FELASA guidelines for education of specialists in laboratory animal science (Category D)

Report of the Federation of Laboratory Animal Science Associations Working Group on Education of Specialists (Category D) accepted by the FELASA Board of Management

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The term competence, as it first appeared in the European guidelines, was rather poorly defined and hence resulted in some confusion. It was FELASA's initiative in working with the various competence categories, which made the concept clear and comprehensive. According to FELASA there are four competence categories (FELASA 1995):

Category A—Animal technicians
Category B—Research technicians
Category C—Scientists
Category D—Specialists

Outside Europe there are reference publications, which are internationally recognized, such as *The Guide for the Care and Use of Laboratory Animals*, which deal with training, qualifications and veterinary and operational responsibilities in an animal facility (NRC 1996). These same topics are also essentially those that form the basis of the European guidelines for Categories A–D, which FELASA has undertaken to develop.

FELASA guidelines for categories A and C have been approved and published (FELASA 1995). This document constitutes guidelines for category D, while those for category B are still in preparation.

FELASA defines category D as laboratory higher management and specialization (FELASA 1995). The European Directive and The European Convention legislation refer to a 'specialist' as a veterinary surgeon or other

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competent person, but fail to define who the other competent person could be.

Articles 5, 9 and 16 of both the Convention and the Directive carry a reference to the competent person. In Article 9 the wording 'veterinarian or other competent person' is shown to be someone who has responsibilities in relation to the assessment of pain and distress. In addition, the Explanatory Report of the Convention, Article 20 suggests that veterinarians should also be managers as well as welfarists and clinicians (CE 1986, Official J EC 1986, EC 1992, CE 1993).

This working group, which has been appointed by the FELASA board, defines the specialist, for the purposes of Category D, to be a person who has the qualifications and experience to carry out at least the following:

(1) Manage all animal, human and physical resources in a laboratory animal facility.
(2) Make provisions for the health and welfare of animals.
(3) Provide advice, instruction and assistance to investigators on laboratory animal related matters and provide practical support of research programmes.
(4) Ensure compliance with all the laws, regulations and guidelines relevant to the production, maintenance and use of laboratory animals and related to management of the animal facility.
(5) Be responsible for the development and presentation of internal and external education programmes in the humane

care and use of laboratory animals, which continue to develop the concept of the Three Rs (Russel & Burch 1959).

(6) Contribute to the in-depth development of innovative concepts in the humane care and use of laboratory animals including carrying out research in laboratory animal science.

Level of studies

Specialist education and training in laboratory animal science should be offered in the form of postgraduate studies. In recent years, following major improvements in the health quality of laboratory animals, the success of which should not be jeopardized, there has been an explosive increase in the awareness of animal welfare and the complexity of biomedical research with animals.

Laboratory animal science is a highly specialized and rapidly evolving field in biomedical science. Since laboratory animal science has an enormously broad scope and a high impact on research with animals, competence in this field should urgently be promoted and provided, especially on the background of a steadily increasing need in the EU.

The working group recognizes that the discipline of laboratory animal medicine has not been addressed in detail in the curriculum for Category D, but only in the sense of providing an understanding of the role of the veterinarian. This is because the working group considers laboratory animal medicine to be the specific and sometimes legal domain of the veterinary profession. It is hoped that veterinary faculties will take this into consideration and provide a curriculum for specialization in laboratory animal medicine.

Specific requirements

A degree in the biomedical or veterinary sciences, or a qualification certified to be equivalent, must generally be regarded as the basic requirement for entry to postgraduate education in laboratory animal science. It is expected that the candidate will have appropriate experience in the field of laboratory

animal science prior to starting the curriculum.

Prior to the training period the candidates are expected to have demonstrated detailed knowledge and skills in accordance with Category C (scientist).

The species to be studied in some detail are the common rodent species, rabbits, dogs and cats, but a basic understanding would also be required for non-human primates, farm animals, amphibians and fish. The outline as described in the section 'Detailed Curriculum' is however sufficiently flexible to allow participants to place emphasis on those species that are most relevant for the person's job.

Evidence of successful completion of the course will only be obtained after the candidate has passed a validated assessment or examination.

By definition, laboratory animal science implies both the understanding and practice of the scientific method as well as the implementation of animal welfare. Both are essential and general knowledge of welfare originates from specific research on animals. In fact, research in laboratory animal science is the safeguard of animal welfare integrity. It is therefore expected that the final assessment or examination will provide evidence of the candidate's ability to carry out research.

