

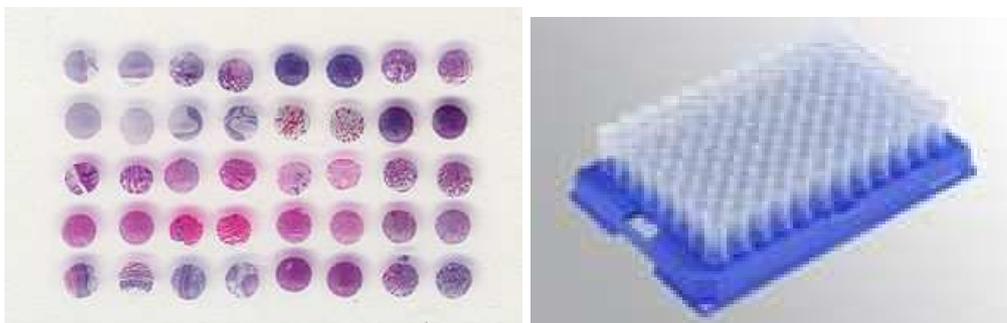
# Selecting a Sample Management System for Biobanking Applications

Biobanking is a term widely used to describe the storage of biological entities for a diverse range of applications. 'Biobanks' in the broadest sense exist for samples ranging from proteins, DNA and tissue, to agronomic seed banks and biodiversity species collections (alive or extinct).

Each of the above types of biobank has widely differing requirements, operates under different legislation and has different usage patterns. The common sample management requirements of biobanks are discussed in this document, and we consider how Mosaic is suited to support particular biobanking applications.

## What are the common sample management needs?

- High quality sample integrity – the system should ensure that samples are affected minimally by storage and usage, and that the sample identity is clear and maintained. Cross-contamination and mistaken usage must be prevented.
- Diversity of sample types- many different sample types might be stored. Each sample type will have its own set of differentiating characteristics, and will demand different storage and handling conditions. Permissions, safety information, hazard information and ownership may also need to be applied uniquely for each sample.



- There are a variety of container identification mechanisms available, and the information presented on the container varies according to the application, e.g. for hazardous materials, or for delicate materials, additional information must be presented to the user.



- Sample relationships e.g. heritage, aliquots – the system should record a sample's heritage, and the sample's division, subsampling or cloning in a comprehensive audit trail.

- Sample collection to sample distribution and analysis needs a full chain of custody – as the number of samples in storage or being handled increases, the risk of errors increases, and the time spent checking or correcting errors increases exponentially. The collection procedure itself may need to be recorded [1]. A sample management system can prevent such errors by tracking samples through defined workflows.
- Diversity of container types, identification and labelling requirements – the rich diversity of physical samples and handling techniques mean that the system must be able to easily record different container types, and where the containers can be stored.



- Some automation for quantification, QC, preparation, reformatting, storage – in larger biobanks, robotic systems are used to perform picking and placing operations in and out of storage [2] and to perform batch operations on samples. If such automation can be linked to the sample management system, then the capabilities of the biobank can be significantly increased.
- Temperature ranges vary, +20 to -160C – a sample management system should understand what samples can be stored under what temperature conditions in order to maintain sample integrity. It should also record changes in temperature that the sample experiences to indicate the likely quality of the contained substance [3], [4].
- Sample separation, cross-contamination – for some sample types, there may be a risk of cross-contamination, and there may be other safety reasons for segregating samples. The sample management system is expected to restrict, guide and inform the users concerning the spatial holding of samples and control permissions for usage.



- Sample consent – for samples collected from human subjects, there is no common form for consent [5].



**Information to participants and consent form**

**PROTOCOL NO:** \_\_\_\_\_  
**SPONSOR:** \_\_\_\_\_  
**INVESTIGATOR (Principal and at least one Co-Investigator):** \_\_\_\_\_

**Name of Participant:** \_\_\_\_\_

**Title:** A single/multiple-center, randomized/non-randomized, double-blind/ open-label trial to determine the efficacy and safety of ..... (name of the investigational drug/intervention/surgery) in patients with ..... (name of the condition).

You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

You are being asked to participate in this study being conducted in ..... (name of the institution) because you satisfy our eligibility criteria which are:

(1) Diagnosis of ..... (name of the disease)  
 (2) Age between ... to ... years  
 (3) No contraindication to the use of the agents to be used in the study, which means absence of any disease or condition likely to get worsened by the drugs under study, which are

There are in practice wide regional and historical and per application variations of consent, with subsequent difficulties in interpretation. Legislation varies widely for example- MHRA-HTA/ HTA-S, FDA CFR-PHSA/FDCA, European EATB (Code of conduct), with some attempts to harmonise [6] with the GHTF initiative. The sample management system must therefore provide access to the consent record and if possible, automated interpretation of the consent, according to the usage.

