



RAMBOLL

CLEAN ROOM TECHNOLOGY

For more than three decades, in close cooperation with the pharmaceutical industry, Ramboll has specialised in cleanroom technology and offers specialist knowledge at a superior level.

Consultant and advisor

Projects with clean room technology, including compliance with GMP rules, require special attention and know-how:

- Ventilation (UDF-moduler)
- Clean utilities
- Water systems
- Validation and cleanroom testing

We work with active knowledge sharing from project to project, which is for the benefit of our customers as well as for the quality and the economy.

HVAC

The HVAC system is central to the design of a controlled area like a clean room or biosafety area, in which the product or the surroundings need protection. The design of the HVAC system requires great professional expertise and knowledge of the effect of the individual component parts to ensure the correct room classification in accordance with the standards prevailing. When required by the clean room classi-

fication, eg in aseptic production, the air will be filtered further by means of UDF modules (Unidirectional flow). Ramboll has provided consultancy services on the design and supervision of UDF modules and has successfully used scale tests and CFD simulation in the design phases. We have supplied multiple solutions for the protection of humans and environments, buoyancy problems in connection with heat emission, uniform velocity of air etc.

Clean utilities

For uniform analysis and production results, full control and knowledge of the quality of the utilities used in the controlled facilities is required. When planning installations for water systems, clean gases, steam etc., it is important to determine the required quality level prior to the design of the systems.

Water systems

Treated water is used in connection with clinical research and production. In order to meet the require-

ments for water quality, the raw water must go through one or more steps of purification. Purification may consist of softening, reverse osmosis (hyperfiltration), electronic deionisation (EDI), continuous deionisation (CDI), ultrafiltration, ultraviolet treatment and distillation. Ramboll has extensive experience in the design of water systems – RO water, purified water, water for injection, etc.

Validation and clean room testing

In our experience, validation should form part of the project from day one. It is important that an early risk assessment includes an assessment of which systems require qualification. Ramboll has extensive experience and knowledge of validation projects and testing in accordance with Danish, European and American (FDA) regulations.

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