

Diagnostic services

# Accelerate diagnostic test development and manufacture





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Our diagnostic services help you break through barriers to get from idea to commercialization faster, with an effective diagnostic test.

Whether you need a customized membrane or magnetic bead, access to specialized infrastructure, or support from our experienced team, we deliver solutions designed to meet your needs.



# Accelerate assay development

## Molecular and immunodiagnostic applications

Molecular and immunodiagnostic point-of-care and lab-based tests using nucleic acid and protein-based assays are now an essential component in the evaluation and early detection of many diseases. Applications include the areas of infectious diseases, oncology, inherited disorders, and prediction of genetic disease risk, with new applications coming to market every day.

We offer laboratory and manufacturing infrastructure, membrane and magnetic bead customization and troubleshooting and consultation services to diagnostic developers looking to convert an idea or prototype into a commercialized diagnostic assay or upscale production.

Take advantage of Cytiva's extensive experience from the design stage through launch to minimize costs and accelerate the timeline for commercialization. Our team of scientists and manufacturing specialists will work with your in-house teams to help optimize components and identify the best-suited technologies. This enables you to expand your customer base and address new markets and applications that may previously have seemed out of reach.



Contact us to learn more about our Diagnostic services





# The right infrastructure, as and when you need it

We provide our development, customization, lyophilization and manufacturing services at our purpose-built facilities in Cardiff, UK, in Dassel, Germany, and in Tonglu, China. Our facilities provide exceptional lab space designed to meet rigorous cGLP and cGMP standards.

Acquiring specialized infrastructure requires capital investment, time to implement, and potentially staffing up, or up-skilling

existing staff. Contract manufacturing converts this to an expense, part of the cost of goods. You can utilize our infrastructure, as and when you need it.

Our dedicated proof-of-principle facility is capable of small-scale optimization and validation of up to 50 plates, facilitating transition through to manufacturing and commercialization of your stabilized assay.

## Stringent standards meet regulatory requirements

- HEPA filtered air
- Humidity and temperature control
- UV scrubbers
- Dry nitrogen dispensing cabinet
- Clean room environment





# Secure, global supply chain

High quality products which deliver reliable and consistent performance start with a reliable, secure supply of consistent raw materials. To achieve this, we take a proactive approach to security of supply, from a comprehensive raw material supplier risk management program and risk mitigation plans, through to rigorous product release testing based on agreed quality control (QC) specifications to support performance claims.

## Through our supplier risk management program, we:

- Reduce the number of high-risk suppliers
- Mitigate risk through improved knowledge and assessment of potential incidents
- Use the most resource effective activities to reduce supplier risks
- Establish multi-sourcing and multi-manufacturing options for critical materials

Effective risk assessment and mitigation strategies require a cross-functional, data-driven commitment to supplier risk management. We take a proactive and strategic stance to global supply-chain risk management to ensure that we are prepared to react quickly and decisively to unforeseen events. By assessing risk in advance, we can determine and plan for the potential impact of raw material variability and availability. Having identified high-risk areas, we can prioritize and implement initiatives to address them. We continuously monitor the points susceptible to potential compromise, with an overarching goal of identifying unexpected issues quickly, facilitating a timely response, and reducing risk in a measurable and objective way.

 Watch our webinar to learn more



# Component and service design process

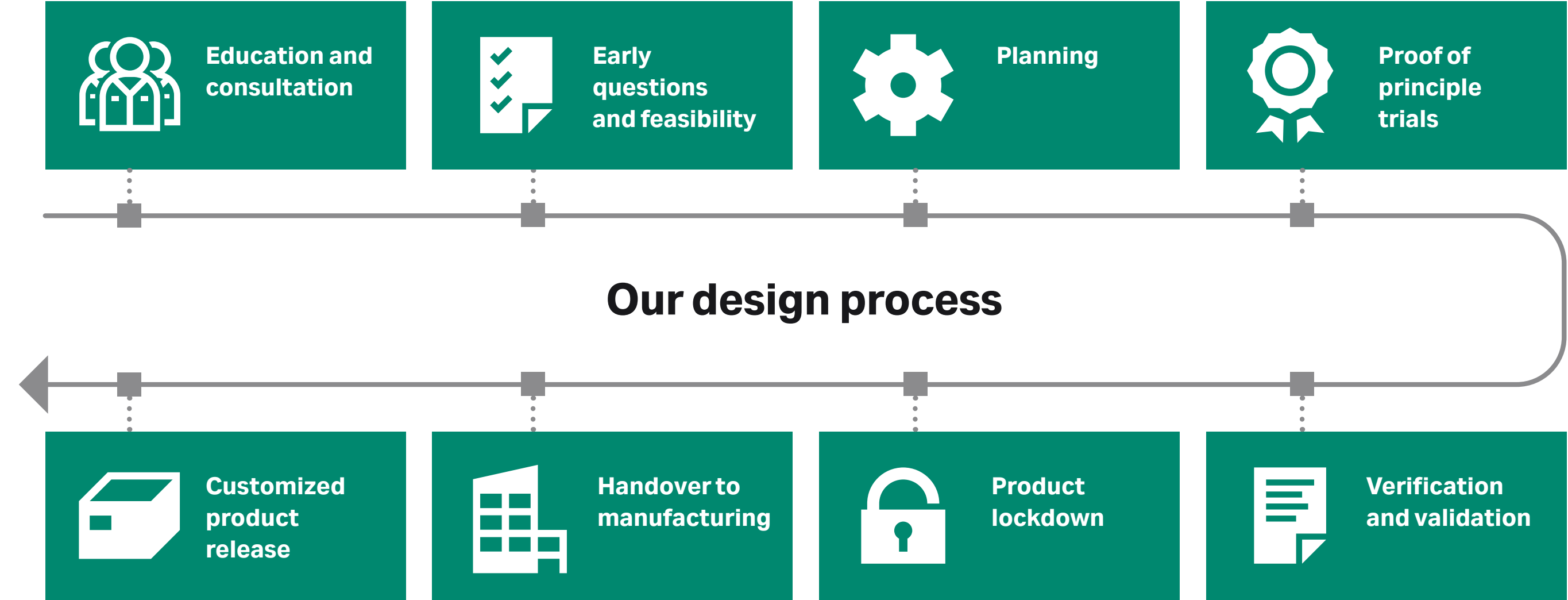
Our custom design function comprises an inter-disciplinary team of engineers, biologists, and filtration and separation specialists.

