bleyco swiss GmbH

Hands-on!

Sampling plans shall be based upon statistically valid rationale

WHO I AM?

bleyco swiss GmbH is a business partner to national and international Medical Device Companies and Pharmaceutical Companies.

YOUR GAIN

bleyco swiss GmbH offers the expertise of highly experienced individuals from the Medical Devices and Pharmaceutical industry.

Our strengths is an incredible network over the globe.

MY EXPERTISE

More than 25 years of experience and knowledge of packaging and process development, verification & validation, extensive networks, lecturer for packaging optimization.

YOUR COMPETENT PARTNER!

Do you need expertise to ensure the compliance of the packaging systems? bleyco swiss GmbH is your competent partner!

YOUR BENEFIT

Once the analysis and assessment of the current status is done, a path forward strategy can be created as well. Save your business!

CONTACT

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STASTIC REALLY NEEDED?

Many SO 11607-1 and ISO 11607-2 have been implemented in 2019 and both were quickly converted into the harmonized standard EN ISO 11607: 2020. Without a doubt, this speed should also be understood as a signal to the manufacturers.

PACKAGING IS ON THE RADAR!

The information on packaging systems in the Technical file and particular the sterile barrier systems will in future be assessed much more precisely by the Notified Body and Health Authorities; which has already been announced in various seminars.

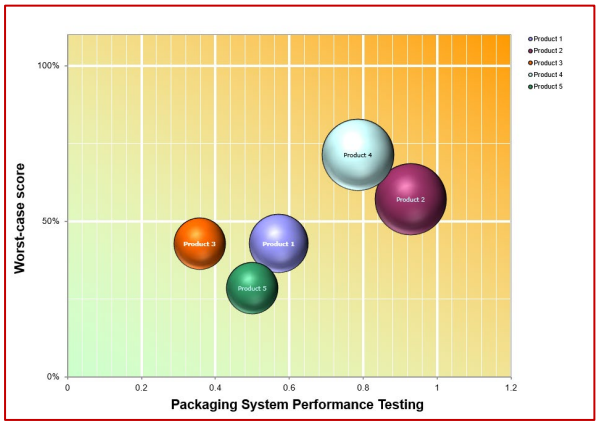
In the past under MDD and ISO 11607: 2006 + amd, let me say cautiously many times "byPass approaches" about packaging integrity were trodden. And I would not say that these were fundamentally wrong, but that these are always critically questioned under the MDR and IVDR is for sure.

Examples of questions:

- Provided rational for determining the worst-case packaging system in order to reduce the test effort to an acceptable level?
- What criteria were used to determine the climatic conditions as part of the performance and stability testing?
- Robust test pattern determination in order to be able to make a statement about the behaviour of an entire population? (keyword: Statistic)

CONCLUSION

The chain of arguments must be conclusive and understandable!



MITIGATE THE RISK

A gap analysis can be used to identify risks, develop strategies and implement improvements, e.g. consistent standardization across the packaging levels. It is obvious that primary packaging and its proof of chem.-phys. compatibility is the critical aspect.