Congenius

5-minute guide to:

# Risk Analysis vs FMEA

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*By Dr. Dirk Hüber*

**According to ISO 14971, legal manufacturers are required to perform a Risk Analysis for their medical devices. However, the expectation is that they also perform Failure Mode and Effects Analyses (FMEAs) regarding design, usability, software, and processes.**

A Risk Analysis and an FMEA differ in what they analyse, and consequently, in their applied methods.

In this 5-minute guide, our Head of Quality Dr. Dirk Hüber shares a useful overview of the key differences to help ensure your risk analysis processes stay efficient and effective…

# Risk Analysis according to EN ISO 14971

**Risk analysis evaluates risks to patients, users, and environment.**

**A risk is described by:**

- The harm to patients, users, and environment
- The hazardous situation that may lead to the harm
- The failure cause that may lead to the hazardous situation

**A risk is evaluated via its harm by:**

- The severity of the harm
- The occurrence of the harm, i.e., the probability that the harm occurs

# Risk Analysis according to EN ISO 14971

# Failure Mode and Effect Analysis (FMEA)

**FMEAs evaluate technical failures of a device, system, or software.**

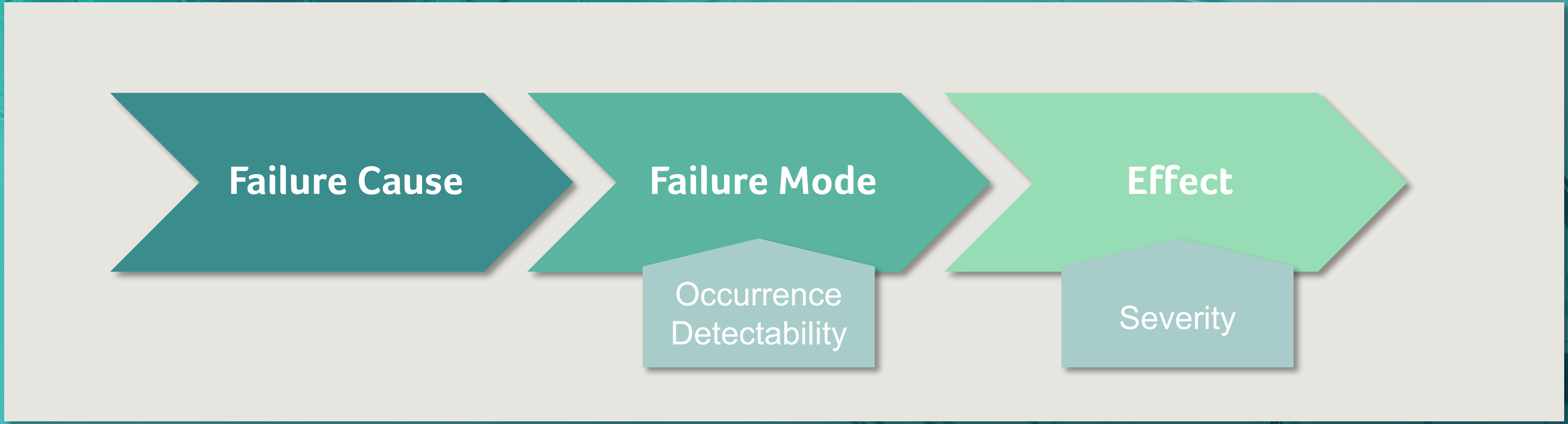
**A failure is described by:**

- The effect on the functionality of the item in scope (e.g., the device)
- The failure mode that may lead to the effect
- The failure cause that may lead to the failure mode

**A failure is evaluated by:**

- The severity of the effect on the functionality
- The occurrence of the failure mode, i.e., the probability that the failure mode occurs
- The detectability of the failure mode, i.e., the probability that the failure mode is detected before the effect sets in, so that the effect may be prevented

# Failure Mode and Effect Analysis (FMEA)



# Risk Analysis vs FMEA

**While risk analyses identify and evaluate risks, FMEAs evaluate failures. Remember:**

! FMEAs do not talk about risks to patients, users, or environments.

! Although both risk analyses and FMEAs use severity and occurrence to evaluate risks and failures respectively, the meaning of severity and occurrence in both cases is different and has no connection to each other.

However, risks and failures as such are connected. To find out how – see our article on connecting failure modes and risks in a risk management file.

**Should you have a Risk Analysis or FMEA challenge related to your medical device, our Quality team is ready and happy to help. Simply get in touch to start the conversation.**

**Contact us:**

E: info@congenius.ch

T: +41 44 741 04 04

Congenius AG

Riedstrasse 1

CH-8953 Dietikon