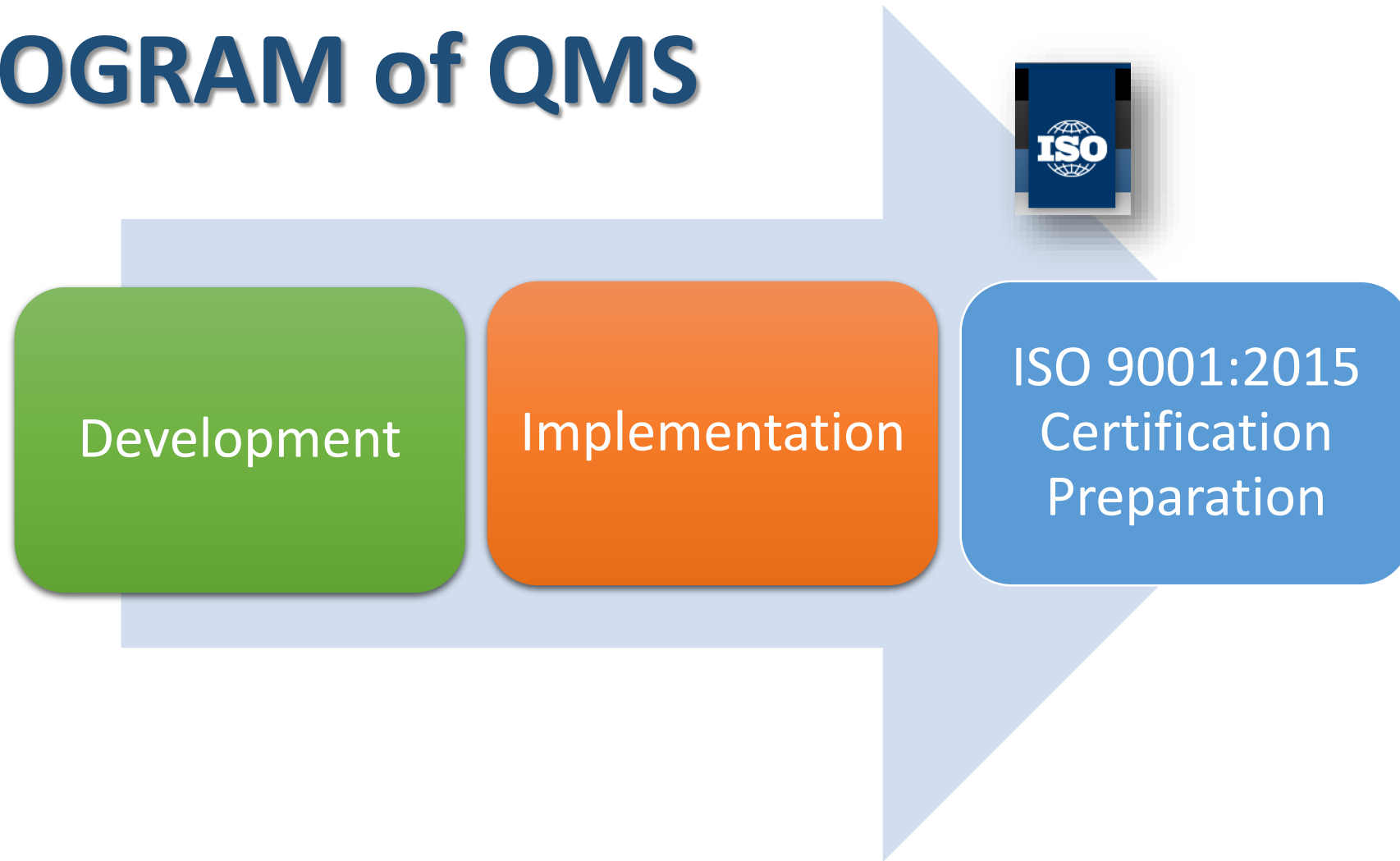
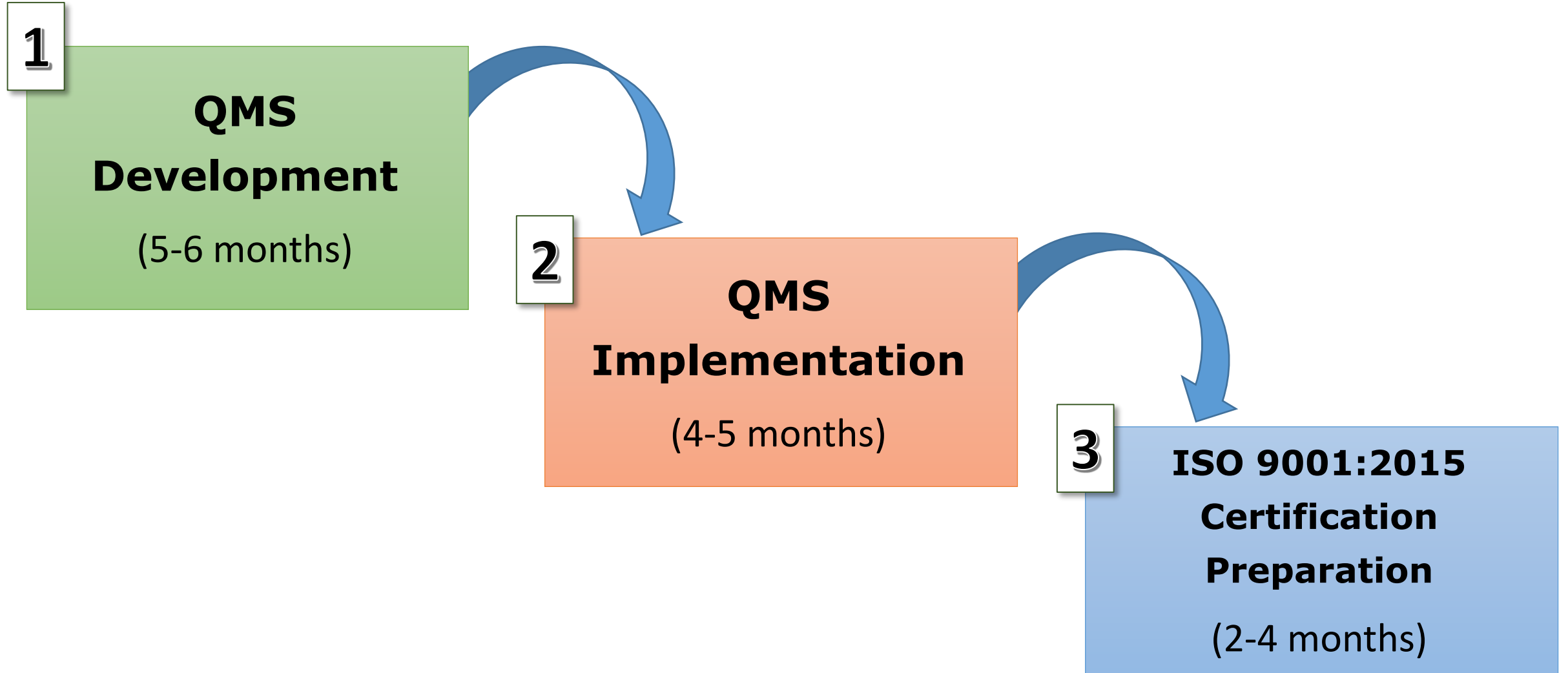


