

## Would your cleanroom pass an inspection tomorrow?



**SMOKE STUDY VIDEO**  
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### ACHIEVING A SUCCESSFUL INSPECTION

Testing and validation of cleanroom ventilation is one of the most critical parameters in ensuring GMP compliance. Most pharma companies find it challenging to achieve the expected – and required – particle classification. Furthermore it can be very hard to control ventilation parameters and validate them continuously. In fact, one third of cleanroom inspections fail due to insufficient test documentation.

### ALWAYS ACCORDING TO INDUSTRY STANDARDS

Our team performs the tests listed below using equipment calibrated according to industry standards (ISO 14644-3):

- Measurement and analysis of airflow velocity and volumes in cleanrooms
- Calculation of room air changes
- Measurement and analysis of room pressure differentials

- HEPA / ULPA filter leak tests
- Non-viable airborne particulate counts for room classification
- Airflow pattern test/smoke visualisation and video recording
- Room recovery test
- Test of unidirectional flow units (LAF)
- Test of c-RABS (gloveboxes), isolators, cleanbenches and work stations, biosafety cabinets, fume hoods and vacuum cleaners
- Factory acceptance tests (FAT) and site acceptance tests (SAT)

### HOW CAN NNE HELP YOU?

With more than 15 cleanroom testers in-house we are a one-stop shop for cleanroom testing services. Every year, NNE executes more than 300 projects and performs more than 28,000 test hours related to HVAC cleanroom testing and qualification. We work with more than 25 different customers worldwide.

We are your guarantee that all regulatory requirements are met. We are examined and accredited by the American National Environmental Balancing Bureau (NEBB) and R3 Nordic for cleanroom testing.

Applying more than 25 years of experience, we offer a range of services, such as:

- Training in aseptic handling in a real-life environment at NNE's premises in Virum, Denmark
- Preparation of protocols, test plans and test forms
- Test execution, conclusion and cGMP-compliant test documentation
- Advice and guidance concerning current local and international regulations
- Training in general cleanroom technology
- Smoke study, visualisation and video recording



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