

BIOBANK:
Should You Build Your
Own or Outsource ?





About the author



Jai Singh, Ph.D

Jai Singh graduated from University of British Columbia, Vancouver, B.C., Canada with a Ph.D. degree in Organic Chemistry. Following this he devoted his time working as Postdoctoral Fellow and worked towards synthesis of Porphyrins and Metalloporphyrins at the University of California, Davis. Soon after completing his Postdoctoral fellowship he joined Baxter Diagnostics, Inc. as Senior Scientist and developed synthesis of Fluorogenic and Chromogenic substrates for bacterial diagnosis in clinical laboratory and implemented the process in manufacturing leading to improved processes and products thus reducing operational cost in manufacturing.

Dr. Singh joined Life Technologies, Inc. in 1996 in Rockville, MD as Staff Scientist and developed processes and implemented improved processes in manufacturing. In 1998 he took a management position at American Medical laboratory, Inc./Quest Diagnostics, Inc. and managed research & development and production of clinical diagnostics reagents and implemented in the diagnostics laboratories. In addition to this he was also instrumental in helping scientists, supervisors and technical directors for troubleshooting of assays in a regulated environment. Dr. Singh has extensive experience in building and managing biorepositories. He helped establish BioReliance Corporation's European biorepository expansion as well as commercial and government biorepository contracts. Most recently, he is working with Fisher BioServices to support clients' biobanking needs.



this "eBook"

Biobanking & Biorepository



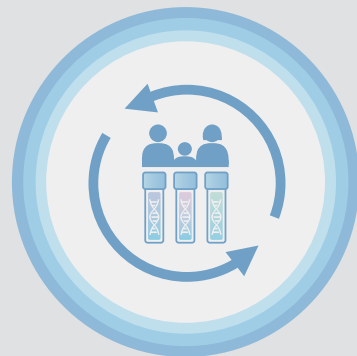
Cell Therapy Solutions



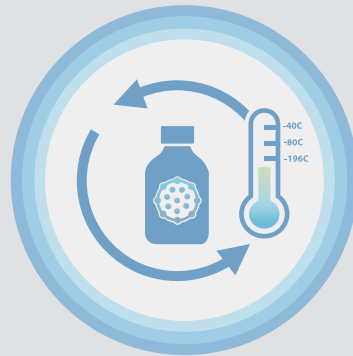
Sample Collection Kit Production



Laboratory Processing



Clinical Trial Sample Management



Biologic-API Management



Qualification / Validation Services



Cold-Chain Logistics

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Introduction

Are you involved in continuing discussions about the need for finding biomarkers and improving translational research? At the core of biomarker development is the global healthcare movement towards personalized Companion Diagnostics (CDx), in which clinicians and doctors will be able to identify the patients most likely to benefit from a particular drug or biologic, and also help determine risk of an adverse drug reaction from a particular therapeutic agent. While biobanking sits at the heart of biomarker development, the key to quality and sound discoveries is quality management of the biospecimens from the very beginning. From my recent participation in biobanking discussions I've heard growing concern over the quality of the biospecimens available and the reliability of research into potential biomarkers. .



Collections of biological materials vary tremendously in size, scope, and quality of handling and storage conditions. You understand the need for high quality biospecimen collections for your research, and you may be thinking of building your own biobank. If so, then it is important to ask yourself the right questions. Establishing a biobank takes time, extreme attention to detail, and facility features that may seem like extravagant redundancies.

Some obvious, and not-so-obvious, factors to consider are:



10

Questions to Consider:

1. How much and for how long?
2. How much does a biorepository cost?
3. Do you have the time to build?
4. Do you have the team?
5. What temperatures?
6. What about risk mitigation? .
7. How will you manage your biobank sample inventory and associated data?
8. What about the support services?
9. Can you manage the regulatory compliance and QA/QC?
10. Are you equipped for cold-chain shipping and distribution?



