

GCP Records Managers Association
GCP-RMA

Guidance Document: Selecting a Commercial Records Storage Provider

1	Selecting a Commercial Records Storage Provider	
1.1	General Remarks	
	1.1.1	The following is a checklist to assist in the selection and evaluation of archive storage facilities, storage locations and infrastructure, particularly if these are contracted to commercial records storage providers.
	1.1.2	This checklist is not intended to be a comprehensive list of requirements and should not be interpreted as "mandatory" or "minimum". It contains a list of standard considerations to make when establishing a commercial records storage contract of suitable quality.
	1.1.3	These considerations go beyond the selection of the physical records storage facility as there are other aspects that are equally important to ensure that the service will be suitable in its entirety for the company's requirements; it is just a piece in the overall process. The primary consideration to be made in the selection of a commercial records storage provider is to contract high quality services that minimize risk and facilitate compliance.
	1.1.4	This checklist should be used in conjunction with the Company's internal archiving and retrievals controls; it does not negate the need for these. Responsibility for ensuring the security and preservation of- and access to- the Company's records held with commercial records storage providers remains with the Company and the function managing the records management services. Internal records management controls should ensure commercial records storage providers deliver optimum benefit to the company.

1.2	Commercial Records Storage Provider Selection Process	
	1.2.1	Where they exist, the Company should follow and use its internal SOPs regarding the selection of commercial records storage providers. In any event, the SOP (or other process) for the selection of third-party vendors should identify several commercial records storage providers and select from them a number for evaluation. Post evaluation a single commercial records storage provider should be subject to a comprehensive QA audit prior to making a final decision.
	1.2.2	The Company should establish whether or not the commercial records storage provider manages records for other pharmaceutical companies or has experience or understanding of applicable GxP standards. If not, the Company should enquire whether or not the commercial records storage provider manages records for companies from other regulated industries.
	1.2.3	The Company should utilise its own procurement department to commence procurement and tender negotiations
	1.2.4	The Company should be mindful during the selection process that low cost storage charges should not be the main determinant of selection of a commercial records storage provider. There are a host of other charges that must also be considered. Moreover, a satisfactory long-term relationship with the commercial records storage provider is of equal -if not greater- importance. Less about price more about long-term working relationship
2	Contract	
2.1	General	
	2.1.1	The Company should ensure that confidentiality agreements are in place with the commercial records storage provider before commencing negotiations
	2.1.2	If the contract is written by the commercial records storage provider, the Company should supplement this with contract and service level agreements to ensure that the Company's needs are being met. The Company should not accept the commercial records storage provider's contract without review and negotiation.

	2.1.3	The Company should ensure that a specified location is designated for the Company's records. The commercial records storage provider must be contractually bound to notify and obtain agreement from the company before moving its records to a location other than the specified location. Specification of location. Obligation to notify and obtain agreement from the Sponsor if documents are moved to another location.
	2.1.4	The Company should ensure that there is a clause in the contract to state that the Company's data and the Company's records are owned by the Company. "Data" and "records" includes but is not limited to: physical records, record containers, barcode information, metadata, data about the Company's records held on commercial records storage provider databases (e.g. historical movement data) and all other information captured to identify records and their movements.
	2.1.5	The Company should ensure that there is a clause in the contract to state that disclosure of the Company's data and the Company's records to third parties requires the Company's prior, express consent.
	2.1.6	The Company should ensure that there is a clause in the contract to state that the Company's data and the Company's records are subject to data protection legislation and may not be accessed by any party other than the Company.
2.2	Pricing	
22	2.2.1	The Company should ensure that costs are fixed for a specified period (generally one year) and are associated with a transparent increment index (e.g. the Consumer Prices Index or Retail Prices Index) as contract termination and switch of established archiving procedures will be expensive due to internal and external costs and efforts.
2.3	Insurance	
	2.3.1	The Company should therefore consult with their own insurers to determine an appropriate level of insurance to cover the risks associated with the loss of records (e.g. costs to recover or reconstruct records). The standard insurance offering from commercial records storage providers covers only the salvage value of records; this is insufficient to ensure the recovery of lost records.

