The PROGRAM of Quality Management System (QMS) Development, Implementation and Preparation for ISO 9001:2015 Certification

Phase #	Phase Title and Content of Activities	Deadline (time frame)	Recommendations
1	**QMS development**	**5-6 months**	
1.1	• Initial audit of the organization • Evaluation of existing management system 'As-is'		During the Initial audit assess the following: a) definition of the structure; b) processes definiteness and inter relationship; c) management, technology, and design documentation availability, completeness and structuring; d) the adequacy and control of resources.
1.2	• Definition of QMS Processes and their Owners. • Forming of the QMS development team. • Executive's order for QMS development.		The following **QMS processes** can be accepted as the base: - 'Management review' (cl.5; 9.3 ISO 9001:2015); - 'Actions to address risks and opportunities' methodology (cl. 6.1); - 'Control of personnel' (cl.7.1.2; 7.2); - 'Technical support' (cl.7.1.3.b); - 'Control of monitoring and measuring resources' (cl.7.1.5)

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			- 'Internal communication' (cl.7.3); - 'Control of documented information' (cl.7.5.2; 7.5.3); - 'Marketing activity' (cl.8.2.1.a); - 'Contract analysis' (cl.8.2.1.b; 8.2.1.d; 8.2.2; 8.2.3); - 'Customer communication' (cl.8.2.1.c); - 'Design and development of products and services' (cl.8.3); - 'Control of external providers of products and services' (cl.8.4); - 'Production and service provision' (cl.8.5.1; 8.5.2; 8.5.3; 8.5.4; 8.6); - 'Post-delivery activity' (cl.8.5.5); - 'Control of nonconforming process outputs, products and services' (cl.8.7); - 'Internal Audit' (cl.9.2); - 'Corrective action' (cl. 10.2) **QMS development team** should include: - quality manager representative; - process owners; - coordinators (employees who are responsible for QMS operating state maintenance, for example, Quality control and Audit department employees).

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			QMS Development Order: - appoints Quality Manual representative; - establishes actions for the QMS development (this ***Program*** can be used as a basis); - assigns Team members responsibilities and authorities; - establishes the development stages periods and deadlines.
1.3	ISO 9001:2015 QMS Development team training.		It is a good practice to have a 24-hour training course. Quality management representative or the external consultant can provide the training.
1.4	Development of the Organization's • Mission • Strategy • Quality Policy • Quality Objectives		ISO 9001:2015 does not require the Organization to have a mission, this is - a good practice. It is beneficial to include Mission into the Quality policy rather than having it as a separate document. The presence of Strategic direction is determined by the requirements of clause. 5.1.1.b, 5.2.a. The requirements for Quality policy and objectives are set out in separate clauses of ISO 9001:2015 - 5.2 and 6.2 respectively.
1.5	QMS Processes development		In QMS processes development, it is expedient to use the Process approach implementation steps (cl.4.4 ISO

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			9001:2015): - [Definition of processes - performed at step 1.2 of the program]; - Process models development; - Linking process models in the Organization's business model; - Processes criteria definition; - Ensuring monitoring, measurement, analysis and evaluation; - Processes to improvement mechanisms development.
1.6	Development of the first edition of the backbone of the Organization's standards.		A list of QMS Processes documented procedures (outlined in sec.1.2 of this document) can be set as a basis. It is acceptable to reduce the number of documented procedures giving detailed description of the processes in the corresponding section of the Quality Manual (QM).
2	**QMS Implementation**	**4 - 5 months**	
2.1	Employees training		A good practice is to include in the training program: - A short course on the ISO 9001:2015 requirements (each employee should comprehend the structure of the Standard to understand the Quality policy and his/her

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			place in the QMS); - Control of documentary information. - 7 Quality Management Tools (with practical illustration of monitoring, measurement, analysis, and evaluation implementation in his/her own process); - Risk management (rather simple methods based on expert evaluation). Training may be conducted by the QMS Development team members.
2.2	Validation and approval of system QSP		It is important to involve all QSP users in the validation and get proposals for corrections from them.
2.3	Checking the third level QMS normative documentation.		The following is attributed to the QMS third level normative documents: - Subdivisions provisions, - Job descriptions, - Operating procedures, and others. At this point, link the existing QMS third level normative documents to the QSP and develop the missing documents.
2.4	'Quality Manual' Development		

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3	**QMS certification preparation**	**2 - 4 months**	
3.1	QMS Internal auditors training		
3.2	Conducting of internal preliminary audit		This Program sections 3.2 and 3.3 activities can be conducted 2-3 times until the Leadership understands that the QMS is functioning well and the decision to enter into a contract with the Certification body is made.
3.3	Corrective actions based on the internal audit results.		
3.4	Signing a contract with the Certification body.		
3.5	Conducting of Certification audit and nonconformities elimination.		

Related ISO 9001:2015 Documents and Templates

ISO 9001:2015 Quality Manual Template

Set of 6 Essential Quality System Procedures

ISO 9001:2015 Audit Checklist

ISO 9001:2015 Overview Presentation for Training

Full list of ISO 9001:2015 Documents and Templates