1. How much and for how long?

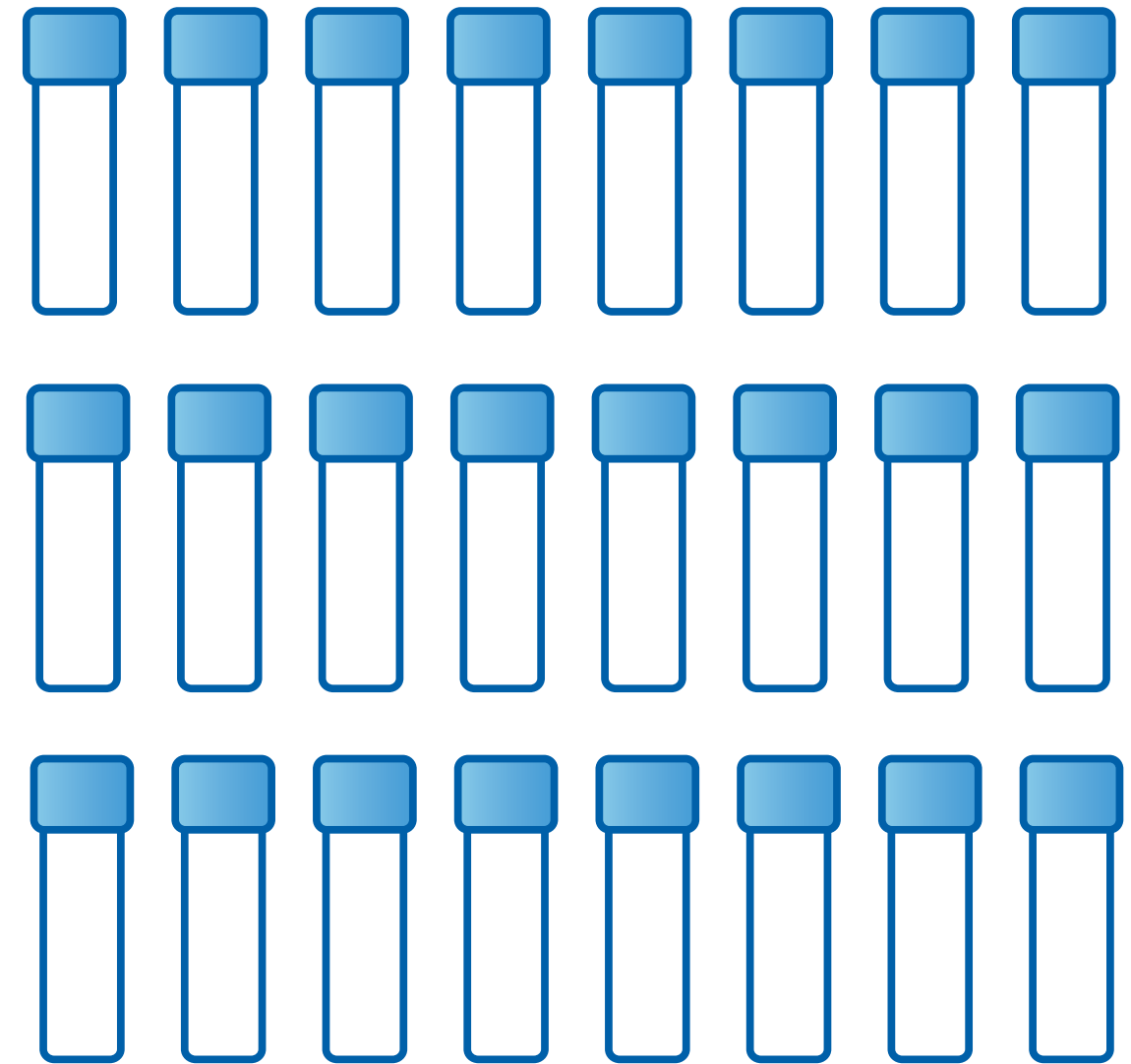


Half a million **samples** sounds like a lot, but a single upright freezer, with the standard **25 ft³** of storage space, can hold **48,000** 0.5ml vials. Your sample storage needs may be smaller than you think, and it may not be worth the cost to build.

