CENTAURI BUSINESS GROUP

Supporting the work of Quality Professionals ™

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A complete set of ISO 9001:2015 Quality System Procedures

- **15** quality system procedures that cover the **major QMS processes**
- Based on the **practical experience**
- Conform to the **requirements of ISO 9001:2015**
- Contain **Process model diagram** with detailed Inputs and Outputs description
- Provide Describe Criteria and Risks
- **User-friendly** format and **professional** layout - **reviewed and approved** by experienced ISO 9001 quality auditors
- **MS Word** - no special software need
- Type of delivery: **Instant download**

Contents

QSP 6.1-01 Actions to Address Risks and Opportunities

The Procedure makes actions to address risks and opportunities a part of decision making on all levels of the Organization and one of the improvement mechanisms of processes and quality management system (QMS).

This procedure covers all processes of QMS and regulates the activity of

- the Organization's Leadership,
- Quality Manager,
- Risk Manager,
- Process Owners,
- Risk Owners,
- experts relevant to risk management.

Actions to Address Risks and Opportunities Quality system procedure:

- Fills the Major gap in ISO 9001:2008 QSM documentation when transitioning to the new version of ISO 9001:2015.
- Based on the practical experience of the Enterprise Risk Management implementation
- Corresponds to the requirements of ISO 9001:2015 and ISO 31000:2009
- Provides detailed description of the distribution of responsibilities and actions to address risks and opportunities, which will facilitate the implementation of the procedure in QMS and Processes.

Template details:

- **17** pages
- PDF **preview**
- More info…

QSP 7.1-01 Control of Personnel

This **Control of Personnel QSP** regulates 'Control of Personnel' process operation aimed at:

- determination of the required competence;
- recruitment, hiring, transfer and dismissal of personnel;
- training, including the QMS awareness;
- evaluation of effectiveness of measures to ensure competence;
- preservation of competence evidence;
- analysis of human resources adequacy, improvement actions.

QSP requirements apply to the activities of human resources department, HR manager, and quality manager, as well as department heads in terms of working with people.

Template details:

- **12** pages
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QSP 7.1-02 Control of Monitoring and Measuring Resources

This Control of Monitoring and Measuring Resources QSP regulates the execution of 'Control of Monitoring and Measuring Resources' process including **definition of the requirements**, ensuring availability and maintenance of the **three components of monitoring and measuring resources**:

- measuring equipment (ME);
- monitoring and measuring methodologies;
- personnel conducting monitoring and measuring.

QSP requirements apply to the activities of

- metrology department;
- owners of quality management system(QMS) processes, where the monitoring and measuring is carried out, including 'Production and service provision' process;
- responsible for monitoring and measuring in QMS processes;
- 'Design and development' process production engineers.

Template details:

- **18** pages
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QSP 7.1-03 Control of Organizational Knowledge

Control of Organizational Knowledge QSP describes the organization activity to implement the **new requirements of ISO 9001:2015** of using the knowledge as a **resource** for the **QMS processes**.

QSP regulates the **implementation of the 'Control of organizational knowledge'** process, which aims at transforming the internally and externally sourced **information flows** into the Organization's **knowledge bank**. The process involves four stages:

- definition of the necessary knowledge;
- creation of the organization knowledge bank;
- maintaining and providing access to knowledge;
- QMS processes improvement through acquired knowledge.

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- **9** pages
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- More info…

QSP 7.5-01 Control of Documented Information

Control of Documented Information QSP establishes a procedure for the creation, approval, revision and control of quality management system (QMS) documented information.

This procedure covers all processes and all parts of the QMS and applies to the following documented information both required by ISO 9001:2015 and determined by the organization as being necessary for the effectiveness of the QMS:

- Quality Policy,
- Quality Objectives,
- Quality Management System Manual (Quality Manual),
- quality system procedures (QSP),
- work instructions,
- documents of external origin,
- records;
- quality system forms (QSF).

Template details:

- **8** pages
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QSP 8.1-01 Marketing

Marketing QSP regulates the operation of the 'Marketing' process in compliance with ISO 9001:2015, and ensures:

a) Relationship with the QMS processes

- 'Management review';
- 'Design and development';
- 'Contract analysis';
- 'Production';
- 'Control of externally provided processes, products, and services';
- 'Control of organizational knowledge'.

b) Relationship with the interested parties:

- Customers;
- Society (contact audiences);
- Suppliers;
- Marketing intermediaries;
- Competitors.

c) Obtaining information for understanding the context of the organization.

d) Creation of a database for obtaining and maintaining of the organizational knowledge.