2.4	Monitoring and Issue Handling		
	2.4.1	The Company should establish an escalation procedure with the commercial records storage provider to deal with unforeseen circumstances	
	2.4.2	The Company should agree in advance the process with the commercial records storage provider for handling and documenting changes to the contract after the contract has been let. Handling and documenting changes in the process, after signing contract	
	2.4.3	The Company should establish a single point of contact with the commercial records storage provider for all enquiries and back-up to contacts on both sides.	
2.5	Contract Termination		
	2.5.1	The Company should ensure that satisfactory mechanisms and controls are established regarding any future large volume transfers or relocations, particularly in relation to bulk withdrawals or contract termination.	
	2.5.2	The Company should agree in advance the charges regarding any future large volume transfers or relocations, particularly in relation to bulk withdrawals or contract termination.	
3	Company Details		
3.1	General		
	3.1.1	The Company should satisfy itself that the commercial records storage provider:	
		a	has been in the commercial records storage business for a satisfactory period. In order not to disadvantage a newly established commercial records storage provider or one for whom no referral information or history is available, the Company may choose to institute a closer level of monitoring;

		b	has a sufficient (inter)-national spread to cater for the Company's current and future needs. It should be noted that data protection issues may apply if the commercial records storage provider wishes to store data in an inappropriate jurisdiction;
		c	has sufficient long-term, full-time, appropriately trained employees to cater for the Company's current and future needs. A high turnover of staff would indicate transient staff who may be employed via an agency or on short-term contract and who may consequently be less qualified, less experienced or less trained than employees of the commercial records storage provider.
		d	has sufficient demonstrable experience as a commercial records storage contractor to cater for the Company's current and future needs
		e	has experience of being able to satisfactorily respond to official audits by regulatory bodies
		f	has the ability to securely handle highly confidential records
		g	has the ability to handle records of high intellectual property worth
3.2	Staff Qualification (Specifically for Involved Sites/Facilities)		
	3.2.1	The Company should satisfy itself that the commercial records storage provider has evidence:	
		a	that established processes are in place regarding staff selection
		b	that established processes are in place regarding staff vetting
		c	that established processes are in place regarding sub-contracting
		d	regarding staff retention and volumes of temporary staff

		e	of established processes to ensure that staff are appropriately trained and qualified for their roles. NB Access to and handling of- individual GxP documents will require different qualifications over and above the logistical handling of sealed boxes.
3.3	Quality Management		
	3.3.1	The Company should satisfy itself that the commercial records storage provider has evidence:	
		a	of sufficient quality control systems being established and followed (e.g. QA function, written procedures, training programme)
		b	that relevant standards are instituted in all applicable locations (e.g. ISO-9001, ISO-11799, GLP certificate)
4	Risks and Risk Mitigation		
4.1	General		
	4.1.1	The Company should satisfy itself that the commercial records storage provider has in place satisfactory:	
		a	risk management measures and plans
		b	business continuity plans
4.2	Environment		
	4.2.1	The Company should satisfy itself that the commercial records storage provider is located at a site that is sufficiently distant of free of potential hazards posed by:	
		a	major transport routes (e.g. railways, airports, motorways)
		b	major waterways (e.g. canals, lakes, rivers, seas, flood plains)

		c	industries or services using volatile substances (e.g. petroleum, gas)
		d	the natural environment (e.g. flood plains, marshes, forests)
4.3	Facilities		
	4.3.1	The Company should satisfy itself that each of the commercial records storage provider premises (inc loading docks and ancillary operational areas):	
		a	is built or adapted to be suitable for storing records (purpose-built, stand-alone buildings without separate floors are preferable).
		b	is designed to prevent or minimize risks (e.g. weatherproof, waterproof, fire-resistant, vermin proof, protected against intrusion)
		c	has facility supply systems separated from the storage area (e.g. heating, electricity, water, sewerage etc)
		d	Is sufficiently protected (e.g. weather protection, fire, security)
		e	is subject to regular documented maintenance (e.g. alarms)
		f	is satisfactorily maintained (e.g. clean, tidy and uniform in appearance)
		g	is capable of storing non-standard sized items, should the need arise
4.4	Security		
	4.4.1	The Company should satisfy itself that each of the commercial records storage provider premises (inc loading docks and ancillary operational areas) offers satisfactory security for:	
		a	perimeter access (e.g. ring fenced, security gates, properly managed)

