Requirements for Quality Management Personnel in Healthcare

- *Quality Management Representative in Healthcare (QMR-HC)*
- *Quality Manager in Healthcare(QM-HC)*

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CoS Quality Management Personnel in Healthcare
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Foreword

The European Organization for Quality EOQ, established 1956, is an association under Belgian law of now 58 organizations: National Representatives (European, non-profit quality organizations) and Associated Members, Affiliated Members and Partners worldwide.

The major goal of EOQ is to promote quality in the widest sense.

EOQ National Representatives (Full Member Organizations) are:

AEC (Spain), **AFQP** (France), **AQBIH** (Bosnia & Herzegovina), **APQ** (Portugal), **ARC** (Romania), **Club 9000** (Bulgaria), **CSQ** (Czech Republic), **CYAQ** (Cyprus), **DFK** (Denmark), **DGQ** (Germany), **EAQ** (Estonia), **ECOFIN** (Moldova), **GQF** (Georgia), **HMA** (Greece), **HDK** (Croatia), **HNC** (Hungary), **KOQIM** (Kazakhstan), **Laatukeskus Excellence Finland** (Finland), **Malta Chamber of Commerce and Industry** (Malta), **MLQ** (Luxembourg), **NFKR** (Norway), **NNK** (Netherlands), **QA** (Austria), **Quality Kosova** (Kosovo), **PCBC** (Poland), **RFATRM** (Russia), **SAQ** (Switzerland), **SFK** (Sweden), **SSK** (Slovakia), **SZKO** (Slovenia), **TSE** (Turkey), **UAQ** (Ukraine), **VCK** (Belgium), **YUSK** (Serbia)

EOQ's Personnel Registration Unit has maintained a Harmonized Personnel Registration Scheme since the 80-ies of the last century. Parts of this scheme were and are competence requirements for quality professionals but also for professionals from other fields like environmental management.

This Competence Specification (CoS) describes the areas of knowledge and the competence requirements for the professional profiles of Quality Manager and Quality Management Representative in Healthcare to be effective in their profession.

The CoS is defined and enhanced by the European Organization for Quality (EOQ) based on decades of experience certifying quality professionals. The job profiles and competence requirements have been updated based on a broad analysis of actual needs in the field of quality management related professions in Healthcare including the positions of interested parties.

This document is intended to be a normative reference in conjunction with certification schemes, but may also be used for other purposes by interested parties.

When used as part of a certification scheme, these requirements will be the basis for developing examinations.

This document has been developed under consideration of EOQ internal rules. This Competence Specification has been prepared by the EOQ Technical Working Group and was submitted as Draft for public comment according to the EOQ Rules for Normative Documents.

The Competence Specification has been approved and released for publication by the EOQ General Assembly in place, on 20.02.2014. Queries regarding technical content can be addressed to the EOQ Technical Working Group. Please direct your queries to: eoq@eoq.org

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1 Introduction

The qualification and certification of Quality Management Personnel along standardized schemes has a long tradition in Europe and worldwide. Based on requirements concerning competent personnel related to functions in the quality management system of organizations the need for harmonized training and certification has been raised already in the 1980`s.

In Europe the EOQ has established harmonized competence schemes for Quality and Management personnel with broad acceptance. These EOQ harmonized schemes have been developed by experts from different nations of EOQ.

The main content of this Competence Specification is dealing with the following aspects:

- Definition of job profiles and task descriptions for quality management personnel
- Definition of competence requirements

This Competence Specification is intended to serve amongst others as normative document for the use of training, the definition of competence profiles for quality personnel e.g. in job description and as accreditation basis for personnel certification organizations.

2 Scope and Application

The scope of this Competence Specification is to define the specific competence criteria for

- Quality Management Representative in Healthcare
- Quality Manager in Healthcare

within the countries with National Representative Organisations of EOQ. This does not exclude the usage of these criteria in other countries.

ISO/IEC 17024 applies when using this CoS for personnel certification purposes.

Claims of conformity to this Competence Specification shall not refer to the terms

- EOQ Quality Management Representative in Healthcare
- EOQ Quality Manager in Healthcare

unless the certification procedures comply with the management system documentation and the specific Certification Scheme of the EOQ Personnel Registration Unit.

