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A quality system for laboratory animal facilities

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Introduction

Quality Assurance is a hot item. Almost every industrial company is working according to a quality system. The awareness that a quality system could be useful to laboratory animal facilities has arisen in the Netherlands. The animal laboratories of Maastricht, Rotterdam, Utrecht and Nijmegen decided to start with implementing a quality system and keep contact with each other about their findings. These four laboratories which are related to a university have chosen the ISO 9000 directive and have started building their quality systems (ISO stands for International Organisation for Standardisation. ISO is a name that is chosen to prevent misunderstanding due to translation in different languages (http://www.iso.ch/9000e)).

If you want to start building a quality system, one of the first things you will do is look around. You will try to compare different quality directives with each other. It is my experience that at this point the confusion starts. For instance what is the difference between a quality system and a quality directive and how to discriminate between quality directives?

By giving an evaluation of different quality directives I hope this will provide such an overview, that will help you to decide, which would be most appropriate for your local situation.

But first things first. There is a lot of confusion about the differences between quality systems and quality directives. The differences will be explained in the next paragraph. Then follows a short introduction of several quality directives. The "differences" between those quality directives will be mentioned in paragraph 3 and at last a motivation for the choice of ISO 9000 in animal laboratories which are related to a university is given.

Quality systems and quality directives.

Quality directives are strictly the guidelines as they are set by the organisations like the International Organisation for Standardisation (ISO) and the Organisation for Economic Co-ordination and Development (OECD).

Quality systems, on the contrary, are the structures, built by individual companies according to those guidelines.

If two companies were to build a quality system, they would both be different even if the companies are producing the same product and using the same quality directive. This is possible because quality directives are written in a way that interpretations can be really different but still comply with the quality directives. Another reason for the differences is that you have to make a system that describes your own company and your way of managing production.

A quality system has to live in the company. This means that everybody has to co-operate to set up a quality system. Because a quality system is nothing but a lot of procedures you agree on with each other. And with that agreement (procedure) you say, this is the way we work.

At first most people, especially older people will be reluctant to co-operate because you have to take a close look at how things are done. You even have to document it in a standard operating procedure and weigh its efficiency. The biggest fears of people are changes! But once you have started building a quality system they will find that there are few changes and the procedures in the company will be much clearer.

2. Short introduction of a few quality directives.

2.1 GLP

GLP is a safety-testing directive of OECD and has

been initiated to reduce fraudulent research in such tests because of the large economic interests depending on it (Carson & Drent 1995). In the Netherlands GLP is required by law for research of food supplements, new chemicals and side effects of drugs. The Veterinary Health Inspectorate (VHI) is the governmental auditor in the Netherlands. The section GLP of the VHI only inspects GLP studies in case the studies have to be done according to GLP guidelines because of the legal requirements.

2.2 EN 45000

Another possible directive is EN 45000. EN 45000 aims at test-, inspection and calibration laboratories. Companies like TNO and AKZO Nobel usually will build their quality systems according to the EN 45000 directive. This directive has been made by ISO. ISO is a world wide non-governmental organisation, which tries to make guidelines for all kind of companies.

2.3 ISO 9000

Both EN 45000 and ISO 9000 are directives that have been made by ISO. Every Standard directive starts with an introduction and a scope. The scope of ISO 9001 is: This International Standard specifies quality system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated.
The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing.
This International Standard is applicable in situations when
design is required and the product requirements are stated principally in performance terms, or they need to be established; and
confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in design, development, production, installation and servicing (ISO 9001 1994). So every company which designs, develops, produces, installs or services can use ISO 9000.

2.4 AAALAC

The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) is an American organisation. The main goal of this organisation is to evaluate animal care. AAALAC relies on the guide for the Care and Use of Laboratory Animals, DHHS Publication 1985, as its primary standard for evaluating laboratory animal care and use programs.

2.5 HACCP

HACCP stands for Hazard Analysis Critical Control Points. This is a directive that has been designed for the NASA to detect the Critical Hazard points in the food delivery for the astronauts. The European Union decided that this directive could be very useful for every food producing company and implemented it in an EU directive. So every company that deals with food or food-supplements in the EU has to implement HACCP. (http://www.safefood.net.au/hccp/codex_guidelines)

3. Differences in quality directives?

At first sight it seems that there are a lot of differences between individual quality directives. The differences exist mainly because of the different scopes of the quality directives. It is obvious that a quality directive for animal laboratories can not have the same requirements as a quality directive for food production.
But if you take a closer look you will find that most quality directives have something in common. All directives are written in a neutral way, a lot of interpretations are possible. In this way it is possible for a lot of different companies to comply with a quality directive. In each quality directive it is considered essential to define, document and maintain your procedures. Every directive demands that you write down how things are arranged in your company.
If chosen for HACCP then you have to make clear where there are critical control points in your process and if you choose for ISO 9001 than you have to document the procedures in the company

to help you manage the production process. The major questions that should be answered are:
does everybody know the things he/she needs to know to do his/her job the best way they can and can you show that for a fact, is it possible to proof that to someone else?
If the answer is YES on both questions, then your company does not need a quality system. If there are still a few things indistinct or even failing in your company then a quality system could help.

4. Why ISO 9000

A few years ago the discussion started in the Netherlands if animal laboratories should have a quality system. And if so which one would be the best. GLP is a directive one can think of but GLP is a study related quality directive. It is not possible to get a certification for the entire company. So for every study you do you have to apply for a GLP certification.
EN 45000 is a directive meant for test and calibration laboratories. For laboratories that perform a lot of routine tests it is the best directive. Animal laboratories related to a university perform a lot of different experiments with animals and do not, or only with a lot of trouble fit in the directive of EN 45000.
AAALAC is a directive, which is too narrow in scope to fit in the entire company. If you certify for AAALAC you will have a certification for good husbandry, care and use of the animals. It does not include management of the company.
HACCP never has been a serious option for animal facilities. It was included in this survey to find differences between quality directives. But even though the scope of HACCP is very different of that of GLP or ISO 9000 it could be possible to implement a quality system according to HACCP in an animal laboratory. (Jansen.1998)
This leaves us with ISO 9000. ISO 9000 is a relatively easy directive to comply with because you have to describe the things the way they are, not the way you would like it to be. It is possible for every company to get an ISO 9000 certification. ISO 9000 is a well-known directive. Even though most people do not know exactly what ISO 9000 is they know that it stands for quality. By introducing a quality system you also get better management. Procedures are much clearer because they are documented. There will be less confusion and therefore fewer mistakes. This results in a wise use of laboratory animals.
Another reason for choosing ISO 9000 is that it will not interfere with the way you work at the moment. You document the way you work right now. So it will be accepted much more easily than a directive that changes a lot in the way you work.
Finally ISO 9000 is also easy to combine with other directives and (inter) national laws.
ISO 9000 has only one flaw. It does not say a thing about animals. That is why the laboratories of Maastricht, Rotterdam, Utrecht and Nijmegen plan to certify for ISO 9000 and AAALAC. That way there will be a specific connection to the use of animals and its management in facilities.

References

Carson PA, NJ Drent: Good Laboratory and Clinical practises, Oxford: Heinemann Professional Publishing. Guide for the Care and use of Laboratory Animals, prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources Commission on Life Sciences, NIH Publication No.1985, *86*, 23.

U.S.. Health research extension act of 1985, provided by the animal welfare information center, United States Department of agriculture, National Agricultural Library, Public Health Service Policy on Humane Care and Use of Laboratory Animals.

ISO 9001, formerly British Standard 5750: part1.

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