Examples of such evidence could be one of the following:

(1) Publication as the main author of a scientific paper of original scientific research (not case history) in a peer-reviewed journal.

(2) Report of a number of case histories in a defined manner.

(3) Undertaking a short research project and showing the utilization of the scientific method. This research project does not necessarily need to be performed at an institute for laboratory animal science.

Curriculum

The existing postgraduate courses in laboratory animal science in Europe take one to four years to complete (see Table 1). This working group recommends that the post-

Table 1   Training in laboratory animal science (LAS) in European countries, which incorporates requirements of Category D

Institute with training programme	Basic training requirement	Duration of training	Degree/Specialty in LAS
Faculty of Veterinary Medicine, University of Milano, Italy	A. Veterinarian	A. Veterinarian/ 3 years	A. Diploma in Scienza e medicina dell'animale da laboratorio (Diploma in LAS and Medicine)
	B. Other Biomedical Scientist	B. Biomedical/ 2 years	B. Diploma in Scienza dell'animale da laboratorio (Diploma in LAS)
Faculty of Veterinary Medicine of Liège, Belgium	A. Veterinarian B. Other Biomedical Scientist	2 years	Medicine Vètèrinaire Experimentale (Experimental Veterinary Medicine)
Several institutes/universities with adequate units/facilities for research in laboratory animal science, Germany	A. Veterinarian	A. 3 years	A. Fachtierarzt für Versuchstierkunde (Veterinary specialist in LAS)
	B. Veterinarian	B. 2 years	B. Fachtierarzt für Tierschutz (Veterinary specialist in animal protection)
	C. Veterinarian, Zoologist and Biomedical Scientist	C. 4 years	C. Fachwissenschafler für Versuch-stierkunde (Science specialist in LAS)
A. The Royal College of Veterinary Surgeons, UK	A. Veterinarian, 2 years experience in LAS	A. 1 year	A. Certificate in LAS
B. The Royal College of Veterinary Surgeons, UK	B. Veterinarian, 5 years experience in LAS	B. 1 year	B. Diploma in LAS
Faculty of Veterinary Medicine, Utrecht, The Netherlands	A. Veterinarian B. Other Biomedical Scientist	1 year	Laboratory Animal Specialist Recognized by the government
A. Department of Comparative Medicine, University of Uppsala, Sweden	A. Biomedical graduate	A. 2 years	A. MSc (Medicine)
B. Laboratory Animal Unit, Norwegian College of Veterinary Medicine, Norway	B. Veterinarian	B. 3 years	B. MSc
Ecoles Nationales Vétérinaires, France	Veterinarian and other Biomedical Scientist with experience in LAS	1 year	
Veterinary Faculties Berne and Zurich and certified commercial research institutions, Switzerland	Veterinarian	4 years	Spezialtierarzt für Labortierkunde (Diploma in Laboratory Animal Medicine by the Swiss Veterinary Association)

graduate education in laboratory animal science should require two years of full-time study to complete or equivalent part-time study to cover all the subjects and requirements of Category D. This should include six months allocated to the research project. Each of the modules A through H should be taken in an approved institution and supervised by a nominated expert. Exemption can be obtained from parts of the course dependent on prior approval of previous qualifications, education or experience.

Detailed curriculum

A. Legislation, welfare and ethical aspects

1. Legislation
(a) Survey of international legislation and regulations with respect to animal use

- *to obtain an overview, to support relevant working practices (e.g. CITES, GLP) and to provide an historical perspective*

(b) European laws (European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, 1986 and EC-Directive 86/609)

- *to facilitate discussion with and counselling of (visiting) scientists from abroad*

(c) National legislation

- *to ensure compliance with the law by scientists*

(d) Notification and authorization procedures, competent persons, animal welfare officers, animal facilities, minimal cage floor area, etc., supply and sources of experimental animals, codes of practice

- *to ensure that the facility management is aware of legal constraints*

(e) Supervision by regulatory bodies and ethics committees

- *to show how legal and ethical supervision of animal facilities and animal experiments function*

(f) Alternatives to animal experiments, selection of species and group size (legal aspects)

- *to ensure that specialists have a good working knowledge of the opportunities and limitations of alternative methods*
- *to offer expertise to scientists concerning all regulatory aspects in the planning of an animal study*

