

## Introduction to **Cryoniss**

Sonia Houghton and Phil Hargreaves founded Cryoniss because they are passionate about storing biological samples ethically, and effectively enabling researchers to carry out exceptional science.

Having established a world class internal service provision for next day delivery of qualified cell lines to Astra Zeneca's global community of researchers and collaborators, Sonia and Phil had the expertise to set up a contract service organisation to provide the same expertise to global research institutions, and both pharmaceutical and biotech companies.

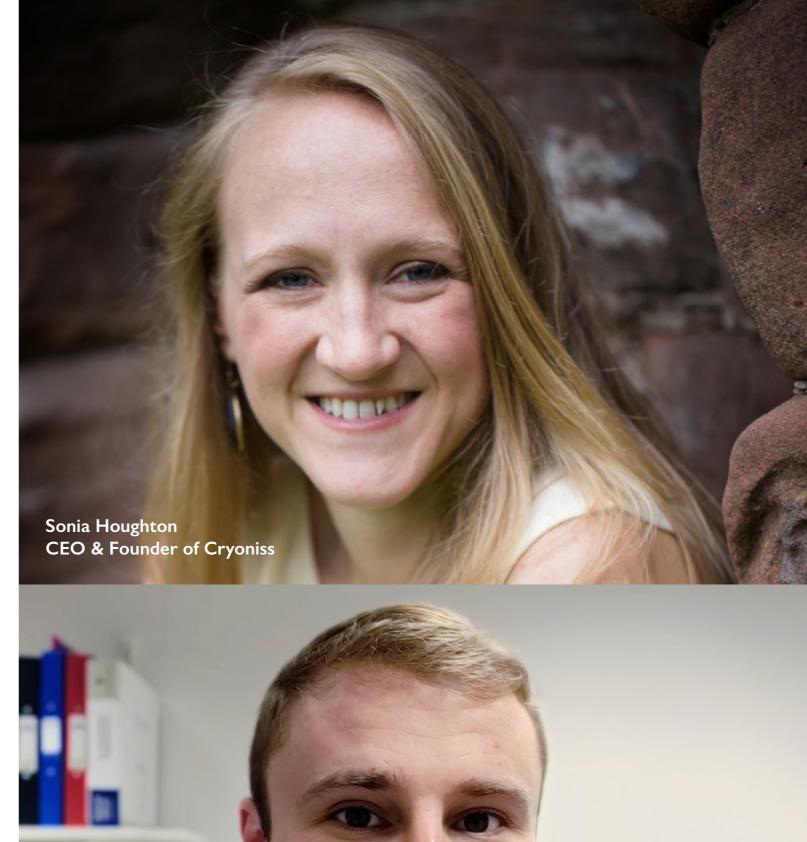
Initially the facility was established at Alderley Park, the UK's largest bioscience park, with over 200 scientific companies registered on-site. Since then, a second site has been opened at The Heath Business & Technical Park, to enable business continuity and expansion for our growing international customer base.

The core of the Cryoniss business model is the storage of biological samples from ambient, +4°C, -20°C, -80°C to vapour phase liquid nitrogen.

With a strong scientific background in supporting early stage drug discovery projects through to clinical trials and life-cycle management, the team understand the daily challenges researchers face. The team provides storage facilities, knowledge and extensive scientific expertise.

Biological sample storage and biological research is a highly regulated field. Cryoniss provides support with regulatory compliance, enabling our customers to focus on their core business.

Working with a network of carefully chosen partners who strive to provide the same exceptional level of customer service, Cryoniss is able to offer holistic support to customers, including the acquisition of quality, ethically and legally sourced reagents, end-to-end premium logistics management solutions and coordination of quality control testing of mammalian cell line reagents.









## A word from our CEO

I have spent much of my career as a research scientist, which is why I understand that high quality samples are the cornerstone of scientific excellence.

We have put a huge amount of thought, effort and scientific knowledge into our procedures and have optimised every stage of the storage and logistics process.

For us, Cryoniss is about managing that process, ensuring the samples remain of the highest quality and providing a world class service.

Sonia Houghton CEO & Co-Founder Cryoniss

## How Cryoniss can help you



Our accreditations and licences allow us to be your storage and logistics partner at every stage of your product cycle, supporting you every step of the way.

