HOW GOOD IS YOUR DOCUMENTATION SYSTEM?

HERE ARE TEN SAMPLE QUESTIONS TO HELP YOU DECIDE

NSF has provided auditing, consultancy and training services to the pharmaceutical industry for over 30 years. Over this period we have seen a lot of documentation systems, both good and bad! As we all know, documents exist for some very good reasons:

- To reduce the likelihood of errors, particularly with the spoken word
- To improve consistency in all activities; that is to describe who must do what, how, when and why
- To provide traceability and a full history of activities and events

Documentation systems come with a huge price tag which our industry has previously accepted without question. As a consequence, the volume of paperwork has grown and grown, adding massive cost and complexity with very little obvious "payback" to either the patient or the company. Many companies now recognise that their "traditional" approach to documentation is totally inefficient and simply unaffordable in the long term. To help you improve your documentation system we have provided you with ten simple questions! They focus attention on the essential elements of documentation systems that really do benefit the patient and the business. To see how your system compares with "best industry practice" simply answer the following questions:

1. DO YOU HAVE A CLEAR DOCUMENTATION HIERARCHY?

You must have a clear and well understood 'hierarchy' of documentation:

- You should have company wide policies relating to all aspects of your business. These high level documents should be short and detail the WHAT and WHY and steer clear of the HOW. If your policies are longer than 3 pages something is wrong.
- These high level policies should be customized and 'translated' into regional/ site specific policies that suit the 'local' business environment. Although there is some operational flexibility, these local policies must comply with the higher level company policies.

Finally, these policy documents should be supported by more detailed 'How to Do' SOPs and Work Instructions, which focus on providing the user with the HOW – the detail to complete the task. All of these documents must be considered 'working documents' and readily accessible to everyone (not filed and forgotten!)

2. DO YOU HAVE A DOCUMENTATION FILTER?

Documents are valuable when they have a clear purpose and provide real benefit. If they don't they become extremely costly. One of the major problems in the pharmaceutical industry is that it is too easy to write new documents! Some companies

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recognise this and take steps to prevent unnecessary documents being written. They stop (filter out) unnecessary documentation by asking the following simple questions:

- "WHY is this new document needed, what has changed?. After all, we've managed without it so far!"
- "What is the COST and what is the BENEFIT"?
- "Is there an alternative?"
- Does the SOP relate to a GMP activity?

3. ARE YOUR DOCUMENTS WRITTEN WITH THE ACTIVE PARTICIPATION OF THE USER?

Documents must be written for, and ideally by, the USER. Not the regulator or company auditor but THE USER! Not only will the document work, but it will be used.

- USERS must be involved at every stage
- By including the users the document becomes 'fit for purpose'
- All authors must be properly trained in technical writing skills (most people are very poor at technical writing!)

4. ARE YOU BEING CREATIVE IN DOCUMENT DESIGN?

Remember, easy reading is hard writing. Easy writing is hard reading. Good documents are well designed documents!

- Each type of document should have a standard template/format to ensure consistency
- Do you use pictures, schematics, drawings and color as much as possible?
- Do you keep words to a minimum?
- Are your documents user friendly, allowing the reader to access the information and guidance quickly?

5. ARE YOUR SOPS RESTRICTED TO GMP RELATED ACTIVITIES?

Ensure that SOPs are only written for GMP related activities and not for activities that have no GMP impact such as putting up the company flag, using the car park, fire drill and security procedures (all real life examples!).

6. DOES EVERY ONE OF YOUR DOCUMENTS HAVE AN OWNER?

This owner (or their successor) is responsible for the document throughout its life cycle:

- Generation
- Amendment
- Implementation
- Trouble shooting
- Further improvement

7. DO YOU ROAD TEST ALL 'HOW TO DO' DOCUMENTS BEFORE IMPLEMENTATION?

There is no such thing as a perfect SOP that works first time! Some companies recognise this and "road test" 'new' procedures before final implementation and approval. These SOPs are given 'interim' approval and a short expiry period. Following operational use they can then be updated in light of operational experience.

8. DO YOU ACTIVELY REDUCE THE NUMBER OF SOPS?

Companies that are 'best in class' realise that the number of SOPs must be managed.

They actively:

- Remove SOPs which have become obsolete
- Minimize duplication of SOPs

9. IS YOUR SOP TRAINING REALLY EFFECTIVE?

The best companies:

- Schedule in adequate training before implementation
- Ensure training is conducted by skilled trainers
- Use a combination of 'hands on' (preferred!) and classroom-based training

10. DO YOU CONSTANTLY MEASURE THE PERFORMANCE OF YOUR DOCUMENTATION SYSTEM?

Do you review:

- The numbers of SOPs in use?
- Numbers of SOPs awaiting/overdue approval?
- Numbers of procedural non compliances?
- Numbers of SOPs removed/archived?

Do you regularly audit your documentation system?

The purpose of these questions is to help you identify what you need to do in order to improve the efficiency of your documentation system. If you would like to discuss any questions in more detail please do not hesitate to contact Martin Lush at **martinlush@nsf.org**. Remember, the quality of your product is very dependant on the quality of your paperwork. Don't ignore your documentation system!

ABOUT THE AUTHOR

Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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