



# 3-Minute GCP Quiz™

## Drug and Device Products Management

	<b>Questions and Answers</b>	Answer
1	According to the ICH GCP Guideline, investigators are required to store study drug supplies however the sponsor directs them to do so.	True
2	All new clinical protocols conducted under the IND regulations are subject to the FDA's 30 day waiting period prior to administering drug.	False
3	At the end of a study, an investigator may discard unused investigational drug, unless the drug was a controlled substance, in which case it must be returned to the sponsor	False
4	For studies with marketed products, investigators may discard unused clinical supplies without any further documentation, or retain it for use in future clinical practice.	False
5	If a subject takes 35 tablets in a study scheduled for QID dosing, and there are 10 days between visits, the percentage of compliance for this study subject is 75%.	False
6	The FDA's IDE regulation requires investigators to maintain records of all persons who received, used or disposed of each device.	True
7	If an investigator maintains a record of the exposure of each subject to an investigational device that includes the date of use and any other therapy, the investigator will be in compliance with the FDA's requirements for documentation of use of a device.	False
8	Clinical investigators are required by US federal law to permit an investigational device to be used only under their supervision.	True
9	The federal regulations governing the documentation requirements for investigational use of devices classified as significant risk differ from devices classified as non-significant risk.	True
10	Due to cost, following the completion of an investigational device study an investigator may dispose of any remaining devices at his or her discretion, or may retain the device(s) for use in clinical practice following the regulatory approval of the device.	False

We hope you have enjoyed testing your GCP knowledge with this quiz.  
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