I know it can be daunting when looking for information about ISO 9001:2015 certification including understanding the process, what options are available & what resources you need, so we have created this FREE implementation guide to assist you!

Comply Guru offers consulting solutions for small to medium sized businesses who are interested in obtaining their first ISO 9001:2015 Certification. We will assist your organization in designing & implementing a lean & simple Quality Management System that will not just obtain ISO 9001:2015 Certification but lay the foundations for future improvement & growth.

If you still have any questions or would like to setup a FREE consultation or quotation, get in touch with us today as we would be delighted to hear from you.

Eoin Philip Kelly
Founder & CEO
With over 1 million certificates issued worldwide, ISO 9001:2015 is the world’s most widely used Quality Management System (QMS). It has been adopted by organizations in a wide range of industry sectors including but not limited to: Manufacturing, Construction, Engineering, Electrical, Metal production, Chemicals, Information Technology, Health care services, Logistics and Distribution, Aerospace etc.

The requirements of ISO 9001:2015 are based on the 7 principles of quality management, which form the foundation of performance improvement:
ISO 9001:2015 contains 10 clauses, the requirements that need to be addressed when implementing a QMS are outlined in clauses 4 to 10.

4 CONTEXT OF THE ORGANIZATION
- Understanding the organization and its context
- Understanding the needs and expectations of interested parties
- Determining the scope of the quality management system
- Quality management system and its process

5 LEADERSHIP
- Understanding the organization and its context
- Leadership and commitment
- Quality policy
- Organizational roles, responsibilities and authorities

6 PLANNING
- Actions to address risks and opportunities
- Quality objectives and planning to achieve them
- Planning of changes
- Awareness

7 SUPPORT
- Resources
- Competence
- Communication
- Documented information

8 OPERATION
- Operational planning and control
- Requirements for products and services
- Design and development of products and services
- Production and service provisions
- Release of products and services
- Control of nonconforming outputs

9 PERFORMANCE EVALUATION
- Monitoring and measurement, analysis and evaluation
- Audits
- Management reviews
- Continual improvement

10 IMPROVEMENT
- General
- Nonconformity and corrective action

THE TEAM

Eoin Philip Kelly
Founder & CEO
Eoin founded Comply Guru & executive manages the day-to-day running of the company. He previously spent the last 12.5 years as a Director, President & Chief Operations Officer in a leading consulting & training provider, including over 6 years based in Chicago, IL.

Breda Kearney
Quality Director
Breda joined in January 2019. She has over 10 years’ experience in the Quality and Food Safety Industry. Breda oversees the development of our online course library and is responsible for managing our Quality Management System.

Will Hurley
Digital Marketing & Graphic Design Manager
Will joined in March 2018. He has over 8 years experience in Website & Graphic Design and oversees Digital Marketing, Graphic Design & eLearning Content Development within Comply Guru.

Comply Guru™ are proud to announce we are now a CQI and IRCA Approved Training Partner (6081148)

The Chartered Quality Institute (CQI) is the only chartered professional body dedicated entirely to quality. International Register of Certificated Auditors (IRCA) is its specialist division dedicated to management system auditors. As a CQI-IRCA Approved Training Partner, you can be assured that Comply Guru™ has met the highest standards through a rigorous assessment process and can be trusted to design and deliver effective training courses that meet the needs for quality and auditing professionals worldwide.

CQI and IRCA members are part of a unique global network of nearly 20,000 quality professionals. The International Register of Certificated Auditors (IRCA) is a globally renowned register of over 11,000 quality auditors. IRCA auditors are held in esteem by the profession and industry alike.
12 Key Steps for Successful Implementation of ISO 9001:2015

1. Understand ISO 9001:2015 Standard Requirements
2. Top Management Engagement
3. Assemble Project Team and Create Project Plan
4. Design and Develop QMS
5. Provide Quality Awareness Training
6. Implement QMS
7. Internal Audit
8. Management Review
9. Stage 1 Certification Audit
10. Stage 2 Certification Audit
11. Continually Improve QMS
12. Surveillance Audits

START
Understand ISO 9001:2015 Standard Requirements
Implementation of ISO 9001:2015 is a strategic decision and may be driven by a desire to improve performance or by customer demand. It’s important that the requirements of the standard are understood from the outset, as this will enable the organization to develop an effective implementation plan which ensures that all requirements of the standard are addressed.