- The variety of samples, their usage and their distribution requires that the sample management system easily supports the creation of multiple label types and documentation. Each location may require different label designs to conform to regional legislation.





## What does Mosaic offer to support these requirements?

Mosaic is an established system (since 2003) for sample management that has been used for small inventories and global multi-site systems.

Mosaic is particularly well suited to biobanks that have automated storage and sample preparation, and already has modules to interface to compatible storage systems from Brooks Automation (Nexus, REMP, RTS), Hamilton, Liconic, Matrical, TTP Labtech, TAP BioSystems, and liquid handling systems such as Agilent (BioCel), Beckman, CyBio, Hamilton, Perkin Elmer, Tecan. Mosaic is inherently designed and proven to handle tens of millions of samples.

Inventory management is a core feature of Mosaic. Different substance types are managed simultaneously, and each substance type can have a unique set of sample characteristics. Rules can be set up to assign storage conditions to each sample based upon those characteristics. Sample collection procedures and consent forms can be associated with the samples by means of hyperlinks, so access to the original consent data is maintained. Hazard and safety data and documentation can also be linked to each sample.

Substance Type	
Type	Antibody
Properties	
Id	<input type="radio"/> Auto <input type="radio"/>
Batch	<input type="text"/>
Expiry Date	<input type="text"/> (Select one)
Notebook Ref	<input type="text"/>
Sub-Type	<input type="text"/> (Select one)
Derivative	(None)
Also Known As	<input type="text"/>
Catalog	<input type="text"/>
Specific For/Target	<input type="text"/>
Storage Temperature	<input type="text"/> (Select one)
Owner	(None)
Species Type	(None)
Disease State	<input type="text"/>
Animal/Subject Number	<input type="text"/>
Drawn Date	<input type="text"/>

Substance Type	
Type	Whole Blood <input type="button" value="Edit"/>
Properties	
Id	<input type="text" value="B0001203"/>
Expiry Date	<input type="radio"/> None <input type="radio"/>
Storage Temperature	<input type="text" value="-70 °C"/>
Patient Id	<input type="text" value="17436"/>
Patient Gender	<input type="text" value="Male"/>
Patient Age	<input type="text" value="62"/>
Collection Place	<input type="text" value="Hospital A"/>
Collection Date	<input type="text" value="05/10/2010"/>
Study	<input type="text" value="Study 2"/>
Disease	<input type="text" value="Cancer"/>
Informed Consent	<input type="text" value="Future research into Disease X"/>
Documents enclosed	<input type="text" value="http://docs.titlan.co.uk/docid=122777"/>
Notes	<input type="text"/>
Risk Category	(None)

Unrestricted

Allow owner, and restrict the following from requesting:

Only  Everyone Except

User or Group	
<input type="checkbox"/>	Wilson, Edmund (eclw)
<input type="checkbox"/>	Yeates, Stephen (sby)



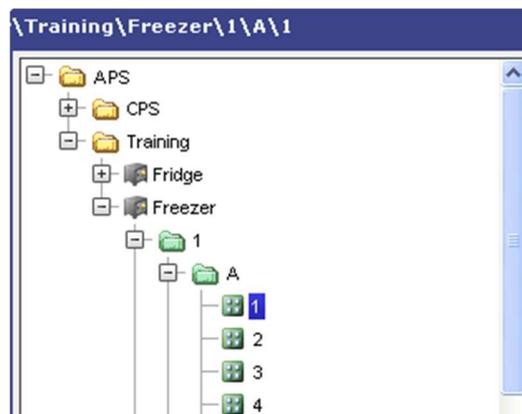
Barcodes are used to positively confirm locations and containers, and barcode ranges can be assigned to differentiate labware types.



Mosaic supports samples that are held in single containers, or that are held in fixed or flexible arrays. The container history is also recorded, and the users are informed of any requests or orders that the containers are associated with.



Container storage is represented using a hierarchical tree view of locations, allowing all storage topologies e.g. laboratories, cupboards, shelving, drawers, dewars, boxes etc. to be defined.



For manually accessed stores, users are guided to the correct using either a web-page diagram, or graphical displays on a hand-held PDA. Storage can be reserved for restricted sample types.



