscopy during procedure** __ Does not use fluoroscopy while advancing the Catheter to the intended site within anatomy **Advance guidewire and introducer sheath** __ Does not advance the guidewire and introducer sheath __ Does not advance the guidewire and introducer sheath to the intended site within anatomy **Advance Catheter into the Introducer Sheath** __ Does not introduce the Catheter into the introducer sheath using standard techniques **Secure Catheter** __ Does not secure the catheter

Surgeons Script Example

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The Script Format and Layout

While there is no required format for the validation script, experience has led to the development of an approach that effectively supports traceability back to the URRA and supports the test team in consistently conducting the study while ensuring that all critical tasks, observations, and knowledge areas are appropriately assessed.

The layout consists of a single column for general instructions to the participant and two columns for parts of the scenario that involve user interaction with the product, such as performance and knowledge tasks.

The right column lists the metrics and potential use errors to aid the moderator in identifying use errors, close calls, and observed difficulties, and thus, what needs to be debriefed. A light blue background denotes moderator-read blocks of text, such as general background information and scenario setup that do not immediately preface a task. A font size of no less than 12 points ensures at-a-glance readability for the moderator. The below example demonstrates how this looks in practice.

A more complex product, such as a left ventricular assist device (LVAD), requires a longer script due to the intricacy of the product. It has numerous complex scenarios, including start of day, bedtime, troubleshooting, and alarms. The set of knowledge tasks is very large as well.

Validation Study Script

Supplies:	
• Prefilled Safety Syringe in Carton with Instructions for Use (stored in refrigerator) • Refrigerator • Injection pad and Velcro band • Manikin (HCPs, Caregivers) • Sharps Disposal Container	• Hand sanitizer • Gloves (HCPs) • Alcohol swabs • Bandages • Cotton balls/gauze • Trash Can

1. Introduction & Unaided Dose

Task/Question	Observations/Comments
Moderator: Welcome to our study. Today I'm going to introduce you to a new product that would be used to treat patients with rheumatoid arthritis. **Patients:** Let's imagine a scenario where you have been prescribed this new medicine and you just got home from the pharmacy with it. **Caregivers:** Let's imagine a scenario where you have volunteered to give your family member their new medicine, and you just got home from the pharmacy with it. **HCPs:** Let's imagine a scenario where you have a patient coming in who has been prescribed this medicine. **[Moderator places product carton in front of participant.]**	
Moderator: You should have everything you need to perform the process here in this room; if there is something you need that you don't see here, please ask and I will get it for you. When you are ready to dose, please use the injection pad on the table **[Moderator shows participant injection pad]** and attach it to the site on **[your body/the patient's body]**	**OBSERVATIONAL TASKS:** **Safe Use** __ Recaps needle prior to injection __ Attempts to remove air from the syringe. **Remove Syringe Carton from Refrigerator** __ Does not remove carton from refrigerator **Allow to Warm to Room Temperature**

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The Script Sections

These standard sections of a HF validation script apply to almost every study:

1. List of supplies and room setup
2. Introductions and scenario setup
3. Performance scenario and task instructions, including the list of potential errors and metrics for each task (and correct responses)
4. Performance Debrief
5. Knowledge Tasks
6. Knowledge Task Debrief
7. Subjective questions/feedback prompts

The study script begins with the list of supplies and any room setup details to remind the test team of all the needed supplies and important room setup considerations.

What's the value of including that level of detail? It ensures consistency across participants and moderators, particularly if parallel studies are conducted in multiple locations. Specifying supplies and room setup ensures that each location and moderator are conducting the study with the same supplies and in the same manner.

Documenting exactly what participants had available to them when performing each task also supports traceability for regulatory transparency. The FDA reviewer can verify that the study supplies are representative of the intended commercial product and use environment.

The below examples demonstrate the organization of a thorough list of supplies and test room setup.

Supplies	
• Prefilled safety syringe in carton with instructions for use (stored in refrigerator) • refrigerator • Injection pad and velcro band • Manikin (HCPs, Caregivers) • Sharps disposal container	• Hand Sanitizer • Gloves • Alcohol swabs • Bandages • Cotton balls/gauze • Trash can

Example 1

Supplies:
• TRADENAME product, including outer packaging • Small backpack/pouch (Lay users only) • One new TRADENAME and two used TRADENAME products in bin • Full-size manikin • Laptop with background/ambient noise audio file • Side table with telephone • Household waste basket • Disposable titrile gloves, various sizes (HCPs only)

Test Room Setup:
• Place manikin on floor and laying on its back • Place two devices in their storage tubes in the bag next to manikin (or have ready to hand to HCP upon entry) • Start sound file on laptop

Example 2

Order of Main Script Sections

Through FDA feedback and experience from successful submissions, the following study flow has proven to work well and satisfy the FDA:

1. Performance scenarios and tasks followed by associated debriefs
2. Knowledge task questions followed by associated debriefs
3. Final subjective question(s)

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How to Script the Performance Section: Intros and Prompts

The entire script, particularly the introduction, should be concise and free of any leading language. Provide only enough information to set the proper context without telling the user what to do or how to do it.

