

## Life Sciences/Pharma

### ALTEN ADDED VALUE

Setting up one single team that manages end-to-end validation of new utilities and equipment;

ALTEN's capacity to act as the central coordination point for the different teams working on the project (engineering, validation, maintenance, production, QA, etc.)

ALTEN is highly qualified to respond to client's expectations and flexible enough to react quickly to business changing priorities

ALTEN's methodology: relevant KPIs, team management tools, governance meetings

### KEY DATA

Team Size: 11 FTE  
Time: July 2017–May 2019  
Location: Wavre, Belgium  
Work Package

**ALTEN TECHNOLOGY**

## FULL-SERVICE VALIDATION CENTER

### OVERVIEW

GlaxoSmithKline Vaccines sought a partner to perform a full pack of validations for its completely new phase III vaccine production building. In total, our client gave the responsibility to ALTEN to perform not less than 122 validation activities and 25 risk assessments for the start-up of the new building, all activities related to the annex 15 of Eudralex.

### PROJECT DETAILS

- Perform PQ (prepare the protocol, execute the runs, and write the final report)
- Write all technical reports and risk assessments related to the activities validated
- Manage all deviations generated during PQ validations
- Write all the SOPs for the equipment validated by ALTEN
- Coordination of validations in terms of planning and resources with stakeholders (production team, C&M, QA, maintenance, QC)
- Validate the following types of equipment/utilities:
  - > Utilities: compressed air, water for injection, pure steam, O<sub>2</sub>, CO<sub>2</sub>, N<sub>2</sub>
  - > Clean rooms: dry-fog, environmental monitoring grades C&D, thermal mapping
  - > Process equipment: autoclave (sterilization and decontamination), washing machine and manual cleaning, decontamination station

