Quality management: burden or opportunity?

Companies are facing increasing demands. Globalisation and an increasingly quality-conscious market increase competition and pricing pressure. To remain globally competitive, companies need a product and service quality that will satisfy the customer in the long term and which can be attested, for example, with a certificate. Alexander Cansier, managing director of OrgaConnect GmbH, has many years of experience in the field of quality management and has specialised in the support of small and medium-sized companies in the life sciences, pharmaceutical and medical technology industries. Speaking with Dr. Claudia Durand and Marina Boose from BIOPRO Baden-Württemberg GmbH, Cansier explains the advantages of certification and how he can assist companies that are planning to implement quality management systems.

Quality is the fulfilment of customer requirements to ensure permanent customer satisfaction.

BIOPRO: Every organisation should strive to deliver products that meet customer demands and strive to enhance customer satisfaction. How can quality management (QM) contribute to this and when does certification make sense?

Cansier: My major aim is to explain the advantages of DIN EN ISO 9001 certification to life sciences and medtech companies. The DIN EN ISO 9001 is a process-oriented QM system that is not mandatory, but rather represents a competitive advantage as it helps companies to optimise their internal processes and make work flow more effective and efficient. This is of particular importance for start-ups and newly founded companies that are seeking investors. ISO 9001 certification is, so to speak, the first step in the industrialisation process, as industry, and hence also customers, are attaching increasing importance to the planning, reassessment and continuous improvement of production and administration processes. It is therefore important for companies to show that they comply with standards and guidelines that are also known to the customers. DIN EN ISO 9001 is the same all over the world, whether a company is located in China or here in Stuttgart. It helps a company raise customer satisfaction by meeting customer demand.

How long is the certificate valid for and what does ISO 9001 certification imply?

Alexander Cansier, Managing Director of OrgaConnect GmbH

The DIN EN ISO 9001 certificate is valid for three years and there are annual audits once the certificate is issued during which organisations have to demonstrate their capability to provide products that meet customer demands. During these audits, the assessors will also check whether processes in the company are being further developed. A major aspect of DIN EN ISO 9001 is that it requires a continual improvement process. Amongst the requirements is the following

information, which needs to be collected and assessed: What kind of customer complaints does the company receive, how often and are they minor or more serious complaints? What is the company doing to ensure it achieves customer satisfaction? Specific management processes need to be established in order to do away with simple gut feeling and to ensure there is a systematic work process.

DIN EN ISO 9001 is a standard that supports process-oriented work. It provides a basis on which quality objectives can be achieved; it provides the framework for staff recruitment, supplier assessment and in-process controls. Continual improvement is a set of activities that an organisation routinely carries out in order to enhance its ability to meet requirements, exclude mistakes or at least reduce the number of mistakes with the overall aim of increasing its effectiveness and efficiency. In addition, the standard also helps an organisation to secure its know-how, i.e. to prevent process knowledge from being lost if an employee leaves the company. A company's ISO 9001 certification can be withdrawn and terminated as a result of failure to comply with re-assessment audits. Companies with DIN EN ISO certification need to have a quality management officer who is responsible for implementing and maintaining a quality plan to ensure that the company's quality system complies with quality system requirements. However, it is the company's senior management that is responsible for the QM system; it also needs to provide the necessary human and financial resources. A QM system is doomed to failure from the very start if it does not have the unconditional commitment of its management to implement and develop a quality management system.

How time-consuming is a QM officer's job?

I would say that a company with around 20 employees only needs a part-time QM officer. However, it is important to point out that QM constitutes a major part of a company's day-to-day operations. There is always the risk that companies focus on other activities and put the quality aspect on the backburner. I would recommend companies to focus on a process that assures that the quality issue is a day to day concern of all employees in a company.

Quality management (QM) is defined as "coordinated activities to direct and control an organisation with regard to quality."[1]

QM involves the determination of measures to implement a company's quality policy. These measures include quality planning, quality control, quality assurance and quality improvement. QM is a method for continuous improvement aimed at fulfilling customer needs and expectations and thereby achieving customer satisfaction.

QM is governed by an international standard. In Germany, the term "DIN EN ISO" means that the German standard (DIN) complies with the European (EN) and the international (ISO) standard. The **ISO 9000 ff.** family of standards is designed to help organisations ensure that they have implemented and are documenting the proper functioning of their QM system. The certificate attests that an organisation has implemented the measures required by a certain standard relating to quality-related activities.

How does DIN EN ISO 9001 certification work and how do you support an organisation that wants to get the certificate?

The DIN EN ISO 9001 certification process is as follows: the first stage evaluates the company's state of readiness; the company has to provide information on how it conforms to the ISO

standard. The auditee will have to correct any first stage non-conformities and implement the necessary measures. We can give the organisation being audited an idea of what it needs to do and provide suggestions as to how it can move forward. Take a customer who wishes to obtain DIN EN ISO certification within a year or so. In this case we will help the company to define the processes that need to be implemented within the given time frame, prepare the documents and train the employees. We can provide advice and input on what the company needs to do. This is easier from an external point of view than from an internal one. However, what we mainly do is to explain what the standards are all about. Many companies do not know what QM is and are afraid of the unknown, afraid that they will have to disclose secret processes and afraid that they will lose their know-how. It goes without saying that we are obliged to maintain confidentiality. The only thing we do is help the company to guide the processes by defining and assessing them. The standard will in no way be just forced onto the company; existing and new processes will be prepared in a way that conforms with the standard and will be achieved without disturbing employees' normal work processes too much.

