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Closed System ✓ An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system. (21 CFR, Sec. 11.3)

Digital Signature ✓ An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified. (21 CFR, Sec. 11.3)

Electronic Record ✓ Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. (21 CFR, Sec. 11.3)

Electronic Signature ✓ A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be legally binding equivalent of the handwritten signature. (21 CFR, Sec. 11.3)

Open system ✓ An environment in which system access is not controlled by persons who are responsible for the content of the electronic records that are on the system. (21 CFR, Sec. 11.3)

Clinical Investigation ✓ Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. (21 CFR, sec. 50.3)

Socra Study Guide

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