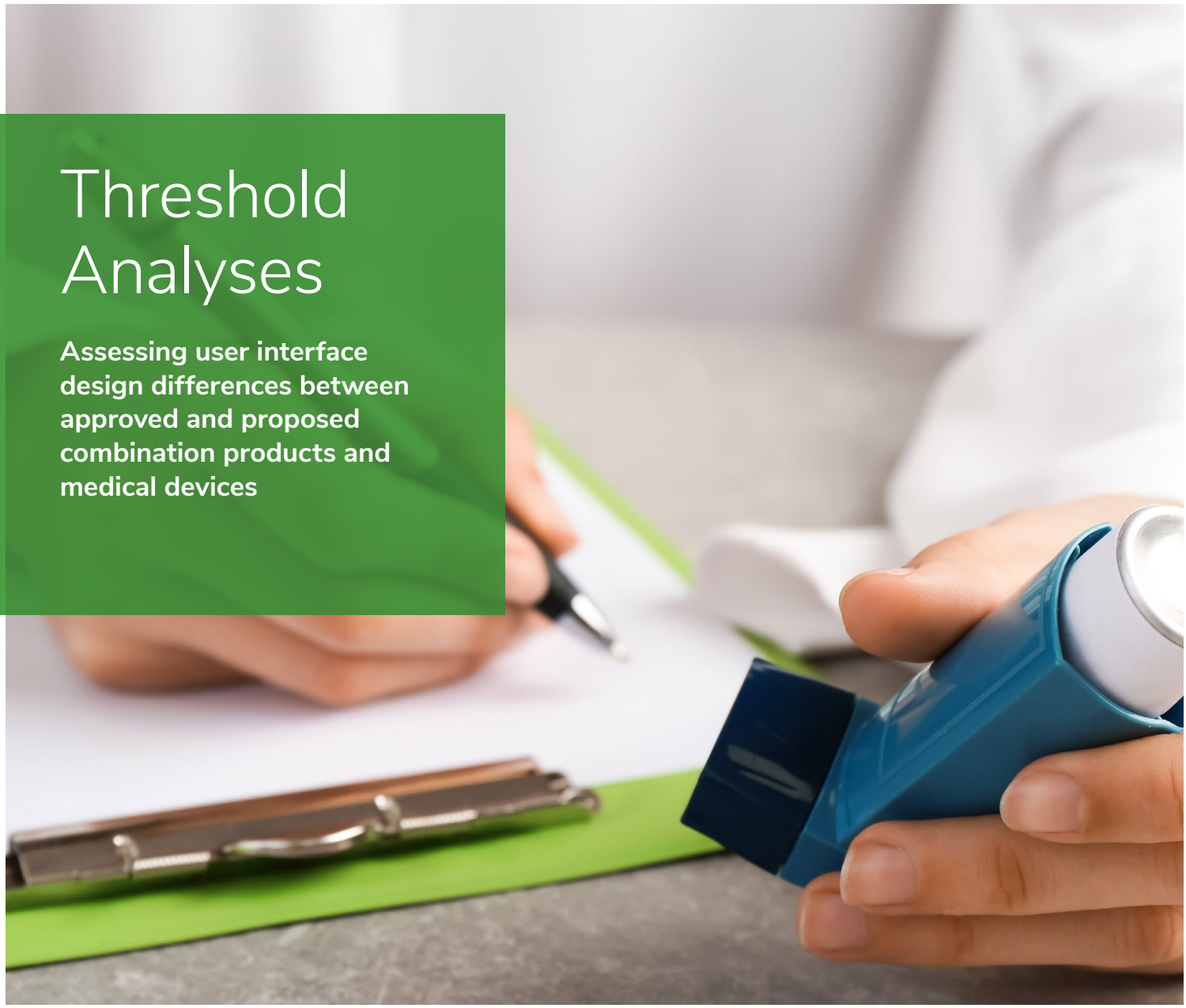
Threshold Analyses

Assessing user interface design differences between approved and proposed combination products and medical devices



Human Factors Research & Design

Allison Strochlic
Research Director
Human Factors Research & Design
allison.strochlic@ul.com

Michael Wiklund
General Manager
Human Factors Research & Design
michael.wiklund@ul.com

Maija Smith
Senior Human Factors Specialist
Human Factors Research & Design
maija.smith@ul.com

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Introduction

General

Threshold analyses are detailed comparisons between the user interfaces of two products to identify and assess the potential impact of any differences. The United States (US) Food and Drug Administration (FDA) first introduced the concept of threshold analyses in two draft guidance documents released in January 2017 by the Center for Drug Evaluation and Research (CDER). While threshold analyses were initially introduced in the context of **generic and interchangeable biological combination products**[1] (i.e., drug delivery devices), aspects of the method **also apply to medical device development**, as described further below.