**Mosaic Stores** 10:52

**Choose Order Group to Pick**

<b>STR-1.1</b>	1 Item
Priority: Normal	Required: 12/23/08
<b>STR-1.2</b>	2 Items
Priority: Normal	Required: 12/23/08
<b>STR-1.1</b>	10 Items
Priority: Normal	Required: 12/23/08
<b>STR-1.2</b>	1 Item
Priority: Normal	Required: 12/23/08

Stores Home Refresh List OK

**PSPS Stores** 12:19

**Placing Plate STR1-06**

**Plate STR1-06 still has work**

Place Plate STR1-06 at  
 Store: F8 - SW  
 Shelf: F08-01  
 XPos: 1 YPos: 1 ZPos: Top

Different Location Stop Placing OK

Mosaic offers sample ordering capabilities (and also offers conventional 'ad-hoc' sample picking directly from stores). Sample ordering means that organisations can benefit by the scaling up and centralisation of operations. Samples can be ordered by users who are remote from the storage and preparation facility, with the samples shipped efficiently to the recipient. Samples can also be removed on an 'ad-hoc' basis.

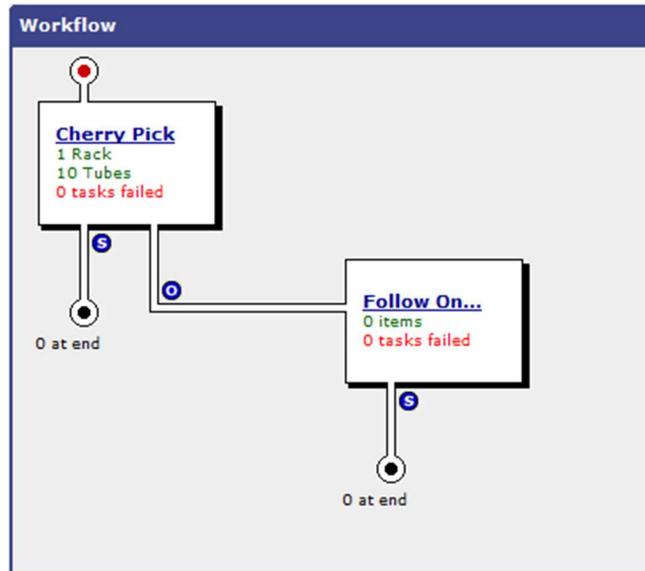
Show Icons Show Barcodes Show Substances

Empty Place Partially Full Full

Standardised workflows for common order types can be defined, and then readily initiated by other users. This means that the user only has to specify parameters for useful variations in the sample order, for

example - hiding the choices of sample format, and intermediate preparation steps, minimising the likelihood of specifying incorrect requirements.

Once the order is placed, the fulfilment of the order is tracked through the expected workflow, checking the samples identities at each step of the process.



A requestor can see the progress of their order through the Mosaic web based interface.

Despatch, Shipping and Receiving interfaces are provided, where despatch notes can be printed, and tracking codes can be recorded. Mosaic uses the Seagull Software 'Bartender' flexible barcode label design suite, which allows labels to be easily designed and applied to the containers or boxes for shipping, or for re-labelling containers on receipt.

Order	Class	Barcode	Action	Ready	Recipient	Destination Location	Comment	Operation
<input type="checkbox"/> [All]	[All]	[All]	[All]	[All]	[All]	[All]		[All]
<input type="checkbox"/> 203	Rack	MRRACK75	Ship	Yes	Rigby, Mike (TITIAN\mpr)	\B\Analytical	to view run details for run associated with an order	3
<input type="checkbox"/> 442	Rack	CSLTEST032	Deliver	No	Moynihan, Cian (TITIAN\chm)	\Cambridge\Goods In		1
<input type="checkbox"/> 394	Rack	CSLTEST002	Deliver	No	Pabis, Martin (TITIAN\mp)			
<input type="checkbox"/> 473	Rack	MRG-R2	Deliver	No	Gedrych, Mark (titian\mrg)			
<input checked="" type="checkbox"/> 474	Rack	MRG-R3	Ship	No	McLachlan, Neil (TITIAN\ngm)			
<input checked="" type="checkbox"/> 451	Rack	MRRACK20	Ship	No	Moynihan, Cian (TITIAN\chm)			
<input checked="" type="checkbox"/> 475	Rack	MRG-R4	Ship	Yes	Wilson, (titian\ewl)			

## What services can I expect to get up and stay running with Mosaic?

Titian Software works with its customers to define the initial Mosaic system configuration. Members of our Application Consultants team are sample management experts drawn from industry who can help capture the full set of operational requirements a customer may have.



Our experienced implementation teams install and configure the system, and provide a choice of training packages to end-users and administrators. Our support teams (UK and US based) are there to keep your system running at its best.

For more information about Mosaic for biological sample management, please contact us at:

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## References:

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