With extensive capabilities and proven methodologies for design concept, optimization, and platform development, we focus on supporting your concept with design for optimal manufacturing. We solve specific design issues with custom components, such as membranes, vials and reagents.

Our structured process enables you to benefit from Cytiva's extensive experience and expertise, not only when unexpected issues emerge, but from design stage through launch helping minimize costs, trial and error and development time.

**Our custom design process advantages:**

- Minimize design complexity and optimize for efficient manufacturing
- Generate prototypes for functional proof-of-principle testing
- Reduce costs of product development cycles
- Shorten time-to-market





# Lyo-Stable lyophilization

The Lyo-Stable™ service provides access to expertise, equipment, proprietary excipients, and decades of experience gained from developing off-the-shelf and custom lyophilized products based on well-established Ready-To-Go™ technology.

Our patented lyophilization technology stabilizes individual proteins and reagents, as well as complete multiplex assays, by providing a molecular environment that protects against conformational changes in protein structure. From simple buffers to multi-component kits, our Lyo-Stable custom stabilization service can develop and manufacture custom products in small or large batch sizes.

Along with your user-defined components, such as primers, probes, and enzymes, your made-to-order cake or bead will contain our proprietary excipient mix to stabilize your temperature-sensitive assay for storage and shipping at ambient temperature. All you need to add is your sample and you are ready to go!

## We offer:

- **Regulatory compliance** – ISO13485 and GMP-certified production (if required) ensures regulatory alignment and quality assurance for sensitive applications globally.
- **Reduced logistical hurdles** – Shorter transit times, fewer regulatory complexities, and a more streamlined, sustainable supply chain.
- **Flexible, scalable lyophilization services** – Lyophilization expertise tailored to meet customer needs at small and large production scales, from early-stage development to full commercial manufacturing.
- **Improved market responsiveness** – Regional production allows customers to more rapidly adapt to market demands and supply fluctuations.

 [Learn more about our Lyo-Stable service](#)



**Find out more** about the process and benefits of lyophilization in our knowledge article.





# Contract manufacturing

Our tailored contract manufacturing service allows you to take advantage of our extensive knowledge and experience as we guide you through the process of developing your minimum viable product to a commercial product.

Our designated team will carry out a full transfer process from the initial proof of concept through to batch validation and into production to improve your existing process and allow a more seamless transition to large scale manufacturing.

With ISO-certified facilities capable of accommodating manufacture of simple buffers through to multi-component kits for both low-throughput and high-throughput customers, we can comfortably manufacture your specific product(s) for use in pharmaceuticals, diagnostic applications, and life science research.

## Stay small, but play big

Utilize our contract manufacturing services to avoid the need to staff up or make capital investments in manufacturing.

- Sourcing and validating raw material
- Custom design services
- Custom formulations, volumes and concentrations
- Custom packaging and labeling
- Custom testing and documentation
- Secured supply and delivery
- Scale-up capabilities to meet your needs
- Stability studies
- Full OEM services

[Learn more about contract manufacturing](#)





# Lateral-flow development services

Rapid point-of-care (POC) tests are among the most widely used analytical technologies in diagnostics.

The development of a POC testing device is a time- and cost-intensive process, with technical, financial, and regulatory hurdles in developing a marketable lateral flow assay. Getting from idea to proof-of-principle as quickly as possible is vital for releasing the next stage of funding. Our lateral-flow development services provide point-of-care lateral-flow expertise, coaching and training workshops as well as the supporting infrastructure and proven development methodologies on a one to one level to make that process as speedy as possible.

## We provide:

- Access to exceptional laboratories and manufacturing facilities
- Experience manufacturing membranes and pads since 1740
- Proven methodologies to accelerate progress between key development stages
- Specialist surface plasmon resonance (SPR) reagent characterization with Biacore™ equipment

We perform the entire assay development process with transparency, sharing the lessons we have learned, and documenting everything to make sure you have complete confidence in the scientific design and robustness. You will have the flexibility to use all or just some of our services, according to your needs.

