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| |  | | --- | | Thank you for all the feedback I receive from you, the readers of the Institute Journal!  We receive questions, tips and comments every day. It is valuable input that helps us to develop new concepts and content. We would like to share these results with you here in the Institute Journal. This week is no exception. Definitions: why they are so important A lot of questions relate to definitions. They are not always precise and complete. However, uniform concepts and precision are necessary if we want to digitize regulatory affairs and quality management.  And by digitization I don’t mean submitting PDFs to notified bodies. It is about interoperability standards and cross-organizational processes. These processes allow for “rolling reviews” during the authorization process, as has been successfully used for vaccine authorizations, for example. Definitions 1: CAPA One of the characteristics of the MDR and IVDR is that they define a lot of terms, e.g., “corrective action”:  **Corrective action** means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation  However, they do not provide a definition of **preventive action**. The regulations even seem to lump preventive and corrective actions together. Why is that a problem?   1. Mixing terms leads to confusion in the minds of readers. For years, our notified bodies have been trying to explain to us that corrective and preventive actions are two independent processes that differ in terms of, for example, their inputs and objectives (read more on this [in this article](https://newsletter.johner-institut.de/cp/55333188/febc054c98-qo5wo8)). 2. Article 120 of the MDR considers design changes that are only a corrective action to be non-significant. Does this also apply for preventive actions? 3. This means that the concepts contained in the MDR and IVDR are no longer the same as those contained in ISO 13485 and ISO 9000. This does not make it any easier for responsible persons at companies,   as the standards differentiate between corrective and preventive actions:   * Preventive action: action to eliminate the cause of a potential nonconformity or other undesirable potential situation. * Corrective action: action to eliminate the cause of a detected nonconformity and to prevent recurrence.  Definitions 2: hazardous situations ISO 14971 defines a hazard as a potential source of harm. This means that every element of a causal chain that starts with a nonconformity and ends with harm is a hazard. This leads to companies discussing what they now have to record as a hazard.  However, it is even worse when the examples the standards give confuse rather than clarify. For example, ISO/TR 24971:2020 gives "Clinician receives the incorrect glucose result" as an example of a hazardous situation. Really?  A **hazardous situation** is defined as a "circumstance in which people, property or the environment is/are exposed to one or more hazards". What hazards is the clinician exposed to?  However, the fact that the clinician receives an incorrect glucose result leads to a hazard for the patient, which ISO 24971 also mentions: “Clinician administers antiglycemic drug”. That would make the antiglycemic the hazard. And the patient being exposed to this drug – i.e., the moment they take it – would be the hazardous situation.  Conclusion: The sequence in which the standard presents the events is easy to understand. The assignment of the defined terms, on the other hand, less so. Definitions 3: intended use vs. purpose There is a difference between an **intended purpose** and an **intended use**. Disinfecting a dialysis machine is part of its intended use. But this disinfection is not its intended purpose. Its intended purpose is cleaning blood.  What does ISO 14971:2019 do? It defines the term “intended use/intended purpose” and so confuses the two terms. Definitions 4: translations Sometimes it's not imprecise definitions that are the problem, but rather:   * A lack of definitions * The incorrect translation of definitions * The inconsistent use of these definitions   The MDR doesn’t define the term “state of the art.” But, at least, the English version uses the term “state of the art” consistently. However, the German version distinguishes(?) between:   * Stand der Technik (state of the art) * ***neuester***Stand der Technik (**latest** state of the art) * ***allgemein anerkannter***Stand der Technik (**generally recognized** state of the art) * ***gegenwärtiger***Stand der Technik (**current** state of the art)   None of this is really bad. But, as your feedback shows, it's these little details that cause problems, hinder digitization and lead to annoying discussions during audits.  Imagine if we had uniform concepts and data models and could automate all regulatory processes, as we have started to do with the [radar](https://newsletter.johner-institut.de/cp/55338467/febc054c98-qo5wo8).    Last week’s feedback also concerned our links to the BSI pages. Unfortunately, the authority changed its page structure hours before we sent out the Journal. We have updated these links.  Our [latest article](https://newsletter.johner-institut.de/cp/55333063/febc054c98-qo5wo8) also has its origins in your feedback. The question was when and how manufacturers are liable for defective devices. You can find the answer in the article.  Warmest regards,  Christian Johner | |
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