The participant should be allowed to determine on their own whether they read the IFU before starting, start without even looking at the IFU, or read and perform each step as they go.

As the examples below demonstrate, instructions should remain as vague as possible while still orienting the participant to the room and the end goal.

To simulate a more naturalistic use scenario, do not interrupt the participant as they perform tasks. All instructions should be provided at the beginning of the test scenario.

The reason for this best practice is that disturbing the participant during tasks is not representative of real-life use and may bias the scenario. If a participant is following along in the instructions, interruption could cause them to lose their place. As such, all knowledge tasks should be asked after simulated use is complete.

It is important to avoid intervention unless the participant is in danger of hurting themselves or unable to perform a task. If the moderator must intervene, the FDA considers that a use error and it should be debriefed as such.

In practice, specifically in scenarios that require placement of an injection pad, providing pre-instruction that directs the user to place the injection pad on themselves (or a manikin) and creating an easier way to enable self-placement prepares the participant to complete tasks without the need for assistance or instruction from the moderator mid-scenario.

This improved practice was developed in response to FDA feedback stating that the study protocol methodology did not allow the user to interact with the product in a naturalistic way. They expressed concern that asking knowledge-based questions or otherwise interrupting the participant during simulated use was not representative of users' actual use interactions with the product and would potentially bias the simulated use scenario.

The most effective standard script format has two columns. The left column contains moderator prompts that provide scenario and task structure. The right column includes metrics taken directly from the potential use errors column of the URRA (refer to example on next page).

Example 1

Task/Question	Observation/Measure
Moderator: Welcome to our study. Today, I am going to introduce you to a new product that would be used to treat patients with rheumatoid arthritis. **Patients:** Let's imagine a scenario where you have been prescribed this new medicine. You just got home from the pharmacy with it, and now it is time for you to dose with it. Do what you would normally do with this new medicine. **Caregivers:** Let's imagine a scenario where you volunteered to give a family member their new medicine. You just got home from the pharmacy with it and now it is time for you to dose your family member. Do what you would normally do with this new medicine. **HCP's:** Let's imagine a scenario where you have a patient coming in who has been prescribed this new medicine, and now it is time for you to dose them with it. Do what you would normally do with this new medicine. **[Moderator places product carton in front of the participant.]**	

Example 2

Task/Question	Observation/Measure
Moderator: Welcome back. Today, we are going to have you perform a Targeted Lung Denervation (TLD) treatment using the system you were trained on yesterday. You should treat this room as if you were performing this treatment in the hospital to a real patient. After you have completed the treatment procedure, we will ask each of you questions about your experience. Do you have any questions before we begin?	

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Example 3

OBSERVATIONAL TASK: Please go ahead and prepare the system for the surgeon. You can start whenever you are ready.	**Obtain Additional Supplies** __ Does not obtain introducer sheath __ Does not obtain guidewire __ Does not obtain additional preparation syringes __ Does not obtain saline __ Does not obtain contrast-saline **Open Product Kit Outside of Sterile Field** __ Does not open Product Kit box __ Opens Product Kit within sterile field **Transfer Inner Tray into Sterile Field** __ Does not transfer inner tray into sterile field __ Does not use sterile technique to open outer tray and transfer inner tray into sterile field

Bolded text in the right column conveys the identical use task description, also taken from the URRA. The items below each use task are the potential use errors, taken directly from the Description of Potential Use Errors column in the URRA. The metrics are listed in the negative to remain consistent with the URRA. This creates easy traceability to the URRA for the test team and the FDA, which helps ensure that all the risks identified in the URRA are covered in the study. Listing the metrics in the script allows the moderator to follow along, taking note of any use errors, close calls, and observed difficulties.

This formatting helps the team evaluate each task consistently and supports moderator-datalogger agreement during observation. Even if the task outcomes are being logged by someone else, the moderator must still be aware of the potential use errors to know when a debrief needs to occur.

