Efficient Creation of a Contamination Control Strategy

Concept and implementation

The contamination control strategy (CCS) is a requirement of the EU GMP Annex 1 for the control of possible particulate, microbial and endotoxin contamination. It is particularly relevant for pharmaceutical manufacturers of sterile medicinal products

The CCS is an overview document that lists contamination controls in an organized manner and evaluates their effectiveness. The contamination controls to be described are company-specific measures, precautions and data collection with the purpose of preventing contamination. Included are the equipment and design of the premises as well as the recording of quality attributes and process parameters.

To develop and create a CCS in an existing manufacturing unit, it is recommended to record the existing contamination controls, check existing risk assessments and optionally carry out a gap analysis in accordance with EU GMP Annex 1

Valicare prepares the necessary GMP-compliant documentation, consisting of a gap analysis report, process risk analysis and contamination control strategy.

Our expertise

- Extensive experiences in GMP-documentation
- Pharmaceutical process knowledge
- Interdisciplinary teams of natural scientists (biologists, chemists and pharmacists) and engineers

Our services

- Carrying out a gap analysis in accordance with the requirements of EU GMP Annex 1
- Process risk analysis for the development of the CCS
- Concept & implementation of CCS based on provided documentation
- Project management and execution

Your advantage

- Relief in personnel and time by outsourcing the activity to experienced GMP experts
- Accelerated implementation based on tried-and-tested templates and experienced employees
- Audit-compliant documentation
- GMP conformity
- Risk reduction through competence

valicare
GMP Compliance Services & Solutions

Contact us if you are looking for a competent partner to develop a contamination control strategy. We look forward to your call!

Dr. E. Sons-Brinkmann
Business Development & Marketing
Phone +49 69 153 293 709
Mobile +49 172 413 0603
Ellen.Sons-Brinkmann@valicare.com

Dr. S. Löffler
GMP- Consultant
Phone +49 69 153 293
Mobile +49 151 744 812 54
Stefan.Loeffler@valicare.com

Valicare GmbH
Eschborner Landstr. 130-132
60489 Frankfurt, Germany

Phone +49 69 153 293
info@valicare.com
www.valicare.com