NEXA | EAM Case Study (IRL)

WuXi Biologics

Validation Services: IQ/OQ/PQ

About Client

Our client, WuXi Vaccines Ireland, WuXi Vaccines, a subsidiary of WuXi Biologics, focuses on human vaccine discovery, development and manufacture. An exciting new addition to the WuXi Biologics family, WuXi Vaccines will bring to the global vaccine industry the world-class integrated platforms and CDMO business model on which WuXi Biologics reputation is based.

Business Challenge

The NEXA Validation team was hired by the WuXi Vaccines' Validation management to carry out validation on CO2 incubators in the potency lab in order to meet the strict target deadlines. Within 48-hours of the client's initial request to us, NEXA was on onsite supporting the project with a full validation team and equipment.

Project Challenges

As this was the first validation project of its type for NEXA within Ireland, our U.S. Validation team was instrumental in supporting the project given their expertise and specialty equipment to validate CO2 incubators. NEXA's Ireland Validation team trained closely with the U.S. team to ensure the highest level of work was carried out.

Scope of Work

In working with the client, the NEXA team executed the validation of three (3) CO2 incubators to the protocol specifications. An initial two incubators were also qualified side by side for dual temperature setpoints; followed by the final validation of the last incubator.

Services performed included:

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Dual temperature setpoints

Key Project Details

Client: WuXi Biologics

Project Type: IQ/OQ/PQ of Incubators

Location: Dundalk, Co. Louth, Ireland

Project Costs: Confidential

Project Duration: 3 Weeks

Staff Assigned:
Validation Manager
Validation Engineer

- Temperature/CO2/Humidity Mapping
- Relative Humidity Mapping
- Pre- and Post-Calibrations onsite

As a result of the NEXA team executing a successful project, the client has requested the validation of a fourth CO2 incubator along with a 3-month staff augmentation for a NEXA Validation Engineer. This will assure quality compliance of the site's manufacturing equipment to continue producing safe and high-quality products.

Results

Efficiency Benefits

- Reduction in downtime due to the ability to map multiple chambers concurrently
- Reduction in admin time due to the generation of validated reports including graphs and summary reports with minimum/maximum/average calculations—no human interaction required on qualified reports.
- Incubators remain closed using wired validation equipment, i.e., less recovery time from opening door or loss of studies from battery failure by using wireless loggers.
- Live, accurate readings throughout the test obtained remotely to ensure test was performing as expected.

Quality Improvements

- Easily review trends to start/stop qualification.
- 21 CFR Part 11 Compliant equipment.