

- ▭ Production scale-up
- ▭ Process control
- ▭ Automated manufacturing systems



### Scale-up for continuous manufacture

Lab-scale manufacturing to full GMP lines

Re-design, simplification and cost-reduction

Microfluidic process scale-up

Compliance & process control



### Cell and gene therapy scale-up ▭

If the full potential of cell and gene therapies is to be realised their production must scale. At the heart of this challenge is the need to design an automated, repeatable and compliant process for generating therapeutic quantities of cells.

We are experienced in developing high throughput, commercial and large-scale manufacturing processes applicable to cell & gene therapies. Our scientists work in biology, fluidics, engineering and process control.

### Sagentia's experience ▭

- Complex system design & development
- Cell identification, expression and expansion diagnostics
- Imaging, optical biosensors, flow cytometry, quartz crystal microbalance
- Electromechanical integration
- ISO & EMC regulatory compliance and Good Manufacturing Practice (GMP)

At Sagentia, we work across the development lifecycle:-



initial need and market analysis



concept generation



technology and product development

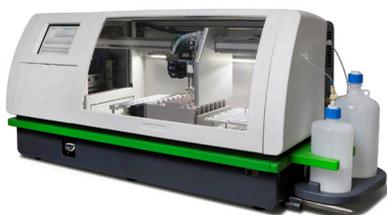


transfer to manufacture

### PathoGenetix Inc

"Sagentia has been a great product development partner. Concept to delivery of the new RESOLUTION™ system took 18 months"

Ann Merrifield  
CEO, PathoGenetix



Full case study overleaf →

### T2 Biosystems

"Sagentia's team has showed that they are willing to own the problem and ensure we meet aggressive timescales"

John McDonough  
CEO, T2 Biosystems



Full case study overleaf →

## PathoGenetix Inc: Commercial-scale, rapid microbial detection system



### Challenge →

PathoGenetix selected Sagentia as their product development partner to take their current laboratory prototype and their proprietary GSS technology and help turn it into a technically successful platform

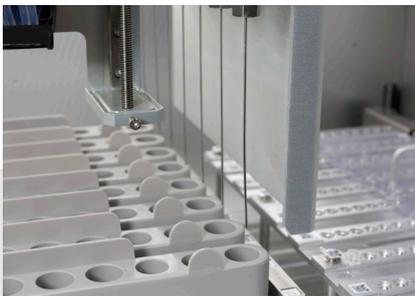
### Approach →

Sagentia worked across the product development lifecycle:

- We undertook concept validation and global VoC analysis to help the client determine and define their go-to-market strategy
- We managed development of the architecture
- We delivered all electro-mechanical and electro-optical aspects that enabled the GSS technology to be taken to market
- We created an alpha prototype

### Benefit →

- We combined two initial bread board systems into an intuitive and usable system with a smaller footprint, as well as a lower per unit cost base
- The system has the potential to identify the specific pathogen causing a foodborne illness outbreak – a critical step in defining the extent of the outbreak, determining the food involved, finding the source of the contamination and defining the scope of a product recall



We combined two initial bread board systems into an intuitive and usable system with a smaller footprint, as well as a lower per-unit cost base

## T2 Biosystems

A flexible platform suitable for the analysis of pathogens, genomics, proteins and small molecule immunochemistry

### Challenge →

Our client required a novel IVD platform with sample PCR sample preparation and magnetic resonance detection

### Approach →

- Sagentia's multi-disciplinary team started with system architecture and concept generation built around the client's proprietary technology
- We continued with Proof of Principle to de-risk and develop key system modules before then completing the detailed design of the entire system
- Finally, parallel activities were used to investigate the user interface, consumable design and ID

### Benefit →

- We delivered a fully integrated system and consumable within the required timescales
- We provided the required functionality within the required footprint and BoM cost
- Verification and testing were made easier with full prototypes



A flexible platform suitable for the analysis of pathogens, genomics, proteins and small molecule immunochemistry



## Contact us

The above are just two recent examples of custom systems that Sagentia has developed for clients. For more information, please email us at:- [info@sagentia.com](mailto:info@sagentia.com) or visit us at [www.sagentia.com/market/cell-gene](http://www.sagentia.com/market/cell-gene)