White paper

Selection of suppliers

Cleanroom protective eyewear

Advice

for manufacturers of sterile products

Theme

Revision of Annex 1 («Manufacture of Sterile Medicinal Products») of the EU Guidelines to Good Manufacturing Practice

Current situation

Compared with the version of Annex 1: “Manufacture of Sterile Medicinal Products” that is currently valid, the new version extends the scope of the Annex to include further sterile products.

The new paragraph 7.12 contains details with regard to cleanroom clothing: all workers in an area classified as Grade A/B must be provided with clean, sterilised cleanroom clothing as well as eye coverings and masks, all in the correct sizes, for each work session.

The problem

Because of these changes to Annex 1, it will be necessary to procure additional cleanroom protective eyewear from qualified suppliers. The process for their treatment must also be validated, and their use managed in agreement with the principles of Quality Risk Management.

We therefore recommend that you consider the effects of this on your internal and external processes in good time, so that the new requirements can be duly implemented.

The solution

bardusch provides you here with a checklist so that you, in your capacity as entrepreneur, buyer, quality management officer, production manager or operator, can quickly and comprehensively determine the suitability of potential service providers.

Supplier offers	yes	no
Certified Management System		
Certified Quality Management System according to ISO 9001	☐	☐
Certified Environment Management System according to ISO 14001	☐	☐
Certified Hygiene Management System according to EN 14065	☐	☐
Product selection and scope of services provided		
Cleanroom protective eyewear: assortment with sufficient choice of models for GMP A/B areas	☐	☐
Cleanroom clothing: assortment with sufficient choice of models for GMP A/B areas	☐	☐
Proven qualified suppliers throughout the entire supply chain	☐	☐
Competent advice on model, quantity, frequency of changing, price model and area concept	☐	☐
Choice between leasing price model or processing of client's property	☐	☐
Provision of product samples	☐	☐
Carrying out wearing test	☐	☐
Professional reprocessing of cleanroom protective eyewear, including logistics, in accordance with agreed trip plan	☐	☐
Warehousing and client storage facilities nationwide	☐	☐
Emergency concept including support contract with qualified cleanroom laundry	☐	☐
Infrastructure and operation of an ISO Class 5 cleanroom in accordance with ISO 14644-1		
Validation and operation of cleaning and disinfection appliances in accordance with ISO 15833-1, -2, -6	☐	☐
Installation and operation of large sterilisers for steam sterilisation in accordance with ISO 285	☐	☐
Validation of steam sterilisation process in accordance with ISO 17665	☐	☐
Batch traceability	☐	☐
Proven validated processes in accordance with validation master plan (decontamination, disinfection, sterilisation, packaging)	☐	☐
In-process controls in accordance with control schedule (sterilisation, microbiological quality and particle emission of textiles, packaging)	☐	☐
Digitisation of customer service		
Online ordering 24/7	☐	☐
Reporting on quantities and costs	☐	☐
Online invoicing	☐	☐
Online tool for concern management, including processing of complaints	☐	☐
Business management		
Business strategy on ecological, economic and social sustainability	☐	☐
Collective working agreement	☐	☐
Established processes for employee training and development	☐	☐
Trained personnel in production, customer service, and management	☐	☐

Contact
your team of cleanroom experts

There for you, personally.
With us, you know who you're dealing with.

Your personal contact is there for you at any time; our experts understand the needs of your sector and answer your questions promptly and competently.

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