COMBINATION PRODUCTS
DEVICE SPECIALISTS®

Risk Management for Combination Products

www.combinationproducts.eu | info@combinationproducts.eu

Quality risk management is a non-negotiable requirement to comply with EU and US combination product regulations.

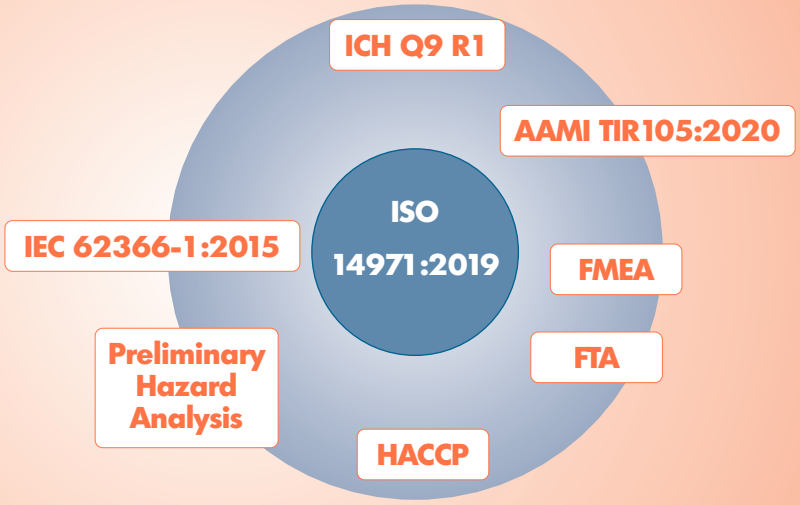
Be the best & save money

CPDS has developed a coherent series of trainings and services to meet the diverse needs of the Pharma combination product manufacturers and their suppliers. The methods used are proven and mature (30 years experience). When followed and applied, Quality Management will become:

- Robust
- Efficient
- Mature
- Globally harmonized

Read more in the recent published white paper (+ link)

Holistic / Global systems and methods used for risk management of combination products



Target Audience

This training is designed for staff who want to familiarise themselves with the holistic approach of risk management for combination products and its possible place in the product lifecycle.

Custom

This training can be customized for your specific needs and preferences at no additional costs.
Contact us to discuss the possibilities.

Availability and Costs:

This is an onsite training. Our training fee is based on a set rate plus expenses, regardless of the number of employees attending. Contact us for availability.

Duration:

This one-day training is a mix of theory and practice. Attendees are requested to actively participate and practice thoughout the day. At the end of the training, a short exam covering all the learned material will be held. Achieving a score of 80% or higher will result in a certificate.

Languages:

The training material is in English.

The training can be given in:

- English
- German
- Dutch

What your team will learn

Upon completion of this combination product Quality Risk Management Training, participants will be able to;

- understand the critical processes of Quality Risk Management in a combination Product context
- know key features of various Risk Management Systems and methods including, 14971, Q9, FMEA, and PHA, FTA, HACCP and more.
- understand how risk management and methods can be embedded in your Quality system, how they can form part of training and updated when knowledge grows.
- completely understand the ISO14971:2019 Standard
- understand ISO 14971 and ICH Q9 and the relationship between these key documents including AAMI:TIR105.

Lead Trainer:

Rene van Melick, PharmD

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Combination product Risk Management

The pharmaceutical combination product industry is experiencing an increased focus on and enforcement of quality risk management (QRM) applications. Between January 2022 and April 2024, about half of all warning letters issued by the FDA include citations for absence of or incomplete risk assessments. With the QMSR (and full 13485 / 14971) mandatory early next year, this number will only increase.

Our training brings to you a pragmatic and holistic risk management approach, based on multiple systems and methods.

Together we study these risk management systems and methods, see in what lifecycle phase they best can be applied and how the documents / quality records could look.

The training includes practical examples to help attendees understand the concepts better.

In this way, you will be well-informed to make your future state choices.

The continuous and whidespread application of appropriate risk management models will make your lifecycle output safer and more effective.

A training with lasting impact.

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contact

For more information or questions, please send an email to

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