2. Welfare
(a) Phylogeny, genetics and ontogeny of behaviour

- *to provide insight into the fundamental processes steering behaviour*

(b) Learning, communication, social organization and interaction with the environment

- *to provide the knowledge to assess the occurrence of and possible reasons for maladaptive behaviour*

(c) Ethological parameters as indicators of basic environmental requirements, environmental enrichment and control of experimental variables

- *to develop professional judgement and the knowledge of how to take appropriate corrective action*

(d) Behaviour characteristics of intact and experimentally treated animals (experimental stress, spontaneous and induced mutations)

- *to obtain skills to identify and diagnose normal and altered behaviour*

(e) Homeostasis, the ability to cope and its limitations, stress and distress

- *to provide insight into the fundamental processes of stress, stress management and distress*

(f) Behavioural pathology, well-being

- *to recognize that well-being is more than absence of disease, pain and distress and the difficulties of proving the state of well-being*

(g) Recognition and assessment of stress and distress

- *to provide the knowledge to assess the occurrence of stress and distress*

(h) Control of stress and distress

- *to develop professional judgement and the knowledge of how to take appropriate corrective action*

3. Ethical aspects of animal experimentation
(a) Man–animal relationship, historic roots and religious involvement exemplified by development of biblical and of Greek traditions; modern concepts of speciesism, egalitarism, animal rights; anthropocentric and biocentric approaches

- *to promote the understanding of the different fundamental ethical positions and their historic roots*
- *to lay the foundation for a reflective inquiry about moral values regardless of one's own particular set of moral principles*
- *to encourage self-responsibility*

(b) Intrinsic value, moral relevance of animals

- *to develop a personal ethical position*

(c) Ethical dialogue and ethical reasoning, pitfalls in the argumentation; the ethics of communication

- *to enhance moral reasoning skills and to develop the correct attitude to the use of animals*

(d) The different positions of the philosophical and the scientific view of life (the concept of the biblical version of creation versus the concept of evolution) and the problem of mutual understanding of philosophers and scientists; the conflict between the ethical principle of reverence for life and the use of animals for man's own self-preservation

- *to efficiently influence political decisions and regulatory acts*
- *to provide a basis for discussion in ethics committees*

(e) Models for ethical reasoning and ethical justification of a research project; ethical principles and guidelines for scientific experiments on animals

- *to persuasively defend one's position toward the public and the media*

B. Management of the animal facility and its resources
1. Direction of programmes of work
(a) Development of policies and working practices

- *to satisfy the requirements for a high quality of care for laboratory animals and their biological and welfare needs*

(b) Development of a staffing structure

- *to enable the operation of all administrative, management and technical functions*

(c) Review processes

- *to enable regular assessment of practices and revision as required*

2. Staff recruitment
(a) Standards for qualifications and experience

- *to define the various job categories*

(b) Development of job hierarchy

- *to show staff organization and interactions; provide job descriptions and management objectives and provide programmes for staff development*

(c) Criteria and review of staff performance

- *to include feedback to staff on performance and introduce programmes to improve performance*

3. Financial control
(a) Provision of a budget

- *to ensure satisfactory categorization of individual items and a process for timely capture of individual expenditure*

(b) Purchasing policy

- *to include negotiating procedures to obtain best price agreements from suppliers*

(c) Animal costing

- *to include purchase, maintenance, staff and overhead costs as needed for full and partial accounting*

4. Strategic direction
(a) Planning strategy

- *to determine future needs and direction*

(b) Impact of institutional policies and guidelines

- *to include implementation of these and assessment of effect on local policies and practices*

5. Computerized management systems
(a) Animal care and information system

- *to facilitate animal ordering; inventory and stock control; maintaining records of animal health and history; quality control and breeding programmes*

(b) Stock control

- *to manage efficient supply and use of equipment and materials*

(c) Cost accounting

- *to allow recuperation of costs for use of animals and facilities; to develop a basis for cost containment*

(d) Environmental control

- *to ensure compliance with guidelines, regulations and animal welfare requirements*

(e) Systems to provide compliance with regulatory controls on animal use

- *to include monitoring the legal use of animals and provision of animal use statistics*

6. Provision of staff training
(a) Development and implementation of programmes

- *to support efficient functioning of administrative, management and technical staff*

7. Liaisons
(a) Liaison internally

- *to ensure a proper service is provided; to understand institutional direction; to effect good communication and understanding of local issues*

