INFORMATION TECHNOLOGY POLICY

1. PURPOSE

The purpose of this policy is to define the company’s requirements for the management and use of computer systems. The requirements are developed to ensure regulatory compliance, the reliability, and security of communication and computing systems, and the integrity of electronic records.

2. SCOPE

This policy applies to the use of company owned hardware and software, including the information systems administered by the IT department, departmental systems, and systems used individually by employees. It also applies to all electronic data, records, and information generated by or used by employees.

3. REFERENCE DOCUMENTS

[Note to the purchaser of this document: The policy documents, procedures, and templates referenced here are available at www.BPAconsultants .com]

3.1. 21 CFR Part 11 – Electronic Records; Electronic Signatures. Food and Drug Administration. Federal Register: March 20, 1977, Volume 62, Number 54.

3.2. VAL001, Validation Policy

3.3. VAL002, Validation Requirements for Computer Systems

3.4. VAL005, Change Control for Validated Systems

3.5. VAL006, Computer System Project Proposal

3.6. VAL007, Computer System Vendor Qualification and Management

3.7. Stein, R. Timothy. Computer System Risk Management and Validation Life Cycle, Paton Press, 2006.

4. DEFINITIONS

4.1. Electronic record: An electronic record includes any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system with the intent of meeting a regulatory requirement for quality records. In short, it is any electronic form of a quality record required by a regulatory body.

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4.2. Electronic Signature: 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.

4.3. GxP: A generic designation for all FDA regulations, including GLP, GCP, and cGMP, as applicable to an industry.

4.4. Protected directories: Network server file directories that have controlled access.

5. RESPONSIBILITIES

5.1. Employees: Each employee is responsible for creating, using, and managing electronic information, resources and records in a manner that is compliant with this policy.

5.2. Head of IT: The Head of IT is responsible for enforcing this policy and its associated procedures. The Head of IT is also required to report on compliance to the president and other directors.

5.3. Senior Management. Every member of the senior staff is responsible for ensuring that employees within their organizations comply with this policy.

6. GENERAL POLICY ON THE USE OF SYSTEMS

6.1. The company values the creation, use, and communication of information as a critical element of business success. Therefore, the company strides to provide the resources needed for efficient creation, use, and communication of information, as well as for effective communication among employees and with our customers and suppliers.

6.2. Data and information generated within the company is considered part of our corporate assets and is appropriately protected from theft, corruption, or destruction.

6.3. Information technology resources are provided to personnel for the express purpose of conducting company business, and are not intended for personal use.

6.4. Users of systems/applications that perform GxP functions, and/or create, modify, maintain, retrieve, and/or transmit electronic records must be trained on the appropriate use of the system/application or must use the system under the direct supervision of a trained individual. The system or directory owner is responsible for providing and documenting training.

user must logoff whenever a new user will access the system or when the user cannot ensure that others will not be able to perform transactions under their logon.

7.2. Hardware and software procurement and use

7.2.1. The IT department procures, configures, and supports company owned workstations and laptops. IT, while maintaining a base configuration for such hardware, may add additional hardware features to individual workstations to meet the business needs of users.

7.2.2. The types of software applications that are used by all employees (e.g., email, word processor software, etc.) will be selected and supported by the IT function. In addition, to guard against the corruption of one desktop application by another, IT will also approve a list of additional applications that are compatible with the standard applications. Employees will obtain copies of such software through IT, which will have responsibility for ensuring that appropriate licenses are obtained. Approval is needed from IT to obtain additional software.

7.3. Electronic mail usage

7.3.1. Users are expected to exercise common sense and discretion when drafting email communications. Electronic mail is considered the equivalent of traditional paper mail and care must be taken to communicate clearly, professionally, and in the company’s best interest. Company personnel are expected to maintain their own copies of critical business email. These critical communications should be filed in a manner to facilitate retrieval like paper records. Personnel are encouraged to print and initial and date (to verify accuracy of printout) emails that contain critical business communication.

7.3.2. Emails are not backed up and retained by IT, unless IT chooses otherwise.

7.3.3. Quality decisions and records are NOT transmitted by email unless permitted by a specific procedure related to such actions.

7.3.4. Using email for purposes other than executing responsibilities within an employee’s job function is inappropriate. We reserve the right to monitor and filter all employee email activity in order to ensure compliance. Information coming to and from company servers and workstations may be reviewed by the IT department at the request of management for compliance with company policy.

7.4. Use of the Internet