



*WuXi Vaccines Ireland Ltd.  
CQV Services*



# CASE STUDY



## KPC INTERNATIONAL

Established in 2001 KPC International is a key supplier of specialist technical services and solutions to the Pharmaceutical Industries.

### Our mission

- Facilitate our clients in achieving their project goals
- Using innovative solutions that focus on delivering exceptional technical expertise
- Building strong relationships between project teams and stakeholders.

To date, our expert team has an excellent track record in achieving schedule certainty while reducing costs and increasing efficiency for our clients.

Commissioning, Qualification and Validation is one of the core services provided by the KPC International team during the facility start-up phase of a project. In the provision of these services, our team places a strong focus on the technical expertise, strategy development and execution, and team integration and training.



## WUXI VACCINES MODULAR LABORATORY IRELAND



KPC International were contracted by WuXi Vaccines Ireland Ltd to manage and execute a range of activities on the Modular Lab Facility, Dundalk Science and Technology Park, Mullgharlin, Dundalk, Co.Louth, Ireland. The specific responsibilities provided by our Commissioning, Qualification and Validation team on this project are as follows:

- Overall project management from MC to PQ
- Schedule development and control / reporting
- Development and management of an integrated commissioning schedule
- Review and approval on vendor SAT, IQ and OQ documents
- Manage vendor site attendance, SAT, IQ/OQ execution review and comment on URS's
- Generate IQ, OQ and PQ test protocol documents
- Execute IQ, OQ and PQ test protocol documents
- Generate and execute RTMs
- QA review of executed test documents before final client sign off
- Generate final reports
- Provide SharePoint document control system for project



# SERVICES

## SERVICES PROVIDED BY THE KPC INTERNATIONAL TEAM

- CTU Temperature Mapping
- CSV, BMS, BAS, EMS
- CQV Management
- CQV Execution Engineers
- Document Control
- Commissioning Document Generation
- Qualification Document Generation
- Vendor Management

## PROJECT CHALLENGES

### COVID-19 Project Challenges

- Remote working
- Restricted numbers on site
- Overseas vendor travel restrictions
- Accelerated start-up
- Managing increased workload with a reduced team.

### Adapting to COVID-19 Project Challenges

- Working from home
- Working with vendors to source local based resources
- Implementing remote SAT activities
- Assigning KPC SME's to support the project remotely

### Early Release of Lab to Operations for Training Purposes

- Scheduling CQV activities outside of normal working hours
- Liaising closely with Analysts to allow full access to Lab Equipment
- Alignment of vendors and staff to prevent schedule interruptions

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*I really enjoyed the experience working with KPC on the project. It wasn't an easy task, but the team has provided professional skills and excellent team work.*

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# PROJECT OUTCOME

The KPC Team accepted all the challenges which arose during the project. Working with the WuXi PEV team across different time zones, we feel we successfully delivered the project objectives.

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*I am very happy with the way KPC International has performed qualification activities within the WuXi modular laboratory and look forward to working with the company again in the future*

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