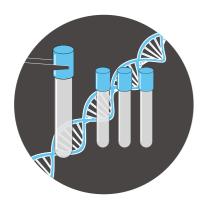


Cryoniss works to the principles of Good Laboratory Practice and Good Clinical Practice, and are licensed to store:

- MHRA Wholesale Distribution Authorisation licence
- GMO Genetically modified organisms, up to and including class II
- HTA Human Tissue Act 2004 regulated research samples
- APHA High risk category 2 animal by products, as regulated by the Animal & Plant Health Agency

### **Our Services - Overview**





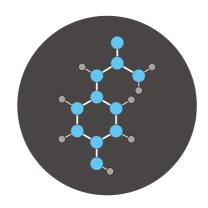
#### **Biobanking**

Whether you need support to source, store or manage daily access for your team, we can provide a tailored solution that works for you.



#### **Medicinal Product Storage**

Working to Good Distribution
Practice, we guarantee the integrity
and security of your medicinal
products as your approved
storage and distribution partner.



#### **Clinical Trial Sample Storage**

Whether you are coordinating early stage Proof of Concept trials, conducting late Phase IV trials, or anything in between, we can provide secure storage samples according to GCP standards.



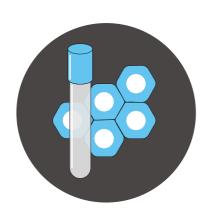
### Investigational Medicinal Product Storage

Supporting your clinical trial with the storage and distribution of your investigational medicinal products.



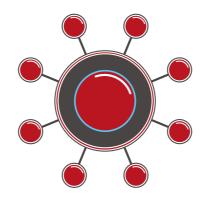
#### **Bioreagents**

Keep your Master stocks of your unique biological reagents secure and fully traceable with a secure cloud-based database.



### Cell Banking

Store your Master and Archival cell banks in our world class facility for longer-term safe storage, or make use of our streamlined processes for daily access to your Working Bank of cells.



### **COVID-19 Storage**

We are able to accommodate storage of any sample type, or tube size, from blood and nasopharyngeal samples through to RNA preparations.



### **Logistics Support**

We work seamlessly with our premium courier partners to provide you with complete end-to-end logistics solutions.



#### Cell Line QC Testing

We provide customers with routine quality control testing of cell lines, covering Mycoplasma screening, cell sterility, viral screening and cell line authentication services.

### Biobanking

Access to high quality, ethically and legally sourced patient relevant material has always been a key challenge for researchers. We have partnered with Tissue Solutions to support our customers in accessing the best samples for their research.

Tissue Solutions are world leaders in the acquisition of relevant material, a company who genuinely put quality at the core of what they do.

Many of our customers need to acquire the right human material for the first time. These samples are highly regulated by the Human Tissue Authority. If you store these samples with Cryoniss you don't need to attain a Human Tissue Licence. You do need to ensure that your research, and procedures, are aligned to the appropriate ethics approval though. This can be a minefield if you are new to these regulations.

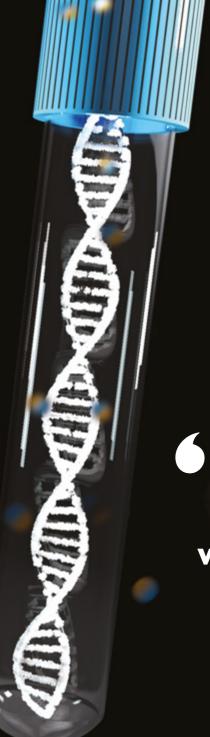
We work closely with our Quality Assurance partner QualiSys, who provide us with compliance advice and also provide our customers with guidance and training to ensure work meets the right legal and ethical standards.











As scientists, we care about the research generated by the scientific community

Sonia Houghton, CEO of Cryoniss



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## Clinical Trial Sample Storage

Cryoniss provide secure storage of clinical samples from Phase 0 through to Phase IV. We have a clear and straightforward pay-on-demand pricing model.

Up-front costs are limited to a small on-boarding charge that covers our regulatory due diligence. We are a highly regulated company and must ensure we have all appropriate legal and ethical documentation captured.