Additional observations about close calls, observed user difficulty, unanticipated events, calls for help, and relevant verbal comments are important to include in documentation. Unanticipated events tend to occur fairly regularly. Although the product and IFU have been vetted and the product has gone through formative testing, you can almost always expect a participant to do something surprising during the validation study.

For example, during a study for a disposable insulin pen, every time the participant turned the dial toward their prescribed dose, they pressed the injection button in slightly. In doing so, the pen would expel a small amount of liquid and the dialed dose value would also decrease. The participant did eventually dial their total dose value, but the behavior (pressing in slightly on the injection button when dialing the dose) was entirely unanticipated.

Calls for help are instances when the participant directly asks the moderator for help or says that they would call their doctor, pharmacist, or a family member to help.

Relevant verbal comments are remarks the participant makes, such as expressing that something doesn't make sense or is confusing. They may also question an attachment or fit of the device. Ideally, the occurrence of these events should be minimal by the time the validation study occurs.

Recording or documenting timing elements should occur when time itself is part of a critical task or could influence safe and effective use. For example, if the IFU instructs the user to hold the autoinjector in place for five seconds after the plunger stops moving, then the hold time for each participant must be recorded to verify that they met the requirement and didn't remove the autoinjector from the site prematurely.

In other examples, if the IFU instructs users to rinse a product component under running water for 10 seconds or to wait two minutes after mixing a medication before continuing to the next step, that must be recorded. When the IFU specifies time, documentation is required.

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How to Script the Knowledge Task Section

The knowledge task introduction should be short and neutral (refer to image below, text highlighted with green border). The IFU should not be mentioned even though that is the object of knowledge task questions. Participants' personal knowledge or their memory of the IFU are not the main focus.

The FDA views specific mention of the IFU as potentially leading. When structuring the script for knowledge tasks, the prompt is located in the left-hand column and content from the IFU is on the right (refer to image below, knowledge task is on left side and answer and measure is on right side).

Knowledge tasks cover content in the IFU that cannot be easily observed through simulated and unaided use, such as checking the expiration date, important safety information, or dosing schedule.

Although it can be challenging, use open-ended questions and avoid leading language. Be prepared for participants to see certain words or phrases as ambiguous, which is an artifact of open-ended questions.

One FDA-accepted strategy for improving open-ended questions is adding "if anything" statements. For example, "What, if anything, should you do before switching types of insulin?" The participant response, based on content in the IFU, should be that they would contact their healthcare provider.

Knowledge tasks should also have a 1:1 ratio; each question should have only one answer. In one study scenario involving a nasal spray, asking a participant what constitutes a full dose should prompt them to respond that the full dosage is two sprays.

Task/Question	Observation/Measure
Moderator: Next, I am going to ask you a few questions about this product and its dosing procedure.	
KNOWLEDGE TASK: What type of injection are you asked to perform with this device?	**A: For subcutaneous injection only.** **Choose Injection Site** __ Does not identify product if for under the skin (subcutaneous) injection only.
KNOWLEDGE TASK: How many doses can you give with a single syringe?	**A: One dose.** **Use Correct Number of Syringes for Dose** __ Does not identify that the syringe is single-use and provides only 1 dose.

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How to Script the Debriefs

Debriefs should happen after task performance is complete. Any use error, close call, observed difficulty, unanticipated event, and any instance of moderator intervention requires a debrief.

Starting a debrief may differ slightly depending on the use error, and in the case of multiple use errors, they should be addressed in chronological order of product use or interaction.

The following prompts can be embedded in the script to assist the moderator with leading the debrief:

1. I noticed you did/didn't do XXX.
2. Why do you think that happened?
3. What, if anything, about the product or instructions contributed to this?
4. What would you change, if anything, about the product or instructions to prevent that from happening?

The goal of the questions is to uncover the root of the error. Ultimately, participant responses help determine whether there was anything about the product or IFU that caused them to make that error.

Below is an example of how the error of not allowing the syringe carton to warm to room temperature is presented in the script to inform the moderator that there is a knowledge task associated with this metric and to not immediately debrief after the performance section.

This observable measure also has a knowledge task associated with the measure since participants will often skip the step in a study scenario.

They may assume that they do not need to wait for the product to warm to room temperature because they are in a study or because the product they are given already feels like it is at room temperature. Although that may be true, it is still important to verify that the participant read and understood the step despite choosing to skip it. That is why the knowledge task question must be asked first, before debriefing.

