

Evaluation of quality systems for animal units: report of the Scand-LAS working group

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Introduction

The Scand-LAS board established a working group to evaluate the existing quality and accreditation systems for animal facilities in November 1998, with the remit to evaluate which of them could be useful/recommendable and for what purposes. The accreditation by AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care International) is originally an American standard of accreditation, currently also entering Scandinavia/Europe (Miller 1998). The question arose, whether a system originally based in the USA, would be practically useful and acceptable in Scandinavia as well. The following questions were formulated for the working group:

1a. Do we need quality systems in our Scandinavian animal facilities?

1b. If yes, which are best and for what reasons?

2. Isn't our national legislation in each of the Scandinavian countries sufficient guarantee for quality and welfare?

3. What about AAALAC accreditation being introduced into Scandinavia?

The working group discussed these questions in the light of the various national legislations in the different Scandinavian countries: Norway, Sweden, Finland and Denmark. The conclusions

were presented at the Scand-LAS meeting in Mariehamn, Finland (May 1999). This article presents the main conclusions.

History

Firstly, Colinda Jansen (Nijmegen University, The Netherlands) and Harry van Herck (Utrecht University, The Netherlands) were contacted. Colinda Jansen executed a literature evaluation on the comparison of suitable quality/accreditation systems for central animal units (GLP, AAALAC and ISO9000), that was published in this journal (*Scandinavian Journal of LAS* 1999, 26(1), 17-19). Harry van Herck successfully introduced ISO 9000 and AAALAC accreditation in the central animal facility at Utrecht University and is presently chairing a Dutch working group investigating the use of animal unit quality systems. They both presented their findings and experiences at the Scand-LAS symposium in Mariehamn. These contacts provided a very useful basis for further evaluation. Moreover, it stimulated discussions on starting a European initiative similar to the AAALAC accreditation.

Background

What is quality? Quality can be defined as follows: how well does a product or service fulfil/satisfy the demands (Colinda Jansen, 1998).

Which demands are there to be found for animal units?

1. Scientist demands: scientists that perform

animal experiments in an animal unit request good service, expect that the personnel has knowledge and experience with animal husbandry and techniques, so that it is performed in a standard and skilful way, and rely on the fact that things are done as agreed upon;

2. *Legal demands*: the society expects that all procedures carried out in laboratory animal facilities satisfy the provisions of the law, thereby fulfilling society's intentions and ensuring that such work is defensible;

3. *Personnel demands*: staff desire high standards of management, including provision of safe working conditions.

Quality systems are the structures built by individual companies, according to guidelines (Quality directives) as issued by e.g. the International Organisation for Standardisation (ISO 9000) and the Organisation for Economic Co-ordination and Development (OECD) and the Food and Drug Administration (FDA) (Good Laboratory Practice (GLP) (Jansen 1999).

Most quality directives are in general rather similar, as one has to define, document and maintain procedures (Jansen 1999). The differences relate to the goals and scope of the target groups (Jansen 1999).

The ISO9000 gives general guidelines for a large number of different institutions and is also suitable for central animal units as a management quality system (Jansen 1999).

GLP guidelines are used for routine safety and toxicity testing in laboratory animals.

AAALAC gives guidelines for the care and housing of laboratory animals, and does not provide a quality system for the entire animal unit (Jansen 1999).

Which systems are chosen, depends on the goals.

ISO 9000 appears to be the best guideline for introducing management quality systems in central animal units at universities. If needed, -for particular studies-, GLP guidelines can be added "on top" of this. As ISO 9000 does not imply an evaluation of animal care, AAALAC can be added "on top" of ISO9000 (Jansen 1999).

Why introduce quality systems into animal units?

After sending out a questionnaire to various Dutch university facilities, the following reasons were

given for wanting to introduce a quality system into an animal unit (Jansen 1998):

- Execute external contract studies
- Perform safety studies
- Registration of animal experiments
- Improve service
- Increase effectiveness of management
- Increase quality of animal experimentation
- Improvement of internal procedures
- Make internal procedures more visible
- Improve working conditions for all concerned

Why is the introduction of quality systems in animal units currently considered important in the laboratory animal science field?

Science: within the scientific field the concept of the 3R's (Replacement, Reduction and Refinement) has become very important (Russell & Burch 1959), together with the pressure to publish many good quality papers;

Society: a. Society is becoming increasingly critical of the use of laboratory animals:

b. Changes in society occur at ever increasing rates. It is therefore increasingly important that experiments provide the correct answer the first time;

Management: the level of education within the laboratory animal science field is improving, which leads to a higher demand for a good and safe working place.

