Chapter N (please do not write anything in this line. Editors will annotate the chapter number)

ISO 9001 certification of the Specialization Schools of the Health Area of the University of Padova

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**Abstract.**

The Project for the implementation and certification of Quality Management Systems of the Specialization Schools of the health area of the University of Padova was conceived, as a first hypothesis, at the end of 2016, anticipating the legislative provisions for the organization of the training and assistance activities of the Schools of specialization in the health area.

After the approval of the University's board of directors, in October 2017, the project was launched, extended to all the Specialization Schools of the health area of the University of Padua with access reserved for medical graduates (a total of 46 active Schools) in which the final goal of obtaining the ISO 9001 certification of the Schools by December 2020 was achieved.

The unitary approach and the participation of the medical residents in the implementation of quality management systems are distinctive elements of the project that allowed the achievement of the objectives on time with a progressive increase in efficiency also with reference to the compliance of the Systems.

**Keywords.** Specialization Schools, Quality Management System, ISO 9001, Health.

1. **Introduction**

The project for the implementation and certification of the Quality Management Systems (QMS) of the Specialization Schools of the Health Area of University of Padua was conceived, as a first hypothesis, at the end of 2016, on the initiative of the “Osservatorio per la formazione specialistica post lauream”, the pro-rector for post-graduate training, the area of teaching and student services of the University and the research centre “Centro Studi Qualità Ambiente (CESQA)” of the Department of Engineering.

The project, in its design phase, anticipates the subsequent legislative provisions of interministerial decree 402/2017 also concerning the "quality management and certification system", taking advantage of the previous experience of the ISO 9001 certification obtained in 2008 by the Specialization School of Paediatrics of the University of Padova.

The project hypothesis, approved by the university's board of directors in October 2017, envisaged the implementation of QMS for the Specialization Schools of the Health Area of the University of Padua and the obtaining of ISO 9001 certification by the end of 2020.

The management of the project has been entrusted, from a technical point of view, to Centro Studi Qualità Ambiente (CESQA), a university research centre which, since the end of the 90s, has been operating in the application of management systems, also providing support to various services of the University. The coordination of the activities has been entrusted to the “Ufficio Dottorato e post lauream - settore Scuole di Specializzazione” which, in its institutional role, provides support to Specialization Schools and resident doctors. As part of the project, the Sector itself has embarked on a parallel path by implementing its own QMS that has led to the achievement of ISO 9001 certification.

Finally, the strategic supervision of the progress of the activities was followed directly by the “Osservatorio per la formazione specialistica post lauream”, a university body that deals with the evaluation, promotion and monitoring of Specialization Schools.

1. **Materials and methods**
   1. ***Implementation of Quality Management Systems***

All 46 Specialization Schools of the Health Area aimed at graduates from Medical Schools active – at the start date of the project – at the University of Padova were involved in the project (of these the Specialization School in Paediatrics was already certified according to the ISO 9001 standard since 2008) in addition to the “Settore Scuole di Specializzazione” which, for uniformity of analysis, is excluded from this discussion. The Specialization Schools belong to 7 University Departments as shown in Table 1.

Table 1. University departments and Specialization Schools involved in the project