## Development expertise to bridge the gaps in your capacity:

- Method development
- Method transfer
- Method qualification
- Troubleshooting
- Full outsourcing of development
- Reference standard characterization
- Stability studies
- Lot release testing
- Raw material inspection testing





# Membrane and pad customization

Our membrane customization provides fast-track access to membranes and pads that can be made to required performance specifications (for example thickness and wicking rates) in chosen formats or adapt the physical characteristics of an existing high performing membrane.

Our team has considerable experience and capabilities in the selection and customization of test components, as well as an understanding of the underlying science of rapid diagnostic test design. We can help with design robustness, work with different design formulations in parallel to minimize time and cost and optimize test conditions so they are repeatable at both small- and large-scale quantities.

Cytiva standard technology components for point-of-care immunodiagnostic assays can be customized to meet the size, format and performance requirements of any of the following assays:

- Lateral flow [membranes and pads](#)
- Flow-through [membranes and pads](#)
- Dipstick colorimetric [membranes and pads](#)
- Track etched [membranes](#)

## Product customization

When off-the-shelf products do not meet specific application requirements, Cytiva can adapt the properties while ensuring the same quality, performance, and reliability as catalogue products. Customizable properties include purities, formulations, blends, pack sizes, dimensions, configurations (e.g., changing from sheets to reels or cut cards), grades, specifications and concentration. Customization options include slitting, cutting, punching and a range of post treatment options.

## Product development

When environmental, regulatory or healthcare changes require the development of a new component, the existing range of high-quality components from Cytiva including cellulose and glass fiber media, nitrocellulose, track-etched polycarbonate, nylon, polysulfone and polyethylsulfone membranes can be used as a base. This saves time and investment in new product development and ensures products used are already quality tested, with lot-to-lot consistency.





# Magnetic bead customization

There are many types of magnetic beads available. Different surface coatings and chemistries give each type of bead its own binding properties, which can be used for magnetic separation (isolation and purification) of nucleic acids, proteins, or other biomolecules in an easy, effective, and scalable way.

Even with all these surface chemistry options, it's impossible to cover every need and eventuality. That's where bead customization comes in. Altering the properties of magnetic beads changes their binding properties and enhances their performance in specific applications. Customization may include: conjugation, concentration, custom packaging, custom kitting and private label, buffer exchange and stabilization.

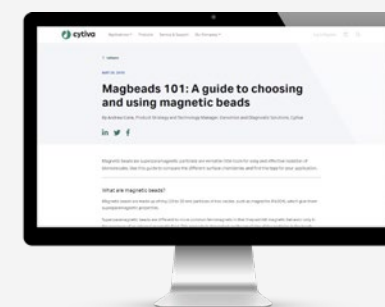
Our magnetic bead customization services draws on extensive experience with magnetic separation technology and applies custom development and modification methodologies to raw beads or final kits, including **Sera-Mag™** magnetic beads and SpeedBeads, **SeraSil-Mag™** silica beads, and **Mag Sepharose™** magnetic beads.

## The convenience and ease-of-use of magnetic beads, customized for your assay

Drawing on our R&D and manufacturing resources, and the deep experience of our team, we provide custom magnetic bead technology that is ready to use with little or no need for further modification. From completing complex conjugations, to performing quality control tests before the beads leave our factory, we are equipped to meet your needs.



**Use our guide** to compare the different surface chemistries and find the type for your application.



[Learn more about our conjugation service](#)





# Molecular biology reagent customization

When our off-the-shelf products do not meet your specific application requirements, our Cytiva Diagnostic Services team can tailor the configurations, formulations, pack sizes and concentrations to your needs, while ensuring the same quality, performance and reliability as our standard catalog products. Molecular biology reagent customization services are possible for any of our protein and nucleic acid sample preparation, labeling and detection kits. If desired, we can incorporate these products into the manufacturing of kits that you design.

## Examples of kits which we have customized:

- PCR Grade Nucleotides
- CyDye™ fluorescent dyes
- PuReTaq™ DNA polymerase
- Thermo Sequenase
- AutoScreen-96

[Learn more about molecular biology reagent customization service](#)





# Custom multiwell plates

Multiwell filter and microplates can be designed for sample collection, analysis, and purification of sequencing reactions with membrane or resin media included. We will work with you to develop a complete custom product including dispensing, packaging and labeling to provide you with a product that is customer-ready.

We apply our expertise in membranes, resins and mold tooling to develop custom plates for a range of applications and sample throughput levels. Our proprietary process to encapsulate the filter media minimizes contamination between wells. The plates are optimized for automated filling, allowing for greater efficiency.

Our dedicated coating facilities are environmentally controlled, meeting strict quality standards. Plates can be tailored to your specifications in terms of labeling and quantity per case.

## Customization options

- Plate material
- Color
- Well bottom shape
- Media
- Surface coating
- Plate well configurations



[Learn more about custom multiwell plates](#)





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CY18791-14May25-BR

