

## Student Handout- Module Number Twenty-Four (24) - Electronic Records and Signatures

# Electronic Records and Signatures

Electronic records and signatures are considered the **legal equivalents of paper records** and handwritten signatures executed on paper.

A **predicate rule** is any regulation or law that includes a requirement to keep a record. Look to predicate rule for:

- what records to keep
- how long to maintain records
- what signatures are required

An **electronic record** is 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.

An **electronic signature** is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

### System Requirements:

- **Validation**
- **Qualification:**
  - **Installation qualification**
  - **Operational qualification**
  - **Performance qualification—test**

Electronic signature mechanisms may be based on:

- ***biometrics* such as scan of retina (eye), face, fingerprint, or voice recognition**
- ***two distinct components* such as identification code or card and password**

**Closed system** means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

**Open system** means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.