(b) Liaison externally

- *to effect good external understanding of needs; as a public relations exercise to benefit the external perception of the*

organization; to improve internal operations by the capture of new scientific and commercial knowledge

(c) Liaison with the public

- *to learn skills for communicating with the public on aims, methods and benefits of research*

8. Collaboration with scientific personnel
(a) Provision of resources

- *to support the instigation and conduct of experimental studies; to care properly for the animals and to offer expertise; to enable experimental assistance to be given; to enable training in animal manipulations*

(b) Conducting research

- *by co-working with other scientists on investigations*
- *by conducting personal research into aspects of laboratory animal science and welfare (see also Specific Requirements and Curriculum)*

9. Operation of the animal facility
(a) Proper hygiene of the facility

- *to include all procedures which support those functions concerned with satisfying the biological and welfare needs of animals; procedures for satisfying the requirements of caretakers, investigators and regulators*

(b) Storage of materials and equipment

- *to provide efficient and regular supply and distribution*

(c) Control and disposal of waste

- *to comply with regulations*

(d) Monitoring and record keeping

- *to ensure efficient working of all operations*

10. Animal facility design
(a) Composition and function of the design team

- *to include architects, engineers, surveyors, service consultants, finance representa-*

tive, administrative representative, and client representative

(b) Consideration of location and siting of facility

• *to take account of the surrounding environment and impact of external factors and the interactions with other areas within the organization*

(c) Considerations relating to the animals

• *to include species, number of animals, breeding and/or purchase, animal holding and/or experimentation, disease category and methods for its maintenance*

(d) Considerations relating to the building

• *to include basic concepts and the type of construction; costs; detailed planning and specifications for animal housing space and functions and support areas and functions; interrelationship between animal housing and support areas; traffic flow patterns; services; environment and its controls, and maintenance programmes*

11. Health and safety
(a) Laws, regulations and policies

• *to ensure safe operations within the facility and legal compliance; to ensure the health of personnel*

C. Biology of laboratory animals

1. Anatomy of mammalian and non-mammalian species
(a) General anatomy

• *to describe the structure and function of the main organs and systems of the most commonly used species*

(b) Comparative anatomy

• *to enable the choice of the most appropriate animal model for potential extrapolation between species*

2. Physiology of mammalian and non-mammalian species
(a) General physiology

• *to provide knowledge of the mechanisms and the physical/chemical principles at the basis of the vital processes*

(b) Comparative physiology

• *to enable the choice of the most appropriate animal model*

3. Immunology
(a) General principles

• *to provide knowledge of the cellular and biochemical components of the immune response*

(b) Immunodeficient animals

• *to characterize the most used strains and species*

4. Comparative clinical pathology
(a) Pre-analytical factors

• *to provide knowledge of the impact of sample collection, handling and storage on the analytical results*

(b) Analytical techniques and instruments

• *to enable the choice and arrangement of the most useful laboratory equipment*

(c) Most relevant parameters in haematology, coagulation, aggregation, blood chemistry and urinalysis

• *to enable the selection of the most appropriate analyses to be checked*

(d) Normal ranges: knowing where to find ranges for different species and their variation in relation to age, sex, strain

• *to enable the interpretation of analytical data and the choice of the most appropriate animal model*

(e) Quality control programmes

• *to ensure quality of the analytical procedures and results*

5. Post-mortem examinations
(a) Necropsy

• *to provide knowledge of the most relevant techniques in performing autopsy*

(b) Gross pathology

• *to enable recognition of the most important macroscopic alterations of organs and tissues*

(c) Organ removal and fixation

- *to ensure appropriate handling of the samples before further processing*

(d) Histopathology and histochemistry

- *to provide knowledge of the most relevant steps and techniques in histopathology and histochemistry*

6. Comparative aspects to man
(a) ADME (adsorption, distribution, metabolism, excretion) and bioavailability of exogenous compounds

- *to enable the choice of the most appropriate animal model according to the classes of compounds to be tested*

(b) Animal models of human pathology

- *to provide knowledge of the most relevant spontaneous and induced models of human disease*

(c) Extrapolation from animals to man

- *to enable understanding of the relevance of the experimental results for human health*

D. Husbandry, breeding and genetics
1. Housing
(a) Caging systems

- *to secure the optimal housing equipment and conditions for the animals*

(b) Environmental enrichment

- *to meet behavioural and socialization needs*

2. Micro and macroenvironment
(a) Temperature, relative humidity, ventilation, relative air pressure and air filtration, lighting, noise, other environmental controls