Template details:

- **19** pages **MS Word** easily editable and customizable **procedure template**
- **PDF preview**
- **Self-calculating** Marketing Efficiency Evaluation **MS Excel** table - ready for use
- More info…

QSP 8.2-01 Contract Analysis

Contract Analysis QSP regulates 'Contract Analysis' process operation aimed at:

- determining requirements for products (services) when preparing the contract draft;
- analysis and ensuring meeting the requirements for products (services) before singing the contract;
- preservation of documented information about any new requirements analysis results;
- making amendments when the requirements for products

QSP requirements apply to the activities of the Sales department, as well as the activity of the '**Design and development**' and '**Production**' process owners of in terms of analysis and meeting the requirements for products (services).

Template details:

- **12** pages
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- More info…

QSP 8.3-01 Design and Development

Design and Development QSP regulates 'Design and development' process execution that provides:

- consideration of the nature, duration, and complexity of design and development activities;
- division of the process into stages, including design and development analysis;
- carrying out design and development verification and validation;
- the level of design and development process control, expected by consumers and other relevant interested parties;
- development of documented information necessary to demonstrate compliance with the design and development requirements;
- control of changes.

Design and Development quality system procedure is focused on Service Provision.

Product design and development recommendations are also provided.

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- **14** pages
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QSP 8.4-01 Control of externally provided processes, products, and services

1) Control of externally provided processes, products, and services QSP regulates the control of external processes, products and services activities, including three categories:

- **Purchase** management - ensuring delivery of products (equipment, raw materials, components, etc.) and services to be included in the Organization's own products and services;
- **Outsourcing** management - interaction with the external providers that perform the process or part of the process for the organization;
- Management of **Supply Chain** on behalf of the Organization, including franchising - interaction with external providers that supply products and services directly to the customer(s) on behalf of the Organization.

2) QSP includes the **original** '**Supplier Evaluation Methodology**' based on **QFD-analysis**.

3) QSP proposes the '**External Provider Efficiency**' **criterion**, which is determined via expert evaluation as a ratio of the supplier actual results and the activities expectations.

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- More info…

QSP 8.5-01 Service Provision

Service Provision QSP regulates 'Service Provision' process execution that provides:

- controlled conditions of service provision, including validation;
- identification and traceability;
- preservation of customer property;
- preservation of service provision process outputs;
- post service provision activity;
- control of changes.

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- **PDF preview**
- More info…

QSP 8.7-01 Control of Nonconforming Outputs

Control of Nonconforming Outputs QSP establishes a procedure for the control and disposition of nonconforming process outputs, to prevent unintentional use or shipment.

This procedure applies to all processes outputs, including nonconforming products and materials detected within Sample Company, whether obtained from vendors, produced in-house, or in company stock.

This procedure is applicable to all employees.

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- **5** pages
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QSP 8.7-02 Control of nonconformities in provision of services

Control of nonconformities in provision of services documented procedure regulates the execution of 'Control of nonconformities in provision of services' process in relation to the QMS of Organizations that specialize in the provision of services.

The Procedure describes the implementation of ISO 9001:2015 requirements, which often cause issues when applied to the services:

- ensuring the identification of nonconformities,
- conducting correction, including the possibility of suspension of the service provision,
- communicating the nonconformity to the customer,
- follow-up, including the analysis.

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- **11** pages
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QSP 9.2-01 Internal Audit

Internal Audit QSP establishes a procedure for conducting periodic internal audits of the quality management system (QMS) to achieve the following objectives:

a) Provide information on whether the QMS conforms to:

- the organization's own requirements for its QMS;
- the requirements of International Standard ISO 9001:2015.

b) Identify undesired effects and ensure their prevention, or reduction.

c) Identify desirable effects and ensure their enhancement.

d) Provide information on whether the QMS is effectively implemented and maintained.

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- **14** pages
- **PDF preview**
- More info…

QSP 9.3-01 Management Review

Management Review QSP establishes a procedure for periodic management review of the quality management system (QMS).

Management review ensure continuing suitability, adequacy, effectiveness of QMS and alignment with the strategic directions of the Organization

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QSP 10.2-01 Corrective Action

Corrective Action QSP establishes a procedure for initiating, assigning, implementing and recording corrective actions (CAR's), aimed at correcting the nonconformities, identifying and removing the causes of nonconformities and the prevention of recurrence of nonconformities in the future.

This procedure applies to all product and process nonconformities whether they are identified in-house or reported by a customer. Corrective actions are applicable to all departments and personnel and may also be directed at external providers of processes, products and services.

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