The guidance documents, which focus on combination products, describe an FDA-approved product – a "reference listed drug" or "reference product" – against which a proposed product in development should be compared. The FDA calls for manufacturers to demonstrate, through threshold analysis and other methods, that their proposed product can be safely substituted for its reference product from a human factors (HF) perspective.[2]

Applicability to combination products reviewed by FDA's CDER

The first of the applicable draft guidances,[3] which still applies today, directs pharmaceutical companies to perform threshold analyses when developing a **proposed generic combination product** to be submitted via an abbreviated new drug application (ANDA).[4] Generic combination products, such as injectors and inhalers, are without question the prime candidates for threshold analyses.

The second draft guidance document originally prescribed threshold analyses for **interchangeable biologic products**.[5] This guidance, in its final form published in May 2019,[6] does not make specific reference to threshold analyses by name. However, the final guidance warns manufacturers against seeking licensure for an interchangeable biologic with a "presentation" (container closure and delivery device components) that differs from the FDA-approved reference product.[7] Even though the final guidance does make specific reference to threshold analyses, performing such analyses might be useful to justify that the proposed product is similar enough to the approved reference product and should be approved without more extensive HF research or analysis.

Image Source: https://rtmagazine.com/products-treatment/monitoring-treatment/therapy-devices/fda-approves-first-generic-advair-diskus/

Image Source: https://www.wixela.com

The ADVAIR DISKUS (left), manufactured by GlaxoSmithKline, is used to administer fluticasone propionate and salmeterol to treat asthma and chronic obstructive pulmonary disorder (COPD). With the ADVAIR DISKUS as the designated reference product, FDA aproved Mylan's Wixela inhaler (right) as the first approved generic for ADVAIR DISKUS.

Applicability to medical devices reviewed by FDA's Center for Devices and Radiological Health (CDRH)

Since the FDA introduced the concept of threshold analyses in 2017, it has asked some medical device manufacturers to compare their proposed medical device to an FDA-approved product. Specifically, the FDA has asked these manufacturers to carefully compare and identify differences between a proposed medical device and either (1) an existing version of the device or (2) a predicate developed by another manufacturer.

For example, we know that the FDA asked a sleep apnea device manufacturer, along with a manufacturer developing Magnetic Resonance Imaging (MRI) system software, to perform a detailed comparison between the user interface of the given device and that of its respective predicate. In both cases, FDA reviewers sought the information to help them determine whether the proposed device introduced (1) any new use cases, including critical tasks, or (2) any new, use-related risks, as compared to the predicate.

In some cases, the FDA has accepted a demonstration of substantial similarity from comparative analysis in lieu of data from an HF validation test, a large-scale study that is often required per the FDA's final HFE guidance.[8] In other cases, the FDA might still require an HF validation test, either due to the extent of differences between the proposed and reference devices and/or the new device's use-related risk profile.

The FDA's final HFE guidance from 2016, published by CDRH, directs manufacturers to compare and consider the use-related risk associated with "modified devices,"[9] suggesting some aspects of threshold analyses apply. However, the CDRH HFE guidance does not introduce or describe threshold analyses, most likely because the term was not formally introduced until the previously referenced, 2017 CDER guidance documents were released.

In this paper, we share our experiences regarding how to perform threshold analyses and present the findings in a clear, compelling manner. Although this paper focuses on an approach and examples for **proposed generic products**, much of the content is applicable to the development of **interchangeable biologic products**, as well as **new medical devices**, being developed based on ones cleared or approved by FDA.

