Added value:

We have the ability to diagnosis faults with equipment and processes and recommend appropriate corrective actions.

We are willing to communicate directly with equipment vendors to help ensure qualification activities are completed in a satisfactory and timely manner.

We have the knowledge and experience required to review cycle operating parameters and recommend improvements.

We offer training and guidance for production staff on correct operation, loading requirements and cycle review.

www.pev.co.uk

"Working with the Client .....not just for the Client."

Pharmaceutical Equipment Validation (PEV) Ltd

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Specialist Validation Services

for the

Pharmaceutical, Biotechnology & Medical Device Industries

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Introduction

PEV has an international client base covering the UK, Eire and mainland Europe.

We offer a high quality validation support service and are Subject Matter Experts (SMEs) in the validation of moist heat sterilisation and dry heat depyrogenation processes.

Our dedicated team of Validation Specialists have considerable knowledge and experience, are GMP trained and come equipped with industry standard GE test equipment

Our approach is to work closely with our clients to ensure their requirements are clearly understood and the objectives achieved in a cost effective and timely manner.

We understand the benefits of a risk based approach to commissioning and qualification in line with that described in ICH Q9 and ISPE guidelines.

Our testing is comprehensive and designed to satisfy the requirements of US (FDA), UK (MHRA) and European regulatory authorities.

Mission Statement

PEV endeavour to bring success to their clients by creating a team of professional, conscientious and well-motivated employees, dedicated to exceeding expectations,

Validation Activities

We can assist with the generation of User Requirement Specifications (URS), perform Design Qualification (DQ) and Validation Reviews.

We are able to generate and execute test protocols covering Factory Acceptance Tests (FATs), Site Acceptance Tests (SATs), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Re-qualification (RQ).

We can perform supplier audits and act as independent witnesses of commissioning tests

We are experienced in the qualification of the following equipment:

- Autoclaves
- Cold Store and Stability Rooms
- Fermenter and Process Vessels
- Fridges and Freezers
- Incubators
- Cryogenic Storage
- VHP Sterilisation
- Unidirectional Airflow Stations
- Blow Fill Seal Machines
- Dry Heat Ovens and Tunnels
- Freeze Dryers
- HVAC and Clean Rooms
- Isolators
- Microbiological Safety Cabinets
- Utilities - clean steam generation and distribution systems, water, air and gas systems.

Test Equipment

We own industry standard thermometric test equipment such as Kaye Validator 2000, IRTD, HTR, LTR and CTR.

We own standard HVAC testing equipment such as ADI Aerosol photometer, Airogene Smoke Generator, Climet Particle Counter and various air flow measurement devices.

All our reference instruments are calibrated to internationally recognised standards. (UKAS) (NIST) (DKD).

Documentation

We provide comprehensive validation documentation including:

Validation Plans, Gap Analysis & User Requirement Specifications (URS)

Protocols and reports for factory acceptance testing (FAT) and site installation acceptance testing (SAT)

Equipment specific protocols for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)

We supply comprehensive reports for all validation activities with clear and concise summaries to assist with presentation and submission to all Regulatory Authorities

Documents can be generated in PEV format or using client templates.