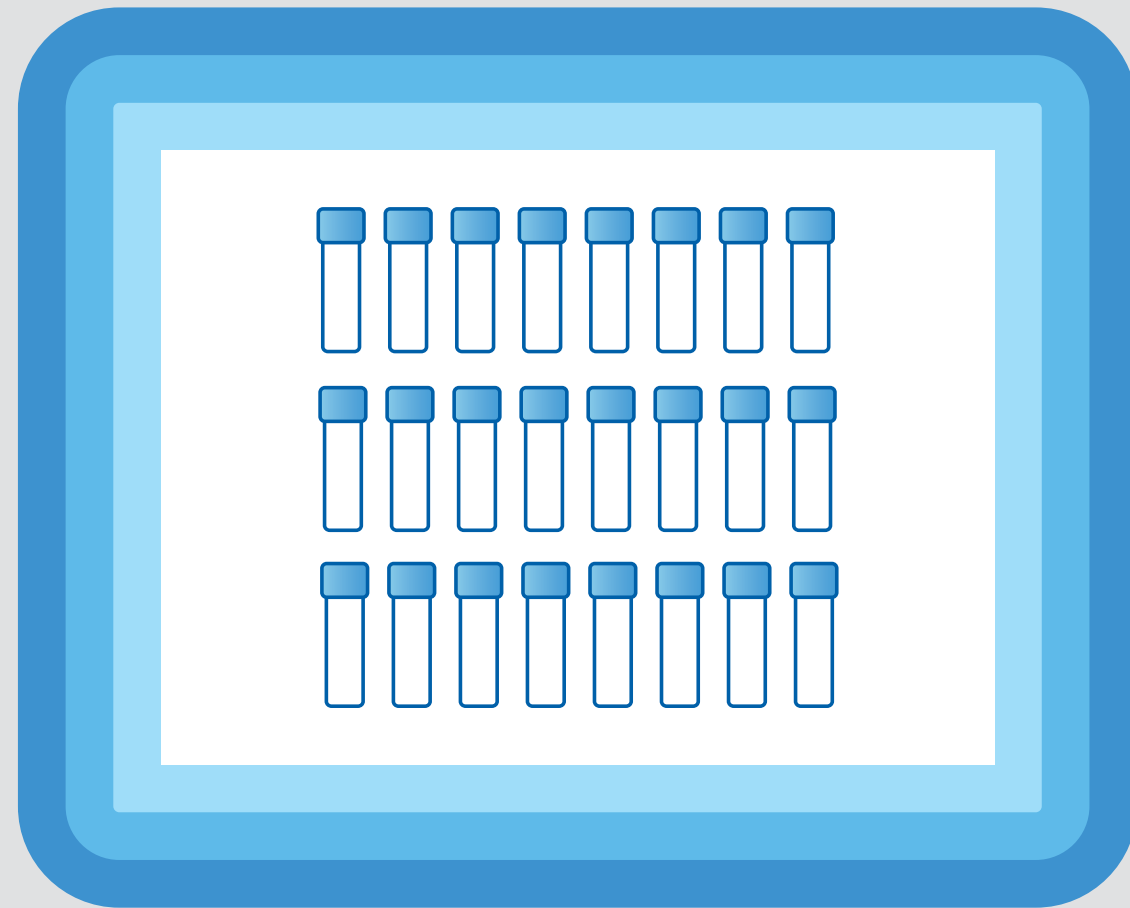




single freezer-
standard 25ft³
storage space=

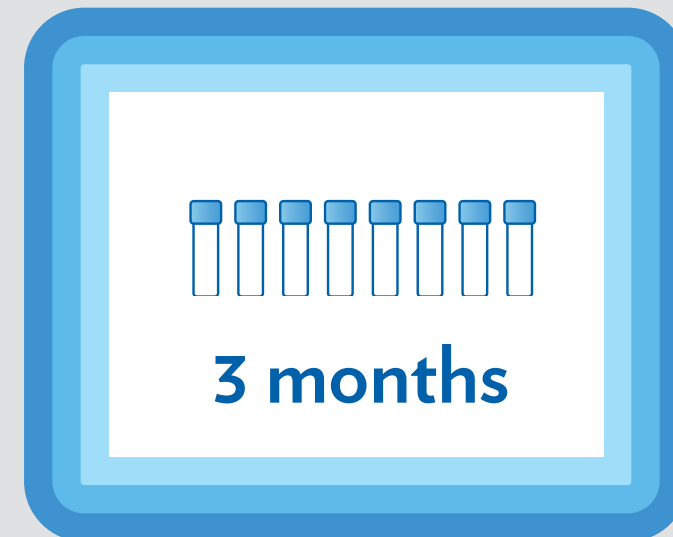


48,000 0.5 ml vials



Outsourced Biobank Provider

**Is it worth
it to build?**



3 months

yours



2. How much does a biorepository cost?



You may think a biorepository is “only” storage. In fact, the support systems and personnel requirements are often under-estimated. A reasonable budget for basic construction is **\$75** to **\$125** per ft². Electrical switchgear can run hundreds of thousands of dollars, back-up generators cost about **\$50,000**, temperature monitoring systems start at **\$50,000**, and additional costs for redundant storage units and emergency services. Annual operating costs can run between **\$9** and **\$17** per ft².



