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QUESTION: What are the characteristics a standard operating procedure (SOP) system should meet for implementing a successful GLP compliance?

2) List 10 benefits the SOPs will provide to the laboratory if properly designed with the appropriate characteristics.

ANSWER

1.

A successful implementation of SOPs requires:

– sustained and enthusiastic support from all levels of management with commitment to establishing SOPs as an essential element in the organization and culture of the laboratory.

– SOP-based education and training of personnel so that the procedures are performed in the same way by all personnel;

– a sound SOP management system to ensure that current SOPs are available in the right place.

2.

1. Standardized, consistent procedures (person-to-person, test-to-test variability reduced).

2. A means of study reconstruction, if needed.Optimum efficiency.

3. Capture of technical and administrative improvements.

4. Demonstration of management commitment to quality as part of theSOP approval process.

5. Ease of documenting complicated techniques (a simple reference to the procedure should often suffice).

6. Continuity in case of personnel turnover.

7. Training manual.

8. Means of communication in case of audit, visits, technology transfer, etc.