
Overview

To perform competently, you will need to demonstrate that you can operate in a range of conditions. You will need to demonstrate therefore that you can deal effectively with the following:

- 1 procedures relating to legal requirements and quality standards in an area where sterile products are made or where aseptic techniques are used
- 2 documentation relating to packaging instructions and packaging records
- 3 problems associated with documentation, equipment and materials, and faults in production quality

This unit has been designed for use in any industry where there is a need for aseptic or clean rooms e.g. pharmaceuticals, food preparation, cosmetics and toiletries, etc.

This unit deals with the following:

- 1 Prepare for work in aseptic or clean room conditions
- 2 Work correctly in aseptic or clean room conditions

During this work you must take account of the relevant worksite operational requirements, procedures and safe working practices AS THEY APPLY TO YOU.

Previous Version

Unit 42: Work in Aseptic or Clean Room Conditions

COGPACK42

Work in aseptic or clean room conditions

Performance criteria

You must be able to:

- P1 obtain the appropriate protective clothing
- P2 carry out the correct changing procedures in the designated area
- P3 dispose of waste according to procedures
- P4 follow the appropriate procedure for entering the clean room/aseptic area
- P5 confirm that the area is safe
- P6 complete appropriate environmental in-process checks correctly
- P7 select appropriate environmental samples correctly
- P8 deal with breakages and machine breakdowns according to specified procedures
- P9 follow the appropriate procedures for working in the clean room/aseptic area
- P10 identify and deal with problems promptly and correctly
- P11 complete documentation accurately and correctly
- P12 follow the exit procedures correctly
- P13 leave the clean room/aseptic area in the correct condition

COGPACK42

Work in aseptic or clean room conditions

Knowledge and understanding

You need to know and understand:

- K1 the implications of clean room and aseptic working in terms of health and safety, legal requirements and quality standards
- K2 the importance of maintaining appropriate conditions in the clean room/aseptic area
- K3 how to put on aseptic or clean room clothing and footwear correctly to ensure that the clothing does not touch the floor
- K4 what the scrub up procedures are
- K5 the condition in which the changing room should be left
- K6 what information should be passed on and to whom
- K7 the procedures for entering and exiting from the clean room/aseptic area.
- K8 waste disposal procedures
- K9 the appropriate procedure for working in the clean room/aseptic area
- K10 at what intervals the checks should be made
- K11 how to document the results of the checks
- K12 how to conduct environmental monitoring equipment
- K13 how to take samples
- K14 how to clear away damaged components
- K15 how to maintain the sterility of the product during breakdown
- K16 the procedures for reporting problems
- K17 the methods for dealing with problems
- K18 which documents should be completed and when
- K19 what written information is needed
- K20 when specified manner for making alterations

COGPACK42

Work in aseptic or clean room conditions

Developed by Cogent

Version number 1

Date approved June 2009

Indicative review date June 2011

Validity Current

Status Original

Originating organisation Cogent

Original URN Unit 42

Relevant occupations Engineering and manufacturing technologies; Manufacturing technologies; Process, Plant and Machine Operatives; Process Operatives

Suite Packaging

Key words clean room conditions, aseptic, work correctly, procedures, quality, documentation, sterile products