Bio Pharma Chem Skillnet

Good Cleaning Validation Practice

Delivered by:

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training@bpcskillnet.ie

Good Cleaning Validation Practice

This course has been developed based upon current technologies and industry trends. The presenters are actively involved in projects around the world dealing with today's technology and current regulatory expectations.

Course duration is 0.5 day.

Who should attend?

The course is suitable for people new to cleaning validation and focuses on the fundamental science and what critical aspects associated with cleaning validation documentation.

The Programme

Regulatory Background

Cleaning methods

- Automated
- Manual
- Development

Established Principles

- MACO
- Health based limits
- Single Use, Dedicated and Multi-Product Equipment
- Hold times

Choice of target molecule

- Worst case molecule
- Reference molecules or placebos
- Detergents

Choice of Analytical Techniques

- Visual Inspection
- TOC
- HPLC and UPLC
- UV
- Conductivity

Choice of Sampling Method

- Visual
- Swabbing
- Rinse samples
- Sample stability

Spray coverage testing

Calculation of Acceptance criteria

Recovery validation

Analytical Method Validation

About the presenter

Stan O'Neill, The Compliance Group

After qualifying as a Pharmacist, Stan spent over five years working in the pharmaceutical industry in Regulatory Affairs, Marketing and Quality Assurance (QP) and then joined the Irish Medicines Board (now the HPRA) for a period of ten years. In his capacity as a Senior Inspector, he performed GMP inspections throughout the world, represented Ireland at European level for the negotiation of standards of inspection for medicinal products (including Annex 1) and trained Inspectors at Irish, European and International levels.

This training is delivered on behalf of BioPharmaChem Skillnet by GxP Training.

For further information please contact training@bpcskillnet.ie or phone 087 997 0848

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