3 Terms and definitions

- Certification: third party attestation related to products, processes, systems or persons
- Competence: ability to apply knowledge and skills to achieve intended results

  NOTE Ability implies the appropriate application of personal behaviour during the audit process. (ISO 19011:2011)
- Qualification: demonstrated education, training and work experience were applicable

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3.1 References

Applicable documents:

(1) The ISO 9000 family of International Standards
(2) EN 15224
(3) ISO 19011
(4) ISO 17021
(5) ISO/IEC 17024
(6) ISO 17007
(7) The EOQ Personnel Certification Scheme for Quality Management Personnel in Healthcare, EOQ CS Quality Management Personnel in Healthcare, Edition 2014 in combination with the set of EOQ Personnel Registration Unit documents, specific to this scheme.

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4 Job Profiles and Task Description

4.1 Quality Management Representative in Healthcare

EOQ Quality Management Representatives have the knowledge and skills needed to implement and maintain a quality management system on the basis of normative requirements (ISO 9000 and/or EN 15224 series with interfaces to other rules and standards as well as legal requirements). They are able to manage corresponding projects and also to analyse and improve processes of the organisation. They can fulfil the tasks of the "Management Representative" according to ISO 9001 and EN 15224 know the main quality management methods and can apply them within a team. They use their communication skills to come across to internal and external interested parties as a professional, knowledgeable and motivational contact for quality management system issues.

4.2 Quality Manager in Healthcare

EOQ Quality Managers in Healthcare have - in addition to the EOQ Quality Management Representatives in Healthcare - the knowledge and skills needed to develop quality management systems in the direction of sustained business success of the organization. In doing so, they take into account the demands of interested parties, market requirements and the organisation's environment. They know the advanced managerial concepts, help make decisions on their application and implement them in the organisation. Through their understanding of models and systems, they are able to integrate the requirements of different standards into the organizations management system. They can fulfil the tasks of the "Management Representative in Healthcare" according to ISO 9001 and EN 15224 as well as the tasks of an audit programme manager.

Through the application of suitable methods including the application of statistics, they are able to analyse, evaluate and present quality-related data as well as to make them available for decisions. They identify customers' interests and represent them in the organisation. They provide information, advice and training on quality-related issues at all levels of the organisation and promote the implementation of the quality management system.

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5 Competence Requirements

5.1 Personal behaviour and mind set

Quality Management Representative and Quality Manager in Healthcare
They should be able to • take and enforce decisions • think and act holistically • work in a results-oriented manner • act genuine act with empathy • recognise and communicate the significance and value of facts • reason, persuade and generate enthusiasm • imagine themselves in other roles and cultures • take into account intercultural/regional peculiarities • communicate appropriately, focusing on the target group • communicate using suitable language • act appropriately according to the situation • deal appropriately with conflict • give feedback • delegate tasks suitably • lead and also be a team player

The mind set and philosophy are geared towards the following:

Quality Management Representative and Quality Manager in Healthcare
• Value to the organisation (e.g. taking into account cost/benefit relevance of own actions) Consideration of customer satisfaction and interested parties • organisation's success and sustainability • Promotion of values of the organisation (e.g. financial or ethical values) • Opportunities and risks for the organisation (e.g. expose and reduce risks; promote innovation and best practice) • Continuous improvement (e.g. stimulating and promoting CIP) • Promotion and support of learning processes and know-how transfer • Monitoring of changes • Thinking in terms of overall context, Business processes and process chains • Application of the PDCA principle • Promotion of commitment • Exemplary personal conduct

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5.2 Knowledge and Skills - specific to the job profiles

5.2.1 Quality Management Representative in Healthcare - Knowledge and Skills

The Quality Management Representatives in Healthcare shall have generic knowledge and skills on a level which can be usually achieved by secondary school education and additionally a minimum full-time work-place experience of 2 years, including at least 1 year in the field of quality management or quality assurance.

The Quality Management Representatives in Healthcare shall have specific knowledge and skills and be familiar with the ISO 9000 series of standards and EN 15224 and competent in quality management methods and techniques based on specific training. This includes knowledge and skills as defined in the following table related to the relevant tasks:

Learning taxonomy
A recognize (have an overview of)
B understand
C apply
D analyse results and evaluate them

Task descriptions for Quality Management Representative in Healthcare (part 1)	**Related knowledge and skills**	**Learning taxonomy**
a) Implement and maintain QM system, taking into account normative requirements	Understand the principle of customer focus, including customer requirements, needs and expectations Understand the basics of organisational governance and management Understand the main structural forms of organisation, management models, decision-making processes as well as their impact on the management system and in particular the quality management aspects.	B
	Understand the term „quality" in the context of health and social services as the fulfillment of standards and requirements. Know the definition of quality in EN ISO 9000	B
	To be able to distinguish and explain „quality management" and „quality management system".	B
	To be able to differentiate the quality dimensions structure quality, process quality and result quality.	B
	Understand the value chain of an organisation Understand the quality terminology as defined by ISO 9000 Understand the 8 QM principles of ISO 9000 and the 11 Quality-attributes of EN 15224	B

