Med Val Pharma CONSULTANTS

ISO 14644-1;2015 CLEANROOM VALIDATION TESTING COURSE

The cleanroom validation training course is designed to provide a comprehensive insight into why and how a classified facility should be tested for commissioning validation or for continued compliance with ISO 14644-2;2015 classification.

The practical training course begins with an introduction to what the Cleanroom is designed to achieve and how the validation process begins.

As part of the classification validation testing, the set up of the cleanroom will be established to provide the validation test protocol and validation test report.

Med Val Pharma Itd will provide the practical testing instruments as part of the training course.

The practical testing methods will follow ISO 14644-3(2005), which outlines the following testing requirements for validation compliance.

Room air flows through supply grilles. Room air change rate calculations. Room differential pressure testing. HEPA filter Installation Leak testing (DOP) Comfort conditions ,temp humidity ,noise and light level checks. Air particle count testing to classification. Room recovery type testing to establish clean up rates. Air visualisation checks. Room fabric checks.

Formulation of the test results into the validation test report.

Test instruments to be used, Bolometer, micro manometer, aerosol generator, aerosol photometer, light scattering airborne particle counter, and comfort condition instruments.

The training course content can be flexible to accommodate specific, more intense training on any of the above test items.

What candidates will achieve from this training course .

How to validation test a cleanroom to ISO 14644-1;2015 classification.

How to formulate particle count test positions.

How to identify the test instrument requirements.

Be able to understand testing companies validation test reports.