



ESTABLISHING AND MAINTAINING A DOCUMENTED INFORMATION SYSTEM ACCORDING TO ISO 9001:2015 QMS REQUIREMENTS



May 13-14, 2026 (Wednesday-Thursday)
8.45 am – 5.00 pm **FMM Institute, Perak**

This training provides a focused and practical introduction to the critical role of **documented information** as the backbone of an effective **Quality Management System (QMS)** in accordance with **ISO 9001:2015** requirements. Participants will gain a clear understanding of how documented information supports process consistency, operational control, evidence-based decision-making, and continual improvement across the organization.

A key emphasis of the course is to clarify the **often-misunderstood distinction between “maintaining” and “retaining” documented information** as mandated by ISO 9001:2015. Through structured explanations and real-world examples, the training explains what information must be created, updated, controlled, and preserved to demonstrate conformity and ensure effective process implementation—without over-documentation.

By the end of this training, participants will be better equipped to design and manage a documented information system that not only fulfills ISO 9001:2015 requirements, but also adds real value to organizational performance, audit readiness, and long-term sustainability.

...COURSE CONTENTS...

MODULE 1 : INTRODUCTION

- SM1.1 – Overview QMS
- SM1.2 – Quality management principles
- SM1.3 – Core roles in a documented information
- SM1.4 – Concepts of documented information

MODULE 2 : CLAUSES REQUIREMENTS FOR DOCUMENTED INFORMATION

- SM2.1 – Clause 4 : Context of organization
- SM2.2 – Clause 5 : Leadership
- SM2.3 – Clause 6 : Planning
- SM2.4 – Clause 7 : Support
- SM2.5 – Clause 8 : Operation
- SM2.6 – Clause 9 : Performance evaluation
- SM2.7 – Clause 10 : Improvement

MODULE 3 : QMS DOCUMENTATION STRUCTURE

- SM3.1 – Documentation hierarchy levels
- SM3.2 – Process approach
- SM3.3 – Interaction between hierarchy & processes
- SM3.4 – Document – process matrix

MODULE 4 : CREATING & UPDATING DOCUMENTED INFORMATION

- SM4.1 – Foundation of documented information
- SM4.2 – Identification and description
- SM4.3 – Format and media
- SM4.4 – Review and approval

MODULE 5 : CONTROL OF DOCUMENTED INFORMATION

- SM5.1 – Required outcomes

- SM5.2 – Distribution, access, retrieval and use
- SM5.3 – Storage and preservation
- SM5.4 – Control of changes
- SM5.5 – Retention and disposition

MODULE 6 : MAINTAINING & CONTINUALLY IMPROVING THE DOCUMENTED INFORMATION SYSTEM

- SM6.1 – Period review of documented information
- SM6.2 – Internal audit technique for documentation
- SM6.3 – Updating after process changes
- SM6.4 – Simplifying overly complex SOPs
- SM6.5 – Lean documentation principles

...TRAINER...

MS ERICA CHONG MEI KUEN is an accredited trainer with extensive experience in manufacturing operations, quality management systems, and organisational development. With over 20 years of professional expertise, she has successfully developed, implemented, and monitored impactful operational strategies and training programmes that drive efficiency, compliance, and employee engagement. Her specialisations include Hazard Analysis and Critical Control Points (HACCP), Good Manufacturing Practices (GMP), ISO 9001 Quality Management System (QMS), internal auditing, and scheduled waste management. Erica is also skilled in leadership, communication, and team building, making her training sessions both practical and engaging.

Previously, serving as Plant Manager at B Plus Q Sdn Bhd for nearly two decades, she oversaw end-to-end operations across multiple departments, ensuring high standards of productivity and quality compliance. She has also held the role of Deputy QMR at Agensi Pekerjaan Philimore Sdn Bhd, where she contributed to ISO system development and auditing processes. Fluent in English, Malay, and Mandarin, Erica is well-equipped to deliver training to diverse audiences. She holds a Professional Degree in Chartered Secretaries and Administrators (MAICSA) and an Advanced Diploma in Commerce (Business Management) from Tunku Abdul Rahman College (TARC). Her mission as a trainer is to empower organisations with the knowledge, tools, and skills needed to achieve operational excellence and sustainable success.

