Compliance & Validation Services

Presents a 2-Hour Online Training Course on:

Particle Counting, Cleanroom Classification and Particle Monitoring

11 August 2020

2-Hour Online Training Course

Start time: **09:00** *London/Dublin* **10:00** *Berlin/Amsterdam*

Finish time: **11:00** *London/Dublin* **12:00** *Berlin/Amsterdam*

Course Description and Who Should Attend

Cleanroom classification is a fundamental qualification activity for pharmaceutical cleanrooms. It is the activity that demonstrates that your cleanrooms will achieve their designated Grade and associated particle limits specification under maximum occupancy and activity (it underpins maximum room occupancy). Leading on from this, it is essential that total non-viable monitoring is performed meaningfully to demonstrate continued performance of the cleanroom during routine operations.

This course covers: how particle counters work and how to avoid under and over-sampling of larger particles (e.g. use of correctly sized and orientated isokinetic probes); setting up the classification exercise and incorporating ISO-14644 / EU Annex 1 / FDA Aseptic Processing Guide requirements (including the implications of the latest draft Annex 1); and effective particle monitoring (probe positioning by risk assessment). It does not cover microbial monitoring.

A worked classification example will be included. The course is aimed at individuals involved directly or indirectly in carrying out classification and particle monitoring. Target disciplines include validation, quality assurance, production (supervisors and management) and engineering.

Course Presenter

Mike James, Training Director, Compliance & Validation Services Limited.: Mike has over 25 years experience in the pharmaceutical industry, working in a variety of compliance and validation roles. His experience includes preparation and delivery of national/client-based validation training courses, hands-on validation work, validation project management and regulatory compliance consultancy. Previously, Mike spent four years as the Site Validation Manager for GlaxoSmithKline (GSK) at Speke, where he was responsible for all site validation activities, including the development and maintenance of the Site Validation Programme. Cleanroom qualification and monitoring is one of Mike's key areas of expertise / experience. Before moving to the pharmaceutical industry he spent 15 years as an industry chemist.

Online Training Platform

We use the industry leading GotoWebinar©, LogMeIn, Inc. platform for our online training courses. It's intuitive and simple to use, however we do recommend that you check your system's compatibility using the **'CHECK SYSTEM COMPATIBILITY'** link provided below (we use 'standard webinar'). To find out more about how our online training process works, from booking through to the end of the course, please click on the **'HOW IT WORKS'** link provided below:

CHECK SYSTEM COMPATIBILITY

HOW IT WORKS

Course Fees & Booking

The course fee is **£200 [GBP].** Please use the links below to book online and to view our Terms & Conditions.

NOTE: If your finance centre or attendees are based in the United Kingdom (UK), or attendees are booking as private individuals (non-company), the course fee will be subject to an additional 20% UK VAT charge (**£240** per attendee including UK VAT).

For EU Countries where finance centres and attendees are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule.

For non-EU countries and non-EU attendees, VAT is not applicable.

CLICK HERE TO BOOK ONLINE

CLICK HERE TO VIEW OUR TERMS & CONDITIONS