



C&Q CASE STUDY



Welcome to KPC International

EXCELLENCE FROM CONCEPT TO COMPLETION

KPC International is a key supplier of specialist technical services and solutions to the Pharmaceutical and Bio-pharmaceutical industries. Since 2001, our team has worked on some of the largest projects throughout Ireland, Europe, the US and Asia, helping our clients to deliver their life changing products to patients.

At KPC International, our mission is to facilitate our clients in achieving their project goals through innovative solutions that focus on delivering exceptional technical expertise and on 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 and Qualification are among 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 technical expertise, strategy development and execution, and team integration and training.

With this approach we have supported our clients by delivering Schedule Certainty - either completing their projects on time or by reducing delays that already exist by the time they start commissioning.

Case Study

DRUG SUBSTANCE BIOTECH FACILITY, CONFIDENTIAL CLIENT EASTERN EUROPE

KPC International was employed by a multinational client in Eastern Europe to provide support in reducing schedule delays that occurred in Design and Construction and to provide guidance and support for post OQ - manufacturing start-up activities and Operational Readiness. This was our client's first Bio-pharmaceutical manufacturing facility and was located a two-hour drive from their Head Office. The project was located outside of the Eurozone and significant downward cost pressures existed.

The specific services provided by KPC International included:

- Develop and execute a detailed C&Q Strategy for all systems including DCS which was designed using S88 standards
- Incorporate client Operational personnel into the Start-up Organisation where possible
- Manage the project schedule/budget
- Develop objective Earned Value based progress reporting tools
- Develop a post OQ Strategy (integrated with C&Q) including Tech Transfer, Cleaning Validation and Operational Readiness
- Oversee the execution of the post OQ Strategy
- Develop and oversee the implementation of Project Management Tools for the full start-up phase of the project

The KPC International approach was designed with a focus on People, Process and Innovation. This meant integrating our team of engineers with client personnel and other onsite providers, and implementing knowledge sharing between the teams to achieve a successful project outcome.

Through this approach, KPC International delivered a successful project outcome for our client, achieving a plant start-up with no batch failures. KPC International's innovative strategies and approach were highly commended by senior client management and other leading consultants.

☑	Schedule	Despite individual system delays, First GMP Batch was started 6 weeks ahead of plan due to successful integration of C, Q and Operational Readiness
☑	Budget	Project completed on budget with no change orders required
☑	Quality	Our customer said “We had no batch failures in the first year of operation, due to the advice and strategy from KPC”
☑	Independent Auditor	A leading global expert in Cleaning Validation, was asked to audit. He said KPC’s strategy was robust and fit for purpose.
☑	Organisation	KPC’s integrated Matrix Organisation for Start-up was hailed a success by Client Leadership Team.

Case Study

BIO-PHARMACEUTICAL BROWNFIELD PROJECT, CONFIDENTIAL CLIENT, EUROPE

KPC International was approached by a multinational client based in Europe to provide integrated C&Q services, from 30% construction completion through to PQ completion. This was a \$400 million biotech facility with 8 large-scale bioreactors, seed trains, 2 downstream suites, production support, utilities and HVAC.

The specific C&Q services provided by KPC International on this project included:

- Develop and execute a detailed C&Q Strategy for all systems including DCS which was designed using S88 standards
- Manage the completion of the Upstream Section
- Develop and implement objective Earned Value based progress reporting tools
- Develop and oversee the implementation of Project Management Tools for the full start-up phase of the project.

Due to delays in Engineering and Construction, the project was running 9 months behind schedule. KPC recovered 6 months with the following actions:

- Complete reorganization of the upstream team into a more focused system organisation
- Change from 8-hour days to 24/7 shift including the engagement and training of cost-effective resources to support
- Standardization of testing approach through standard documentation and tests all across systems. Also through strong training regimes
- Organisational development: Creation of an integrated multi-discipline team structure including client Operations, QA, Maintenance personnel, KPC personnel and third-party suppliers

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Case Study

GLOBAL PHARMACEUTICAL COMPANY, IRELAND

In 2018, KPC International was invited by an Irish-based multinational to help qualify the Equipment and Facility for an Ocular Insert Project, having successfully delivered a Pilot Plant Project for the same customer

On this project, KPC provided onsite and offsite Commissioning & Qualification services, which included:

- Validation Strategy
- Documentation generation
- Validation Execution
- Validation Summary
- Report Generation

This project concluded with the handover of the Facility and Equipment to the operations team on schedule. KPC also successfully supported our customers in a corporate audit in June 2019.

The team at KPC International recognise the importance of developing long term relationships with our customers and we continue to engage with this particular customer on several projects as a result of the strong working relationships established on these Pilot Plant and Ocular Insert Projects.





Case Study

NEW MULTI-PRODUCT API FACILITY, IRELAND

KPC International was contracted by a North American client to develop a strategy for the start-up of their \$300 million API facility. The strategy encompassed Operational Readiness across all client departments. Upon completion of this strategy, KPC were engaged to provide Commissioning, Qualification and Validation Document Generation and Execution services.

The services by KPC International on this project included:

- Integrated Operational Readiness workshop across all client disciplines - Operations, Engineering and Maintenance, QA, QC, HR and Organisational Development
- Production of a detailed Start-up Strategy for each department which were integrated into an overall strategy for the department
- Development and oversight of a Tech Transfer strategic framework including PMO tools, resource loaded schedule and SOP's
- Development of an integrated C&Q Strategy incorporating client Operations personnel
- Generation of Test Documentation remotely and establishment of a Time Critical Document Review and Approval Process
- Management and oversight of the execution of the C&Q activities
- Development of a bespoke Earned Value Monitoring System to track progress against baseline
- Established a Standard Guidance Document (PMO Handbook) to create oversight structure for Senior Management for site projects to ensure alignment to strategic plans, financial plans, resourcing plans and development
- KPC also established a Project Review Forum and a PMO process

Case Study

GLOBAL PHARMACEUTICAL CLIENT, IRELAND

Following on from two previous successful projects together, KPC International was invited in 2018 by a global pharmaceutical client based in Ireland to project manage a Laboratory Systems Upgrade and the associated Validation Processes for a globally initiated program within the organisation.

The requirement for KPC International's expertise arose as the QC laboratories at the client facility identified a number of systems which required upgrading in order to mitigate the potential security risks identified as part of the program.

KPC International provided the following services:

- Project Management
- Computer Systems Validation Consultancy
- Document Generation and Execution Services

These services included streamlining the specification and design for the infrastructure to provide a robust platform which met the GMP Annex 11 requirements and Data Integrity Requirements.

The Document Generation and Execution covered Qualification Plans, User Requirement Specification, Functional Specification, Design Qualification, Requirements Traceability Matrix, Installation Qualification, Operational Qualification and Summary Reporting.

Additional Process Risk and Impact Assessments were also introduced as part of the project.



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WHY WORK WITH KPC INTERNATIONAL?

The KPC International team brings an unrivaled breadth and depth of knowledge to plant facility start-up projects and is highly experienced in the areas of Commissioning and Qualification, Tech Transfer, Regulatory Compliance and Operational Readiness.

Our focus on integrating with client project teams to facilitate knowledge sharing and communication ensures a unified team approach in meeting project goals and sets them up for sustainable success.

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I was advised by internal and external consultants to allow for 5 to 6 batch failures during the first year of start-up. We had none and that was largely due to the team at KPC.

**-Global Head of
Manufacturing**

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