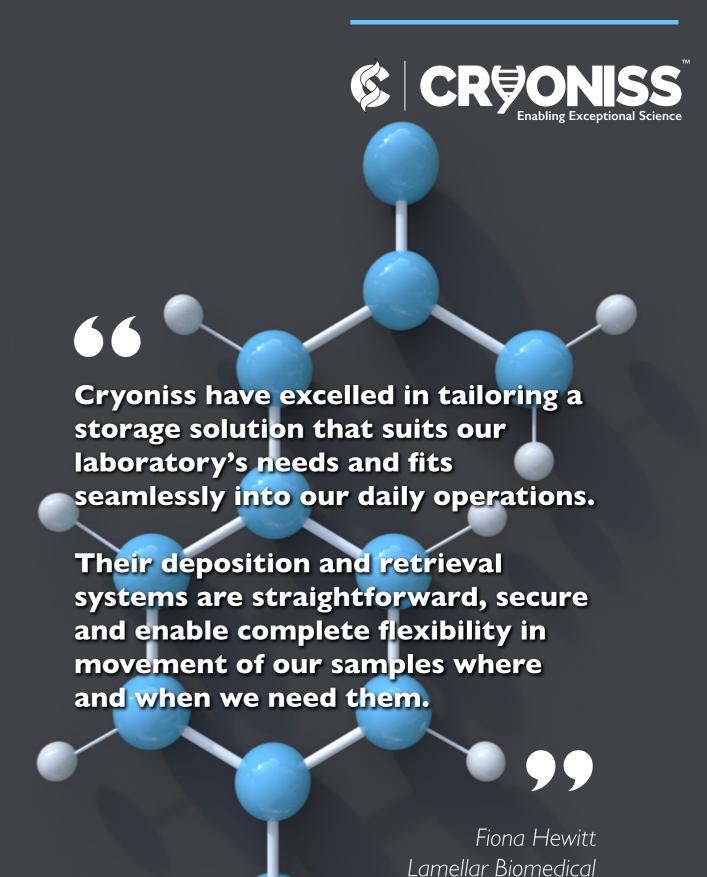
At Cryoniss, we have developed our service to ensure that you can see and access your samples at any time. We provide next day dispatch and receipt of samples as standard and are very happy to accommodate urgent requests. Likewise, our premium courier partners have placed sample integrity and customer service at the heart of their business model.

Upon completion of your Clinical Study, we can continue to store samples under our Human Tissue Authority licence, if required for future research purposes. We also have appropriate procedures in place for the repatriation or disposal of samples.









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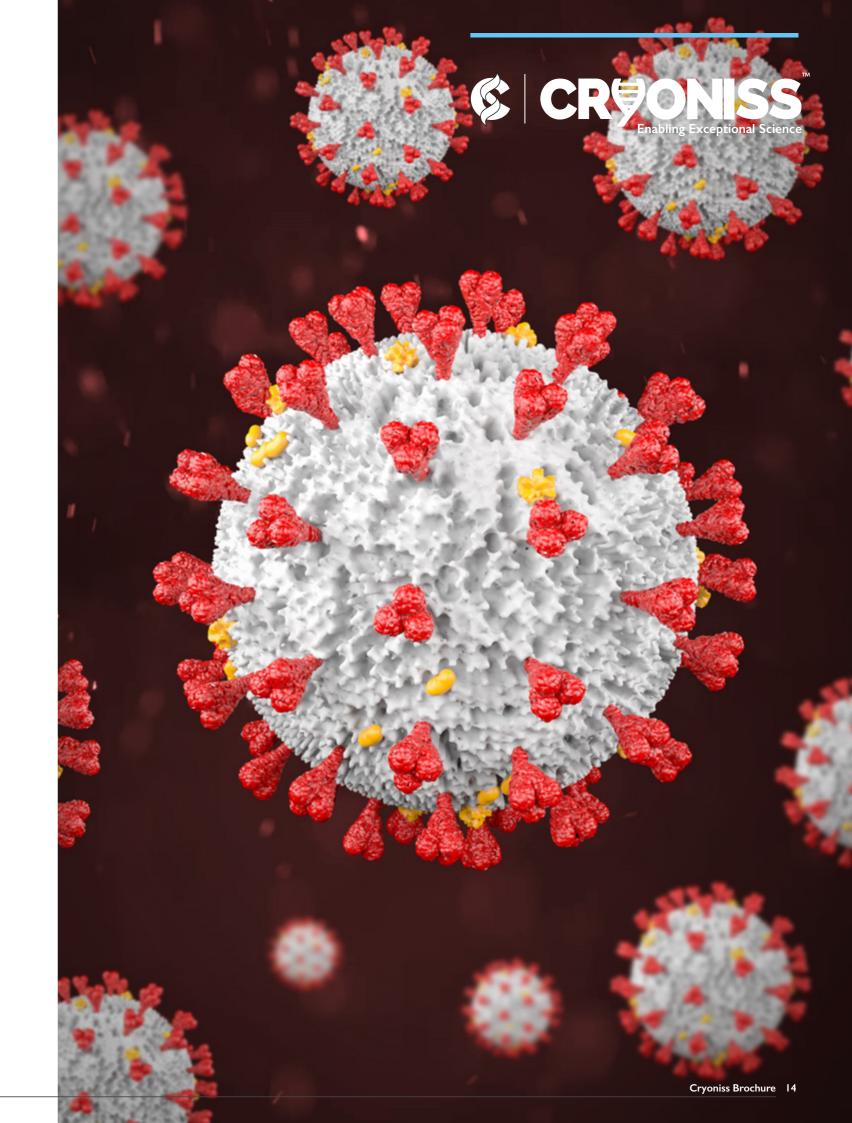
## COVID-19 Storage