basic
construction
\$75~&125
per ft²



pipng-
\$200 per
linear foot



Annual operating
cost-**\$9~\$17** per ft²



back-up
generators
\$50,000



LN₂ bulk
tank-**\$30,000**



3. Do you have the time to build?



Renovation of warehouse space can take **6** to **18** months for design/approval, permits, construction, equipment, validations, and start-up. Construction from the ground up requires an additional **9** to **18** months.



design approval



permit



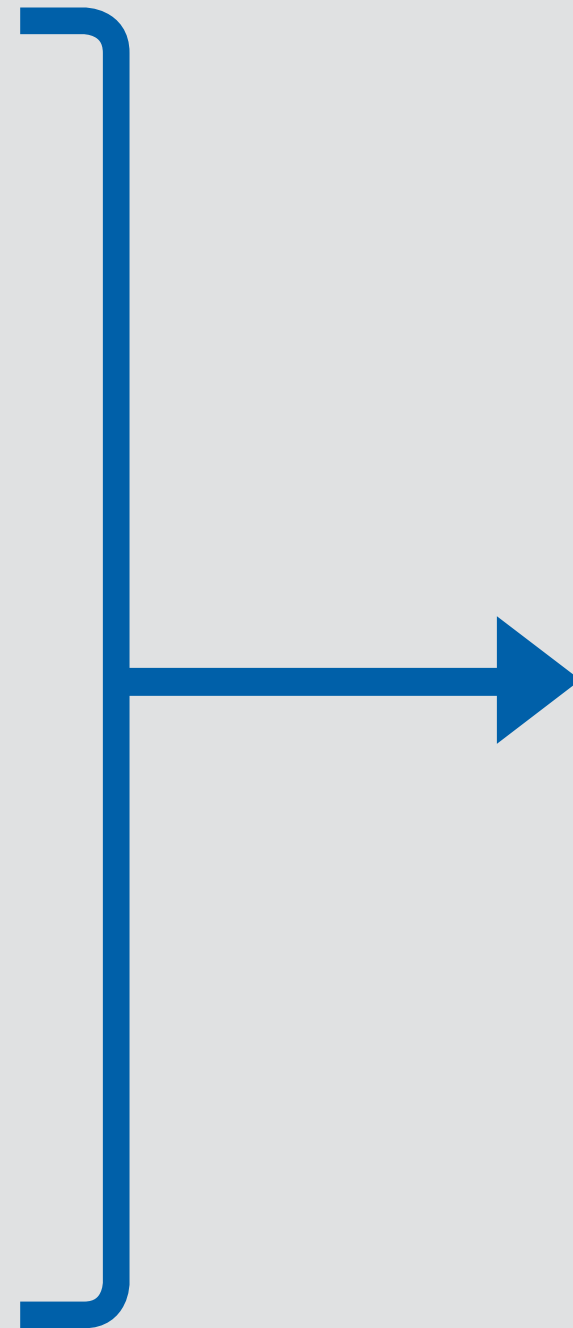
construction



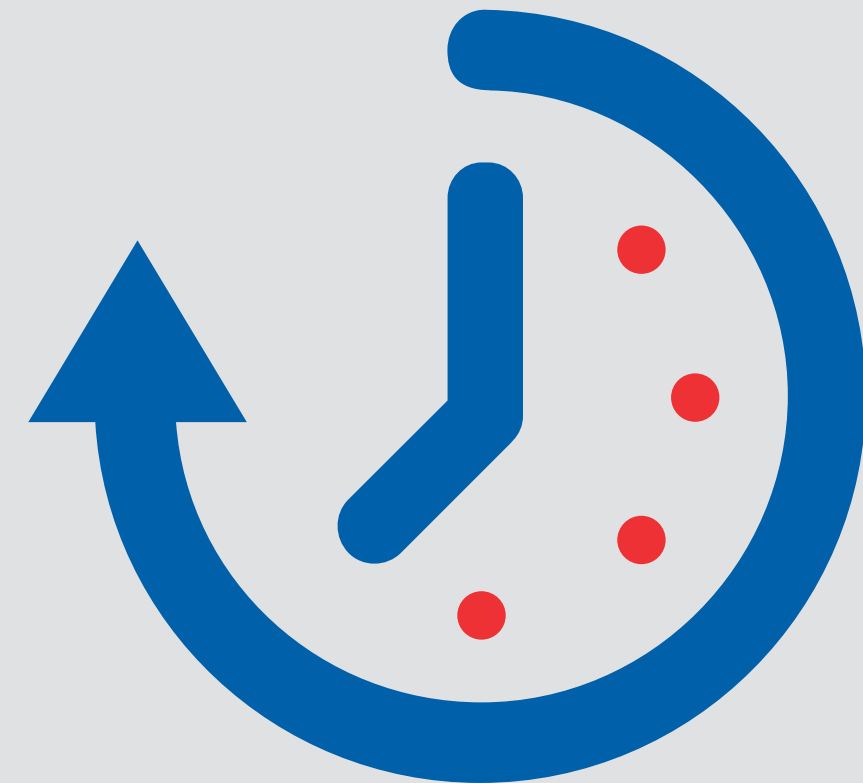
equipment



validations



**15~36
months**





4. Do you have the team?



USD - OPERATIONS - REPOSITORY SERVICES

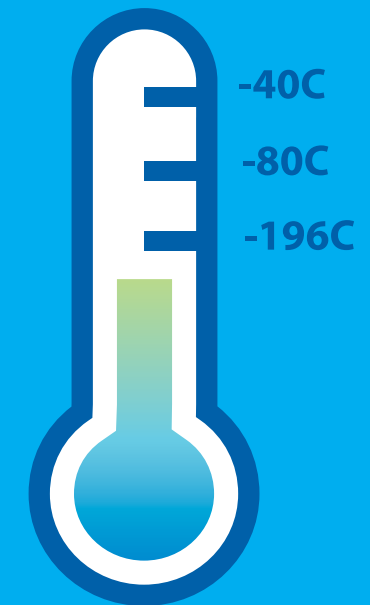


Do your facility staff members have the time and experience to make the right decisions and guide contractors?

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5. What temperatures?





Some samples can be stored in mechanical freezers at -20°C or -80°C

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while others should be stored in **liquid nitrogen**.

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6. What about risk mitigation?



Biorepository facilities require back-up generators, a fuel supply, uninterruptible power supply (UPS) to protect electronics from power surges, temperature monitoring systems, redundant HVAC capacity (mechanical freezers generate a lot of excess heat), a disaster response plan, and on-call staff to respond to alarms after hours.



7. How will you manage your biobank sample inventory and associated data?



You may also need a bioprocessing lab that can prepare aliquots, extract buffy coat, DNA/RNA purification, and further downstream sample analysis such as biomarker studies or DNA sequence comparative analysis.



Summary of Stock AEROSIL

Current Inventory: 150 kg
 Last Restock Amount: 50
 Last Restock Total: 150
 Units: kg
 Percent Remaining: 100

Location	Current Inventory	Last Restock Amount	Last Restock Total	Unit
LAB_01	10 kg	10	10	kg
LAB_02	25 kg	25	25	kg
WH_01	115 kg	115	115	kg

Amount by location in kg

Location Details: LAB_01, Laboratory 1 - Water Based Paint, ROOM

Location Chart: Samples processed by Location

A comprehensive Laboratory Inventory Management System (LIMS) that is capable of managing sample inventory and associated sample data annotation is key enabler to translational and biomedical research.