...OBJECTIVES...

- Identify the mandatory and required documented information under ISO 9001:2015
- Understand the types of documentation necessary for an effective Quality Management System
- Establish efficient procedures for document approval, review, and updating
- Implement effective controls to manage documented information
- Develop a robust system for the identification of quality records
- Manage the storage, protection, retrieval, and retention of quality records
- Ensure proper disposition and disposal of obsolete or retained quality records

...WHO SHOULD ATTEND...

Quality representatives, document controllers, process owners and records management personnel who are directly involved in the creation, control and upkeep of the QMS documentation.

...TRAINING METHODOLOGY...

This highly interactive methodology combines instructor-led explanations and step-by-step guidance on developing a functional document control procedure.

Closing Date: MAY 6, 2026

...COURSE DETAILS...

Date **May 13-14, 2026 (Wednesday-Thursday)**
Time **8.45am - 5.00pm**
Venue **FMM Institute Perak**
No 1, Lorong Raja DiHilir, 30350 Ipoh, Perak
Medium of Instruction **English**
CPD **14 hours**
Fees **Members RM1,134.00/pax**
 Non-Members RM1,296.00/pax
(Fees inclusive of Service Tax at 8%, Course Materials, Refreshment, Lunch and Certificate of Attendance)

...ADMINISTRATIVE DETAILS...

HRD CORP CLAIMABLE COURSE DETAILS

- Training Provider: **FMM Institute Perak** ■ MyCoID : **475427W_PERAK**
- HRD Corp Programme No: **Provided upon confirmation**

DISCLAIMER

The FMM Institute reserves the right to change the facilitator, date and to vary / cancel the course should unavoidable circumstances arise. All efforts will be taken to inform participants of the changes.

REGISTRATION

- Upon **Faxing/Mailing** the completed **Registration Form** to FMM Institute, you are **deemed** to have read and **accepted** the terms and conditions. The **course** would also be **deemed** as **confirmed** unless informed otherwise.
- Will be based on First-Come-First served basis.

PAYMENT

- **Cheques** made in favour of "FMM Institute" should be forwarded to FMM Institute Perak.
- For HRD Corp Claimable Course, an **Attendance of 100% is a must**, in any case, **employers will be billed in full**.
- FMM Institute SST Registration No. **W10-1901-32000105**
- FMM Institute TIN No. **C10626805080**

CANCELLATION

Must be in Writing with Reasons ■ 7 days before the course – No payment charged ■ 3 – 6 days before the course - 50% payment charged ■ < 3 days before the course – Full payment charged ■ Participants who did not turn-up will be charged full payment ■ Replacements can be accepted at no additional cost.

~ Registration Form ~

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FMM Institute

No 1, Lorong Raja DiHilir, 30350 Ipoh, Perak

Fax: 05-5488221

Dear Sir / Madam, please register the following participant(s) for the above programme.

1.	Name	Designation	
		HP No	
	NRIC	Email	
2.	Name	Designation	
		HP No	
	NRIC	Email	
3.	Name	Designation	
		HP No	
	NRIC	Email	

(Please attach a separate list if space is insufficient)

We hereby confirmed that *(Please tick (✓) in appropriate box):-*

- We **will be claiming from HRD Corp** and full payment would made to FMM Institute in the event that no disbursement from HRD Corp under any circumstances
- We will **NOT BE CLAIMING from HRD Corp**. Enclosed cheque/bank draft No _____ for RM _____ being payment for _____ participant(s) made in favour of the "FMM Institute".

Submitted by:

Name:	Designation:	
Company:	Tel:	Fax:
Address:		
Email:	FMM Membership No	