info@atecid.com
https://www.atecid.com

GMP - Validation of cleaning in the Pharmaceutical Industry, application of risk analysis

"Useful Training for you and your company"

Objetives

This training has been developed so that the participant can learn how the Cleaning Validation is carried out, a key aspect for compliance with the GMP (Good Manufacturing Practice = Good Manufacturing Practice or GMP, Good Manufacturing Practices) of medicines, following the risk analysis process, with exhaustive planning, for the manufacture of the pharmaceutical product.

Before any manufacturing operation is to begin, steps must be taken to ensure that the work area and equipment are clean and free of any starting materials, products or residues that could alter the safety, identity, potency, quality or purity of the pharmaceutical product.

We highlight two main objectives:

1- Develop a universal, effective, economical and extrapolable methodology in time to carry out the validation of cleaning processes in a pharmaceutical laboratory, with the application:

ICH Q9 risk analysis tools (according to annex 20 GMP) for choosing the equipment to be studied and also applying the TTC concept, for calculating the residual permissible limit.

2- Establish a methodology to carry out an effective cleaning procedure based on ICH Q8.

To achieve these main objectives in training, we will carry out the following stages:

- Determine the critical points of the equipment.
- Determine the acceptable limits of the indicator active ingredient.
- Determine the analytical method and validate it using reverse phase high performance liquid chromatography (HPLC) with DAD detector as the analysis technique for residues.
- Establish the sampling method for validation.
- Calculate the recovery factor in two types of materials: stainless steel and plastic, which are the usual materials for equipment surfaces.
- Optimize the cleaning procedure.

As a summary, the participant will see how the correct manufacturing standards (NCF) are achieved, establishing logical and acceptable acceptance limits.

Creating a validation management system for cleaning processes, which serves to quickly detect whether the system remains validated or requires more validation effort each time a new active ingredient has to be worked on.

Contents

The contents are the proper GMP Cleaning Valiation practices, together with risk assessment practice so the participant will be able to put in practice in his workplace/laboratory, with a full understanding of them.

The training is organized into 4 modules.

Methodology and extras

Training in GMP and Cleaning Validation constitutes, like other quality reference systems or frameworks, a field of concepts and abstract content, which turning into the real world must be developed in each case and company in which they are applied. This course combines explanations and illustrations that clarify and allow ideas and concepts to be visualized.

For this reason, the platform also provides several messaging tools to contact the course teacher for further explanations or clarifications, which enlivens the monitoring and sequence in the training content as well as its similarity with the dynamics of the business or distribution processes.

Assessment and Certificates

There is an assessment at the end of the course. Each participant getting 50% of qualification will get an achievement Diploma.

Participant Profile

The contents are adjusted to the needs of any personnel of Pharma Labs, Pharma Manufacturing sites, Cosmetics Manufacturind and production, etc, that manage or are in relation to cleaning and industrial services of sites, or want/need to be aware of it handling a different job content.

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Tutor:

Isabel Cartas: Pharmaceutical Graduate, and Master in Pharmaceutical Industry, with a long career as Technical Director and Responsible Person in Medicines Distribution Entities.

Dynamizer:

Javier Aseguinolaza: Chartered Engineer (UK Engineering Council), Master in Industrial Environment Management, consultant with extensive knowledge and experience in Quality, Innovation, Organization, Lean Six Sigma, etc.

Registrations:

Please get in touch with ATEC+ID at javier@atecid.com if you have any question.

The Price is 600 € per person and can be paid by different methods, just follow our online shop or get in touch with us for further guidance.

Module 1

1-Introduction and Regulation.

2-Contamination

3-Cleaning methods.

4-Clean rooms

5- Detergents

Module 2

1- Validation of cleaning procedures.

2- Prepare the CVMP.

3-Equipment qualification

4-Calculation of criteria and acceptance limits.

5-Sampling

6-Validation of analytical methods

7-Monitoring of a validated cleaning process.

8- Microbiological analysis.

Module 3

1-Risk management ICH Q9.

2- Risk analysis in cleaning validation.

3- Tools for risk analysis.

4- Risk analysis associated with cleaning validation.

5- Change management.

6- Quality by design and cleaning validation.

7- Application of Q8 concepts and design space to cleaning validation.

8- PAT (Process Analytical Technology) and cleaning validation.

9- Analytical techniques that use PAT technologies for cleaning validation.

10- Parametric release for cleaning.

Module 4

1-Validation of the analytical method.

2- Development and validation of the analytical methods used for the determination of residues by UPLC/HPLC.

3- Definition of validation parameters.

4-Practical case.