Top Management Engagement
Top management support and engagement is essential for successful implementation of ISO 9001:2015. It is also a mandatory requirement of the standard. Therefore, it’s important that the top management team understand their important role and responsibilities both during implementation and post certification. Top management also need to be aware of the resource requirements and costs involved.

Assemble Project Team and Create Project Plan
The project team are responsible for implementing ISO 9001:2015 and will be led by the project lead. The project lead is responsible for developing the implementation project plan: Details the tasks to be completed, timelines and assigned responsibilities. To successfully implement the project plan, it is important that all members of the project team have a good understanding of the requirements of ISO 9001:2015.

See page 15 for an important note on Employee Involvement
Design and Develop QMS
Design and development of the QMS is the most resource-intensive stage and must be carefully managed by the project lead as it requires input from all process owners, top management, employees and other relevant stakeholders. It is critical during this step, that all applicable requirements of ISO 9001:2015 are addressed but care must be taken to ensure that the QMS aligns with the business needs.

Provide Quality Awareness Training
On completion of the design and development of the QMS, awareness training on the different elements of the QMS should be provided to all employees, including how it might affect their work and the location and use of documents that they may need. Awareness training will help to foster motivation and engagement with the QMS. The internal auditors should also be selected and arrangements made for internal auditor training.

Implement QMS
Implementation of the QMS, requires all employees including management to follow the documented QMS. In other words: “Do what you say”. During implementation, records and other data will be generated and analysis performed to evaluate QMS performance. Changes to the QMS are often requested during implementation, but these should be noted and the QMS allowed to operate for a number of months prior to making any changes.

Internal Audit
Internal audits are an important tool for identifying weaknesses in the QMS, which can be acted upon to continually improve performance. The purpose of the internal audits is to ensure that each QMS process is effectively implemented and maintained, policies, procedures and other QMS documentation are adhered to, and that the QMS conforms to the applicable requirements of ISO 9001:2015.

Management Review
The management review provides top management with the opportunity to evaluate the QMS to ensure that it is effective and is aligned with the strategic direction. It provides an opportunity to identify if any additional resources are required, opportunities for improvement or if changes to the QMS are needed.

Stage 1 Certification Audit
The certification process involves 2 audits: stage 1 and stage 2. For stage 1, the chosen certification body auditors will review the documented QMS to verify that all applicable requirements of ISO 19001:2015 have been addressed by the company. The auditors may raise “Areas of Concern” which indicate a gap in the QMS which must be addressed using the corrective action system prior to the stage 2 audit.
Stage 2 Certification Audit
For stage 2, the auditors will verify that the QMS is effectively implemented. Typically, this will involve review of records, data, information and other documentation, interviews with employees, observations of work being performed etc. Identified non-conformities must be addressed using the corrective action system prior to granting of certification. Once certification has been granted, the company will receive their certificate which is valid for a period of 3 years.

Continually Improve QMS
Post certification, the effectiveness of the QMS must be continually improved. This is achieved by monitoring QMS performance through data analysis and evaluation, the internal audit system and the management review. System weaknesses should be addressed through the corrective action system and changes made as appropriate.

Surveillance Audits
On a pre-defined schedule (typically once a year), the certification body auditors will visit and conduct a surveillance audit. The purpose of the surveillance audit is to sample the QMS and verify ongoing conformance and continual improvement.

