

Contamination Control

Visual Inspection and Good Practices in the Management of Gloves/Sleeves for Isolators

MC15



2 p.m. In-person session 14 and 15 May 2024 -

€ 1,600 excluding taxes

https://www.a3p.org/formation-aux-bonnes-pratiques-de-gestion-dinspection-gants-manchettes/ Document downloaded on 2023-11-30: Subject to changes and typographic errors.

PROGRAM

OBJECTIVES

Provide theoretical knowledge to:

- understand the characteristics of gloves (glove materials, uses, advantages and limitations, glove manufacture).
- apply good practices in the use of gloves/sleeves to maintain the sterility assurance of grade A areas and of the product.
- to apply an analysis and decision-taking approach when a hole is detected in a glove or a sleeve.

Provide practical knowledge to:

- ensure that the mounting of gloves and sleeves is compliant.
- be able to detect holes in gloves/sleeves.
- be authorized in the visual inspection of gloves/sleeves.

AUDIENCE

Persons operating on isolators: users, operators, technicians, production managers, production maintenance personnel, microbiologists, quality personnel.

PREREQUISITES

Knowledge of Good Manufacturing Practices, knowledge of isolator technology and constraints relating to its use.



A questionnaire is sent to participants in advance of the training course, to adapt the type of gloves to those used on the production sites.

PROGRAM

DAY 1 - MORNING: (theoretical approach)

Introduction and presentation of the training course sequence: Expression of the expectations of participants, presentation of objectives and of the training program

Reminders of regulatory requirements/GMP for the management of gloves for isolators

Understanding the characteristics of gloves (glove materials, uses, advantages and limitations, - glove manufacture)

Comprehensive management program for gloves/sleeves for isolators:

Reminder of good practices in the management of gloves and introduction of a decision flowchart in the event of breach of integrity

Presentation of the different physical integrity tests and their limitations

DAY 1 - AFTERNOON: (practical training)

Visual inspection as routine and at the end of the campaign

Visual inspection before decontamination

For this practical training, videos will be shown to explain how to inspect a glove and a sleeve. Each participant will then have at their disposal a test bench with a glove/sleeve to practice the detection of different types of holes.

DAY 2 - MORNING: (practical training)

Qualification of participants in visual inspection according to the methodologies learned the previous day for the 2 techniques (before decontamination and routine): each participant will have at their disposal a test bench and a set of 5 gloves on which they must find the number of holes and their location. An authorization certificate will be issued at the end of qualification.

MCQ on the key points of the training Correction of the MCQ and conclusions Participant satisfaction questionnaire

DAY 2 - AFTERNOON:

Visit to PIERCAN glove production units

SATISFACTION

To provide high-quality training, A3P has implemented a satisfaction survey system. At the end of all our training courses, an evaluation questionnaire is administered to trainees on different points: **content, facilitation, teaching resources, logistics & organization**.

This session has already been taken by 78 trainees.

The grade below is the average grade given by 68 trainees from previous sessions.

Satisfaction: 19.0 /20



PRACTICAL INFO

This practical training will take place in: Hôtel Mercure Chemin du Colombier 14520 / PORT-EN-BESSIN Tel. 02 31 22 44 44

CONTACT

Depending on your priorities and preferences, you can contact Julie Morel: **Telephone:** +33 (0)4 37 28 30 54 **Email:** a3pformation@a3pservices.com **By post:** A3P Formation, 30 rue Pré-Gaudry - Lyon 69007 **In person:** 30 rue Pré-Gaudry, in Lyon, from Monday to Friday

DISABILITY

Depending on your type of disability, our teaching methods and/or equipment will need to be adapted. Please contact us so that we can make the necessary arrangements.

If we do not have the teaching resources necessary to adapt the training, we will approach our partner AGEFIPH to agree on a solution adapted to your situation.

Our training courses can be accessed by persons with reduced mobility.

Please contact Hugo Rose, Disability Advisor, to organize your reception: 04.37.28.30.54. or hrose@a3pservices.com.