

QUICK REFERENCE GUIDE

Quality management systems – Requirements (ISO 9001:2015)

INTRODUCTION

By specifying requirements for a quality management system, ISO 9001:2015 enables organisations to demonstrate their ability to provide products and services that consistently meet the requirements both of customers and of applicable regulations.

Ideagen's Q-Pulse quality management system (QMS) solution helps organisations worldwide gain and maintain ISO 9001:2015 certification by:

- Releasing resources to help improve the quality of products and services
- Verifying competence of management and staff on a regular basis
- Demonstrating compliance with ISO 9001 to assessors on demand



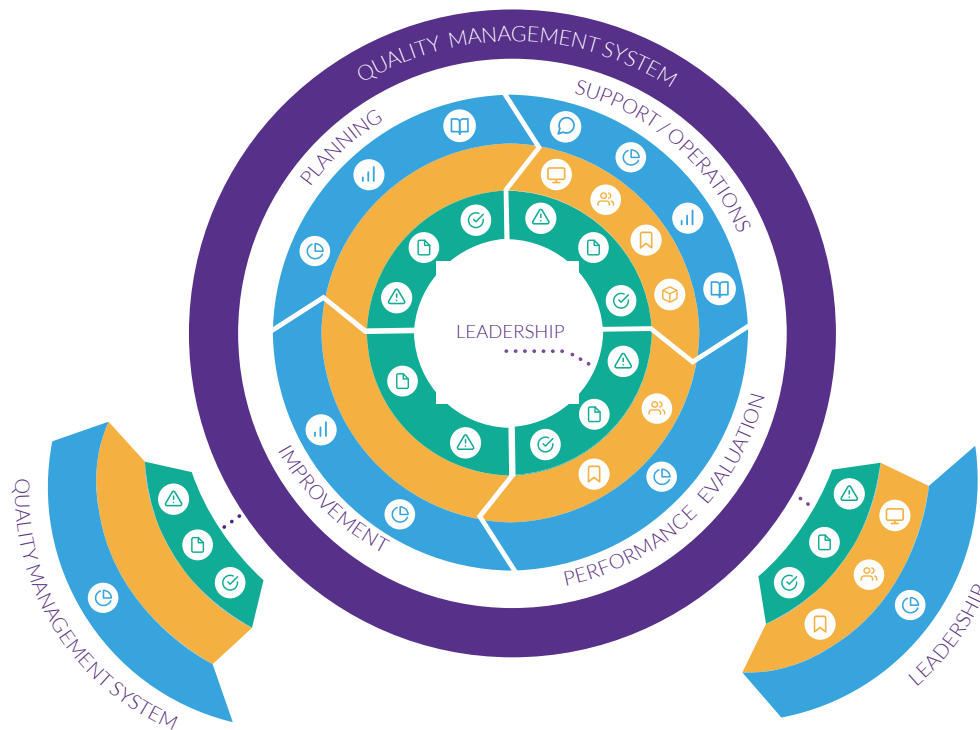
Quality and Safety Management Solution

HOW TO USE THIS GUIDE

This quick reference guide shows how Q-Pulse can help organisations implement a QMS that demonstrates conformity to the specified requirements of ISO 9001:2015. The guide lists the standard's clauses and subclauses and details the modules of Q-Pulse appropriate to each.

This guide also supplements our ISO 9001:2015 quick reference chart, which shows the relevant Q-Pulse modules against the Plan-Do-Check-Act cycle and the clauses and subclauses it's associated with.

Q-PULSE FOR ISO 9001



DOCUMENTATION

Define and document the scope of your system, policies and procedures, all with robust document control



AUDITS

Verify policies and procedures through regular internal audit and demonstrate compliance of systems with requirements



NON-CONFORMITIES

Capture and analyse incidents, non-conformities and complaints, create action plans and track through to completion



EQUIPMENT

Track and monitor calibration, maintenance and safety tests to achieve a higher standard of equipment control



TRAINING & COMPETENCE

Maintain and improve competence with a flexible framework to monitor and analyse staff training and development



CUSTOMERS

Record and investigate complaints from customers and stakeholders to ensure action can be taken to resolve



SUPPLIERS

Monitor and evaluate the performance of external providers, including processes, products and services, to ensure quality



REPORTING

Report and classify incidents, accidents and near-misses, including equipment, hardware and software



