

## Validation and monitoring of HVAC systems and clean rooms Rev.3

### Day 1

Module	Topics
<b>Session Kick-Off</b>	<ul style="list-style-type: none"> <li>• Introductions</li> <li>• Course objectives and expectations</li> </ul>
<b>Introduction to HVAC systems and clean rooms</b>	<ul style="list-style-type: none"> <li>• Major components of an Industrial Air Handling Unit</li> <li>• Pressure, Filtration and Air movement inside an AHU</li> <li>• Clean rooms engineering overview</li> <li>• Design features for prevention of cross-contamination</li> <li>• Differential Pressure and Airflow regimes</li> </ul>
<b>Air Handling Units</b>	<ul style="list-style-type: none"> <li>• The science that preceded the development of HVAC Systems</li> <li>• Working principles of HVAC</li> <li>• Properties of Moist Air</li> <li>• The Psychrometric table and charts</li> <li>• Heat Exchangers, Fans and Duct Systems</li> <li>• Equipment Selection</li> <li>• Air Filtration for Quality Control</li> <li>• Examples</li> </ul>
<b>Qualification of Clean rooms and HVAC Systems</b>	<ul style="list-style-type: none"> <li>• Risk-Assessment</li> <li>• Design Qualification</li> <li>• IQ/OQ/PQ</li> <li>• Periodic requalification</li> <li>• P&amp;ID Symbols and How to read it for an HVAC systems</li> <li>• Documentation examples</li> <li>• How should a protocol look like</li> </ul>
<b>HVAC Knowledge Extension</b>	<ul style="list-style-type: none"> <li>• Useful links</li> </ul>

## Day 2

### Module

### Topics

#### Session Kick-Off

- Reflections from last session

#### Particle Monitoring

- How optical particle counters work
- Particle counting technology (including airborne rapid micro sampler and how they work)
- Classification vs. monitoring of clean zones
- Classification examples
- FDA CGMP & EU GMP Annex 1
- Monitoring systems
- Understanding particle monitoring data

#### Microbial Monitoring

- What has to be monitored and when?
- Routine and periodic monitoring requirements
- Differences between Aseptic and Non-Sterile Areas
- What equipment is needed?
- Where should we monitor?
- What standards should be applied?
- Location and frequency examples
- Effective data management and reacting to data

#### Cleaning and Disinfection

- Difference between cleaning and disinfection
- Types of cleaning and disinfecting materials
- Cleaning program and rotation
- Removal of residues
- Important instructions for correct and efficient cleaning
- Disinfectants efficacy Validation

#### Maintaining the Validated State

- Ongoing Quality Risk Management
- Continuous Improvement
- Non-Conformance Management
- Change Management and Change Control

#### Session Wrap-Up

- Feedback