- *to ensure an understanding and working knowledge of these parameters and their control; to ensure maintenance of proper environmental factors contributing to the well-being of animals and staff; to ensure compliance with all regulations*

3. Nutrition and feeding
(a) Formulation of diets

- *to obtain understanding on the effects of various aspects of feed and feeding on animals and research*

(b) Energy sources, fibre, vitamin, minerals, others

- *to define and meet their requirements by the body*

(c) Feeding regimens

- *to assess differences of ad libitum, restricted and pair-feeding*

(d) Variation in diet composition

- *to explain the reasons for variation and the associated problems*

(e) Special diets

- *to explain the needs during different periods of life (weanling, young and aged animals) and those for specific research objectives*

(f) Impact of coprophagy and caecotrophy

- *to understand biological impact and associated problems*

(g) Influence of diet on experimental results

- *to be familiar with the effects of over and under feeding and of diet composition; effect of social deprivation*

(h) Contaminants and controls

- *to detect and control chemical, microbial and parasite infestation*

(i) Effect of sterilization techniques

- *to compare the advantages and disadvantages of thermal treatment, chemical treatment, irradiation and ethylene oxide*

(j) Storage and quality control

- *to regulate and record temperature, humidity and ventilation of diet storage; importance of chemical analysis*

4. Watering
(a) Water bottles and self-watering devices

- *to define advantages and disadvantages of using various systems*

(b) pH, hardness, microbiological and chemical contaminants

- *to define effects on health and research results*

(c) Treatment and sterilization

- *to understand effectiveness and cost*

(d) Water deprivation

- *to understand the ethology and the need for care in delivery of water and measurement of consumption and effect on health*

5. Bedding
(a) Types of bedding

- *to understand optimum requirements and advantages and disadvantages of different types*

(b) Contaminants

- *to understand effects on health and experimental results*

(c) Treatment, sterilization and storage

- *to define needs dependent on types of husbandry*

(d) Use of solid versus grid/slatted bottom cages

- *to define conditions when bedding is inappropriate*

6. Hygiene
(a) Viruses, bacteria, fungi and protozoa

- *to understand the impact of hygiene on the microbiological environment of the animals*

(b) Chemical contaminants

- *to assess sources resulting in chemical contamination of the animal environment*

(c) Cleaning, disinfection and sterilization

- *to define the optimum treatment of facility, equipment and utilities in different types of animal care*

(d) Microbiological, vermin and chemical controls

- *to learn to establish and operate monitoring programmes needed for high-quality animal care*

(e) Waste disposal

- *to define and use appropriate methods and comply with regulatory requirements*

7. Breeding
(a) Reproduction in vertebrates: reproductive cycles, environment and stimulus, species, strains and substrain differences

- *to understand theoretical and practical aspects of reproduction*

(b) Breeding methods; productivity, permanently and temporarily mated groups, breeding stock turnover, mating programmes needed to obtain various demands (number, age, sex, etc.), genetic characteristics and breeding schemes (backcross, intercross, random breeding, control of the inbreeding level, genetic controls), influence of husbandry and environment

- *to obtain theoretical and practical knowledge needed for the choice of optimal breeding method in various situations*

(c) Health status in breeding; influence on the productivity, techniques and equipment used for decontamination, maintenance of animals with a defined health status, health status monitoring

- *to learn the importance of health status of animals and methods used for its maintenance, and solutions available to eradicate certain pathogens*

(d) Organization and management; cost analysis

- *to define educational programmes to establish and run animal breeding units efficiently and economically*

8. Genetics
(a) Introduction; Mendelian inheritance, polygenic characters

- *to become familiar with the theory of genetics*

(b) Outbred colony; definition, advantages and limitations, management of outbred colonies, standardization and genetic drift

- *to learn to implement proper maintenance and breeding of an outbred strain*

(c) Inbred colony, F1-hybrids; definition, advantages and limitations

● *to understand how inbred and recombinant inbred strains and F1-hybrids are maintained and produced*

(e) Genetic animal models of disease; polygenic models obtained by selection, spontaneous mutations, transgenic and knock-out animals (definition, overexpression of a gene, homologous recombination, expression and transmission of the gene, model validation), influence of the genetic background

● *to learn various methods in production and maintenance of genetic animal models*

(f) Genetic quality controls; phenotype, skin grafting, biochemical markers, immunological markers, DNA markers

