ABOUT THIS CASE STUDY
Belfast-based Bio-Kinetic Europe Limited worked with the University of Ulster to deliver this Knowledge Transfer Partnership (KTP). The project set out to plan and implement an effective quality management system within the company, with particular emphasis on proactively addressing the effects of emerging European legislation in the clinical trials sector.

ABOUT THE SPONSORS
The Department for Trade and Industry (DTI) drives the ambition of ‘Prosperity for All’ by working to create the best environment for business success in the UK. The DTI helps people and companies become more productive by promoting enterprise, innovation and creativity.

Invest Northern Ireland is Northern Ireland’s main economic development organisation, working to increase wealth and prosperity by delivering expertise and resources to accelerate the creation and growth of businesses.

FAST FACTS
- Integrated quality management system in place
- Continuous quality improvement incorporated into business
- Focus on quality improvement securing new business, with sales expected to rise by 25%
- Rework reduced, increasing profits by 8%
- Academic partner developed a template for helping organisations incorporate quality management principles for business benefit
- Associate’s personal, managerial and professional capabilities enhanced

The Company

“I can only highly recommend the KTP experience. The Partnership allowed us to implement processes which were of strategic importance to our company in a clear and systematic manner and gain enhanced credibility in a highly competitive market.”

Moira Burke, Managing Director

Bio-Kinetic Europe Limited (BKE) carries out clinical trials on humans, to determine the efficacy of pharmaceutical products as part of the drug validation and approval process. Clients are spread across Europe, Japan and the USA.

ABOUT THE PROJECT
Since 1997, trials have been carried out in accordance with the internationally-recognised ethical and scientific quality standard ‘Good Clinical Practice’. However, moves to close a legal loophole, that left Phase I clinical trials in the UK without central regulation, meant BKE needed to review quality procedures to ensure compliance under full regulation.
This KTP was initiated to develop and implement an effective quality management system within BKE, taking into account compliance with emerging legislation, sub-contract auditing and quality service provision to clients and customers.

**BENEFITS**
This successful KTP has given BKE the opportunity to increase the viability of its business through quality and performance improvements. The company’s integrated quality management system offers a flexible, small-company approach that ensures compliance without compromising on non-negotiable standards. Improved strategic planning will help the company keep up with future legislative changes in clinical trials.

Through process re-design activities, BKE now has an increased awareness of quality assurance and a structured quality audit programme is in place. Standard operating procedures have been revamped to reflect current working practices and up-to-date legislation, as well as being user-friendly, structured and consistent.

In the far-reaching programme of work, sub-contracting procedures have been reviewed and updated. Continuous quality improvement has been incorporated and is considered key to business success. BKE’s ability to demonstrate compliance with new legislation is predicted to increase sales by around 25%, while profits are expected to rise by some 8% because of the reduction in rework resulting from the improvement in quality management systems.

**RESULTS**
- Flexible quality management system in place
- Business more viable through quality and performance improvements
- Demonstrable compliance with emerging legislation for clinical trials, attracting new and repeat customers
- Better quality management reducing rework and increasing profits

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**The Associate**

“The KTP experience is a very challenging but highly rewarding one. I have no hesitation in encouraging any highly-motivated graduates to avail themselves of KTP. I not only gained industry-recognised qualifications, but enhanced my management and communication skills.”

Elizabeth Murray, Quality Assurance Officer

Elizabeth Murray, the Associate on this KTP, was instrumental in carrying out and implementing the project, and helped to ensure its success.

**BENEFITS**
The work at BKE provided Elizabeth with the scope and opportunity to develop both personally and professionally. Excellent management support contributed to the development of her skills, knowledge and competence.

Elizabeth's achievements and commitment did not go unnoticed. She received an ‘Endeavour Award’ from the Northern Ireland Chartered Management Institute and the Chartered Institute of Personnel and Development, in recognition of developing her knowledge and skills and making a measurable difference to her talents and abilities. The company also recognised her progress and appointed her as its first Quality Assurance Officer.

**RESULTS**
- Enhanced personal, managerial and professional capabilities
- Accepted job with company as Quality Assurance Officer
- Obtained NVQ Level 4 in Management
- Completed Post-Graduate Diploma in Industrial Practice
- Progressed towards MSc

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**The Academic Partner**

“Our involvement in this KTP and exposure to quality management in Clinical Trials has broadened and strengthened the University’s business and management expertise in a new business area, and provided valuable teaching and research outputs.”

Professor Rodney McAdam

Rodney McAdam, Professor of Innovation Management in the School of Business Organisation and Management at the University of Ulster, was lead academic on this cross-faculty partnership, which also involved the Schools of Marketing, Entrepreneurship and Strategy, and Biomedical Sciences.

**BENEFITS**
The project’s outstanding success reflected the high quality of the University of Ulster’s KTP activity and has helped to enhance its reputation locally, nationally and internationally.

Academics gained experience of quality management and operations in the clinical trials sector, thereby strengthening the University’s business and management expertise in a new area of industry. A generic template was developed that will help other organisations to incorporate quality management principles for business benefit. Project work has been incorporated into various teaching modules, learning materials and activities on BSc and Masters courses, and new ideas and agendas for research have been generated.

**RESULTS**
- Cross-faculty project awarded a Grade 1 for achievement
- Improved inter-faculty relations
- Useful course work developed
- Paper published in international professional journal
- Professorship for lead academic