MESSAGING

Provide point-of-need access direct from email notification of overdue or outstanding activities to accelerate completion of actions



ANALYSIS

Analyse corrective and preventive actions, incidents and audit findings to ensure quality can be continually improved



WORKLOAD

Track and monitor quality actions to encourage greater staff commitment, motivation and participation















4 Context of the organisation

4.1 Understanding the organisation and its context		 
4.2 Understanding the needs and expectations of interested parties		
4.3 Determining the scope of the quality management system		 
4.4 Quality management system and its processes	4.4.1	   
	4.4.2	









5 Leadership

5.1 Leadership and commitment	5.1.1 General	    
	5.1.2 Customer focus	    
5.2 Policy	5.2.1 Establishing the quality policy	 
	5.2.2 Communicating the quality policy	
5.6 Organisational roles, responsibilities and authorities		    

6 Planning






6.1 Actions to address risks and opportunities	6.1.1	 
	6.1.2	   
6.2 Quality objectives and planning to achieve them	6.2.1	    
	6.2.2	
6.3 Planning of changes		 

7 Support









































7.1 Resources	7.1.1 General	
	7.1.2 People	   
	7.1.3 Infrastructure	
	7.1.4 Environment for the operation of processes	  

ISO 9001:2015			Q-Pulse
	7.1.5 Monitoring and measuring resources	7.1.5.1 General	 
		7.1.5.2 Measurement traceability	   
	7.1.6 Organisational knowledge		   
7.2 Competence			  
7.3 Awareness			 
7.4 Communication			 
7.5 Documented information	7.5.1 General		       
	7.5.2 Creating and updating		
	7.5.3 Control of documented information	7.5.3.1	
		7.5.3.2	

8 Operation








































8.1 Operational planning and control	    
--------------------------------------	---

KEY:  Documents  Audit  Non-conformities  Equipment  Training  Suppliers  Customers  Reporting  Messaging  Analysis  Workload  People  Administration

ISO 9001:2015		Q-Pulse
8.2 Requirements for products and services	8.2.1 Customer communication	   
	8.2.2 Determining the requirements for products and services	
	8.2.3 Review of the requirements for products and services	    
	8.2.3.1	
	8.2.3.2	
8.3 Design and development of products and services	8.2.4 Changes to requirements for products and services	   
	8.3.1 General	
	8.3.2 Design and development planning	  
	8.3.3 Design and development inputs	  
	8.3.4 Design and development controls	   
	8.3.5 Design and development outputs	
	8.3.6 Design and development changes	   
8.4 Control of externally provided processes, products and services	8.4.1 General	    
	8.4.2 Type and extent of control	    

KEY:  Documents  Audit  Non-conformities  Equipment  Training  Suppliers  Customers  Reporting  Messaging  Analysis  Workload  People  Administration



ISO 9001:2015		Q-Pulse
	8.4.3 Information for external providers	    
8.5 Product and service provision	8.5.1 Control of production and service provision	     
	8.5.2 Identification and traceability	  
	8.5.3 Property belonging to customers or external providers	    
	8.5.4 Preservation	 
	8.5.5 Post-delivery activities	   
	8.5.6 Control of changes	   
8.6 Release of products and services		  
8.7 Control of non-conforming outputs	8.7.1	 
	8.7.2	    

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation	9.1.1 General	    
	9.1.2 Customer satisfaction	   
	9.1.3 Analysis and evaluation	 

KEY:  Documents  Audit  Non-conformities  Equipment  Training  Suppliers  Customers  Reporting  Messaging  Analysis  Workload  People  Administration



ISO 9001:2015		Q-Pulse
9.2 Internal audit	9.2.1	
	9.2.2	
9.3 Management review	9.3.1 General	
	9.3.2 Management review inputs	
	9.3.3 Management review outputs	

10 Improvement

10.1 General		
10.2 Nonconformity and corrective action	10.2.1	
	10.2.2	
10.3 Continual improvement		

KEY: Documents Audit Non-conformities Equipment Training Suppliers Customers Reporting Messaging Analysis Workload People Administration

For more on how Q-Pulse can help your organisation gain and maintain ISO 9001:2015 certification, contact us now:

 info@ideagen.com

 +44 (0) 1629 699 100

 www.ideagen.com/ISO-9001