● *to be able to establish genetic monitoring programmes and comprehend their value*

E. *Microbiology and diseases*

1. Microbiology
(a) Specific review of bacteriology, parasitology, virology of laboratory animals; notions including: classification (taxonomy); physical aspects, characteristics, structures and resistance to external environment (physical, chemical, biological); multiplication and survival conditions; detection methods including microscopical, cultural, serological and DNA analysis

● *to understand their aetiology and differentation from infectious diseases and to have some rudimentary awareness of the possible options for treatment that would be the responsibility of the institutional veterinarian*

(b) Microbiological status of different categories of laboratory animals; gnotobiotic, germfree, specified pathogen free and conventional animals; modified animals (irradiated, transgenic, or other); microbiological procedures; screening programmes

● *to be aware of the immunological and sanitary status of some specified categories of laboratory animals and to recog-*

nize interactions between animals and external agents

2. Diseases
(a) Non-infectious diseases to be found in laboratory animals such as physical, chemical, radiation and other injuries; natural physiological disturbances (pregnancies, birth, fighting, ageing problems); congenital diseases; immunological diseases; tumorigenesis; nutritional diseases (overfeeding, starvation, deficiencies etc.); intoxication: experimental or unexpected; abnormal behaviour: tics, self-mutilation, stress related; surgical pathology

● *to have basic understanding on their aetiology and differentiation from infectious diseases, to have some awareness of possible treatments*

(b) Infectious diseases; range of the laboratory animal diseases; zoonosis, epidemiology and specific safety procedures; general and specific symptoms of individual diseases; diagnosis; prevention, treatment and their effectiveness; special attention for provoked infectious diseases

● *to have a general understanding of strategies for identifying a health problem, and on how institutional veterinarian identifies the underlying causes and agents and takes the appropriate measures*

3. Manifestation of clinical diseases
(a) General manifestations; appearance, weakness, body weight, temperature, skin disorders etc., specific manifestations by system; neurological system: pain, syncope's, paresis, paralysis etc.; musculoskeletal system; cardiovascular and respiratory system; gastrointestinal system; urinary and reproductive system; endocrine system; abnormal analysis values and corresponding symptoms

● *to understand, on a general level, aetiology and symptoms and effect on experimental results*

(b) Diagnosis; principles of differential diagnosis

● *to have a basic understanding of how institutional veterinarian monitors and reports the health status of laboratory*

animals, and draws conclusions on clinical manifestations of altered health

F. Design and conduct of research programmes and animal experiments

1. Defining the objective of a study

(a) Literature survey

- *to become familiar with searching in general biomedical/veterinary databases (e.g. MEDLINE; CAB-I; CSA, AGRICOLA) and in specialized databases (e.g. PREX; T-BASE; TOXLINE)*
- *to set up a literature storage and retrieval system*

(b) Analysing relevant information and formulating a hypothesis

- *to train in sorting out relevant information and to define the objectives of an animal study while taking into consideration the limitations set by restrictions of budget, time, equipment, facilities etc.*
- *to create a plan of action for an animal experiment*

2. Choice of an animal model

(a) Formulating the criteria

- *to obtain a clear view on the requirements to be met by the animal model and to summarize arguments for/against the use of alternatives*

(b) Species and strain specific characteristics

- *to stimulate the search for the best match between the animal model and the requirements of the experiment*

(c) Requirements for microbiological standardization, microbiologically defined animals

- *to learn about the impact of the microbiological status of the animal on the experimental results*

(d) Requirements for genetic standardization; genetically defined models (see also D8).

- *to obtain information on the various classes of genetically defined animals and to learn about the advantages and limitations of using inbred strains, co-isogenic strains, congenic strains, transgenic strains, F1-hybrids, outbred strains, hybrid populations*

(e) Genetic models versus induced models

- *to obtain an overview on the various categories of animal models*

(f) Acquisition (procurement, transport, species specific, environment-dependent adaptation time, quarantine)

- *to provide insight into the practical and organizational aspects of the acquisition of animals for research*

(g) Species specific environmental requirements

- *to become familiar with the requirements and problems that may arise when different animal species are maintained in an animal facility;*
- *to obtain insight into the relationship between housing and welfare of the animals*

3. Experimental design

(a) Determining the required number of animals in test and control groups; power analysis