As SARS-Cov-2 has spread across the globe, we have been working closely with our customers and suppliers to assist the scientific effort to support research into the virus and the development of subsequent therapeutics and vaccines.

Applying our specialist knowledge in temperature-controlled storage and logistics management services from vapour phase liquid nitrogen (-196°C), -80°C, -20°C, +4°C and ambient temperature, we have rolled out several Covid-19 related storage and logistics management services, which include:

- Acquisition of Covid-19 positive samples for research purposes via our partner Tissue Solutions.
- Storage of Covid-19 positive samples on behalf of customers under our Human Tissue Authority licence.
- Storage of clinical trial samples for Covid-19 vaccines and therapeutics from Phase I – IV.
- Storage of Investigational Medicinal Products in support of clinical trials for vaccine and therapeutic products.
- Storage of vaccines and therapeutics as regulated by the Medicines and Healthcare products Regulatory Agency.
- Storage of Covid-19 testing kits.

Providing an agile and tailored service, we are able to accommodate storage of any sample type, or tube size, from blood samples, nasopharyngeal samples and RNA preparations.



## Bioreagent Storage

We are passionate about the biological sciences and the drug discovery process. Many years' experience working as bench scientists in the pharmaceutical industry have given Cryoniss a clear perspective on the importance of preserving sample integrity and ensuring that critical reagents are stored carefully and remain accessible to future researchers.

Enabling our customers to ensure their research always remains of the highest possible standard is the cornerstone of our business. We work tirelessly to maintain optimal storage and end-to-end logistics services, providing our customers with next-day access to their samples with minimal effort.

We have all worked in laboratories, and had projects change, staff leave, and highly-prized constructs lost. Whether the samples are glycerol stocks, DNA, frozen cultures or key batches of antibodies for future batch-to-batch analysis, the loss is immeasurable.

We are licensed to store:

- Human Tissue Act 2004 regulated research samples
- Genetically modified organisms, up to and including class II
- High risk category 2 animal by-products, as regulated by the Animal & Plant and Health Agency





We are a contract research organisation providing ion channel screening data to clients.

Our clients demand we provide this data quickly, so our processes and workflows need to be quick and efficient. Everything we do in the laboratory is cell-based.

With Cryoniss, we know our cells are safe and accessible the next working day. Sonia and her team are incredibly helpful and provide us with a great service.

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Michael Morton ApconiX

## Cell Banking

Our customers can either store their Master or Archival cell banks with us or utilise our services as their primary Working Bank, giving the whole team daily access to samples.

We can even implement a routine quality control testing process for you, providing the assurance you need that your data is of the highest quality.

Individual cell banks can also be reserved for specific members of staff if required. We know there's nothing worse than validating your high screening assay on a specific bank of cells, only to find out a colleague has used up the remaining vials of that bank to run a Western Blot when other banks, for whatever reason, just don't work quite as well.

It is well documented that whilst cryopreservation remains the primary method of choice, long-term cellular viability is dependent upon an optimised freezing, thawing and recovery process.

At Cryoniss we use the latest technologies and have optimised our cryo-handling procedures to ensure sample integrity. These procedures include the use of liquid nitrogen adsorbed workstations and dry shippers for shipments between sites.











We use Cryoniss to store our cell lines. All the systems and procedures they have in place gives us the confidence we need, entrusting them to keep our valuable assets safe.

They are fast and efficient at delivering our cells to us when we need them.

Sonia and her team are friendly, knowledgeable and approachable. They are always happy to discuss any issues we have about new testing, protocols, reagents and government legislation.