Step 3: Important note on Employee Involvement
As the QMS encompasses all parts of the business, it’s important that all employees are informed of the business reasons for adopting ISO 9001:2015, what is expected from them during the implementation project, the ongoing status of the project and that any concerns are alleviated. Lack of communication and awareness may become an obstacle to implementation due to lack of employee support and engagement with the QMS.

Step 4: Important note on Procedures and Work Instructions
Procedures and work instructions are an important element of any QMS, but they should only be created where they add value. Often there is a large focus on generating a large amount of procedures and work instructions, but this is resource intensive and often takes precedence over other critical elements of the QMS. On the other hand, too few procedures and work instructions may result in work being performed incorrectly.
Comply Guru™ consulting services are ideal for any company that is looking for an expert to lead and manage their ISO 9001:2015 implementation project through to certification.

- Consultant-led Project
- Gap Analysis Included, if required
- Key Knowledge Transfer between Consultant & Customer Included
- Remote & Onsite Support Included
- Documentation Templates Included [tailored to each customer]
- Online Leadership, Requirements & Internal Auditing Training Included
- Coaching & Mentoring Included
- Onsite Internal Audit & Hosted Management Review Included
- 3 Month/90-day Project [can vary based on client needs]
- Main Goal is to implement a Lean, Simple & Effective Quality Management System

Our Consultants come from a rich consulting background to offer you their experience at affordable rates. We can tailor our support based on your needs so whether you prefer to be guided through the process or need a more hands-on approach - we can help!

**Consulting Services**

- **Lean & Simple Design**: We know this will be your first ISO Certification. So it’s important that we keep things lean & easy for you to follow and maintain!
- **Great Customer Service**: All our clients will benefit from access to our great customer service during & after the ISO Consulting Project.
- **Maintenance Program**: We offer an optional service to assist our clients continue with the successful maintenance of their Management System.

Schedule a FREE consultation today!

Contact us today where we can schedule a FREE initial consultation with one of our Quality Experts! We would love to hear from you!

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ONLINE ISO 9001:2015 TRAINING COURSES

**Online ISO 9001:2015 Requirements Training**

This online course is ideal for anyone looking to gain a comprehensive understanding of the core requirements of ISO 9001:2015. Check out our free introduction course on ISO 9001!

- **6.5 Hours**
- **Price:** €195

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**Blended ISO 9001:2015 Internal Auditor Training**

This blended course (online & classroom) is ideal for anyone that has a basic understanding of Quality Management Systems (QMS) and the requirements of ISO 9001:2015 and needs to perform an internal audit of part of their organizations QMS.

Did you know? This course is delivered both online & in a classroom. Each learner must complete a 5.5hr online training course before attending a classroom-based 1-day skills-based training session. The major benefit to this approach is that it offers each Learner the flexibility to learn at their own pace and reduce the overall time spent in a classroom!

- **16 Hours**
- **Price:** €495 €395

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**Blended ISO 9001:2015 Lead Auditor Training**

This blended course (online & classroom) is ideal for anyone that has a good understanding of Quality Management Systems (QMS) and the requirements of ISO 9001:2015 and wants to gain the knowledge and skills required to perform first, second and third-party audits of quality management systems against ISO 9001:2015, in accordance with ISO 19011:2018 and ISO/IEC 17021-1:2015.

Did you know? This course is delivered both online & in a classroom. Each learner must complete a 12hr online training course before attending a classroom-based 3-day skills-based training session. The major benefit to this approach is that it offers each Learner the flexibility to learn at their own pace and reduce the overall time spent in a classroom!

- **40 Hours**
- **Price:** €1195 €995

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**Online ISO 9001:2015 Requirements Training**

- **6.5 Hours**
- **Price:** €195

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**Online Quality & ISO 9001:2015 Training Subscription**

Welcome to the future of Quality Training! Now available is a world-first online quality training subscription service giving each Subscriber access to a library of online ISO 9001:2015 & related courses under a single, affordable subscription.

Check out our website to find out more: [www.complyguru.ie](http://www.complyguru.ie)
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