		b	internal warehouse access (e.g. biometric, keypad, swipe card etc) which should be restricted to nominated individuals and be able to produce a record of access to the archive including staff name and time of access
		c	visitors (who should be checked, documented and escorted all times)
		d	site and building access (which should include 24-7-365 monitoring via regularly serviced motion detectors, CCTV surveillance, security guards, alarm systems connected to a police station or security service)
4.5	Fire		
	4.5.1		The Company should satisfy itself that each of the commercial records storage provider premises (inc loading docks and ancillary operational areas) offers satisfactory protection against fire by:
		a	prohibiting smoking in working and storage areas
		b	limiting potential sources of [particularly flammable] heating devices (eg storage heaters)
		c	prohibiting the storage of explosive or inflammable materials
		d	the installation of fire-rated walls and doors
		e	ensuring that staff are trained in fire detection and suppression
		f	regular assessment and inspection by the fire service.
		g	locating fire extinguishers & hoses appropriately
		h	having sufficiently designed automated, intelligent sprinkler systems and smoke detectors in place
		i	having shelves and storage racks constructed of fire resistant materials
		j	having fire/heat/smoke detection and alarm systems installed and connected to nearest fire station

		k	having regularly tested and documented alarm tests
		l	having gas fire suppression protected rooms e.g. using Inergen/FM200 or similar (if required)
4.6	Flood		
	4.6.1	The Company should satisfy itself that each of the commercial records storage provider premises (inc loading docks and ancillary operational areas) offers satisfactory protection against flood by:	
		a	having sufficient space between floor and shelves to protect against risks from the ground (flood, fire water)
		b	avoiding overhead water services in the floor above (eg water pipes, service pipes and sewerage pipes)
		c	having storage areas that are not located in an area lower than the surrounding ground (basement)
		d	having water sensors/detectors installed, maintained, inspected and tested
4.7	Storage Conditions		
	4.7.1	The Company should satisfy itself that each of the commercial records storage provider premises (inc loading docks and ancillary operational areas where relevant) offers satisfactory storage conditions that:	
		a	allow the establishment of Company dedicated space (to mitigate against loss this is NOT recommended)
		b	provide sufficient capacity for future needs
		c	have sufficient controls in place to prevent cross-contamination
		d	do not permit the storage of non-paper items with paper records
		e	provide shelving of sufficient quality in terms of build, materials, anchorage and hazard resistance

		f	offer temperature & humidity controls that are regularly monitored, maintained and recorded (a log of measurement recordings and CAPA records should be maintained)
		g	allow air to circulate to provide sufficient ventilation and prevent mould, dust and other pollutants
		h	benefit from a regularly conducted and documented pest monitoring program
		i	offer environmentally sound facilities for electronic media storage if required that meet applicable standards listed in the standards appendix.
4.8	Business Continuity		
	4.8.1	The Company should satisfy itself that the commercial records storage provider has documented evidence of:	
		a	plans for disaster response and recovery, which should extend beyond personnel safety and include all aspects of business continuity). The commercial records storage provider should provide documentation to demonstrate that the plans have been tested and passed
		b	contracts and/or relationships with document recovery providers in the event of damage to the Company's documents

5	Storage Logistics	
5.1	Storage	
	5.1.1	The Company should satisfy itself that the commercial records storage provider has documented evidence of:
	a	procedures that prevent the records being identified as belonging to the Company (as a first line of defence to protect itself, the Company should use unmarked records and boxes and permit only a non-Company specific, unique identifier and barcode to be affixed to its records and boxes).
	b	the locations of multiple sites at which the Company's records are located (where permitted)
	c	the procedures used by the commercial records storage provider during records retrieval, especially procedures to ensure confidentiality when retrieving loose files from boxes and when replacing damaged boxes (these procedures should include instructions for obtaining written authorisation from the Company to deal with boxes that are security sealed)
	d	the procedures used when handling records to ensure that they are handled with care and appropriate equipment
	e	the measures in place to avoid short and long term damage to the records (refer to the standards listed in Appendix1)
5.2	Records Ingestion/Inventory	
	5.2.1	The Company should satisfy itself that the commercial records storage provider has documented evidence of:
	a	the techniques and processes employed to capture the movements of records, including inherent mechanisms used to ensure quality, prevent errors and mitigate against risk. The mechanisms will include but not be limited to:
	b	barcodes or RFID labels and accompanying readers