When to perform threshold analyses during development

Manufacturers are advised to decide early in the product development process which approach they will take to generate HF-related data to support a submission claiming that the product can be used safely and effectively by the intended users. For generic combination products in particular, the FDA's guidance suggests performing threshold analyses early in the process. Specifically, the FDA encourages manufacturers to "carefully consider the design of the user interface of a proposed generic combination product and seek to minimize differences from the user interface for the [reference listed drug (RLD)]."[10]

Some pharmaceutical companies might decide early on to market their generic drugs in a redesigned, optimal delivery device—for example, an innovative, electronic versus "standard" mechanical autoinjector. These companies should be aware that the FDA might request additional data, such as a comparative use human factors study (see sidebar on page 10), to support the chosen ANDA pathway, even if the new delivery device is demonstrably easier and arguably safer to use. See *An inconvenient truth – When "other" differences are likely design enhancements* for more on this scenario.

Image Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020080s039s040s041s045lbl.pdf

Image Source: https://sumatriptanpen.fromsunpharma.co.uk

Image Source: https://www.drreddys.com/unitedstates/our-products/sumatriptan/pdf/Sumatrip-Suc-Instr-x1a.pdf

Image Source: https://www.antaresharma.com/medicines/our-medicines

Pictured above (left) is GlaxoSmithLine's IMITREX injection device, which is used to administer sumatripan to treat migraines. The three other injection devices (right) are approved generics for which IMITREX was cited as the reference listed drug, manufactured by by Sun Pharma, Dr. Reddy's and Antares Pharma (from top to bottom). As compared to the ADVAIR DISKUS and Wixela products pictured earlier, the sumatripan generic products represent more variation from its reference listed product.

The three types of threshold analyses

Summary

The guidance published by FDA's CDER division[11] outlines three types of threshold analyses that manufacturers should perform to thoroughly compare the proposed and reference products:

Labeling comparison

A side-by-side, line-by-line comparison between the proposed and reference products' labeling, including (but not limited to) the full prescribing information, instructions for use, product labeling, and packaging

Comparative task analysis

A systematic "deconstruction" of the user-product workflow, which involves "analyzing and comparing the sequential and simultaneous, manual and intellectual, activities for end-users" interacting with each product[12]

Physical comparison

A thorough, visual and tactile examination of each product's physical features and characteristics (e.g., delivery device constituent part(s) and/or container closure)

Below, we describe and share our interpretation of each of these threshold analyses, all of which should be performed to thoroughly compare a proposed product against the reference one.

Pharmaceutical companies developing proposed generic products should take care to conduct thorough threshold analyses, noting that such analyses may serve as a primary reference for the FDA to consider the suitability and interchangeability of the proposed product as compared to the reference. As noted earlier, **the FDA wants proposed products to be suitable for substitution to the end-user without additional training or other HCP intervention**. As such, substantial differences in the user interface, including the product's use steps, physical form, on-product labels, and other labeling (e.g., instructions for use) might be unacceptable.

That said, the FDA understands that designing the proposed product to be identical to the reference product might not be practical or even possible. The FDA recognizes that there may be differences between the two products, only some of which might have any effect on the quality of user interactions. However, the FDA expects that the differences shall not affect someone's ability to use the proposed generic product if it is substituted for the reference product without additional instructions or intervention.

Part 1: Labeling comparison

While a labeling comparison is rather straightforward from an HF assessment standpoint, it can be quite time-consuming. Manufacturers should examine all pertinent aspects of the products' labeling, including content appearing on the product and any packaging, as well as content in the instructions for use (IFU) and the package insert (if separate from the IFU). The labeling comparison should be extremely detailed, driven by concern that a design difference might introduce new, use-related risks or use issues.

Notably, the FDA does not expect that a generic combination product can be used following the reference product's instructions. Rather, it expects that the generic product in its entirety (including instructions) can be substituted for the reference product without requiring additional clinician intervention and/or training.[13] As such, there are some "permissible differences" within labeling that FDA will accept, including those that are due to a different manufacturer producing the product.

Individuals performing the labeling comparison should review the IFU, on-device label, packaging, and other labeling components in detail, checking myriad aspects of the labeling, including but not limited to the following:

- Alphanumeric text size and style (i.e., font)
- Format of special content (e.g., warnings, notices, expiration dates)
- Graphic (e.g., illustrations, photos) style and quality
- Graphic format, including color and size
- Line and paragraph spacing (as related to readability and relative "white space")
- Organization / layout of specific content and overall
- Page breaks
- Pagination
- Phrasing used for step-by-step instructions and other written content
- Use of paragraph versus bullet-point text

FDA defines *labeling* as:

"All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article at any time while a device is held for sale...."[14] The term "accompanying" goes beyond items physically associated with the product to include arguably supplemental items presenting information, including posters, pamphlets, and brochures.