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Task descriptions for Quality Management Representative in Healthcare (part 1)	**Related knowledge and skills**	**Learning taxonomy**
	Be able to explain and apply the PDCA principle	C
	Know and be able to apply the content of the relevant quality management rules and standards (especially ISO 9000, ISO 9001, ISO 9004)	C
	ISO 9000: Understand the objectives and scope of the standard. Be able to interpret the quality management concepts unambiguously in an application context.	C
	ISO 9004: Understand the objectives, scope and structure of the standard. Understand the distinction from ISO 9001 Be able to explain the approach	B
	EN 15224: Understand the objectives, scope and structure of the standard. Be able to work out and interpret requirements as well as to realise them in a manner appropriate for and specific to an organisation	C
	have an overview of other specific QM standards like EFQM, JCI and KTQ	A
	Be able to understand the differencies between EN 15224 and ISO 9001 and to be able to work out the specific requirements	B
	Have an overview of the existence of other management system rules and standards on quality management in healthcare, that are relevant to an integrated management system (e.g. Occupational Health and Safety, Environment, Information-safety)	A
	Be able to analyse the requirements of relevant rules and standards (in particular: be able to work out generic content or shared elements in all management system standards relevant to the organisation as well as requirements that are specific to a set of rules or standards).	D
b) Recognise legal and other normative requirements and coordinate their assessment and	Understand and be able to explain the importance of standards and harmonised EU standards Be able to identify laws and regulations relevant to the	C

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Task descriptions for Quality Management Representative in Healthcare (part 1)	**Related knowledge and skills**	**Learning taxonomy**
implementation in the organisation	organization and to interpret their significance for the organization, particularly as regards liability law (e.g. for services and organizational culpability) Be able to assess contractual arrangements with customers and suppliers Be able to integrate requirements from rules and standards into processes	
c) Specific regulations in Healthcare	Know about commonly used models in Healthcare and social services.	B
d) Process Management	Be able to identify target-group-specific requirements of markets and interested parties and to incorporate them into the organisation processes Be able to determine and present process flows Be able to model processes (i.e. to identify interfaces and dependencies between processes, to coordinate processes and to update/redefine them) Be able to identify and manage process interactions in an organisation Be able to define and measure process performance Understand and be able to apply/use process performance indicators (systems) To be able to integrate requirements of regulations and standards in the processes.	C
e) Manage and moderate groups	Understand moderation techniques Recognise group-dynamic processes	B
	Be able to conduct and moderate QM-related discussions	D
	Be able to use creativity techniques like Brainstorming, Card Technique, Force Field Analysis	C
	Be able to conduct Quality-circles	C
f) Present and report quality-related results to different target groups	Be able to present quality-related results adequately for specific target groups	C
	Be able to use techniques for information collection and preparation	C
g) Be a contact person and motivator for employees in the organisation	Be able to generate acceptance of the management system and changes Motivate: Be able to take into account motivation	C

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Task descriptions for Quality Management Representative in Healthcare (part 1)	**Related knowledge and skills**	**Learning taxonomy**
	theories (e. g. Maslow, Herzberg and others)	

Task descriptions for Quality Management Representative in Healthcare (part 2)	**Related knowledge and skills**	**Learning taxonomy**
h) Perform the role of Management Representative or support the Representative with the following tasks: Advising top management Top-down communication Reporting to top management	Be able to recognise and discuss the business impact on the organisation of quality-related decisions in the own area of responsibility.	C
	Be able to analyse and consolidate facts and figures as well as to process them in a decision-making relevant manner	D
	Be able to develop and prepare quality-related reports suitable for the target group	D
	Be able to develop and prepare risk-related reports suitable for the target group	C
i)recognize the importance of knowledge management for the organization	Understand knowledge management as the basis of decisions	B
	Know methods of knowledge management: e.g. Blogs, Wikis, Communities of Practice, Lessons Learned, competence-management, portals, knowledge-cards	A
j) Be the contact person for external interested parties (e.g. for suppliers, customers, certification body)	Be able to deal with feedback from interested parties appropriately (e.g. good communicator)	C
	Be able to represent the organisation's interests on quality related topics	C

