COURSE INFORMATION

**Course Title: Advance Documentation Control Professional**

**Training Body: Jk Michaels**

**Venue: Plot 14, Odeniran Close Opebi, Ikeja.Lagos**

**Date: 2nd – 5th of march,2021**

**Report From: Mr. Ayo Daisa (Chief Detail)**

Training overview

The training was held on the 2nd to 5th of march,2021. the program starts 9am and end 4pm daily for the four days. Daily tea break was 11am, while lunch was 2pmdaily. It was a three-day rigorous training with the last day a writing examination. At the end of the exam, the exam sheets are sent to Jk Michael institute marking and recording which later end up with award of certificate. As at the time of completion of this training, a certificate of completion of an executive course in Advance Documentation control professional was issued to me.

**Day one**

Scope of training for day one program.

1. Configuration management controlled:

Is another world for documentation controlled? A configuration management is to make sense documented, fact, accurate, efficiency, well understood, minimally controlled, effective, measured, process approach to project design and definition throughout a product lifecycle.

Most of things needed to be done can be accomplished by a proficient cm manager, if he or she has the resources, training dedicated executive champion.

1. Configuration management control consist of the following basics process.

* Release
* Making changes and
* Bill of materials

There are two other process that might also be included under the cm umbrella.

* Orderly entry, and
* Deviation/wavier/off-specs

Product design must be documented and controlled effective for profitability, sustainable, production, service and sale of our products.

Summary

Configuration management is almost every product manufacturing operation because of the following:

* Design documentation is one of the four critical element of product manufacturing.
* Design document is engineering product and that documentation is required by almost all the company functions.
* Design do change and changes need to be accurate, understood, communicated and tracked.
* Most companies have a degree of whether chaos or vertical or both in the CM world.
* A function is needed to bridge the gap often found between engineering and the rest of the company.
* An executive champion is needed for fostering best-in-class CM.

**Day Two**

CM Responsibilities / ISO / USFDA Regulatory Document Control Requirement

Bellow are some of the Responsibilities of Configurations management control.

1.Coordinate all the technical document control function activities.

2.Train all the key personnel on CM and the company CM system.

3.Ensure that nonvalue=added requests for change are filtered out (the primary purpose of the request process.)

4.Develop metrics.

5.Do the revision (incorporation drafting for design document changes.)

6.To ensure that the changes are tracked to the actual date or specific units affected.

7.Control all design data and document transmittals to customers and agencies.

8.Ensure easy access to a tracking data base and ensure that reports can be produced as required.

9.Ensure the quality of all design documents and changes there to via application of the CM and drafting standard.

10.Benchmark the CM system and ensure continuous improvement of the CM processes.

**ISO / USFDA Regulatory Document Control Requirements**:

the vast majority of ISO requirements are configuration requirements

. Companies that are certified written standards and follow them to a degree accepted by an ISO cerfier.

Bellow are some regulatory document control requirement’s;

1. Process approach
2. Identify the process you are going to be dealing with
3. Improving on the version
4. There should be improved format
5. You must keep periodic check of your documents control
6. Protect document information
7. Confidentiality
8. Proactively manage access retention and disposition of obsolete documented information.

**USFDA Regulatory Document Control Requirements:**

1. **There must be pre=approval of documents.**
2. **Approval of changes and changes that are to the documents.**
3. **There must be identifications numbers, date, version.**
4. **Document must have history of change.**

**Manual Document Control System Versus Electronic Document Control System**

1. **Wet ink signature approval**
2. **Metrological and artifact control system**
3. **Printed documents are stored in a filling cabinet**
4. **Manual system depends on man arrangement**
5. **Know backup of documents**
6. **It requires more personnel**

**Electronics Document Control System**

1. **Installation of software**
2. **Lower overall cost**
3. **Less personnel**
4. **It can be protected by backup**

**DAY THREE**

Documents Control Management System.

All document information control system is the foundation of a quality management system. It is the first quality system element that must be implemented because of the establishment and control of documented process and information inequality controlled environ is dependent on the ability to pro=actively manage access to document and the movement of documents through the document lifecycle.

DOCUMENT MANAGEMENT VERSUS DOCUMENT CONTROL

* Document management simple file structure that people establish on their personnel computer tom organize and redrive documents that can be considered as basic document management system.
* This basic document organization method allows the user to name group documents making them easier to locate identification and redrive
* Share point is a commonly used document management tools that enables multiply users to set up shared folders to organize and redrive documents
* How ever document management strategies do not compromise a document control system from an ISO or USFDA regulatory perspective since the simple act of organizing documents promote standardization in terms of format and music content providing management of the document throughout its lifecycle.

DOCUMENT CONTROL SYSTEM

* A document control system establishes a document lifecycle for some business document, and a document management strategy may be sufficient.
* But when it comes to documents, that impact customer satisfaction quality of products and quality system management the document control system is required.

**BENEFITS OF DOCUMENT CONTROL SYSTEM**

1. **Improving knowledge retention and knowledge transfer within and across business units**
2. **Improve access to knowledge-based information**
3. **Improve employee performance by providing standard processes and communicating clear expectations**
4. **Improving customers communication and satisfaction by providing document information from which common understanding can be archived.**
5. **Providing trace ability of activities and documentation throughout the organization**
6. **Improving organization of an access to documents and data.**

**CONTROLLED DOCUMENT POLICY / PROCESS**

**The following document depicts a representation policy for a controlled docm**

**ent process. The document identification represents the following document identification characteristics.**

* **POL: INDICATES DOCUMENT -TYPE**
* **DOC: INDICATES DOCUMENTS -SUBJECT**
* **O1 : INDICATES SERIES -SERIES**

**Controlled document policy also covers the following:**

1. **Purpose**
2. **Scope**
3. **Roles and Responsibilities**
4. **Reference Related Document**
5. **Exceptions**
6. **Quality Records**
7. **Document History**

**DOCUMENT CONTROL LIFECYCLE**

**Controlled document exists within a defined controlled document lifecycle. The following are the primary steps in the controlled document lifecycle:**

* **Writing documents**
* **Review of draft documents**
* **Approval of draft documents, resulting in controlled documents**
* **Access and use of controlled documents**
* **Periodic review of controlled documents**
* **Revision of controlled documents if necessary**
* **Retirement of controlled documents**
* **Archiving of controlled document.**