| **Department** | **Afferent Specialization Schools** |
| --- | --- |
| Medicine (DIMED) | Allergology and clinical immunology; Anatomic pathology; Intensive Care and Pain Therapy; Dermatology and venereology; Haematology; Endocrinology and metabolic diseases; Geriatrics; Emergency medicine; Sports medicine and exercise; Internal medicine; Nuclear medicine; Nephrology; Radio diagnosis; Radiotherapy; Rheumatology; Nutritional sciences. |
| Surgery, Oncology and Gastroenterology (DISCOG) | General surgery; Digestive diseases; Oncology; Orthopaedics and traumatology; Urology. |
| Molecular Medicine (DMM) | Infectious and Tropical Diseases; Microbiology and virology. |
| Neuroscience (DNS) | Audiology and phoniatrics; Plastic, reconstructive and aesthetic surgery; Physical and rehabilitation medicine; Neurosurgery; Neurology; Ophthalmology; Otolaryngology; Psychiatry. |
| Cardiac, Thoracic, Vascular Sciences and Public Health (DSCTV) | Cardiac surgery; Thoracic surgery; Vascular surgery; Preventive medicine and hygiene; Diseases of cardiovascular apparatus; Diseases of respiratory tract; Occupational medicine; Legal medicine. |
| Biomedical Sciences (DSB) | Clinical pathology and clinical biochemistry. |
| Women’s and Children’s Health (DSDB) | Paediatric surgery; Medical genetics; Gynaecology and obstetrics; Community medicine and primary care; Child Neuropsychiatry; Paediatrics. |

As regards the training offer, 15 Schools provide for a training course lasting 5 years, 31 Schools provide for a training course lasting 4 years.

For the implementation of the QMS in the Schools, a shared approach was adopted and developed in successive phases, defining intermediate milestones in order to allow for a gradual implementation of the QMS. In addition, the Schools were divided into three "implementation groups" which started and completed the activities in different periods, based on internal organizational needs.

Specifically, the implementation phases are summarized below:

* General plenary training, aimed at all Specialization Schools and all personnel involved.
* Specific training relating to the methods of implementation of the QMS and carried out in subsequent moments for the various "implementation groups".
* Implementation of the QMS in the Schools with specific deadlines for the different "implementation groups"; the activities were carried out by the staff of each school with the technical support of CESQA taking into consideration the reference legislative requirements (interministerial decrees 68/2015 and 402/2017) and the applicable University regulations
* Internal audit carried out at each school by the qualified technical staff of CESQA
* Management review carried out by each School.
* Certification process for each School implemented by an accredited certification body (QCB Italia, now part of the TÜV Austria group).
  1. ***Project highlights***

Two elements of the project are emphasized, functional to achieving the objectives and increasing the efficiency in the implementation process of the QMS.

First of all, the unitary and shared approach and the involvement of all the Schools, allowing the development of synergies between the staff employed in the activities and stimulating dialogue between the subjects in order to seek the most efficient solutions for achieving the goals. All the actors of the project (including the research centre that supported the activities and with the obvious exception of the certification body) were selected within the University of Padua, in order to further stimulate synergies and unity during the implementation process, both from a strategic and technical point of view.

Secondly, the involvement of medical residents in all operational phases of the project, from the first general training activities to the implementation of the QMSs and audit. The participation residents, on a voluntary basis, had the dual objective of making the implementation process more efficient while guaranteeing maximum transparency towards the main recipients of the service offered by the Schools.

Table 2 shows the data relating to the staff of the Schools and to medical residents who actively participated in the implementation of the QMS. The data (average number per School) relates to all 46 certified Schools, divided into 4 groups based on the total number of attending residents (data updated in April 2022 and provided by the dottorato e post-lauream office of university).

Table 2. People (average number per School) actively involved in the project

| **School groups by attendance** | **n. of Schools in the group** | **Attending residents** | **Structured university staff involved** | **Technical-administrative staff involved** | **Residents involved** |
| --- | --- | --- | --- | --- | --- |
| Group 1  ≥ 100 attending | 6 | 155,67 | 1,83 | 1,17 | 1,83 |
| Group 2  50 ≤ attending < 100 | 10 | 70,80 | 1,90 | 1,20 | 0,70 |
| Group 3  20 ≤ attending < 50 | 21 | 30,48 | 1,90 | 0,95 | 0,95 |
| Group 4  < 20 attending | 9 | 13,67 | 1,89 | 1,00 | 1,00 |

The very high-attendance group includes only Schools that provide for 5 years of training; in the group with the lowest attendance, only Schools with 4 years of training.