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Task descriptions for Quality Management Representative in Healthcare (part 2)	**Related knowledge and skills**	**Learning taxonomy**
k) Recognize customer-specific requirements and coordinate their assessment and implementation in the organisation	Understand methods for identifying customer requirements, needs and expectations	B
	Be able to integrate customer demands into processes and take appropriate actions to assure the satisfaction of customer demands.	D
l) Apply QM methods	Understand the relevant Quality techniques (Q7) and be able to apply appropriate methods and tools in connection with relevant activities or in processes: Ishikawa, Pareto, histogram, flow chart, data collection sheet, brainstorming, control chart, inspection chart, scatter diagram.	C
m) Decide on additional methods for evaluating service quality	Benchmarking, Quality Function Deployment, FMEA, Poka-Yoke, Blueprinting, Critical-Incident-Technique, assessment, audit	B
n) Manage (QM) projects	Be able to apply project management processes and methods (e.g. for the implementation and maintenance of management systems, for improvement projects, audit planning)	C

5.2.2 Quality Manager in Healthcare - Knowledge and Skills

Quality Managers shall have generic knowledge and skills on a level which can be usually achieved by a university / higher education degree and additionally a minimum full-time work-place experience of 4 years, including at least 2 years in the field of quality management.

Quality Managers shall demonstrate all knowledge and skills as required for Quality Management Representatives and in addition shall be able to apply generic management systems practice, general office practices, systems and technologies, cultural norms and be able to apply language and communication skills appropriate to all levels.

They shall be able to judge quality management systems, related to standards and normative documents and to apply relevant quality management techniques. This includes knowledge and skills as defined in the following table related to the relevant tasks:

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Task descriptions for Quality Manager in Healthcare	**Related knowledge and skills**	**Learning taxonomy**
a) Analyse quality-related data, assess facts, consolidate and present (and also report) them, particularly with regard to the following application fields: Quality situation (e.g. relating to efficiency, effectiveness, productivity) Process adherence and performance (e.g. time aspects, error rates) Product quality Suggestion system (e.g. improvement suggestions) Customer satisfaction (e.g. customer complaints) Supplier management (e.g. development/support, appraisal) Management evaluation (e.g. establishing principles, creating basis for decisions) Improvement programmes	Understand statistical principles: Probability, histograms, distributions, the Normal Distribution. Understand distribution characteristics: Indicators for central tendency and dispersion: Arithmetic middle, median and mode. Variance and standard deviation. Understand the principles of correlation and regression. Be able to select, produce and interpret graphical presentation methods for statistical data (diagrams, charts) Understand the principles of Design of Experiments Understand the principles of reliability theory: Mean Time Between Failure, failure rate. Understand the principles of: Sampling inspection, Statistical Process Control (Control charts: X diagrams, X-middle/R diagrams, Analyse deviation) Understand process capability and measurement of capability. (Balanced Scorecard) Understand measurement capability and typical measurement errors; capability of measuring equipment. Understand statistical tolerance; statistical addition of several tolerances (dimensional chain of tolerances vs. individual tolerances)	B B C B
b) Continuously analyse customer interest, represent them in the organisation and implement them where applicable	Be able to apply methods for surveying and analysing customer satisfaction, to rate their adequacy and propose relevant actions	C
c) Develop QM system in the direction of sustained business success of the organization	Understand the influence of the organisational context / of interested parties in relation to the organisational development;	B
	Be able to align the management system to the future requirements of the markets and interested parties;	C
	Know advanced managerial concepts and be able to select and implement them organisation-specifically, in particular be able to apply TQM-related guidelines from	D