Part 2: Comparative task analysis

A comparative task analysis focuses on how the product developer intends a user to interact with a product – for example, as outlined in the IFU – as opposed to the potentially endless alternative ways that a person might interact with it. As such, the analysis is more constrained compared to conducting a usability test to see how users might choose to perform a task, regardless of the developer's intent.

There are many ways to trace the flow of user tasks in the course of "deconstruction," as mentioned earlier. Some methods employ tables and others employ flow charts; all methods involve identifying each individual use step involved in product use. Initially, identified differences might not seem to introduce new risks, but they still will require further analysis in the context of FDA's guidance and the use-related risk analysis (see page 9).

Part 3: Physical comparison

Whereas comparing labeling is fairly straightforward, comparing the physical user interfaces is usually even more so. Yes, threshold analyses can be relatively simple, even if they require you to be detail-oriented!

The comparison should cover various physical aspects, including (but not limited to) the following:

- Actuation force
- Audible and tactile feedback
- Cleanability (as a function of physical features, such as screw bosses, part connections)
- Color
- Security of any connected tubes and/or cables
- Indicator location, visibility, size, shape, and color
- Label positions
- Material finishes (e.g., color, texture)
- Mechanical part movement
- Shape
- Size (physical dimensions of each component)
- Solidity (i.e., effect of forces on material shape)
- Weight

Categorizing differences and determining whether any "others" exist

Understanding the categories

Once you complete the comparisons described above and identify any differences, you must determine and justify the extent of the differences. Specifically, you must determine whether any substantial ("other") design differences exist, or if the proposed and reference products are substantially and demonstrably similar.

Before explaining further, we must introduce an unwieldy bit of jargon: "external critical design attributes." The FDA defines this term as "features that directly affect how users perform a critical task that is necessary in order to use or administer the drug product."[15]

According to the FDA, each threshold analysis finding should be categorized based on whether or not a design difference impacts an external critical design attribute. Specifically, each threshold analysis finding is placed into one of three categories, as outlined in the table below.

Category	Key HFE implications
No design difference: a given user interface feature, function, or characteristic is the same between the proposed and reference products.	Additional HFE-related data, such as those from a comparative use human factors study, are likely not needed to support ANDA approval.
Minor design difference: a user interface difference does not impact an external critical design attribute and, therefore, should not affect the performance of a critical task.	The FDA will likely judge minor differences to be acceptable if the threshold analyses are comprehensive; additional HFE-related data is likely not needed.
Other design difference: a user interface difference that may impact an external critical design attribute that involves drug administration. **Note**: The FDA has not clarified what it considers in scope in regards to "administration of the product." We expect that "administration of the product," as it's phrased in FDA's guidance, goes beyond the specific drug delivery action (e.g., inhalation, injection) and includes peripheral critical tasks associated with product preparation and/or disposal.	The generic product manufacturer should consider modifying the proposed product's delivery device components to minimize differences from the RLD. If no further modifications are possible or performed, the FDA might request additional HFE-related data, such as data from a comparative use human factors study (see sidebar on page 10). This might seem like an initial rejection of a submission. However, the request is actually just something that will cause delay, leaving the door open for future success.

Comparative use Human Factors Study

A comparative use human factors study is a simulated-use study in which representative end-users – most often, individuals with experience using the reference product – simulate using both the proposed and generic product under close observation by human factors experts. The test personnel observe for use errors that arise during critical tasks, and later calculate and compare the use error rates between the proposed generic and referenced products. Overall, the study objective is to demonstrate that the use error rate for the proposed product is not worse than the corresponding use error rate for the reference product when used by representative users in representative use environments.[16]

Identifying and categorizing differences

In cases where the products seem at first to be identical, there might actually be several differences to categorize. More often though, threshold analyses identify a few dozen differences warranting further consideration. Some differences might be judged to be "minor," and others might be categorized as "other" due to their relationship to external critical design attributes. As defined earlier in this paper, FDA defines the term "external critical design attributes" as "features that directly affect how users perform a critical task that is necessary in order to use or administer the drug product."

