TEST OG DOKUMENTATION AF RENE RUM

Rambøll har specialiseret sig i renrumsteknologi og er altid på forkant med de nyeste standarder inden for klassificering og testning.

Rambøll tilbyder

- Projektledelse
- Udarbejdelse af kvalificerings-/ valideringsdokumenter
- Gennemførelse af test; bl.a.
  - luftskifte
  - lækagetest af HEPA-filtre
  - partikeltest i rum
  - recovery test

Dokumentation af rene rum

I dag er mange industrier afhængige af rene rum (clean room) i forbindelse med deres forskning, udvikling og produktion. Rambøll har gennem flere årtier arbejdet med rene rum, bl.a. kvalificering/ validering af rene rum til den farmaceutiske industri.

Rambøll har specialiseret sig yderligere i test og dokumentation af rene rum - Clean room Performance Testing (CPT). Rambøll har deltaget i NEBB's (www.nebb.org) CPT Technician Seminar og R3-Nordic's "Clean room Testing and Certification Board (CTCB). Vi er derfor rustet til at teste rene rum uafhængig af rummenes anvendelse, og vi er altid på forkant med de nyeste standarder inden for klassificering og testning.

Kvalificeringsprocessen

Kvalificering/validering af rene rum er en lang proces, der allerede starter i designfasen ved fastlæggelse af kravspecifikationer. Efter opførelsen af de rene rum, skal det dokumenteres, at de lever op til kravspecifikationerne.

Dokumentation

Dokumentationsniveauet kan afhænge af virksomhedens egne retningslinier/SOP'er og den godkendende instans (f.eks. Sundhedsstyrelsen og FDA). Vi indgår gerne i en dialog for at finde det rigtige niveau for den enkelte virksomhed. Vi har stor erfaring med at udarbejde dokumenter som valideringsmasterplan, IQ og OQ protokoller mv.

Rambøll gennemfører alle nødvendige test for at dokumentere, at de rene rum lever op til kravspecifikationerne. Vi har eget kalibreret måleudstyr, bl.a. laserpartikeltæller, photometer, aerosol generator og hood.

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CLEAN ROOM PERFORMANCE TESTING

Ramboll is specialized in clean room technology and we are always ahead adopting the latest standards in classification and testing.

Ramboll offers:

- Project management
- Preparation of qualification and validation documents
- Tests - for instance
  - air change rate
  - HEPA-filters
  - test of airborne particles
  - recovery

Clean room documentation
Today, research and production in many other industries also depends on clean rooms and controlled environments.
During the last three decades we have specialised in design of clean room solutions for the pharmaceutical industry, including qualification and validation of clean rooms.
Ramboll has furthermore specialised in Clean room Performance Testing (CPT) and has been examined by NEBB as CPT Technician R3-Nordic "Clean room Testing and Certification Board" (CTCB).

Ramboll therefore is able to test clean rooms to be used in any line of industry. Ramboll always applies state-of-the-art regulatory standards concerning classification and testing of clean rooms and controlled environments.

Qualification process
The qualification/validation process of clean rooms begins in the early stages of the design with the definition of User Requirement Specifications (URS).

Documentation
After construction and commissioning it must be documented that the clean rooms are in compliance with the URS. The level and extent of the documentation can vary depending on industrial standards, own SOPs and the approving regulatory authority, eg. FDA.

Ramboll takes pride in assisting the client in finding the right level and extent of documentation for clean rooms. We are very experienced in the preparation of documents such as Validation Master Plans, IQ and OQ protocols, etc.

These documents will help client in documenting that any facilities meets the required standars.

Ramboll also performs all required tests to classify clean rooms and documents that the clean rooms are in compliance with official standards. We have our own calibrated instruments, such as laser optical particle counter, photometer, aerosol generator, etc.

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