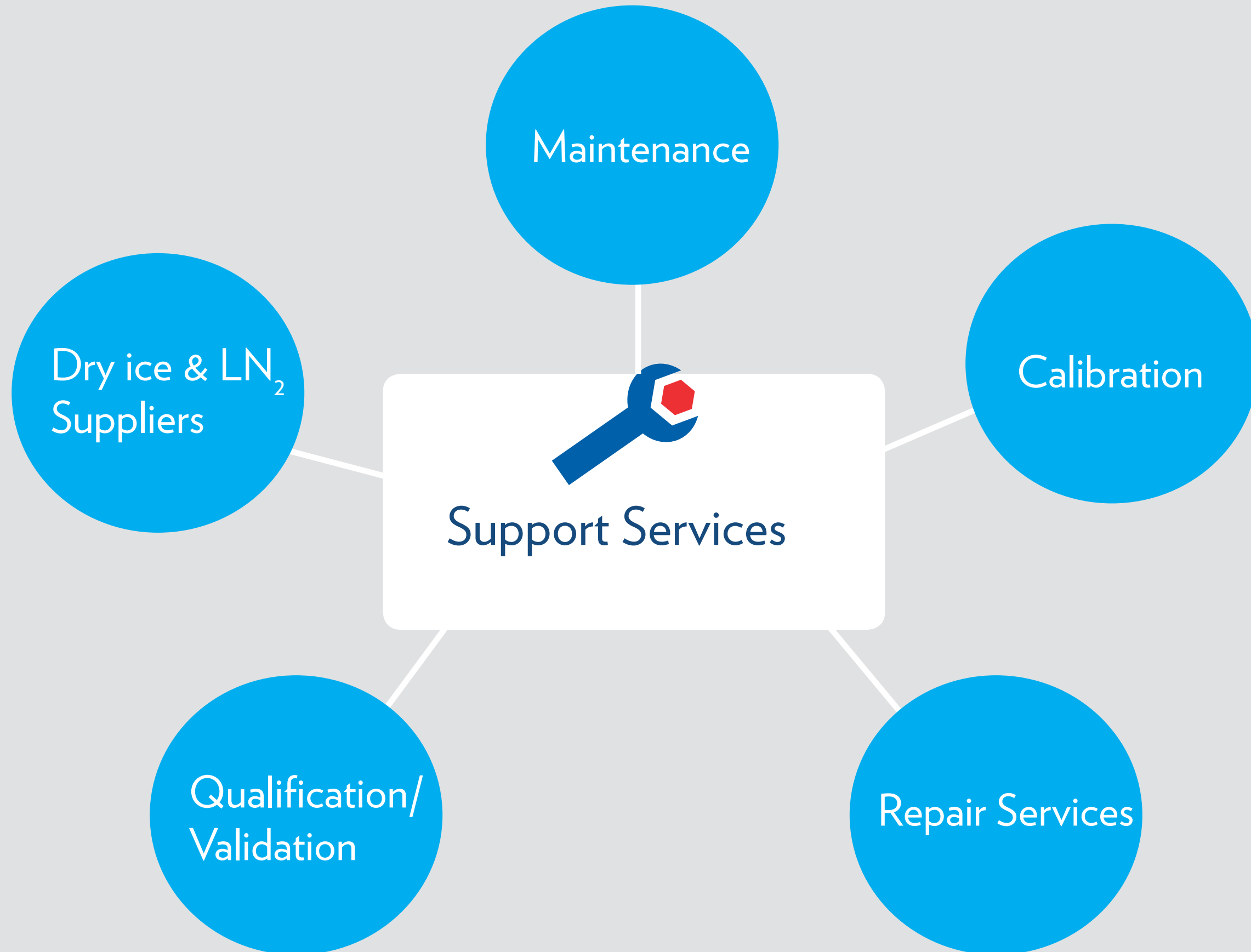


8. What about the support services?



Biobanks need dry ice and LN₂ suppliers as well as maintenance, calibration, qualification/validation, and repair services for the freezers, refrigerators, temperature monitoring system probes, back-up generators, fire suppression systems, and laboratory equipment.







9. Can you manage the regulatory compliance and QA/QC?



Depending on what is stored, biorepositories are subject to regulations issued by the Environmental Protection Agency (EPA), US Department of Transportation (HAZMAT), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), US Department of Agriculture (USDA), as well as state and local agencies.





10. Are you equipped for cold-chain shipping and distribution?



Biospecimens must be correctly packaged in qualified shippers and may also need an **onboard temperature data logger**. Staff must be trained in the regulations mentioned above, and also to work with dry ice and perhaps liquid nitrogen, especially in areas of the world that prohibit the use of dry ice.