As for the staff who actively participated in the implementation of the QMS, it includes:

* structured university staff (school directors, professors, researchers) for a total of 87 people;
* the technical-administrative staff employed by the Schools or Departments for a total of 48 people;
* residents for a total of 47 medics.

Analysing the data, it can be seen that, while the average number of structured and technical-administrative staff who participate in the implementation of the QMS is almost uniform among the groups, the average number of participating residents is higher for very high-attendance Schools (group 1: number of attending residents ≥ 100).

* 1. ***Results and discussions***

As regards the achievement of the project objectives, excluding the already certified School of Paediatrics, 7 Schools obtained certification in 2019 (certification group 1), 13 Schools obtained certification in the period May-September 2020 (certification group 2), 25 Schools obtained certification in the period October-December 2020 (certification group 3) in compliance with the general deadlines set by the project.

It is noted that the certification group 1 does not include very high-attendance Schools (≥ 100 attending residents) as evidence of how the number of attending residents influences the organizational complexity also requiring, in general, a longer path for the implementation of the QMS.

As indicators of efficiency, it is useful to take into consideration the results of the internal and external audit conducted (to date all the Schools have completed at least the external certification and first maintenance audit as well as two internal audit for a total of 4 audit for each).

The total number of findings issued in the 4 considered audit (including the School of Paediatrics) was 844 with an average of 18,35 per School. The findings mainly concern the control of documented information, the control of service provision and the process monitoring.

As regards the classification of findings, these are mainly comments (833 in total). Only 11 findings classified as nonconformities were issued during the pre-certification internal audit; considering this result, in the rest of the discussion the findings are considered without distinction of classification.

Considering the Schools in which at least 1 resident has participated in the implementation of the QMS (in total 33 Schools), the average of the findings per School is equal to 17,61; for the remaining 13 Schools in which no resident has participated in the implementation of the QMS, the average of the findings per school is equal to 20,23; this result highlights how the active participation of residents has positive effects also in terms of compliance of the QMS.

Table 3 shows the data relating to findings (average number per School) issued during the 4 considered audit (data provided by QCB Italia and CESQA).

Table 3. Audit results: findings issued (average number per School per audit)

| **Certification groups** | **n. of Schools in the group** | **Pre-certification internal audit** | **Certification external audit** | **Pre-first maintenance internal audit** | **First maintenance external audit** |
| --- | --- | --- | --- | --- | --- |
| Group 1 | 7 | 10,29 | 4,14 | 6,14 | 2,29 |
| Group 2 | 13 | 7,46 | 3,69 | 4,00 | 2,08 |
| Group 3 | 25 | 8,32 | 3,32 | 4,12 | 2,00 |

It is noted that the findings issued in the internal audit (pre certification and pre-first maintenance) are greater in number than those issued in the external audit and that, for the Schools in group 1 (Schools that first completed the implementation), a higher average number of findings was issued in all audit with respect to the Schools that concluded the activities subsequently; the result testifies to the validity of the unitary and shared approach adopted for the implementation and the effectiveness of the progressive transfer of know-how between Schools.

1. **Conclusions and future perspectives**

The objectives of the project were achieved within the established time frame by obtaining the ISO 9001 certification of all the Specialization Schools of the Health area of the University of Padua (the only university in Italy to date to have achieved such a result).

The unitary development of the project and the shared and phased approach made it possible to efficiently tackle the activities also allowing a progressive improvement of the audit results, as can be seen from the analysis of the number of findings.

The participation of medical residents, a peculiar element of the project, was useful in the implementation phase (especially for Schools with greater complexity in terms of number of course years and number of attending residents) and also led to positive results in terms of compliance of the QMS, as emerges from the analysis of the findings issued in the audit.

With regard to future developments, a further study of the project results is hoped for at the end of the first three-year certification period for all Schools (December 2022). Following the important results achieved and the positive effects for the management of the Specialization Schools, the University of Padova has decided to promote and launch a further project for the certification of other Specialization Schools relating to various scientific fields.

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