If the participant answers correctly, the moderator can proceed to the next debrief. If they do not know, ask the participant if they can find the information in the instructions. For an incorrect answer, ask where they got the information from. The moderator may eventually need to point out the answer in the instructions and ask if the information is clearly presented.

For negative responses, it is important to ask what could change about the product or IFU to prevent the use error.

ERROR DEBRIEF

Debriefing (As needed if user experiences close call, use error, or difficulty): To include a comprehensive open-ended interview to determine root cause.

Allow to Warm to Room Temperature

__ Does not allow the syringe carton[s] to warm to room temperature (sit for approximately 1 hour) *[Measured via Knowledge Task if Participant Does not Perform Task]*

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How to Script the Subjective Section

At the end of the study feel free to ask a limited number of subjective questions. Do note, however, that the primary purpose of the validation study is to objectively demonstrate that intended users can use a device safely and effectively, not collect opinions about the product or procedure. For the final question, the addition of "if you needed to" maintains focus on the usability aspect of the product rather than participant preferences (refer to example below).

3. Final Disposition

Task/Question	Observations/Comments
Moderator: A final question for you.	
Q: Do you think you could safely and successfully prepare and dose with this product if you needed to? **If no:** please explain.	Verbal Response:

Helpful Tips

- Avoid using leading language.
- Ensure debriefs are open-ended and applied to all use errors, close calls, difficulties, and moderator interventions.
- Ensure traceability between the IFU, URRA, script tasks, and metrics.
- Remember that the script writer and moderator may not be the same person. Make sure that the script is clear and communicates exactly what is needed to run the session, including:
  - → How the room should be set up
  - → When to present the product to the participant
  - → When to take out a dose card
  - → When and where to move the manikin
  - → When to switch out any props

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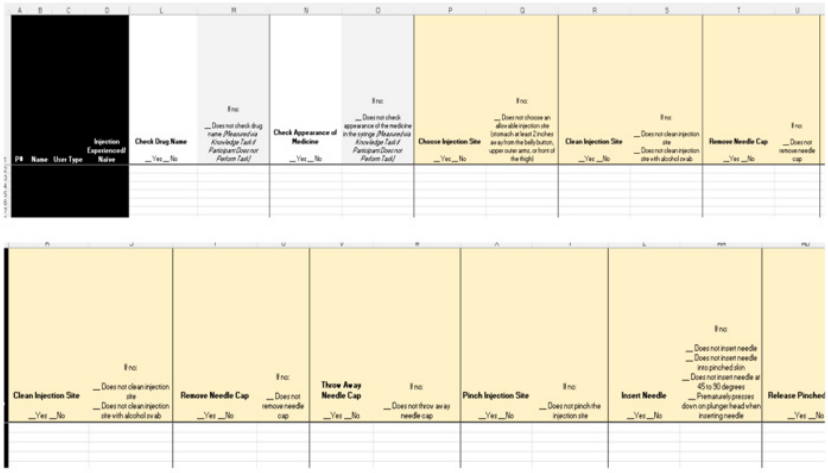
Using the Script to Create the Data Log

One added benefit of the format outlined in this paper is that the script can directly be used to create the data log. It is important to note that the data log should only be created after the script is finalized. The script is a regular document, but data logs are completed in a spreadsheet format.

The right-hand column of the metrics and potential use errors in each of the scripts feeds into the creation of the data log, creating symmetry and common language between both documents.

On the left side of the below example is part of a script for a combination drug product with different subtasks and potential use errors visible. That can be converted to the columns of tasks and users in a data log, as shown on the right side of the graphic. The process of creating the data log after script finalization is very efficient using this structure.

Task/Question	Observations/Comments
You can start whenever you are ready. **[Moderator moves manikin patient closer to HCP/Caregiver participant.]**	__ Does not allow the syringe carton[s] to warm to room temperature (sit for approximately 1 hour) *[Measured via Knowledge Task if Participant Does not Perform Task]* **Check Drug Name** __ Does not check drug name *[Measured via Knowledge Task if Participant Does not Perform Task]* __ Uses incorrect drug **Check Expiration Date** __ Does not check expiration date *[Measured via Knowledge Task if Participant Does not Perform Task]* __ Uses expired drug **Check for Damage** __ Does not check for damage __ Uses damaged syringe **Check Appearance of Medicine** __ Does not check appearance of the medicine in the syringe *[Measured via Knowledge Task if Participant Does not Perform Task]* **Choose Injection Site** __ Does not choose an allowable injection site (stomach at least 2 inches away from the belly button, upper outer arms, or front of the thigh) **Clean Injection Site** __ Does not clean injection site __ Does not clean injection site with alcohol swab **Remove Needle Cap** __ Does not remove needle cap **Throw Away Needle Cap** __ Does not throw away needle cap **Pinch Injection Site**