- *to become aware of the importance of consulting a statistician before the start of an experiment e.g. in order to estimate the validity of a sample, to assess the reliability of the results and to decide whether to accept or reject the hypothesis*

(b) Sampling

- *to decide what strategy should be followed in obtaining a representative sample of the population*

(c) Randomization; randomized block design; cross-over design; Latin square design; split-plot design

- *to provide some insight into various approaches of experimental design, depending on the problem to be solved*

(d) Statistical approaches

• *to obtain insight into the general aspects of statistical analysis of animal experiments and the possibilities of statistics in reducing the required number of animals*

(e) Experimental variables

• *to provide a definition and description of these, their effects on research and their control by statistical means*

4. Treatment of test and control groups
(a) Experimental procedures (see also H)

• *to provide insight into estimating the degree of discomfort and to what extent this influences the welfare of the animals and the experimental results*

(b) Possibilities for refinement

• *to stimulate the search for refinement alternatives*

(c) Placebo/sham-operation

• *to ensure the choice of appropriate control groups*

(d) Anaesthesia/Analgesia/Surgery (see G and H)

• *to ensure that the effect of treatment is adequately differentiated from the effect of the use of anaesthetics/analgesics or the effect of the surgical procedure*

5. Organization and management aspects of animal experiments
(a) Submitting a protocol for reviewing

• *to learn about the general principles that must be considered when submitting a protocol for review by an ethics committee or other review body*

(b) Description of logistics, expertise of personnel, collecting and processing data

• *to obtain the information needed for an efficient performance of the study, including the division of the work between various persons involved in the experiments*

6. Reporting of experimental results
(a) Oral presentation of the study

• *to train in presenting a paper*

(b) Writing of a manuscript according to the requirements of a primary international journal

• *to train in publishing the results of a study*

G. Anaesthesia, analgesia and euthanasia
1. Physiology of nociception
(a) Peripheral pain perception

• *to define the modern concept of pain and to introduce the species- and individual-specific perception of and response to acute and chronic pain*
• *to point out the location of pain receptors in the skin and tissues of animals and the chemical mediation of nociceptor activity*

(b) Conveyance

• *to learn species-specific ascending pathways of transmission*

(c) Peripheral and central recognition of pain

• *to obtain insight in the complexity of neural and endocrine processing of acute and chronic pain and ways of modulation of the input signals*

(d) Pain response

• *to become familiar with descending pathways, local and general reaction to qualitatively and quantitatively different input*

(e) Realization of pain in different species

• *to demonstrate species and individual specificity of pain experience*

2. Pharmacology and pharmacokinetics of substances, used for anaesthesia, analgesia and euthanasia
(a) Substances, antagonists, muscle relaxants

• *to become familiar with the most common substances, their effectiveness and pharmacokinetics*

(b) Species differences

• *to illustrate the wide response spectrum to substances*

(c) Exogenous and endogenous factors affecting pharmacokinetics

• *to consider the effects of environment (e.g. circadian phase, temperature) and subject*

(e.g. gender, health and nutritional status, age)

(d) Effect on organ systems

- *to emphasize special considerations to homeostasis and pathological effects*

(e) Impact on experiment

- *to identify factors biasing experimental outcome*

(f) Safety of staff

- *to draw attention to safety with respect to teratogenic and enzyme-inducing effects; prevention of self-administration (drug addicts)*

3. Anaesthesia
(a) Equipment

- *to introduce equipment applications, care and safety*

(b) Pre- and post-anaesthetic procedures

- *to ensure best practice and species-specific care*

(c) General and balanced anaesthesia

- *to learn theory and practice of inhalation anaesthesia, anaesthesia with injectable agents; principles of spontaneous/artificial ventilation*

(d) Local and regional anaesthesia

- *to understand when, where and how to carry this out*

(e) Management and monitoring

- *to evaluate the depth of anaesthesia and various vital functions, maintain homeostatic threshold values and counteract complications; response to emergency*

4. Analgesia
(a) Assessment of pain

- *to be able to recognize and assess ethological and vital parameters of acute and chronic pain*

(b) Animal welfare
- *see A 2*

(c) Experimental target

- *to identify factors biasing the experimental outcome*

(d) Consequences

- *to understand effect of substance on homeostasis, wound healing, behaviour etc.; administration schedules*

(e) Addiction and tolerance

- *to place special consideration on opiate-like substances and administration schedules*