I would be happy to recommend them.

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Karen Jones ApconiX

## Cell Line QC Testing

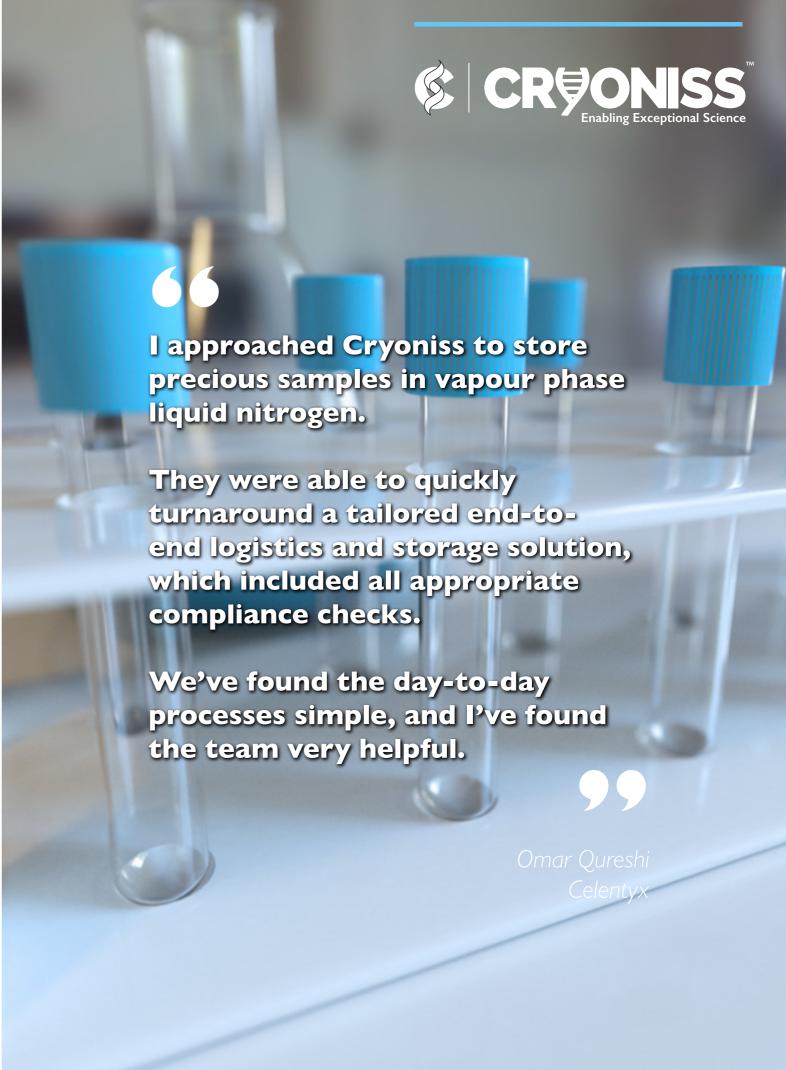
At Cryoniss we believe that reagent quality is the cornerstone of research excellence. As such, we endeavour to provide our customers with the most up-to-date guidance on sample handling and best practices.

Alongside this, we provide coordination services for the quality control testing of research cell lines. We have identified key contract research organisations who, in our experience, provide the most sensitive and reliable screens

We provide weekly shipments to the appropriate contract research organisations, coordinating all sample testing submissions and courier requirements. We combine several companies' samples, leveraging bulk purchasing savings and logistics fees, all of which are distributed across our customers per shipment.

Screenings currently available are:

- Mycoplasma detection and elimination services
- Cell line authentications services (human, mouse, rat, dog)
- Species contamination services
- Cell sterility services
- Murine virus screens
- Human virus screens



## Logistics Support

Cryoniss work with experienced couriers who serve the medical, biological, pharmacological and biotech sectors to ensure the needs of our customers are effectively met.

We appreciate how vital your shipments are and how critical it is to give you peace of mind. We know it's not just about getting the package from A to B.

Instead it is understanding the importance of storing samples correctly, successfully negotiating customs without delay and utilising our extensive experience of the regulatory landscape on a global level.

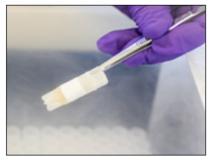
We provide our customers with a tailored approach to suit their end-to-end logistics requirements.

