Cleaning Validation

Support from planning to implementation

Cleaning procedures and the associated validation require a risk-based approach to ensure the safety of products, personnel, and the environment. Cleaning in the pharmaceutical environment, particularly in drug products and medical device manufacturing, requires a high level of chemical, pharmacological and process knowledge. The type, quantity, and source of potential contaminants, as well as cross-contamination, affect the reproducibility of the cleaning process. In pharmaceutical manufacturing, and especially in multi-product facilities, cleaning procedures must be validated according to national and international regulations.

Valicare prepares the necessary GMP-compliant documentation, consisting of risk analysis, validation plan and report, and all required attachments.

Our competence

- Many years of experience in performing cleaning validations for pharmaceuticals and medical devices
- Interdisciplinary team of natural scientists (biologists, chemists, and pharmacists) and engineers

Our services

- Preparation of the risk analysis for cleaning validation
- Procurement of the required PDE limits
- Calculation of tolerable surface concentrations
- Implementation of product and equipment bracketing
- Preparation of qualification plans with all necessary attachments
- Project management and execution

Your advantage

- Relief in terms of personnel and time by outsourcing the activity to experienced validation experts
- Accelerated implementation based on field-proven templates and experienced staff
- Audit-compliant documentation
- GMP compliance
- Risk reduction through competence

For the European legal area, a paradigm shift was introduced in 2015 by a new directive of the "European Medical Agency". This directive introduced a risk assessment based on toxicological findings. With the help of the values for the maximum daily exposure of a patient ("permitted daily exposure", PDE values), a binding standard is set for the consideration of impurities in the subsequent product. The use of PDE values to set limits has also become established for medical devices.

Other contaminants considered during cleaning validation are the cleaning agents and possible microbial contamination. The limit values are defined need to be defined on the planned application of your products.

Contact us if you are planning a cleaning validation. We will support you!

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