In a case of "no design differences," or when all differences are deemed "minor," it is likely that no additional HFE research or analysis is needed. However, if one or more "other design differences" are identified, the FDA will likely require additional data to determine whether the design differences introduce any new or greater risks that might impact the clinical effectiveness or use-safety of the proposed generic product if it were substituted for the reference product.

Keeping the end-users at top of mind

When evaluating and categorizing the differences, it is important to keep the product user in mind. Specifically, consider when an end-user – particularly someone who has been using the reference product – seeks a refill and receives the proposed product instead of the reference product. Suppose that the reference product emits an audible "click" sound once the dose has been *delivered*, but the proposed product emits a "click" when dose delivery *starts*. Might the difference in the audible signal timing confuse the user? Might they mistake the click made by the proposed product as the signal that the dose has been delivered and, therefore, prematurely remove an injection device from the skin, or perhaps an inhaler from their mouth, before receiving a full dose?

Using the use-related risk analysis as a guide

Throughout the FDA's guidance and other standards and literature outlining HFE best practices, the use-related risk analysis (URRA)[17] is cited as the pivotal, foundational element manufacturers should rely upon to make decisions throughout product development. As such, it makes sense for the URRA to take center stage when identifying external critical design attributes and categorizing design differences as "minor" versus "other" during threshold analyses.

To assess the potential affect (i.e., impact) of a design difference on an external critical design attribute, it is essential to first determine if a difference – or at an even more basic level, the product feature or characteristic related to the difference – is related to a critical task. The URRA, when developed properly, is the primary tool to facilitate this determination. The FDA's draft guidance[18] defines critical tasks as "user tasks that, if performed incorrectly or not performed at all, would or could cause harm to the patient or user, where harm is defined to include compromised medical care." A difference in the placement of the manufacturer's name on the proposed versus reference product's outer package likely constitutes a "minor difference," noting that identifying the product manufacturer is likely not related to a critical task. Conversely, anything related to placement of instructions about setting and/or administering a dose of the medication likely constitutes an "other" difference.

Justifying your design difference categorizations

Identifying and categorizing differences between the proposed generic and reference products comprise the bulk of the effort associated with performing threshold analyses, but this is not the final step. Before concluding whether a comparative use human factors study or other follow-up HFE activities are warranted, and certainly before submitting threshold analyses findings to the FDA, manufacturers should document the rationale for having characterized each difference as none, minor, or other.

Notably, although perhaps not surprisingly, the FDA will carefully review and potentially disagree with provided categorizations. Presenting a strong rationale might reduce the likelihood of the FDA taking a different view of these findings. Our experience suggests that a few sentences of cogent explanation usually suffice. For illustrative examples, refer to the sample threshold analyses report content on page 13.

An inconvenient truth – When "other" differences are likely to be improvements

It is clear why the FDA would be concerned about user interface design differences that might compromise the user interaction quality of the proposed generic product, such as displaying the expiration date in a much smaller font size, and/or in a less clear format. However, in some cases, the generic product might show promise to improve upon the reference product (e.g., displaying the number of remaining doses in larger, higher-contrast numerals).

Even if a design change seems to be an improvement as compared to the reference product, it will not automatically be deemed as minor or otherwise acceptable. Good or bad, any difference between the proposed generic and reference products must be evaluated in relation to its effect on a critical task in the ways we have previously described. What might seem like an obvious improvement might actually induce unexpected user interaction problems, so diligence is warranted.

Conclusion

Threshold analyses require analysts to apply human factors science and exercise good professional judgment. In our view, performing the three types of threshold analyses represents a sensible approach to comparing proposed generic combination products – and other drug delivery and medical products – to FDA-approved ones. In addition to facilitating a detailed comparison, the analyses can help manufacturers identify potential use errors and interaction difficulties that might arise with the proposed product due to "negative transfer" (defined as inappropriately applying experience from one product to another).

Threshold analyses can spare the manufacturer the time and expense of fully applying human factors engineering to products that are generics, which are intended to be just like a marketed product. The underlying logic is that performing various research, analysis, design, and iterative testing activities is unnecessary when duplicating a product that the FDA considers safe and effective. Therefore, the key task is to perform threshold analyses and, if required by the FDA, studies (e.g., a comparative use human factors study) that support the claim that a proposed product is equivalent to a reference product in ways that are pertinent to safe and effective use.

