bleyco swiss GmbH
Hands-on!

"Packaging Experts" guide your product to success!

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 experienced individuals from the Medical Devices and Pharmaceutical industry.

Our strengths are an incredible network over the globe.

MY EXPERTISE

More than 30 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 status is done, a path forward strategy can be created as well. Save your business!

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No medicinal product shall be applied to the patient without appropriate packaging and meets the intended purpose of the use - whether for clinical trials or later for commercialization.

Therefore, the selection of all packaging cannot be made at random!

When compiling the packaging information in the submission chapter P 7. it is often forgotten that the requirements, e.g. according to Eudralex volume 4, Annex 15 in **chapter 6 and 7,** must also be fulfilled as well. Other countries such as the USA, Brazil or China have similar requirements - see also PIC/S-GMP.

In addition, the evidence by document for medical devices, especially for sterile MD, is definitely part of the submission documents. (Keyword: Usability at point of use)

And suddenly, quite late in the process, a moment of "aha" popped up and the clock is still ticking.

To do's:

- ✓ Medicinal product must be produced in the final packaging,
- ✓ What must the sample size be for which test?
- ✓ Organize transport tests quickly!
- ✓ Which test laboratory?
- ✓ Which test conditions (environmental conditioning)?
- ✓ Which standard (ASTM or ISTA)?
- ✓ Which acceptance criteria?
- ✓ Permitted temperature and / or r.H. excursion also known?
- ✓ Has the packaging process already been validated?
- ✓ Have the test methods also been validated?
- ✓ Analyse the data!
- ✓ Create reports!
- ✓ And keep the fingers cross!

Every SME is needed in the regCMC process!

For example, would you expect that a biochemist and/or a pharmacist and/or a biologist need to have detailed knowledge of packaging materials, packaging systems and shipping systems?

Why is the knowledge of packaging experts not used at the beginning of the regCMC process?

To be honest: I do not understand why packaging is so underestimated! Integrating knowledge and expertise does not even increase the overall costs.

Experienced SMEs know when to collect which data in the regCMC process, where it makes sense and finally can be used for the submission. **Hands-on and "Do it right first!"**