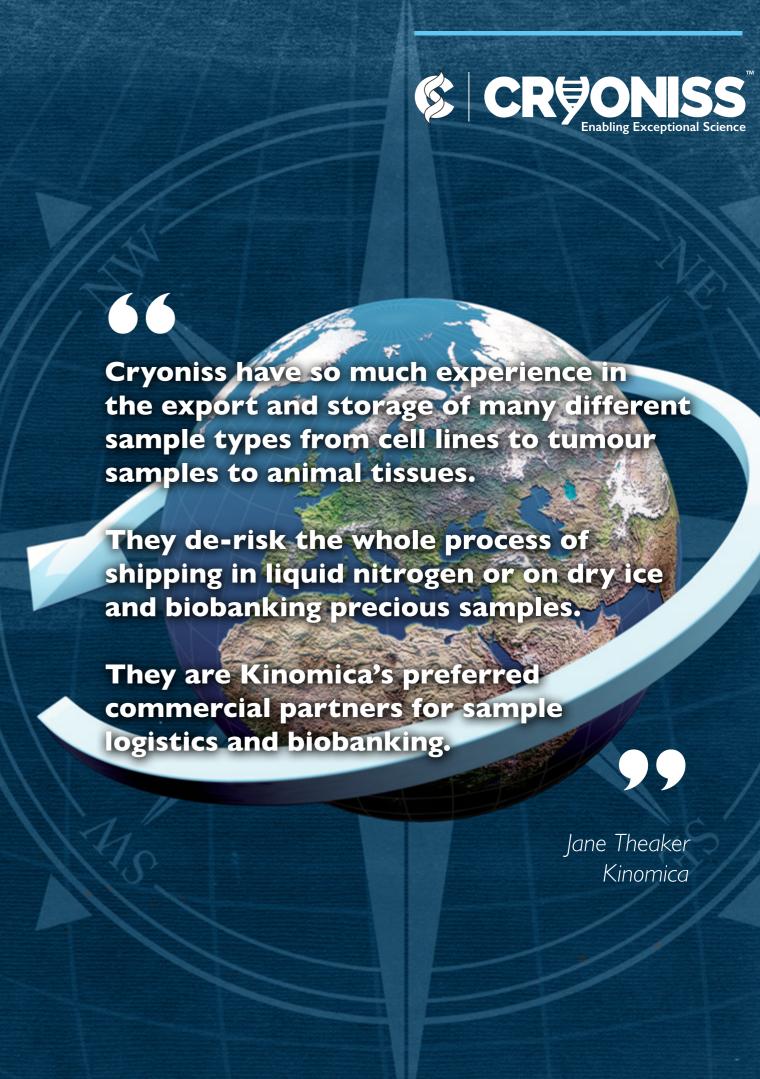
We can ensure customers are provided with all consignment documentation, packaging materials (including dry ice) and coordinate all the courier's logistics arrangements through a simple and compliant process.

We can guarantee that all our couriers place sample integrity at the core of their service provision. They all work to the same high standards of customer service as we do at Cryoniss, to ensure our customers are confident in the complete sample logistics and storage management process.









# Investigational Medicinal Product Storage

Supporting your clinical trial with the storage and distribution of your Investigational Medicinal Products.

As an MHRA approved Wholesale Distribution Authorisation (Human) holder, Cryoniss can provide support the storage and distribution of your investigational medicinal products (IMPs) as well as your clinical samples.

Providing Good Distribution Practice compliant end-to-end cold chain logistics management, with the support of our premium courier partners Cryoniss can lead the coordination of all sample and IMP logistics, guaranteeing the security of the supply chain and ensuring the integrity of the products.

With secure facilities at The Heath Business and Technical Park, IMPs are stored at temperatures from room temperature down to -80 °C. All of our capabilities are covered by our extensive Business Continuity Management System.

Get in touch to see how we can support your next clinical trials.