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Task descriptions for Quality Manager in Healthcare	**Related knowledge and skills**	**Learning taxonomy**
	ISO 9004 appropriately in a manner specific to the organisation	
	Understand and take into account the structure and elements of the EFQM excellence model (RADAR-logic, model and fundamental concepts)	C
	Know the methods for carrying out assessments (based on EFQM and ISO 9004):	B
d) Integrate/combine requirements from different management system standards and other internal and external requirements	Apply methods and possibilities for merging management subsystems Based on a fundamental understanding of models and systems be able to create one management system or to structurally enhance / merge a complex management system with different disciplines	D
e) Be an internal QM service provider / consultant for all levels of the organisation	Be able to explain complex issues appropriately to different target groups Be able to organise persons in teams, projects and programmes Apply target-group specific moderation techniques in meetings Recognise group-dynamic processes and be able to moderate them and resolve conflicts Coordinate and lead quality management activities within the organisation Prepare, conduct/moderate and follow up on events, and also be able to evaluate them	C
f) Be able to act as internal trainer/instructor for topics of relevance to organisation QM and other management systems	Be able to provide trainings, promote and advice topics to different target groups Know techniques analysing training needs Organize and evaluate trainings	C
g) Promote the organisation's management system	Be able to develop future scenarios, vision, mission and strategy Be able to apply leadership principles, methods and techniques Be able to raise employee awareness of individual issues	D
h) Create, implement, assess and improve audit programs	Be able to create, implement, review and improve audit programs (according ISO 19011), in particular: Be able to define an audit program appropriately in terms of objectives, scope and resources Be able to recognise and minimise risks, obstacles and difficulties related to the audit program Be able to carry out an audit program in terms of	C

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Task descriptions for Quality Manager in Healthcare	Related knowledge and skills	Learning taxonomy
	informing the parties about the program; specifying the objective, scope and criteria of individual audits; organising the execution of individual audits (audit teams, time, resources); guiding and recording audit programs, individual audits and audit staff. Be able to select and use appropriate audit methods and tools regarding audit scope and objective (e.g. being able to select suitable audit types depending on the set objective, scope and criteria (system, process, product and compliance audit)) Know the process of competence determination and evaluation of the persons involved in the audit including auditors Know the competence requirements for auditors (personal behaviour, knowledge and skills) and be able to apply them when forming the audit team. Be able to monitor an audit program Be able to review and improve an audit program	

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6 Basic Requirements related to the Profiles

6.1 Quality Management Representative in Healthcare

	Quality Management Representative
Generic knowledge and skills	Generic knowledge and skills on a level which can be usually achieved by secondary school education.
Specific knowledge and skills	shall be achieved through • Participation in relevant **training programme**. Content of the training programme: the learning targets and objectives shall cover the 'Quality Management Representative in Healthcare' specific knowledge and skills defined in section 5 Duration and methods: 80 hours (per 45 min.) classroom based training. Alternative learning forms may be defined in the training program by the training provider(s), if suitable to the learning objectives, but not more than 40% of classroom hours should be replaced by them. Alternative learning forms may be applied, when the following conditions are fulfilled: The learning form is suitable to the learning objectives Any learning form has to be specified in a training plan by the training institution. The fulfilment of the training plan has to be documented by the training institution. and additionally • **Workplace experience** in the specific field of quality management or quality assurance (minimum one year is considered as sufficient).

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	Quality Management Representative
Personal behaviour and skills	• Generic work skills and personnel behaviour developed in a professional or technical position involving the exercise of judgement, problem solving and communication with other managerial or professional personnel, peers, customers and/or interested parties at a level which can be awaited after two years of **work experience**. • Mind set and personal behaviour shall be geared to the approach defined in chapter 5.1 and be demonstrated by signing the **EOQ Code of Professional Conduct**.

6.2 Quality Manager in Healthcare

	Quality Manager
Generic knowledge and skills	Generic knowledge and skills on a level which can be usually achieved by a university / higher **education** degree.
Specific knowledge and skills	shall be achieved through • Specific **training programme** (in addition to the training programme for QMR in 6.1) Content of the training programme : the learning targets and objectives shall refer to the 'Quality Manager in Healthcare' specific knowledge and skills defined in section 5 Duration and methods: 136 (80 QMR plus 56 QM) hours (per 45 min.) classroom based training. Alternative learning forms (e.g. self-study, eLearning) may be defined in the training program, if suitable to the learning objectives, but not more than 40 **%** of classroom hours should be replaced by them. Alternative learning forms may be applied, when the following conditions are fulfilled: The learning form is suitable to the learning objectives. Any learning form has to be specified in a training plan by the training institution. The fulfilment of the training plan has to be documented by the training institution. and • **Workplace experience** in the specific field of quality management (two years is considered as sufficient).
Personal attributes and	• Generic work skills in a professional or technical position involving the exercise of judgement, problem solving and communication with other

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	Quality Manager
skills	managerial or professional personnel, peers, customers and/or interested parties and managing a group of people in a job situation at a level which can be awaited after four years of **work experience**. • Mind set and personal behaviour shall be geared to the approach defined in chapter 5.1 and be demonstrated by signing the **EOQ Code of Professional Conduct**.

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