In practice, threshold analyses should not be particularly time-consuming; the work might be accomplished in a matter of days or a few weeks, depending on the product. This level of effort contrasts sharply with the many months or even years of human factors work that normally goes into the development of products subject to a more comprehensive review by the FDA.

We advise manufacturers to develop a detailed procedure for performing threshold analyses based on applicable guidance and industry best practices, as described in this paper. Developing such a procedure – and following it to a hyper-conscientious degree – will help ensure that a proposed generic product, or other type of product, has been thoroughly examined against the reference product.

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Sample threshold analyses report content

Background

There are many different ways to document the results from threshold analyses. We typically present the results from the labeling, task, and physical comparisons in dedicated tables, describe and/or depict each difference in a dedicated row, and then indicate the categorization (no difference, minor difference, or other difference) and a brief rationale. We also comment on the potential impact a difference might have on the effective substitution of the proposed generic for the reference product, noting that the FDA aims to ensure that a product can be substituted without additional clinician intervention and/or training. That said, the FDA does not require that individuals performing threshold analyses make this judgment. Ultimately, the FDA will render this decision based on all data submitted in the ANDA or other submission package.

The sample below represents one way to report threshold analyses findings, but there are likely other acceptable approaches, noting that the FDA does not prescribe how the results should be presented, but rather that differences must be analyzed and categorized.

Proposed generic product and caveats

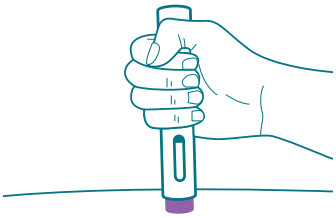
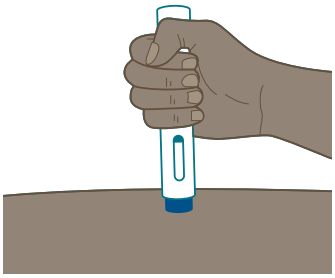
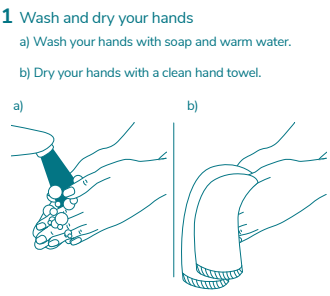
The proposed generic and reference products presented in this example were invented based on our knowledge of autoinjectors and are not intended to represent any specific actual products. Similarly, the referenced use-related risk analysis was conceptualized for this paper, and tasks have been deemed “critical” only for the purpose of presenting an example.

Proposed generic product: single-use, disposable auto-injector that delivers a pre-set dose of medication

Intended use: treatment for rheumatoid arthritis

Intended users: healthcare professionals, adult patients (age 18+), and lay caregivers

Labeling comparison

Labeling attribute	RLD auto-injector	Generic proposed auto-injector	Evaluation of differences
IFU text color	Black	Black	**No difference**
"Inject" IFU graphic			**Minor difference** – The color of each autoinjector's needle end differs to represent each product's actual appearance (permissible difference). The skin tone is different and, even though this step depicts a critical task, this difference is not expected to affect product substitution.
Outer carton text size presenting manufacturer's address	16 pt	18 pt	**Minor difference** – The size of text used to present the manufacturer's address on the outer carton is not associated with a critical task.
Expiration date format on outer carton	2025-Jan-02	2025-01-02	**Other difference** – The expiration date is related to a critical task and is an external critical design attribute. The format difference might affect product substitution.
"Washing hands" IFU step design	Graphic in step "Wash your hands" present 	Graphic in step "Wash your hands" absent 	**Other difference** – Washing hands is a critical task, and the absence of an accompanying graphic might affect product substitution.

Comparative task analysis

Task	RLD auto-injector	Generic proposed auto-injector	Evaluation of differences
Clean the injection site before the injection	User cleans the injection site before the injection	User cleans the injection site before the injection	**No difference**
Take the needle cap off	User unscrews the needle cap in a counter-clockwise direction	User pulls the needle cap straight off	**Minor difference** – Needle cap removal is not related to a critical task.
Hold the AI after the injection at the injection site to ensure the full dose delivery	User has to hold the AI at the injection site after the injection and count slowly to 5	User has to hold the AI at the injection site after the injection and count slowly to 10	**Other difference** – The difference in hold time is related to a critical task and might affect product substitution.