		c	databases and IT systems (inc validation, backup and recovery procedures, business continuity planning)
		d	procedures and mechanisms in place to capture additional metadata e.g. (product name, document type, retention period)
		e	the application used by the commercial records storage provider to track records and whether or not this is interoperable with the Company's records tracking system (e.g. barcode readability)
		f	procedures used to generate reports and any associated costs so that the Company can effect periodic reconciliation reports
5.3 Transfers			
	5.3.1	The Company should satisfy itself that the commercial records storage provider can provide documentary evidence that:	
		a	it maintains auditable chain of custody documentation (e.g. real-time tracking receipts and reports)
		b	no documents or records are left in vehicles overnight. .
		c	only own transport or Company approved couriers are used to transport records. The circumstances under which transportation may be sub-contracted should be agreed prior to use.
		d	the use of transport hubs used for delivery and collection is adequately controlled by procedures (e.g. via a flowchart) NB For GCP records particularly, the use of hubs is not recommended not least because the hub storage facilities may not have been subject to evaluation, inspection or audit and may not provide suitable security, protection or environmental conditions.

6	Services	
6.1	General	
	6.1.1	The Company should satisfy itself that the commercial records storage provider provides:
	a	hours of operation suited to the Company's needs
	b	methods of operation and communications suited to the Company's needs (e.g. e-mail, telephone, fax, web-based online ordering, call centres, direct to site)
	c	adequate arrangements for emergency out of hours deliveries
	d	maximum retrieval times for regular and urgent deliveries and collections
	e	facilities for viewing boxes on site
6.2	Supplies	
	6.2.1	The Company should satisfy itself that the commercial records storage provider provides:
	a	supplies of a suitable quality and price (e.g. boxes, files, labels, barcodes) NB It is not recommended that the Company purchases security seals from the commercial records storage provider seals
	b	satisfactory delivery timescales on supplies
	c	boxes designed to permit the use of security seals without causing damage to the box

6.3	Indexing	
	6.3.1	The Company should confirm with the commercial records storage provider:
	a	the level and cost of any indexing the Company requires the commercial records storage provider to undertake
6.4	Retrieval	
	6.4.1	The Company should satisfy itself that the commercial records storage provider provides:
	a	a database of the Company's records that is accessible to the Company for the purposes of ordering collections and deliveries and maintaining a stock record and an auditable history of the movements of the Company's records NB For security and confidentiality reasons it is recommended that the Company provides the commercial records storage provider with minimal information regarding the content of the Company's records
	b	periodic reports on the Company's records. The format and charges associated with these reports should be agreed up front
6.5	Delivery/Collection	
	6.5.1	The Company should satisfy itself that the commercial records storage provider provides:
	a	same day deliveries and collections
	b	urgent deliveries within agreed timelines
	c	ordering via an online web portal, e-mail or telephone or a combination of one or many that conform to the Company's security requirements
	d	dedicated delivery van and courier services (these may be satellite tracked)

6.6	Destruction	
	6.6.1	The Company should satisfy itself that the commercial records storage provider provides:
	a	if required, secure, confidential and environmentally responsible destruction services that includes the provision of certificates of destruction and are compliant with applicable standards (please refer to Appendix 1)

Standards Appendix	
	BS 5454:2000 Recommendations for the storage and exhibition of archival documents
	BS 1153:1992 Recommendations for processing and storage of silver-gelatine-type microfilm
	BS EN 15713:2009 Secure destruction of confidential material: Code of practice
	ISO 9706:1994 Information and documentation: Paper for documents -requirements for permanence
	ISO 11799:2003 Information and documentation: Document storage requirements for archive and library materials
	ISO 16245:2009 Information and documentation: Boxes, file covers and other enclosures, made from cellulosic materials, for storage of paper and parchment documents
	MHRA GLP Guidance on Archiving