

Key Takeaways from FDA's 2026 Human Factors Guidance

Summary of the revised “Applying Human Factors and Usability Engineering to Medical Devices” guidance and related 2026 submission framework

FDA guidance issued August 3, 2026

Executive takeaway

The 2026 update is best viewed as an operational realignment, not a redesign of FDA Human Factors (HF) practice. The familiar core process remains: understand users and use environments, perform use-related risk analysis, conduct formative work, identify critical tasks, apply risk controls, and validate the final user interface. The major changes strengthen the connection of HF to formal design inputs and risk management, make lifecycle and cumulative-change evidence more important, and create a more proportional framework for what HF information is submitted to FDA.

1. Overall Direction of the 2026 Update

FDA now more clearly separates two questions: (1) how HF/UE should be performed and integrated into development and risk management, and (2) what HF information should be included in a marketing submission. The revised Applying Human Factors guidance addresses the development process; the separate 2026 Content of Human Factors Information in Medical Device Marketing Submissions guidance addresses submission content.

2. Key Changes and Practical Impact

Area	2026 Change / Clarification	Practical Impact
HF as a formal design input	FDA states that design and development inputs must include applicable outputs of risk management and usability requirements according to intended use.	Usability requirements should not remain isolated in an HF file. They should enter the formal design-input system and trace to user needs, risk controls, verification/validation, and design reviews.
Risk-management integration	Terminology is more closely aligned with formal medical-device risk management, emphasizing risk control measures and effectiveness.	Integrate the URRAs with the product risk-management process. Use the risk-control hierarchy and document how HF controls are implemented and evaluated.
Critical-task determination	Critical tasks remain driven primarily by the severity of potential harm because probability of use error is often difficult to estimate.	Do not use a low estimated occurrence probability to downgrade a task that could lead to serious harm. Criticality should be clearly justified from the risk analysis.
URRA completeness	The current framework emphasizes a complete task structure in the URRAs, with critical tasks identified from that structure.	Avoid beginning with a preselected list of critical tasks. Show the logic from task to use error, hazardous situation/harm, severity, criticality, risk control, and control-effectiveness evidence.

Area	2026 Change / Clarification	Practical Impact
Submission proportionality	The old 2016 Appendix A universal HFE/UE report model is no longer the single submission architecture. The 2026 content guidance uses Categories 1, 2, and 3.	Maintain a comprehensive internal HF file, while tailoring the amount of information submitted to FDA to the applicable submission category.
Decision Point D	Even when critical tasks exist or are impacted, new HF validation data may not always need to be submitted if objective evidence shows existing risk controls remain effective.	This can reduce unnecessary repeat validation for appropriate new or modified devices, but only when the lifecycle evidence is strong and well documented.
Lifecycle / post-market evidence	Complaint history and other lifecycle data can become important evidence for whether existing risk controls remain effective.	Complaint and CAPA investigations should capture HF-relevant details: UI involvement, use error, root cause, and whether the applicable risk control performed as intended.
Cumulative modifications	For modified devices, the analysis article highlights the need to assess multiple changes collectively rather than only one change at a time.	Add cumulative-change assessment to HF change-control and revalidation decision processes.
Revalidation after changes	The revised guidance uses clearer revalidation language when risk controls or the user interface are modified after validation findings.	Treat the decision as formal design validation/change control. Revalidation may be focused on affected interactions and tasks; a full repeat of the original study is not automatically necessary.
Residual risk	The 2016 “true residual risk” concept is removed in favor of conventional risk-management logic.	After considering additional controls, evaluate residual risk acceptability and use benefit-risk reasoning where needed. Align HF residual-risk conclusions with the overall risk-management file.

3. HF Validation Expectations That Remain Important

- **Representative users and distinct user groups:** FDA continues to expect representative users. Where user populations differ in ways that could affect interactions or use-error potential, they should be treated as distinct populations.
- **At least 15 participants per distinct user population:** FDA continues to describe 15 participants as the general practical minimum for HF validation, with higher numbers possible for specific device types.
- **All critical tasks:** HF validation should include all critical tasks identified through preliminary analyses and evaluations.
- **Final / representative user interface:** The validation interface, including labeling, should represent the final design, and the use conditions should be sufficiently realistic to support generalization to actual use.
- **Qualitative purpose:** HF validation remains primarily qualitative, intended to identify use-interface problems and root causes rather than estimate use-error rates or satisfy numerical acceptance criteria.

4. Validation-Specific Clarifications

Labeling and training representativeness: The 2026 wording is somewhat less literal than the 2016 “correspond exactly” phrasing, but this should not be interpreted as permission to validate materially different labeling or training. The study materials still need to represent what users will actually receive.

Training: Training in validation should approximate real-world training. If actual users receive little or no training, the validation design should reflect that. Changes to labeling or training after critical-task failures require evidence that the changes are effective.

Repeated use / learning curve: Repeated use should be included when it is relevant to reasonable proficiency or when actual use involves repeated performance of critical tasks. The rationale should be based on the real use context.

Terminology: “summative” vs. HF validation: FDA notes that “summative testing” may be defined in ways that omit elements FDA expects. Calling a study “summative” does not by itself demonstrate that it meets FDA HF validation expectations.

5. Formative Evaluation: More Flexibility, but Sample Size Must Follow the Question

The revised definition of formative evaluation is more intent-based: exploring user-interface strengths, weaknesses, and unanticipated use errors. This does not create a universal formative-study sample size. Small iterative samples can be appropriate for discovering usability problems, but larger or statistically justified samples may be needed for quantitative comparisons, preference estimates, claims, or other questions requiring statistical inference.

Practical rule: “Formative” describes the role of the evaluation in development; it does not determine the appropriate sample size.

6. Special Consideration for Combination Products

The analysis article notes that the 2026 Content of Human Factors Information in Medical Device Marketing Submissions guidance does not directly address combination products and directs sponsors to the appropriate FDA Center/review division for combination-product-specific HF questions. Therefore, the Category 1/2/3 framework should not automatically be written into a drug-device combination-product procedure as though FDA has formally applied it to all combination products. The concepts may still be useful, but the regulatory pathway and review division remain important to the HF strategy.

7. Recommended QMS / SOP Updates

- Make usability requirements formal design inputs and require traceability to user needs, URRAs outputs, risk controls, design reviews, and verification/validation.
- Update the URRAs template so it begins with the complete task structure and identifies critical tasks based on potential severity of harm.
- Align HF risk controls and residual-risk evaluation with the organization’s ISO 14971-style risk-management process.
- Add a formal HF change-impact and revalidation assessment, including cumulative changes and comparison with the previously validated user interface.
- Strengthen complaint/CAPA data capture so post-market evidence can support HF lifecycle decisions and Decision Point D rationales.
- Replace any SOP or template that still treats the 2016 Appendix A format as the universal FDA HFE/UE report structure.

- Maintain comprehensive HF evidence internally even when the submission package is reduced under a lower HF submission category.
- Update terminology and definitions, including URRR, abnormal use, residual risk, revalidation, and human factors validation testing.

8. Bottom-Line Conclusion

FDA has made the HF submission framework more flexible while making the quality, traceability, and continuity of the underlying HF and risk-management evidence more important. The most significant operational implication is that manufacturers need stronger connections among usability requirements, design inputs, URRR, risk controls, validation, change control, complaints/CAPA, and post-market evidence across the product lifecycle.