Physical comparison

Physical attribute	RLD auto-injector	Generic proposed auto-injector	Evaluation of differences
Autoinjector length	180mm	180mm	**No difference**
Outer carton pull tab's width	5mm	10mm	**Minor difference** – Opening the carton is not related to a critical task, and the pull tab is not an external critical design attribute.
Audible feedback	The device emits one click once the dose delivery has completed	The device emits two clicks when delivering the dose – one click once the dose delivery has started, a second once the dose delivery is complete	**Other difference** – The audible feedback (clicks) are related to a critical task and represent an external critical design attribute.

End Notes

1. Combination Product Definition Combination Product Types https://www.fda.gov/combination-products/about-combination-products/combination-product-definition-combination-product-types.
2. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017. Section II, Background. Available for download at https://www.fda.gov/media/102349/download.
3. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017.
4. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017.
5. Considerations in Demonstrating Interchangeability With a Reference Product. FDA Draft Guidance. January 2017.
6. Considerations in Demonstrating Interchangeability With a Reference Product. FDA Final Guidance. May 2019.
7. Considerations in Demonstrating Interchangeability With a Reference Product. FDA Final Guidance. May 2019. Section VIII.
8. Applying Human Factors and Usability Engineering to Medical Devices. FDA Final Guidance. February 2016. Section 8.1. Available for download at https://www.fda.gov/media/80481/download.
9. Applying Human Factors and Usability Engineering to Medical Devices. FDA Final Guidance. February 2016. Section 8.2.
10. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017. Introduction.
11. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017.
12. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017. Section B, 1, a, footnote 17.
13. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017. Section IV, footnote 12.
14. FDA website, Device Labeling, Introduction to Medical Device Labeling, https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling.
15. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017. Section IV, B.

16. Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA. FDA Draft Guidance. January 2017. Appendix A.

17. We use the general term use-related risk analysis, abbreviated as URRA, to refer to analyses of a given product's risk, harm, severity, etc. Some manufactures might use different terminology to refer to the specific approach taken to URRA, such as referring to a use Failure Modes and Effects Analysis, or uFMEA. For the purposes of this paper, these terms and abbreviations are considered synonymous.

18. Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development. FDA Draft Guidance. February 2016. Section III.B.1. Available for download at https://www.fda.gov/media/96018/download.

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About the authors

Allison Strochlic, MS, CHFP is the HFR&D team's Research Director based in Concord, MA. Allison has over 15 years of experience applying human factors engineering to medical and pharmaceutical products. She routinely advises clients on how to meet regulators' HFE expectations, and frequently supports or leads clients' meetings with FDA to discuss various human factors topics and concerns. She contributes to and manages a wide range of research projects such as usability testing, contextual inquiry, and interviews, and helps clients develop key HFE documents for their design history files. Allison is a board-certified human factors professional, and has undergraduate and graduate degrees in HFE. She is a co-author of Usability Testing of Medical Devices (2nd edition published in 2015) and several technical articles, and was a part-time lecturer at Tufts University, where she co-taught a graduate-level course on human factors in product design.

Michael Wiklund, MS, CHFP, PE serves as General Manager of the Human Factors Research & Design practice at Emergo by UL. He has over 35 years of experience in human factors engineering, much of which has focused on medical technology development—optimizing hardware and software user interfaces as well as user documentation. He is a Certified Human Factors Specialist and Licensed Professional Engineer. He is author, co-author, or editor of several books on human factors, including Writing Human Factors Test Plans and Reports for Medical Technology Development, Medical Device Use Error – Root Cause Analysis, Usability Testing of Medical Devices, and Handbook of Human Factors in Medical Device Design. He is one of the primary authors of today's most pertinent standards and guidelines on human factors engineering of medical devices: AAMI HE75, IEC 62366-1, and IEC 62366-2. In addition to leading UL's human factors engineering practice, he is a Professor of the Practice at Tufts University where he teaches graduate courses on HFE.

Maija Smith, MS is a Senior Human Factors Specialist based in Cambridge, UK. Maija has experience delivering HFE services to the medical device and pharmaceutical industries and has been involved in managing usability tests, conducting human factors research, analyzing data, and developing reports that satisfy regulators' expectations. Maija has developed great interest in threshold analyses and performed numerous threshold analyses to support the clients with their regulatory submissions.

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