By successfully introducing a quality system into an animal unit, this can help to prevent unnecessary duplication of animal experimentation (Reduction), because studies are properly documented and archived. A standard description of e.g. the proper blood collection technique will ensure that it is carried out correctly each time (Refinement). As everything is documented, the quality of scientific protocols, reports and papers will improve, ensuring that everything is performed correctly the first time, helping to prevent fraud. This will increase the reliability of the results and will make it easier to reproduce the experiment in another laboratory. A quality system provides improved transparency in what is going on as it gives insight in all aspects of the animal unit, including external independent control.

External control will also help the unit to improve its procedures, assuring responsible animal use. The introduction of management quality systems ensures that responsibilities and procedures are discussed, agreed upon and documented. If this is done openly and with respect for all involved, it will promote a feeling of security and job satisfaction.

Conclusions of the working group

1a. Do we need quality systems in our Scandinavian animal facilities?

Yes, because they can help to improve quality assurance and animal welfare. Especially on the subject of how procedures need to be executed and documented, it will be an advantage to introduce quality systems.

1b. If yes, which are best and for what reasons?

ISO 9002 is a good management quality system for animal units at universities. GLP and AAALAC can be added on top of this. GLP is used for safety studies. AAALAC guidelines are intended to improve animal welfare and husbandry. AAALAC's inspections offer inspections of laboratory animal units by laboratory animal experts. External inspections are useful to improve animal welfare continuously.

2. Isn't our national legislation in each of the Scandinavian countries sufficient guarantee for quality and welfare?

National legislation and inspecting legislative authorities vary in different countries and in different regions. These authorities may not have a broad experience in laboratory animal science, which implies that laboratory animal scientists, responsible for managing the animal units, have better knowledge and judgement than the inspecting authorities.

Legal inspections do not require detailed descriptions of all steps in procedures, documentation, archiving, etc. We need more to improve quality. As legislation covers minimum requirements, we need to achieve more in the field of animal welfare. We shall not wait to be forced

by legislation and public opinion, we shall take the initiative.

In conclusion, for obtaining better guarantees on quality and welfare, we can and should do more than our legislations tell us to do.

3. What about AAALAC accreditation being introduced into Scandinavia?

Denmark has not ratified the Convention of the Council of Europe: does this imply a lower standard of well being?

The US Guide for the Care and Use of laboratory animals (*National Research Council 1996*) gives in principle the same rules as the European Convention (*Council of Europe 1985*) does. There is probably not any consistent difference in standards between Nordic countries that have or have not ratified the Convention, it is more up to local ambitions and standards. Northern European standards are generally believed to be higher than in the US, especially when judging animal welfare aspects. However, we do lack a system to harmonise and describe our institutions and professionalism, and that part is very well covered by AAALAC, as AAALAC's Program Description has a template for describing units, that encourages harmonisation and description of units. AAALAC may fill in the "animal welfare" bit, which GLP and ISO lack. We could make a similar European or integrated US/European identity, which could also do certifications of laboratories according to ISO standard. This way we could have both: the quality standard and guarantee of animal welfare.

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However, we do have no "proof" of that. A system like AAALAC is appealing, in that it offers inspections and certifications, to give "guarantees" on animal welfare and husbandry. A similar European system is considered desirable, which can profit from the already established and well-functioning AAALAC accreditation process.

General conclusions

AAALAC is not a quality standard, offers no full quality control, but does give a good focus on

animal welfare. ISO or GLP are good quality management standards for animal units.

ISO and GLP are means of documenting, they give no guarantees for animal welfare.

Depending on the goal of an animal unit, the desires differ. Units working on drug development and manufacturing, with a lot of contract research, will focus on ISO 9002 and GLP. Units working with researchers, who do not demand high standards of quality assurance, may suffice with AAALAC plus a comprehensive set of SOPs and some quality assurance.

Recommendations

Minimum requirement lists of procedures and matters that must be included in quality and welfare management systems of animal units should be defined. Different grade levels for the requirements can be formulated, dependent on the goals/desires within particular animal units. A minimum requirement list can include, e.g.:

- * A health monitoring system
- * Quality control of washing, autoclaving and other sterilisation procedures,
- * Control of personnel education and training
- * Records of used bedding, food and disinfectants
- * SOPs for daily care
- * Control of temperature, humidity, light, etc.

Reference needs to be made to the appropriate legal guidelines and FELASA documents.

This way we can come with concrete advice for managing the introduction of quality systems in laboratory animal units. It must also be made

visible which organisations deal with certification/accreditation of laboratory animal units in Europe.

The working group advised the Scand-LAS board that it would be most appropriate to establish a FELASA working group, so that the work can be done on a European level. This working group should formulate general quality and welfare guidelines to animal units. The FELASA Board has agreed on the proposal and the working group is currently being established.

References

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