COMPUTER SYSTEM PROJECT PROPOSAL

1. PURPOSE

This procedure provides a form for creating a Computer System Project Proposal and provides directions for completing it as required by VAL002.

2. SCOPE

This procedure applies to all computer systems designed and developed internally, or obtained from external sources, which are used for GXP functions, including applications built with such tools as Excel, Access and SAS.

3. REFERENCE DOCUMENTS

3.1. VAL002 - Validation Requirements for Computer Systems

3.2. VAL003 - Lifecycle for the Selection, Implementation, Validation and Use of Off-The-Shelf Computer Systems

3.3. COMP002 - Determining 21 CFR Part 11 Applicability

3.4. RISK002 - Risk Management Procedure

4. DEFINITIONS

NA

5. RESPONSIBILITIES

5.1. The System Owner develops the Computer System Project Proposal.

5.2. Validation assists the System Owner in preparing the Computer System Project Proposal.

5.3. IT assists the System Owner in preparing the Computer System Project Proposal.

5.4. The head of the Owner's functional area, QA, and IT approve the proposal.

6. METHOD

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6.1. The System Owner prepares a proposal for the system using the Computer System Project Proposal form attached to this procedure.

6.2. A draft of the Proposal is written in advance of the preliminary risk assessment, and then revised and completed as necessary after the preliminary risk assessment.

6.3. System name.

6.4. Organization

6.4.1. System Owner.

6.4.2. Owner's Department.

6.4.3. Project team members: Provide the names of the team members, if appropriate, in addition to the System Owner. Members normally include QA, Validation, IT and may include additional representatives from user organizations.

6.4.4. Organizations: Identify the organization(s) that will use the system.

6.4.5. Number of users: Give the approximate total number of users. Estimate the total number of users who will be given access and the anticipated number of concurrent users.

6.5. System description.

6.5.1. Describe the system, albeit a preliminary description, including:

6.5.2. System boundaries: Provide a high level description of what is included in the system and what isn't.

6.5.3. Software and vendor names: Identify the potential software that will be part of the system, such as the application, or the package used by the application (e.g., Excel, Visual Basic, and Access), the operating system, communication and interface software, and system management tools.

6.5.4. Hardware: Identify the potential hardware, such as servers, data capture and input devices, data storage devices, and communications/network equipment. Note that if the system plugs into the network, then network can be listed as a subsystem without identifying all of its components. If an attached system specification contains a list of the hardware, refer to it rather than listing the information in this section.

6.6. System requirements

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6.6.1. Attach any of the following requirements documents if available. Check "Yes" if they are attached and "No" if they are not.

- User requirements
- Technical requirements
- System specification

6.7. System Functionality

6.7.1. Intended uses: Identify, at a high level, the intended uses of the system, and the associated major functions performed by the system to achieve the intended use.

For example, one intended use of a document control system is to make approved documents available for use in manufacturing product. Some of the functions that the system must perform for that use include:

- Controlling access to the system.
- Providing read only access to documents.
- Securing documents so that they cannot be changed via network access to file folders.

6.7.2. Give enough information so that a risk assessment can be performed, that is, potential failures/hazards can be identified, possible consequential harm can be projected and the severity of the harm estimated.

6.7.3. Data: Identify the data that will be captured, stored and retrieved.

6.7.4. Electronic quality records

6.7.4.1. Identify whether or not the system will create, manipulate, change, manage, or store any electronic quality records or electronic copies of paper quality records that will be used as the record.

6.7.4.2. List all such records.

Note: Be careful to distinguish between a record and a quality record. A record is a quality record only if it is required by a quality regulation, or if it is defined in the quality system as a quality record.