

Quality management standards in Switzerland

The GSASA developed quality management standards for hospital pharmacies, the QRHP, which is ISO 9001-compatible and professional-oriented, and helps to build up and develop quality management systems (QMS)

Since 1996, the Swiss health legislation states that healthcare practitioners must develop quality programmes that need to be agreed upon by health insurers. After having developed a quality concept in 2001, the Swiss Society of Public Health Administration and Hospital Pharmacist (GSASA) decided to develop its own professional quality management standards to fulfil this demand and help its members build up their QMS, and mandated its Quality Department to do this.

The Quality Department of the GSASA is a work group of seven members representative of the Swiss hospital pharmacy in terms of hospital size and linguistic regions. It works closely with a consultant (*Agence pour la promotion et l'évaluation de la qualité; APEQ*) which has a broad experience in the building of healthcare ISO 9001-compatible standards.

Discussion

In 2003, a first draft of the Quality Referential for Hospital Pharmacies (QRHP) was developed by the members of the Quality Department and other GSASA volunteers, who each invested about 20 days to accomplish this work. From the beginning, the system was built up as a bilingual (German/French) tool.

After an internal hearing by the members of the GSASA and an external hearing by health authorities, the Swiss Hospital Society and certifying organi-



Selection of a drug formulary should take into consideration the cost/benefit ratio

sations (Autumn 2003), inputs and proposals were integrated and a final version was elaborated (Spring 2004).

In September 2004 a test audit was conducted

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Table 1. Service processes

Demands	Indicators	Standards	Evaluation	Comment
<p>The pharmacy coordinates the updating and distribution of drug formulary</p> <p>The selection should:</p> <ul style="list-style-type: none"> ● be done in an objective and transparent way ● follow the legal framework ● take into consideration the benefit/risk and cost/benefit ratios 			Good, fair or bad	
The drug committee meets regularly or is consulted regularly	Frequency of meetings or consultation	Twice a year or more		
The drug formulary and its updates are communicated regularly to the users	Frequency of information	Once a year or more		
The procedure for obtaining nonformulary drugs is described				

Resources

QRHP (German and French)
W:www.gsasa.ch
 (password-protected area).

in a small hospital pharmacy. Two months later the QRHP was officially approved by the GSASA. Since March 2005, the QRHP is also recognised by the Swiss Federal Office of Metrology and Accreditation. It is therefore possible to certify a hospital pharmacy according to the QRHP.

Features of the QRHP

The QRHP is designed for hospital pharmacies of any size. It combines the ISO 9001 generic quality management concepts and the requirements of the GSASA for Swiss hospital pharmacies. The QRHP therefore includes criteria for the structure, processes, services and output management. The QRHP does not reinvent technical norms (eg, GMP/PICs), nor does it replace any state or federal authorisation, but it clearly states that these points must be fulfilled when necessary.

Use of the QRHP

- Reference guide for every hospital pharmacy, keen to build up or further develop its own QMS.
- Self-evaluation tool: the QRHP is designed as a checklist.
- Officially recognised standard for certification.
- Proof of quality of pharmaceutical services for government or health insurances.

Structure of the QRHP

The QRHP is structured into three parts (services, resources, management), 20 chapters, and subchapters. General and specific requirements are presented in the form of checklists. For some of the requirements an indicator and a minimal standard are stated. Three columns allow an easy evaluation of the requirements. Table 1 shows an example of a checklist for the chapter "Pharmaceutical Services" of the QRHP.

The QRHP includes a correlation matrix with the EFQM (European Foundation for Quality Management) model and ISO 9001 standards version 2000.

Conclusion

During the last four years, the Quality Department developed this tool for the GSASA members. The test audit and the first official certification audit according to the QRHP (June 2005) showed that the QRHP could be used in hospital pharmacies of any size. It is an efficient tool to "translate" the ISO 9001 requirements in a professional language and define what level of quality can be expected for a hospital pharmacy in Switzerland. As incentives to develop QMS will continue to increase, the GSASA hopes that most of its member will adopt the QRHP. ■

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