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QUAY MARKS NEW FACILITY WITH MAJOR INVESTMENT AND MHRA RE-ACCREDITATION

As part of the move to its purpose-designed facility in Deeside, North Wales – which was officially opened by the Deputy First Minister of Wales last year - pharmaceutical outsourcing specialist Quay Pharma has invested in a variety of new equipment to further enhance its range of support services for clients. The new site has also now undergone a successful re-inspection by the MHRA (the UK Medicines and Healthcare products Regulatory Agency), confirming that Quay is fully compliant with good manufacturing practices (GMP).

The new equipment includes a state-of-the-art ion chromatography system which has been added to Quay's portfolio of analytical development instrumentation to support two new projects requiring specialist analytical capability. For most developments, drug substances are assayed using conventional high performance liquid chromatography with ultraviolet (UV) detection but the compounds involved in these latest projects are transparent to UV light making this standard technique impossible.

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The first of the projects concerned is for a leading French biopharmaceutical company, which is seeking to develop products for severe neurological disorders. The system will be used with pulsed amperometry electrochemical detection to monitor extremely low levels of sugars in a combination drug product. The second project, for a new UK pharmaceutical company, involves measurement of a cationic drug (API) and its degradation products by conductivity detection.

In addition, the Formulation Development department, which specialises in the development of solid dosages, creams, liquids and gels, has been expanded to include a new pilot facility alongside the laboratory. The pilot lab will offer the capability for early phase work in standard techniques such as tableting, coating and capsule filling, as well as more complex processes such as extrusion spheronisation and semi-solid and liquid filling and banding of capsules. It will assist in the scale up of production prior to full manufacture as well as providing proof of concept studies and samples for pharmacokinetic (PK) studies.

As well as the investment in new equipment, Quay is also planning to introduce new GMP manufacturing suites, with work on these expected to commence in the autumn.

“The move to the new premises has effectively quadrupled the available space for these important departments and will allow us to provide a greatly enhanced range of services to both existing and new customers,” comments Quay Pharma’s Chief Executive Mike Rubinstein.

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“At the same time, we are delighted that our commitment to the highest quality and best practice has been confirmed by our successful MHRA inspection.”

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Caption:
Quay’s new facilities have also undergone a successful re-inspection by the MHRA.

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