The PROGRAM of QMS



QMS Program



1. QMS Development

1.1

Content of Activities

- Initial audit of the organization
- Evaluation of existing management system 'As-is'



Recommendations

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. QMS Development

1.2

Content of Activities

- Definition of QMS Processes and their Owners.



Recommendations

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);
- '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)

1. QMS Development

1.2

Content of Activities

- Forming of the QMS development team



Recommendations

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).

1. QMS Development

1.2

Content of Activities

- Executive's order for QMS development



Recommendations

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. QMS Development

1.3

Content of Activities

- ISO 9001:2015 QMS Development team training



Recommendations

It is a good practice to have a [24-hour training course](#). Quality management representative or the external consultant can provide the training.



1. QMS Development

1.4

Content of Activities

Development of the Organization's

- Mission
- Strategy
- Quality Policy
- Quality Objectives



Recommendations

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. QMS Development

1.5

Content of Activities

QMS Processes development



Recommendations

In QMS processes development, it is expedient to use the Process approach implementation steps (cl.4.4 ISO 9001:2015):

- 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. QMS Development

1.6

Content of Activities

Development of the first edition of the backbone of the Organization's standards.



Recommendations

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

2.1

Content of Activities

- Employees training

Recommendations

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.



2. QMS Implementation

2.2

Content of Activities

- Validation and approval of system QSP



Recommendations

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. QMS Implementation

2.4

Content of Activities

- 'Quality Manual'
Development



Quality Manual
Template



3. ISO 9001:2015 Certification Preparation

3.1

Content of Activities

- QMS Internal auditors training

3.2

- Conducting of internal preliminary audit



Recommendations

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. ISO 9001:2015 Certification Preparation

3.3

Content of Activities

- 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](#)

Download the PROGRAM
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Full list of ISO 9001:2015
Documents and Templates