

## GCP COMPLIANCE CHECKLIST: SPECIFIC CLINICAL TRIAL<sup>1</sup>

The aim of this Checklist is to verify if the trial has been conducted, data has been generated, documented and reported in compliance with the protocol, GCP principles and sponsor procedures. The procedures and requirements applicable at the time of the trial should be considered, and compared where relevant to those applying at the time the Checklist is used.



<b>1.</b>	<b>Implementation and Termination of the Clinical Trial</b>	
	Review the following to determine if all legal and administrative aspects of the clinical trial have been accomplished:	
1.1	Distribution of Sponsor's duties or functions	<input type="checkbox"/>
1.2	Information given to investigators and/or specific training	<input type="checkbox"/>
1.3	Investigator selection and agreements (FDA Form 1572)	<input type="checkbox"/>
1.4	Fulfillment of regulatory requirement: IRB/IEC approval/favorable opinion and necessary authorizations	<input type="checkbox"/>
1.5	Submissions and approval of amendments	<input type="checkbox"/>
1.6	Critical dates: IRB/IEC approval/favorable opinion, regulatory authorizations (where required), initiation of the study, patient enrollment period, closing of the trial sites, termination of the study	<input type="checkbox"/>
<b>2.</b>	<b>Monitoring</b>	
	Review:	<input type="checkbox"/>
2.1	Monitoring plan/SOPs (availability, content and compliance to it)	<input type="checkbox"/>
2.2	Frequency and extent of monitoring activities that occurred	<input type="checkbox"/>
2.3	Monitors' qualifications	<input type="checkbox"/>
2.4	Monitoring visit reports and the review of the reports by Sponsor/CRO	<input type="checkbox"/>
2.5	Corrective actions taken as a result of monitoring visits	<input type="checkbox"/>
<b>3.</b>	<b>Investigational Medicinal Product</b>	<input type="checkbox"/>
	Review documentation for:	
3.1	Manufacturing, packaging, labeling and quality control	<input type="checkbox"/>
3.2	Supplying, accountability, returns and destruction (IMP tracking system)	<input type="checkbox"/>
3.3	Randomization and code breaking	<input type="checkbox"/>
3.4	Blinding	<input type="checkbox"/>
3.5	Shipment	<input type="checkbox"/>
3.6	Condition of shipped product on receipt and during storage	<input type="checkbox"/>

<sup>1</sup> 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.

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<b>4.</b>	<b>Safety and Adverse Event Reporting</b>	
	Verify:	
4.1	Notification, follow up and reporting of serious adverse events and other non-serious adverse events requiring expedited reporting according to protocol	<input type="checkbox"/>
4.2	Safety updates and their communication	<input type="checkbox"/>
<b>5.</b>	<b>Case Report Form Data Verification</b>	
	A selected number of CRFs should be reviewed to verify:	
5.1	Adherence to the protocol, as well as data accuracy, completeness, legibility and timeliness	<input type="checkbox"/>
5.2	CRF corrections	<input type="checkbox"/>
5.3	Correspondence of the dates of first patient in and last patient out with the dates of study initiation and completion, as well as with IMP delivery	<input type="checkbox"/>
<b>6.</b>	<b>Clinical Trial Documentation and Archiving</b>	
	Determine if all essential documents listed in the Section 8 CPMP/ICH/135/95 Note for Guidance on GCP are available during the inspection	<input type="checkbox"/>
<b>7.</b>	<b>Audits</b>	
	Determine:	
7.1	If the clinical trial was audited and audit reports exist	<input type="checkbox"/>
7.2	Qualifications of the auditors	<input type="checkbox"/>