

The aim of this Checklist is to evaluate the quality assurance and quality control systems established by the Sponsor/CRO to assure that clinical trials are conducted and data are generated, recorded and reported in compliance with the protocol, GCP and applicable regulatory requirements.



1.	Organization & Personnel	
	Evaluate if the sponsor/CRO has a well-established organization for clinical research activities and has a sufficient number of properly qualified and trained personnel for each area. Review:	
1.1	Org charts that identify key personnel in each area	<input type="checkbox"/>
1.2	Independence of the quality assurance unit	<input type="checkbox"/>
1.3	Job descriptions, qualifications and training of the individuals involved at any stage of the clinical trial process	<input type="checkbox"/>
2.	Facilities & Equipment	
2.1	Identify and evaluate the facilities used for archiving or investigational medicinal product (IMP) storage as well as the equipment used. Special attention should be paid to computer systems (e.g. hardware, software, communications), in order to evaluate their validation status, and their adequacy for the requirement of the trial(s) being inspected.	<input type="checkbox"/>
3.	Sponsor/CRO Operating Procedures: Implementation and Termination of the Clinical Trial	<input type="checkbox"/>
	Review the procedures for:	
3.1	Document preparation: format and content and distribution of protocol, protocol amendments, informed consent documents, investigator brochure, CRF and any other trial documents	<input type="checkbox"/>
3.2	Investigators selection and training	<input type="checkbox"/>
3.3	Regulatory compliance: obtaining IEC approval/favorable opinion and necessary authorizations, providing notifications and reports as required by GCP and local regulations	<input type="checkbox"/>
4.	Sponsor/CRO Operating Procedures: Monitoring	
	Determine if procedures include:	
4.1	Description of monitoring activities: visits, frequency and extent of data review	<input type="checkbox"/>
4.2	Content and handling of monitoring reports	<input type="checkbox"/>
4.3	Agreements for direct access to source documents by the sponsor personnel (or their appointed representatives) and by regulatory authorities and confidentiality of information about subjects	<input type="checkbox"/>
5.	Sponsor/CRO Operating Procedures: Investigational Medicinal Product	
	Determine if Sponsor procedures for different stages of the IMP cycle are compliant with the current GMP, GCP, ICH and local regulations, and establish provisions for:	
5.1	Quality control requirement	<input type="checkbox"/>
5.2	Manufacturing, packaging and labeling	<input type="checkbox"/>
5.3	Supplying, accountability, returns and destruction	<input type="checkbox"/>
5.4	Randomization and code breaking	<input type="checkbox"/>

¹ Adapted from FDA Compliance Program Guidance Manual, Chapter 48: Bioresearch Monitoring; Sponsors, CROs and Monitors, February 21, 2001, and from EU Annex IV to Guidance for the Conduct of GCP Inspections: Sponsor and CRO, 28 May 2008.

The aim of this Checklist is to evaluate the quality assurance and quality control systems established by the Sponsor/CRO to assure that clinical trials are conducted and data are generated, recorded and reported in compliance with the protocol, GCP and applicable regulatory requirements.



6.	Sponsor/CRO Operating Procedures: Sample Management	
6.1	Review procedures established for handling samples obtained in clinical trials	<input type="checkbox"/>
7.	Sponsor/CRO Operating Procedures: Safety and Adverse Event Reporting	
	Verify procedures for reviewing and communicating findings that could adversely affect the safety of subjects and the reporting of serious adverse events to regulatory authorities, investigators and IRBs/IECs, where applicable. Review procedures for:	
7.1	Expedited Adverse Drug Reaction reporting to regulatory authorities, investigators and IRB/IEC, where applicable	<input type="checkbox"/>
7.2	Serious adverse events notification by investigators	<input type="checkbox"/>
7.3	Safety updates and periodic safety reports	<input type="checkbox"/>
7.4	Validation of computer systems used	<input type="checkbox"/>
8.	Sponsor/CRO Operating Procedures: Data Handling and Clinical Trial Reporting	
	Determine if the procedures establish:	
8.1	Data handling, data analysis and their control procedures	<input type="checkbox"/>
8.2	Clinical trial report preparation according to ICH standards	<input type="checkbox"/>
8.3	Validation of computerized systems used	<input type="checkbox"/>
8.4	Audit trails (for paper and computer systems)	<input type="checkbox"/>
9.	Sponsor/CRO Operating Procedures: Documentation Archival	
	Determine whether the system established by the Sponsor/CRO guarantees that the general documentation which has to be archived at the Sponsor/CRO site (according to Section 8 of the CPMP/ICH/135/95 Note for Guidance on GCP) is available, complete and maintained in good conditions during the period of time established. Determine if procedures include:	
9.1	System for archival and retrieval of documents	<input type="checkbox"/>
9.2	Controlled access to the archives	<input type="checkbox"/>
10.	Sponsor/CRO Operating Procedures: Sponsor Audit and Quality Assurance System	
	Determine if the Sponsor/CRO has established an audit system, as part of its own quality assurance system, in order to evaluate its activities related to clinical trials. Determine if the procedures include:	
10.1	Audits of key clinical trial processes, including monitoring, data management, safety reporting, clinical study report production, archiving and computer system validation activities	<input type="checkbox"/>
10.2	Audits of contractors/sub-contractors	<input type="checkbox"/>
	Also review:	
10.3	The processes for communicating and addressing audit findings, including the format and distribution of audit reports	<input type="checkbox"/>
10.4	The procedures for dealing with serious and/or persistent GCP non-compliance	<input type="checkbox"/>



GCP COMPLIANCE CHECKLIST: SPONSOR/CRO SYSTEMS

The aim of this Checklist is to evaluate the quality assurance and quality control systems established by the Sponsor/CRO to assure that clinical trials are conducted and data are generated, recorded and reported in compliance with the protocol, GCP and applicable regulatory requirements.		<input checked="" type="checkbox"/>
10.5	Audit trails	
10.6	Procedures for generation and implementation of audit programs/plans	
11.	Sponsor/CRO Operating Procedures: Delegation of Duties	
	Verify procedures for reviewing and communicating findings that could adversely affect the safety of subjects and the reporting of serious adverse events to regulatory authorities, investigators and IRBs/IECs, where applicable. Review procedures for:	
11.1	Pre-selection and ongoing assessment of contractors/subcontractors	<input type="checkbox"/>
11.2	Documentation of duty delegation and its time recording	<input type="checkbox"/>
11.3	Handling contract amendments	<input type="checkbox"/>