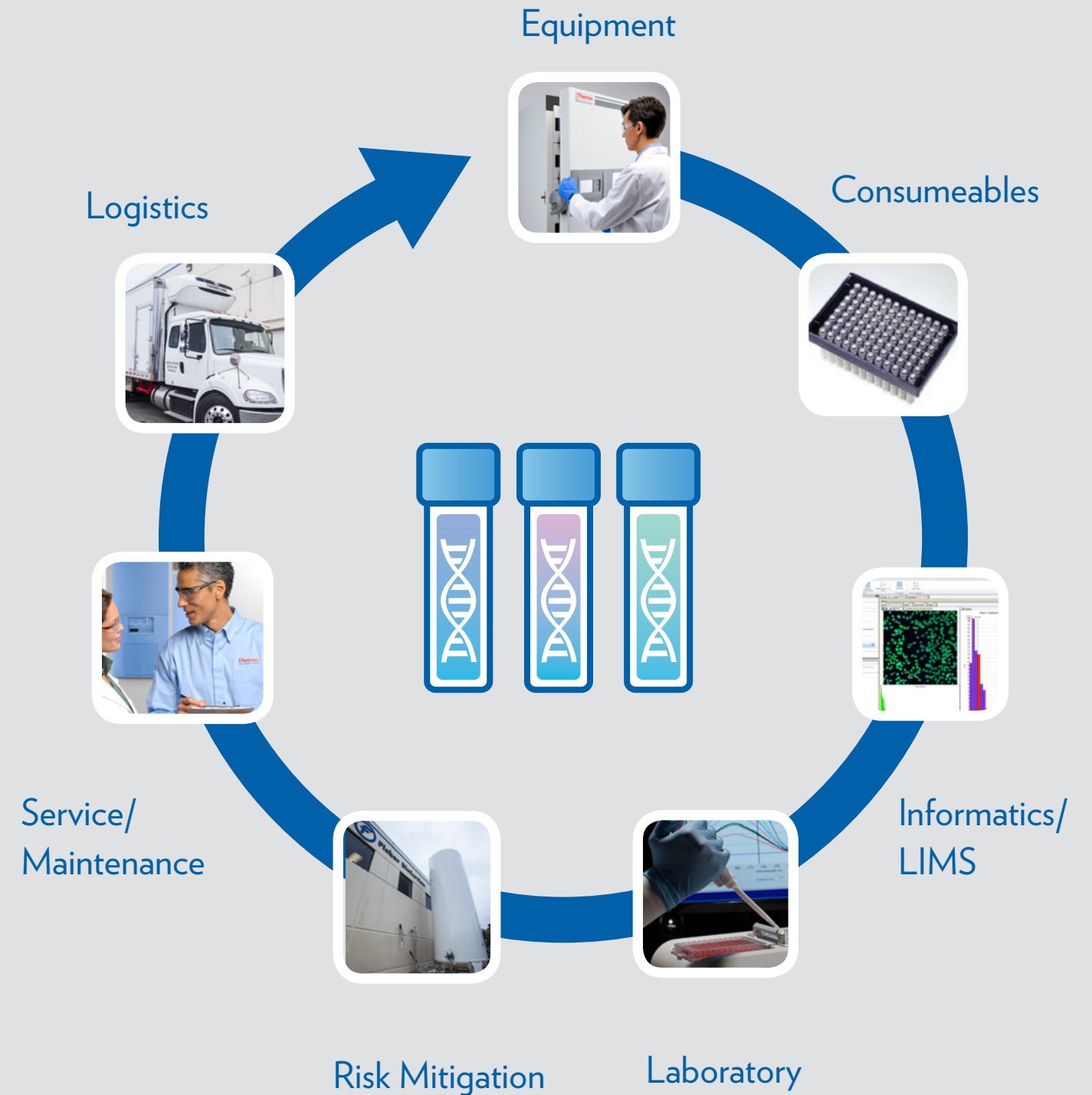




Additional Resources

You can also consider using a biobank service provider to provide you on-site biobank management support, or off-site storage of your samples for risk mitigation.

► **Comprehensive Biobank Resources**



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Additional Resources

You can also consider using a biobank service provider to provide you on-site biobank management support, or off-site storage of your samples for risk mitigation.

- **Professional Staffing Services**
- **Information Technology Systems**
- **Biobank Equipment & Maintenance**

▶ **Outsourcing Solutions**



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