Script and Data Log Example

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Formative vs. Validation Scripts

Applying this proven design approach for validation scripts to formative studies is very effective. However, the design and execution are slightly different for formative studies, which results in some changes in the script. A formative study may differ from a validation study in the following ways, including (but not limited to):

- **Forced IFU use:** One goal of a formative study may include optimizing the IFU, so participants can be asked to read and follow the IFU. This helps determine whether IFU use translates to a successful interaction.
- **Discussion of past products or experiences:** Whether verbalized or not, most participants will compare their use of the study product to other similar products they've used. It is beneficial to address these experiences in a formative study to identify expectations, preferences, and potential sources of confusion that may influence how users interact with the study product and inform opportunities for improvement.
- **More exploratory interaction:** This type of interaction reveals how users naturally approach and interact with a product without being constrained by predefined tasks. This helps identify unexpected use patterns, product usability issues, and opportunities for improvement.
- **More subjective feedback and opinions related to usability:** This may also include more marketing-related objectives that the client wants to gauge participant response to, which is not appropriate for inclusion in a validation study.
- **More follow-ups and debriefs:** In a formative study, this can include things that are not classified as difficulties, close calls, or use errors. Hesitations or other concerning observations can be investigated further.
- **Product comparisons:** It is possible to discuss how the present product relates to other products the participant uses, which is not included in a validation study.

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Winning Strategies

- Remember, the FDA's approach to the script or design of a validation study is not directly based on any other standard or any other region's regulatory approach. Be sure to adhere to FDA-specific best practices.
- The URRA and the IFU are the most direct inputs to the script, so traceability back to both of them is important. The FDA will be referring to those documents as they evaluate the moderator's script.
- Have other team members not directly involved in study development review the script for leading language.
- Apply usability principles and appropriate font design to your script.
- Practice, practice, practice! Each script should be practiced in real time to refine flow, eliminate potential ambiguity, and develop the moderator's comfort.
- Develop a format and template that can be reused for every study.
- Submit the protocol, including the script, for review by the FDA whenever possible.

Conclusion

An FDA-compliant moderator's script should be an efficient and useful tool, both for HF validation study execution and development of supporting data.

The best practices and recommendations outlined in this paper have been honed through significant experience and FDA feedback to deliver a moderator's script that fulfills those goals for both validation and, with a few modifications, formative studies.

Frequently Asked Questions

Click here for the companion FAQ sheet.

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About the Authors



Margarita Cajina

Margarita earned her Master of Science degree in engineering with a focus on Human Factors and Ergonomics from San Jose State University. She also holds a Bachelor of Science in Psychology (with a Certificate in Human Factors) and a Bachelor of Arts in Political Science from the University of Utah, graduating in 2008. Before joining IAA, Maggie interned at NASA Ames Research Center, where she completed her thesis on the effects of automation levels and failure frequency on simulated lunar lander performance. This work was featured in the 2014 IEEE Aerospace Conference Proceedings. In addition to her technical expertise, Maggie has experience in Sales and Marketing and is fluent in Spanish. In her free time, she enjoys spending time with her family and running half marathons.



Anthony Andre, PhD, CPE

Anthony Andre is a world-recognized thought leader in healthcare human factors. He is Director of Interface Analysis Associates LLC, a leading healthcare human factors consultancy in business since 1993. He is a recently retired Professor of Human Factors/Ergonomics at San Jose State University, the Founding Chair of the International Symposium on Human Factors and Ergonomics in Healthcare and the Founding Editor-in-Chief of the journal "Human Factors in Healthcare."

Dr. Andre and his staff have been at the forefront of the combination drug product and medical device Human Factors movement, having managed and executed hundreds of HF validation programs for pharma, biotech, and medical device sponsors all over the world. IAA's 33 years of healthcare human factors experience is incomparable. Dr. Andre has provided human factors training to the FDA reviewers, and for 10 years moderated an annual FDA-Industry human factors workshop.

About Interface Analysis Associates

Interface Analysis Associates (IAA) is a human factors engineering and usability consulting firm specializing in medical devices, combination drug products, and other regulated technologies. Since 1993, IAA has supported product development and regulatory programs through user-centered research, usability testing, and risk analysis, helping organizations improve safety, usability, and overall product performance. Learn more at interfaceanalysis.com.

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