## **Medicinal Product** Storage

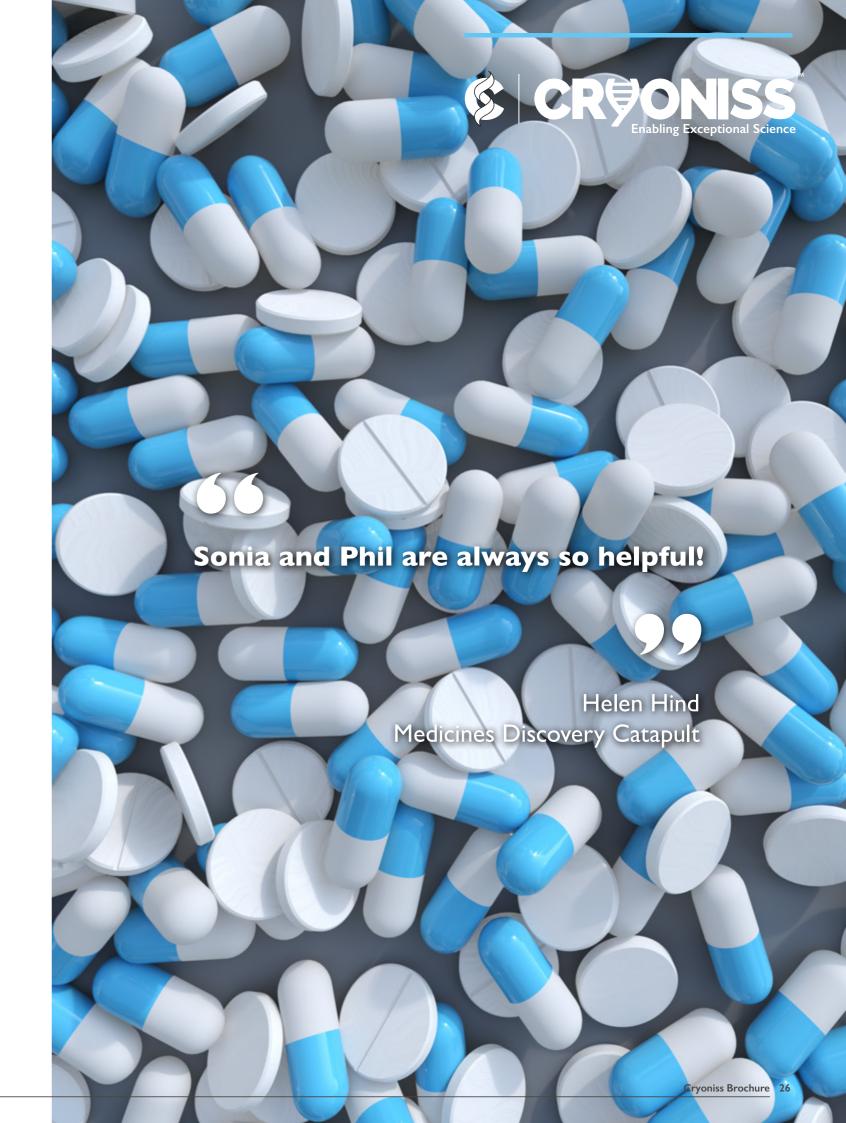
**Working to Good Distribution Practice** standards we can guarantee the integrity and security of your medicinal products as your approved storage and distribution partner.

Regulated by the Medicines and Healthcare products Regulatory Agency as a Wholesale Distribution Authorisation (Human) holder, Cryoniss is able to support its customers with the storage and distribution of medicinal products once approved by the appropriate regulatory authority. Placing patient safety at the heart of our operations, Cryoniss has implemented a robust Quality Management System, aligned with its bespoke facilities to ensure the safety and integrity of medicinal products and the wider supply chain.

Cryoniss's specialist capabilities for storage of medicinal products from room temperature down to -80oC are located at The Heath Business and Technical Park. With a robust Business Continuity Management System, back-up procedures are in place to ensure the integrity of the products is maintained at every stage. The Park itself is a secure bioscience business provision / resource with 24/7 on-site security team and CCTV monitoring.

The Science Centre, where Cryoniss is based, has card-key restricted access and entrance to Cryoniss' facilities is secured by two different digi-locks. All of our premises are digitally monitored, and all storage units individually locked to ensure maximum security. With due diligence checks and extensive training in place, bolstered by extensively audited procedures, our employees can be trusted to keep product safe and secure.

Product stock management is maintained using a cloud-based inventory management system, where First Expiry First Out stock rotation is guaranteed. Our Quality Management System ensures that, together with our customers and suppliers, we manage the supply chain, providing end-to-end cold chain logistics support compliant with Good Distribution Practice.





### Our **Facilities**

We have a wealth of experience in supporting drug discovery projects from early stage target identification through to clinical trials and life cycle management.