5. Euthanasia
(a) Legislation

- *to point out legal aspects and European recommendations*

(b) Ethics, objectives and welfare

- *to consider moral aspects of euthanasia, the reasons for euthanizing an animal and ensure most humane accomplishment*

(c) Fear and distress of animal

- *to consider and minimize aversive responses of the animal*

(d) Emotions of performer

- *to accept human emotions but to consider primarily the zoocentric point of view; to discuss aesthetic versus ethical aspects*

(e) Equipment

- *to get acquainted with their variety, handling, safety and care*

(f) Method

- *to know species characteristics, ease of accomplishment, reliability and effectiveness, speed and irreversibility, impact on organ system and economy*

H. Surgery and experimental procedures
1. Surgery
(a) Definitions

- *to understand the principles and requirements of aseptic technique, survival and terminal surgery and those of major and minor operative procedures*

(b) Preparation for surgical procedures

- *to assess and produce all preparative procedures necessary on the animal, the operation site, the instruments and equipment, and the operator in various surgery types*

(c) Anaesthesia (see G)
(d) Operative complications

- *to obtain and use relevant recording apparatus to detect and correct possible complications (hypothermia, dehydration, haemorrhage, changes in acid-base balance) during the procedure*

(e) Operative approaches

- *to learn optimal incision lines, tissue handling, haemostasis, and wound closure on relevant species*

2. Care of surgical patients
(a) Pre-operative preparation

- *to evaluate the suitability of the animal for intended procedure, to ensure that proper adaptation has been achieved and to emphasize adequate hydration and fasting as required*

(b) Intra-operative care

- *to secure and monitor proper respiration, adequate cardiovascular function, body core temperature and hydration and other basic functions whenever necessary*

(c) Post-operative care and pain relief

- *to ascertain that both preplanned elements and those based on clinical evaluation are followed precisely in order to minimize morbidity and mortality*
- *to exercise proper pain relief when indicated (see G4)*

3. Specific surgical procedures

- *to encompass a wide variety of specific surgical interventions as exemplified by the following, but not excluding others*

(a) Transplantation techniques, tumour transplantation

- *to include basis of transplantation immunity: histocompatibility, graft rejection and privileged places*

(b) Instrumentation implants

- *to assess and be able to carry out the most commonly used implants (cardiovascular, stereotactic, urinary, gastrointestinal tract), to know the essentials of exteriorized connections and telemetric techniques, and understand the basics of implant care*

(c) Endocrinectomies

- *to achieve the basic knowledge and skills to carry out the most common ones in relevant species including the special considerations and after care*

4. Administration of substances
(a) Handling and restraint

- *to ensure completeness of the procedure with least stress to the animal and the investigator*
- *requirements, methods and care*

(b) General aspects

- *to include various characteristics required of substances to be administered*

(c) Administration routes

- *to include enteral and all the parenteral routes for relevant species*

(d) Administration techniques

- *to perform and assess various routes, administration volumes and species specific applications*

5. Sample collection
(a) Sites for collection

- *to describe and evaluate various sites for the different species*

(b) General aspects

- *to include both quantitative and qualitative characteristics*

(c) Methods for sampling body fluids

- *to include blood, urine and faeces, gastrointestinal contents, semen, cerebrospinal fluid, milk, peritoneal fluid and cells, bronchoalveolar lavage, exocrine fluids*

6. Miscellaneous techniques
(a) Recording methods and physiological data

- *to obtain reliable recordings of essential body systems (e.g. cardiovascular, respiratory, nervous) for both patient care and research purposes*

(b) Antibody production

- *to become acquainted with both animal and non-animal methods of antibody production*

(c) Perfusion methods

- *to become familiar both with in vivo perfusion (e.g. liver, intestine) and perfusion aiming for fixation of various organs*

(d) Restraint

- *to define requirements for use and the methods and care needed*

Accreditation

Obviously, not all aspects mentioned in the modules A–H can be studied in depth during the two-year programme. Prior to the start of the postgraduate study for category D a personal training programme should be prepared by the training institute. Depending on previous experience and personal interests emphasis may be placed on different aspects of the proposed curriculum. Thus, time allocated to each of the modules A–H may differ.

In order to harmonize specialist education in Europe it is strongly recommended that an Accreditation Committee be established. The task of this committee could be to approve proposals for personal training programmes, to allocate the time to be devoted to each of the modules and to develop an accreditation scheme for training institutes. FELASA should take leadership in promoting the establishment of such an Accreditation Committee.

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