WALKING THE TIGHTROPE BETWEEN LEAN PRINCIPLES AND GOOD DOCUMENTATION PRACTICE (GDP) –

Barbara Manahan

BA Mod Hons MBA – JSC Management- und Technologieberatung AG und Lehrbeauftragte in den Studiengängen International Business Administration und Business & Law.

Documentation of IT infrastructure and processes in the pharmaceuticals sector

An increasing number of industries including food and pharmaceuticals are becoming subject to legislation and interpretations thereof which require compliance with certain good practices. GxP is the name given to Good Practice where the x stands for M (manufacturing) or L (laboratory) for example. The purpose of the GxP guidelines is to ensure that a product is safe and meets its intended use. For a medicine to be produced in a GxP-compliant manner, specific information technology practices must be observed. Computer systems and the IT infrastructure involved in the development, manufacture and sale of regulated product must meet certain requirements including secure logging, accountability, auditing, non-repudiation and litigation and regulation support[1]. Failure to comply can have serious legal implications with severe penalties for the business.

The knock-on effect of GxP for the documentation of IT infrastructure, systems and processes in the pharmaceuticals industry is commonly called GDP or Good Documentation Practice. In concrete terms, this means that the documentation must be contemporaneous at all times, reviewed regularly and any changes have to be traceable. It also has to fulfil accountability requirements which stipulate that the documentation has to be checked, aapproved, signed and dated by qualified authorized personnel. The type of documentation under scrutiny here includes manuals, standard operating procedures, operating concepts and checklists for example.

Paradoxically, the procedures used to document the infrastructure and information systems put in place to optimize processes are themselves often inefficient, delivering results that are in breach of GDP rules.

When needed, the documentation is sometimes difficult to find, its scope is not clear and its content or level of detail unsuitable.

Whereas in some cases the inefficiencies are inherent in the processes being documented, the obligation to document on the other hand is sometimes viewed as a necessary, time-consuming evil that is produced too late using more time and resources than would otherwise be necessary.

However, compliance and a lean approach are not necessarily mutually exclusive.

A set of principles designed to eliminate non-value-adding or wasteful activities from work processes in the automotive industry lends itself to identifying inefficiencies in documenting IT infrastructure and processes. Exalted as the cradle of 'lean management', the Toyota Production System (TPS) strives to eliminate activities that consume time, resources or space but do not add value or are wasteful. Removing this waste will reduce leadtimes, improve quality and with it motivation. Working on the premise that value is determined by the customer as opposed to the service-provider, the TPS defines seven types of waste (refer to chart next page).

Some types of waste in the documentation processes are immediately apparent, but identifying others requires experience, a trained eye and, in some cases, an entirely new way of perceiving what waste actually is. A case in point is where quality content is created efficiently using templates, but in two or more documents whose owners are not aware that the other documents exist. This can happen when cross-functional processes are

[1] Wikipedia GxP

Type of waste	In GDP context
Overproduction waste	More documentation is produced than required. This is the waste involved in creating, reviewing and releasing these documents. Leads to inventory waste.
Overprocessing waste	More work is performed on producing the documentation than is necessary. Too many editors and reviewers. The same information is depicted in several ways in the same document.
Defect waste	Incorrect and/or not current information. The same term is defined differently. Incorrect translations. Poor compliance with documentation rules.
Standby waste	Delays caused by the slowest link in the editing, review and approval process causing the total documentation leadtime to last months. Delays also caused by poorly defined processes, the documentation of which becomes difficult and sometimes political in a corporate context.
Inventory waste	Too many documents with the same content. In the same way that physical inventory is exposed to loss and damage and incurs cost for its maintenance, this superfluous documentation wastes storage space, requires updating, review and approval and is exposed to loss and damage.
Movement waste	Ineffective processes or lack of workflow automation necessitating otherwise unnecessary work steps and longer leadtimes . Repeated correction of the same errors.
Transport waste	Transporting information by e-mail instead of downloading the draft status for processing from the document management system is more work-intensive and increases the risk of parallel modification and loss requiring subsequent rework.

each documented by two or more of the departments involved. A further manifestation of so called hidden waste occurs when users spend more time than necessary in trying to find or apply the required documentation because it is unstructured or templates have not been used. Some types of waste will result in other types, for example, overprocessing will lead to standby waste.

The application of this lean approach to making inefficiencies transparent provides a basis on which to identify the root causes and find viable solutions.

In the same way that the TPS integrates quality control into the manufacturing process rather than testing a product at completion, IT documentation should be an integral part of the specification and development processes. It should also be noted here that effective document management involves a lot more than an automated creation, review and approval workflow with versioning functionality and accommodation of parent/child relationships. The ultimate aim must be to generate content once and reuse it in different media. Information created well at the outset can be reused in other documents and contexts.

However, before creating any more new documents, the first thing to do is to take a step back and get the whole picture. The outcome should be a stocktake of existing document types and the purpose they serve respectively. These should be aligned with current document requirements, which incidentally, may have changed since some of the existing document types were created. The next step is to define and agree the minimum number of required document types clearly explaining their purpose and providing concrete examples. The so called document administration data, for example revision interval, should be defined per document type. All of this information and the relationship between the document types should be made transparent in the form of a hierarchy. The time and effort exerted to this end will pay off in terms of having less redundant information to process and revise later on. Templates of the agreed document types should be created and made available for use. It is also recommendable to name or train a contact person who can help in identifying the document type required in a specific case and in ensuring that the structure and content are compliant. This will reduce the leadtime lost in sending document drafts back to their authors for correction. Needless to say, if fewer persons are assigned the role of author or editor, the document will pass quicker to the next stage in the document approval workflow. Controls must be in place to ensure that changes in the organisation or work content are documented immediately even if the set revision interval is not pending. Finally, the active involvement of team leaders, quality coordinators and management is critical in creating awareness for GxP issues and keeping IT documentation compliant.