puracon GmbH
Isarstraße 1
83026 Rosenheim, Germany

P +49 8031-900 587-0
F +49 8031-900 587-73
E info@puracon.com

www.puracon.com

puracon
more than packaging

Secure Validation Programs

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Secure validation programs
for a safe medical device

Medical devices demand the highest degree of safety, functionality and efficiency. A well planned and performed validation program is the basis for a safe and efficient product and a successful product approval. puracon can support you not only in setting up a product-based validation program, but also in organizing and performing the selected validation program in-house or with expert partners.

Our experience does not end at validations, but also covers all quality topics – from audits and CAPAs to nonconforming products and complaint handling. Our experienced and well-trained employees are ready to consult with you on these topics.

We cover all validations to prove conformity, efficiency and safety of your product:

- Cleaning validation
- Packaging validation
- Sterilization validation

All packaging tests are available with our in-house testing services:

- Packaging OQ/PQ
- Shelf-life testing

Validations, time and cost efficiency –
we help you to combine these

The field of validations is wide and a lot of time and money can be wasted when the validation program is not the right one for your product.

With our extensive experience in validations and validation programs, we can help you establish a validation program that proves safety and functionality of your products – and is time and cost efficient.

CONSULTING

We share our expertise and know-how to help you develop a validation program as well as an efficient quality system.

We will assist you in the following areas:
- consulting on quality topics
- consulting on product approvals
- consulting on validation programs and test setups
- organizing all validation activities
- in-house packaging tests

CLEANING

The cleaning validation shall provide evidence, that the product is free of any contamination such as production residues or microbiological organisms.

A cleaning validation normally includes:
- LAL endotoxin
- cytotoxic testing
- bio burden
- particulate burden

PACKAGING

The packaging is the only thing, that keeps a product sterile and safe after sterilization. Therefore, packaging validation must provide evidence that the process is stable during production, storage and transportation, and that a shelf-life of the packaging and product can be obtained.

- OQ (determination of sealing parameters)
- PQ (evidence that the process is stable)
- shelf-life testing
- transportation validation

STERILIZATION

Sterilization must ensure a SAL 10^{-6} to mark a medical product as sterile. For sterilization, multiple options, such as gamma radiation or ethylene oxide gas are available. The tests to be performed vary from sterilization method to sterilization method.

We will assist you in selecting the right sterilization method and best sterilization validation program for your product.

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