Do you have a strategic objective to access the Molecular Biology Market, or simply wish to extend your portfolio offering for the Research and/or In Vitro Diagnostic sector?

Is a key deliverable of that goal to introduce novel, bespoke and profitable solutions for this rapidly growing market?

Is time of the essence but your staff and facilities are fully committed for the foreseeable future?

If you recognise any of these issues, then we may be in a position to help. Isohelix is a versatile and credible source of product development support.
The Isohelix Offering

Isohelix has established a respected position within the global Molecular Biology market in both the Research and In Vitro Diagnostic sectors through the provision of a comprehensive portfolio of products, which deliver superior DNA management ([www.isohelix.com](http://www.isohelix.com)). As an operating company within the Cell Projects stable, Isohelix has been equally successful in harnessing its knowledge and expertise in offering corporate development alliances with partners seeking to enhance or extend their product portfolios, whether that be through Joint Ventures, OEM or Contract Manufacture.

Co-development, Corporate Relationships and Commercialisation Projects

Bespoke in-house Molecular Biology and DNA laboratory facilities, coupled with extensive experience in product and technology development, has provided Isohelix with the opportunity to build commercially successful corporate partnerships through the establishment of Joint Venture and Co-development projects. This is evidenced in the enviable track record of historic and current third party programmes which include:

- Isohelix entered into an agreement with the Twins Research Unit at St Thomas’ Hospital to Purify and Isolate DNA from a large number of particularly challenging materials, the samples were processed at the companies laboratories in Maidstone UK.

- Co-development project and commercial licence agreement with Queen’s University, Kingston, Ontario, Canada covering key Adherent Cell Electroporation Technologies.

- In co-operation with Guys and St Thomas’ Hospital Medical School, the Research and Development of a device (Spin+Collect™) which significantly improves DNA yields from buccal and saliva collection devices.

- Several OEM and Private Label agreements are in place with global distributors, including Japan, Germany, Italy, USA, UK and Scandinavia.

The Genomics Core for the BRC for Mental Health in the MRC SGDP Centre at King’s College London is providing experimental data for newly developed products by Isohelix, for Saliva, Buffy Coat and Blood DNA Collection. Charles Curtis, Core Facility Manager, comments,

“We are excited to work with Isohelix as they share our goal to enable robust and economical collection and isolation of high quality genomic material for use in large-scale and longitudinal studies.”

“Our experience with Isohelix was both enjoyable and technically very rewarding. The executives’ knowledge and expertise coupled with the company’s flexibility delivered exactly the DNA sample conclusions and observations we had asked of them.”

— Gabriela Surdulescu, Department of Twin Research, St Thomas’ Hospital, London UK

“Tom’s commitment to continuous communications far exceeded expectations! His openness ensured that issues were addressed before they became obstacles.”

— Anne Vivian Scott, Vice President of Commercial Development, PARTEQ Innovations, Queen’s University, Canada


DNA Knowledge and Expertise Translated into Commercially viable products

The emerging market for sensitive and commercially viable molecular biology technologies has demanded an ever expanding requirement for developing increasing attainments of yield, and purity in DNA sample extracts.

The discovery and optimisation of the individual steps within the research process were adopted as a vital development focus for Isohelix scientists. The fruits of that work are now enjoyed by the scientific community, active in this exciting new sector. Specific successes have included:

- The design, research and manufacture of a buccal swab material dynamically capable of having a quick release surface, yet delivering an enhanced yield of intact and high quality buccal cell genomic DNA optimally suitable for new process methodologies.

- The development of a unique and efficient sample recovery device (Spin+Collect™) to significantly increase sample yields from swabs and other collection materials.

- The development of a DNA drying technology to facilitate the long-term and room temperature storage of fully stabilised DNA and other biological samples.

- The Research and Validation of several competing phase chemistries resulting in demonstrably cleaner DNA whilst maintaining yields. Up to 20μg of previous isolated DNA can be bound to the mini silica-based membranes with almost complete recovery of intact DNA.

The Absolute Contract Manufacturing Solution

Isohelix offers a complete contract manufacturing service for companies wishing to out-source their prototyping through to product design and production. Our experience comes first hand from many years of producing complex products for the Life Science, Molecular Biology, Genomics and High Throughput Screening markets. Companies (both large and small) using these services have found many benefits from using Isohelix as their manufacturer including:

- Reduced costs and transparency for development and manufacturing set up.
- Lower unit component costs.
- Biocompatibility.
- Considerably shortened timeframes to production.
- Active support in stock management.
- Project management interaction by defined goal.

Isohelix is able to integrate the following techniques into your custom or OEM project:

- Initial prototyping for feasibility studies.
- High precision production from drawing inception using high tolerance designs.
- Products manufactured to defined exacting standards and where required will include:
  - DNase, RNase, DNA, Endotoxin free certification for Biocompatibility.
  - Full clean room facilities for manufacture and assembly.
- Additional Assembly, QC and support for:
  - Visual, physical and Bio QC testing for product performance.
  - A full quality audit and batch-dating trail.
  - Assembly to fully wrapped/boxed ready to ‘ship and sell’.
  - Certified gamma irradiation and ethylene oxide treatment.
  - Design and print for wrapping, manuals and packaging.

The company was awarded the BS EN ISO 9001:2008 Quality Certification for the Supply and Manufacture of Molecular Biology Solutions in May 2007 and BS EN ISO 13485:2003 for the supply and manufacture of devices used in In-Vitro diagnostic kits.
Why Choose Isohelix

Isohelix is a small flexible company with an in-depth and practical understanding of all aspects of the development and commercialisation of products for the Research and Diagnostics markets.

» Senior Management Expertise

Managing Director and owner of Isohelix Tom Hole has an exemplary career within Life Sciences, with a strong pedigree of Senior Corporate Executive and Non-Executive roles in start-up, medium and plc organisations. He has an enviable track record of serially founding and ‘turning around’ companies culminating in profitable trade sales. He has driven several joint ventures to agreed investment and commercial conclusions.

“I am confident you will find the Isohelix partnership both a scientifically and commercially profitable experience.”
— Tom Hole, CEO, Isohelix

To open a corporate discussion, or to seek additional information, please contact:

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» Comprehensive Sector Knowledge

Isohelix executives have a considerable understanding of the molecular diagnostics and DNA markets, including:

• Extensive Network of sector key opinion leaders.
• Practical knowledge of international and technical file regulatory requirements.

» Accomplished Product Design, Development and Manufacture

• Full in-house Molecular Biology and DNA Laboratory facilities.
• A track record of historic and current product manufacture for third parties.

» Continuous Programme of Product Technology Enhancement

Over the last 20 years, the company has strived to optimise its existing manufacturing processes. One such example is the validation of Ethylene Oxide sterilisation enabling the discontinuation of Gamma Irradiation technology.

» Quality Management

• High Quality audit standards for component and manufacturing control.
• ISO 9001 & ISO 13485.

» Comprehensive, Global, Marketing and Distribution Facilities

Potential partners seeking to reach international markets may be able to utilise Isohelix’s comprehensive distribution and dealer networks.