Cryoniss facilities in the North West of the United Kingdom provide vapour phase liquid nitrogen (-196°C) storage at Alderley Park whilst -80°C, -20°C, +4°C and ambient temperature storage is at our Runcorn site on The Heath Science Park. Cryoniss have robust business continuity plans in place for both facilities. We operate to the principles of Good Clinical Practice and Good Laboratory Practice. Our processes and procedures have been developed by our highly trained staff to ensure sample integrity is of the highest standard.

We understand the value of your biological samples to your experiments, your business and to future research. It is for this reason we place customer satisfaction at the heart of our business.

We have world class storage facilities providing alerting and reporting functionalities which are monitored 24/7 with 21 CFR Part II, ISO9001 and ISO17025 compliant laboratory systems. All our storage is secure, supported by audit-ready procedures that enable you to have total confidence in us.

Sample data is stored on a secure, HIPAA compliant and fully auditable, cloudbased laboratory inventory management system. Bespoke, secure customer portals can also be created, providing visibility of customer's samples at all times. Inventory reports are of course also available.

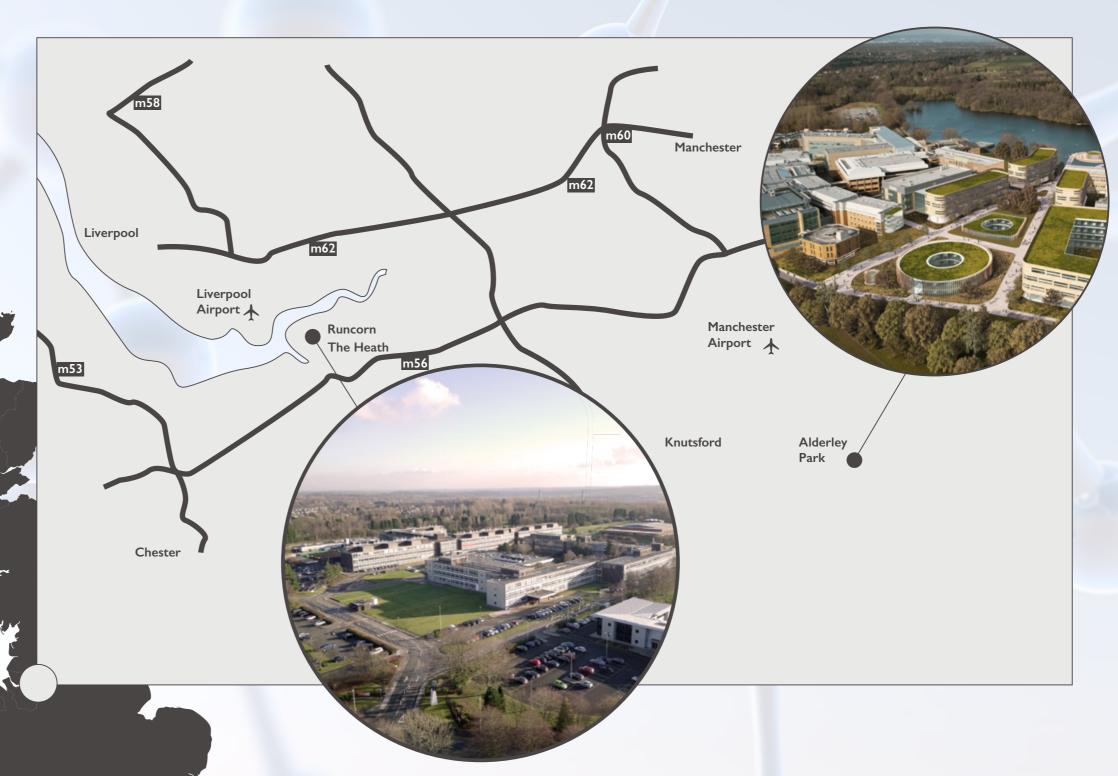
Our customers are located around the world and we work closely with our premium logistics partners to provide a seamless end-to-end service for delivery and pick up of samples. Customers simply inform Cryoniss of their request, and we coordinate the entire shipment on their behalf as required, including provision of appropriately labelled packaging materials, such as dry ice for example, completion of all shipping work and regular updates of progress of the consignment.







How to find us



Cryoniss is located in the North West of the UK.

We are well served by motorway networks and 2 International airports.

Both facilities are approximately 2 hours train journey from London.

### **Contact Us**

Thank you for taking the time to read our brochure. We look forward to hearing from you in the future.

For more information, please get in touch.

### **Operations:**

The Heath Business and Technical Park, Lab 101, Runcorn, Cheshire, WA7 4QX, UK

### Headquarters:

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