Does this imply that DIN EN ISO is not only a burden, but also has advantages?

Yes, that's right. The objective and purpose of the DIN EN ISO standard is to establish an international standard of business practices, organisation and production. There are clear guidelines a DIN EN ISO certified company needs to abide by. The standards are an objective and transparent system, they are the same for all companies and ensure that products and services are safe, reliable and of good quality. Of course, the implementation of a quality system costs money, at least at the beginning. The company has to pay the consultant and do work that is not really productive. However, it needs to be pointed out that a company that has implemented quality standards and develops them further as the company grows will eventually make more money than it invests in the quality assurance process.

Can a company that is already certified also hire you?

Yes. All certified companies have to carry out internal audits at least once a year. Internal auditing is a form of self-appraisal. I would say it makes sense to hire external people to provide an independent appraisal as company employees are often biased in their appraisal. This said, DIN EN ISO certification requires companies not to carry out self-appraisals. This means that at least the QM department, which provides the internal auditor, needs to be audited by an external, independent auditor. Internal auditing is primarily directed at evaluating internal control. They help a company accomplish its objectives and improve control and governance processes. Quality meetings will be held at which solutions will be found to certain topics. These meetings will for example focus on the following questions: Can procurement processes be improved and how? What needs to be done with suppliers who do not deliver as required or who only deliver products of inferior quality?

Everything we have talked about so far is related to quality management. What is the difference between quality management and quality assurance?

QM is the umbrella term and is used by a company's management to guide their organisation towards improved performance, to make sure that their organisation and product is of consistently high quality. Quality assurance (QA) is only one component of quality management and requires companies to work in compliance with GxP guidelines and regulations (ed. note: GxP is a general term for GMP, GLP, GCP, GAMP or FDA 21 CFR Part 820). QA means ensuring that no faulty products leave the company. Different methods and systems can be used to assure the quality of a product or service, including sample audits or in-process controls. GxP offers the security that data are not lost as a result of a server breakdown, and the integrity of the data are

not falsified. In the pharmaceutical and medical technology industry, GxP also involves defined methods of risk management. It is our task to decide which topics and standard-related work instructions are required. In order to do this, we will look at specific aspects of a company's system and improve them if it proves necessary.

Quality assurance (QA) is "part of quality management, focused on providing confidence that quality requirements will be fulfilled."[2]

Does it make sense for companies that do not work according to GxP to implement a QM system according to DIN EN ISO 9001?

GxP usually guides quality manufacture, testing, development and approval of drugs. These guidelines ensure that a product is safe and fulfils its intended use. Quality management is therefore mandatory in regulated industries like the pharmaceutical industry. Companies that produce testing methods for academic, non-clinical applications do not need GxP or other similar guidelines, but they can nevertheless implement a DIN EN ISO 9001 compliant QM system in order to make sure that their manufacturing processes take place in a controlled environment. DIN EN ISO 9001 is not a product standard; but applies to company activities related to assuring constantly high quality of products and services and comprises all business areas, including senior management, sales and production.

It sounds like a lot of work. What about small companies? They do not usually have the personnel to set up everything that is needed for quality system documentation. How can you assist these companies?

Our "scientific & technical writing" department can support companies that have to prepare new QM and QA documents. Although we are always dependent on the company's help, we can nevertheless take over a lot of work related to the writing of such documents. We have people who have done this for many years and who also have the necessary industry experience. The documents will be discussed and verified with the company. Typical areas where we can offer our support are the operation of devices or the carrying out of processes, methods and tests. We can also assist companies in preparing validation documents. Technical writing is a relatively big part of our work. It is time-consuming work and companies do not usually like doing it. Scientific writing is only a minor part of our work. We can assist companies that would like to promote a product or service in the scientific yellow press, for example companies that would like to publish an article about a newly established method. We can help them prepare the article in a journalistic manner and also give editorial support.

How and where can companies that are interested in implementing a quality management system find out more details? How much will it cost them and how much time does it involve?

I offer small and medium-sized companies a half-day workshop free of charge. Companies can book a workshop where we will provide them with information about quality management and quality systems. The workshops are rounded off with a brief evaluation of the financial and internal management aspects of the company. We hope that such workshops will help us acquire new clients.

I am also planning a seminar. This will also be free of charge. Experts will talk about particular quality management-related topics. I hope that the seminar will provide insights into why quality

management is necessary. I also hope to reach students who are thinking about working in the industry or setting up their own company.

And last but not least, is there anything you would like to tell companies?

It is extremely important that companies deal with quality management at an early stage. The earlier a company deals with this issue, the easier it will find it to implement a quality management system. I would like to show companies that the establishment of QM processes is not a necessary evil but instead offers them a market advantage and is even able to generate growth. As far as I am concerned, quality management is not a burden, but an opportunity.

Thank you for the interview.

References:

[1] Eurogentest (https://www.biooekonomie-bw.dewww.eurogentest.org/web/info/public/unit1/qmanagement/definitions_v1.xhtml); ISO 9000:2005

[2] DIN EN ISO 9000:2000

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