



CHECKLIST VALIDATION OF VENDORS FOR COMUTER SUPPLY



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1.0 Company Information

- 1.1 Human and Financial resources.
- 1.2 Knowledge of GMP requirements
- 1.3 Organization
 - a) Structure
 - b) Responsibilities.
- 1.4 Customer Support
 - a) Installation and service.
 - b) Technical support
 - c) User training.

2.0 Quality System –General

- 2.1 Management's stated policy and commitments.
- 2.2 Quality group's responsibility and authority.
- 2.3 Written Company quality plan.
- 2.4 Management Review of quality system.

3.0 Quality System –Software Development

3.1 Development Plan

- a) Functional Requirements.
- b) Software design specifications.
- c) Programming standards and procedures.
- d) Programming tools.
- e) Review procedures.

3.2 Test Plan

- a) Types of Tests.
- b) Test tools and methods.
- c) Error correction and re-test.
- d) Test review.
- e) Acceptance criteria.
- f) Test reports.



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3.3 Configuration Management

- a) Organization and responsibilities.
- b) Identification and traceability.
- c) Configuration tools.
- d) Change control procedures.
- e) Version identification control policy.
- f) Release approval procedures.
- g) Configuration history and status report.

3.4 Program Documentation

- a) Source code.
- b) Logic diagrams.
- c) List of all inputs and outputs.
- d) List of all modifiable parameters.
- e) List of all operator inputs.
- f) Description of interfaces to other systems.
- g) Description of alarms and interlocks.
- h) Description of error detection and recovery.
- i) Description of all data displays.
- j) Description of all reports.

3.5 Document Control

- a) Documents to be controlled.
- b) Approval of issue procedures.
- c) Change control procedures.
- d) Retention and security procedures.

3.6 Personnel Qualification

- a) Formal education.
- b) Internal training.
- c) Experience in software development.
- d) Experience with specific programs used.
- e) Experience with application.

4.0 Product Information

4.1 Validation Features

- a) Security.
- b) Self documentation.
- c) Automatic program change audit trail.
- d) Simulation capability.
- e) Program compare.
- f) Revision documentation detail.



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4.2 History of Use

- a) Customers of all versions.
- b) Customers of present version.
- c) Configuration history and status report.

4.3 Expected File

- a) Present version
- b) Revised products.

4.4 Revision Policy

- a) Notification of problems.
- b) Change required to fix problems.
- c) Change to add or modify features.
- d) Notification of revisions.
- e) Support old versions.