Clean Room Expertise through all Project Phases

AFRY and Emtunga have a long experience of delivering modular pharmaceutical production plants together and have completed several global joint projects historically.

Both companies also have long documented experience working with clients in segments such as Pharmaceutical, Food and Oil & Gas industry, always with focus on quality and safety.

Our projects are managed by our own key personnel with long experience from pharmaceutical projects. We have expertise within all areas covering all project phases, from the early conceptual design study to the detailed project execution including construction and commissioning/validation on site.

We have a global network of several hundred high qualified suppliers. We also have a broad network of sub-contractors for all disciplines who offer high quality services and workmanship. We have a history of working together with many of them going back 30 years.

This is a guarantee for a high-quality delivery of a clean room system.

AFRY & Emtunga in Short

AFRY is a European leader in engineering, design, and advisory services, with a global reach. We accelerate the transition towards a sustainable society.

At AFRY we are 16 000 devoted experts in infrastructure, industry, energy and digitalisation, creating sustainable solutions for generations to come.

AFRY is ISO certified according to ISO 9001, 14001 and 45001.

Emtunga Solutions is a Swedish company 100% owned by the Norwegian Moreld group. Emtunga is a leading supplier of complex modular EPC projects. Over 45 years of experience from the offshore industry and 25 years from the pharmaceutical industry, gives us the ability to deliver fast and effective offsite construction based on world class project execution.

Emtunga Solutions is ISO certified according to ISO 9001, 14001 and 45001.

Design of Clean Room Installations

The design of the clean room functionality and requirements starts from the product and the environment required to protect the product and to ensure the quality and patient safety. The layout/process/personnel flows etc. are developed from the need of the product. The expertise within the Process Architect set the functional layout including room classifications.

All supporting system such as HVAC (supply and extract air), electrical (lighting, power, data), instrumentation, clean utilities and environmental monitoring need to be coordinated and integrated in the clean room installation. This is also applicable for the process equipment and automation (HMI panels). All this coordination work requires both careful design work and a lot of experience within each competence area.

AFRY/Emtunga has its own expertise in the various areas to be able to offer a first-class clean room installation with full integration of process and utility systems.

- Process Architects
- Clean Room Specialist
- Project Process Engineer/Clean room expertise
- Project Engineers within the different areas (process, architectural, HVAC, piping, electrical, instrumentation and automation)
- Project Designers within the different areas
- Procurement, sourced suppliers
- Construction Management including installation leads
- Test leads within commissioning, validation

All expertise with many years of experience in each area.

Different Areas - Different Expertise

Process Architect Layout & Logistics

The Process Architect will be a part to define the User Requirement Specification (URS) for each part of the total facility. These requirements together with process functional description and applicable Good Manufactoring Practice (GMP) regulations will be the input for overall layout. The Process Architectural Engineer coordinates the process layout, working environment, personnel and material flow and possibilities for building construction realization. This will set the Design specification for the clean room.
The design is developed in accordance with applicable standards, e.g. ISO 14644 (Cleanrooms and Associated Controlled Environments) and ISO 14698 (Cleanrooms and associated controlled environments — Biocontamination control).

Cleanroom QA & Validation

Commissioning and qualification ensures traceability throughout the entire project until the completed clean room. Support in all phases from URS, risk assessments to sampling and validation.

Cleanroom Process & Systems

The engineering and design of all equipment including utilities to meet all hygienic requirements. This also includes the integration and coordination to connecting systems and utilities. As a result the process layout can be set in detail.

Cleanroom Design

The cleanroom design team is making sure that the cleanroom is designed to meet the required hygenic standard and materials such as surface materials to match with specific cleaning procedure/agents and room requirements. The design shall also be in accordance with requirements for fulfilling differential pressures, pressure regimes and airlocks.

HVAC

Engineering and design of the HVAC system in order to fulfill the room specification with respect to temperature, air changes, humidity, room classification and air distribution.

Building Automation

The clean room including all supporting systems needs to be controlled by a Building Automation System (BAS). The GMP critical enviromental parameters to be monitored by an Enviromental Monitoring System (EMS). Our Automation Leads are experts when it comes to engineering of these systems.

Construction – Clean Room Installation

Our construction and installation management leads and coordinates all activities during the construction phase as well as the site installation work of the clean room system including installation systems (equipment, HVAC, piping, electrical, instrumentation and automation).

Project Management & Procurement

The project management including planning and procurement of the engineering, design and construction of the cleanroom installation. The scope can be done as a turnkey delivery.

The project is always executed in accodance with our company´s project execution processes. Our Quality Management System (QMS) incorporates Good Manufacturing Practice and our business has been audited by global pharmaceutical manufacturers (e.g. AstraZeneca, Cytiva and Octapharma).

Our turn-key plants are delivered fully qualified and include facility and equipment qualification (IQ, OQ) and Computerized System Validation (CSV) of all GMP-critical parts.

Contact

AFRY

Katrin Hedvall
katrin.hedvall@afry.com

Lars Wikström
lars.wikstrom@afry.com

Emtunga Solutions

Lars-Gunnar Wallenius
lars-gunnar.wallenius@emtunga.com