OMCL Network of the Council of Europe QUALITY MANAGEMENT DOCUMENT

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AIDE MEMOIRE FOR ENVIRONMENTAL CONDITIONS AND TREATMENT OF BIOLOGICAL MODELS

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Concerned Network	GEON

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

Aide mémoire for environmental conditions and treatment of biological models

I. Introduction

This document was elaborated by experts and it is based on the current state of the art knowledge and OMCL in-house practices.

The questions in the first column are addressed to the testing laboratories; they are to be answered thoroughly by the laboratory itself before the evaluation takes place, with indication of corresponding reference documents (e.g. Quality Manual, SOP, working instructions etc.), in order to provide an efficient assessment basis to the auditors. Should any requirement be non-applicable, this must be indicated by "NA" under the "References" column and fully justified.

During the audit, this document provides a practical tool for the auditors to make sure that all elements are covered, but it will not be used as such to prepare the audit report.

This document may also be used by OMCLs as self-assessment of the implementation status of the Management System, independently of any external assessment.

II. Definitions and Abbreviations

OMCL = Official Medicines Control Laboratory

Authority = competent authority that gives the order to test a medicinal product

III. Reference documents

1) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010.

2) OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring.

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General considerations	**Y**	**N**	**References / Comments**
Is compliance with all the laws, regulations and guidelines relevant to the production, maintenance and use of laboratory animals ensured?			
1 Personnel and Competence	**Y**	**N**	**References / Comments**
1. 1 Legislation, welfare and ethical aspects			**NOTE**: some information related to §1 might not be available at the animal house, and it should be checked during the audit of the Quality Management System.
1.1.1 Are qualification, education and experience sufficient to ensure compliance with the law?			
1.1.2 Are qualification, education and experience sufficient for ethical supervision of animal facilities?			
1.1.3 Are qualification, education and experience sufficient to ensure that specialised staff members have a good working knowledge of the opportunities and limitations of alternative methods?			
1.1.4 Has the laboratory implemented 3R methods (replacement, reduction and refinement)?			
1.1.5 Ethical considerations : - are projects submitted to an Ethical Committee for evaluation and authorization? - are projects performed taking into account the degree of severity of the procedures? (see Annex VIII of EU Directive 2010/63) - are methods selected, where possible: o to use the lowest possible number of animals? o to cause the minimum pain, suffering or distress? o to replace death as an end-point by more humane end-points using appropriate clinical signs? - are animals euthanased by competent staff using appropriate methods? (see Annex IV of EU Directive 2010/63)			

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1.2 Training		**Y**	**N**	**References / Comments**
1.2.1	Is a training plan set up and approved in order to guarantee up to date training for the personnel?			
1.2.2	Is there any obligation for personnel to participate in training courses and to which extent?			
1.2.3	Is the information on relevant qualifications, training and experience of the staff documented and up to date? Is it possible to consult it? Where?			
1.2.4	Do qualification, training and experience of the personnel correspond to the requirements for the assigned work?			
1.2.5	Are overlapping of or gaps in responsibilities avoided?			
1.2.6	Are personnel aware of their area, extent and the limit of their duties and responsibilities?			
1.2.7	Are the necessary competence and the qualifications of the technical manager of the laboratory (training, courses, publications, experience) recorded?			
1.2.8	Is there a deputy for the technical manager?			
1. 2.9	Are the necessary competence and the qualifications of the quality manager responsible for the follow up of the management system (training, courses, publications, experience) recorded?			
1.2.10	Is there a deputy for the quality manager?			
1.2.11	Are the competencies for the personnel doing the tests specified?			

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		Y	N	References / Comments
1.2.12	Are the personnel aware of ethical regulations and animal suffering?			
1.2.13	Is the organisation of the testing laboratory documented and put under the documentation and change control?			
1.2.14	Is the organisation adequate for: - finding mistakes or doubts related to a test method, within a given time period? - finding solutions - checking the effectiveness of these solutions?			
1.3	***Occupational health and safety of personnel***	**Y**	**N**	**References / Comments**
1.3.1	Is an institutional program for a safe and healthy workplace established and implemented?			
1.3.2	Does the program cover all personnel who work in the animal facility?			
1.3.3	Does the program include: - training on zoonoses, hazards and pregnancy/illness/immunosupression precautions? - training on personal hygiene procedures (i.e. work clothing, eating/drinking/ smoking policies)? - training on specific procedures for personnel protection (shower/change facilities, injury prevention)? - preventive medicine for personnel (i.e. immunizations, as appropriate, for rabies, tetanus. etc.)?			

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2	***Premises*** ***Animal Facilities***	**Y**	**N**	**References / Comments**
2. 1	***General arrangements of the premises***			
2.1.1	Are the animal facilities designed in accordance with the provisions of the Directive 2010/63/EU of the European Parliament and of the Council of 22/09/2010 on the protection of animals used for scientific purposes?			
2.1.2	Are there separate areas for simple observation, for surgical procedures, collection of samples and post-mortem examination?			
2.1.3	Is manipulation of level 2 microorganisms correctly performed?			
2.1.4	Is the laboratory arranged so as to minimize the risk of cross-contamination, where this is significant to the type of test being performed (i.e. “no way back layout”, to carry out procedures in a sequential manner to ensure test and sample integrity, to segregate activities by time or space)?			
2.2	***Environment and monitoring***	**Y**	**N**	**References / Comments**
2.2.1	Is the laboratory aware of the potential for contamination of areas both inside and outside?			
2.2.2	Has the laboratory demonstrated that it has taken appropriate measures to avoid contamination?			
2.2.3	Is the space sufficient to allow work areas to be kept clean and tidy?			
2.2.4	Are the rooms appropriately ventilated?			

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		Y	N	References / Comments
2.2.5	Are air-filters appropriate, inspected, maintained and replaced according to the type of work?			
2.2.6	Are the following environmental factors in the animal facility sufficiently controlled so that tests can be executed reproducibly? – temperature, – relative humidity, – steam, – noise and vibration, – electromagnetic interference, – pest infestations (e.g. insects, rodents) – other elements, e.g. dust			
2.2.7	Are there facility standard operating procedures in place?			
2.2.8	Is there a documented animal room environmental monitoring procedure in place?			
2.3	***Access***	**Y**	**N**	**References / Comments**
2.3.1	Is the access restricted to authorized personnel only?			
2.3.2	Is the access sufficiently controlled to limit or make impossible, if necessary, the access of unauthorised persons?			
2.3.3	Where such restrictions are in force, is the staff aware of: (a) the intended use of the particular area, (b) the restrictions imposed on working within such areas, (c) the reasons for imposing such restrictions?			

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2.4	***Hygiene***	**Y**	**N**	**References / Comments**
2.4.1	Is the clothing worn appropriate to the type of testing being performed and removed before leaving the area?			
2.4.2	Do the personnel wash their hands after handling cultures and animals, after removing gloves and before leaving the animal facilities?			
2.4.3	Are eating, drinking, smoking, handling contact lenses, applying cosmetics and storing food for human use forbidden? Are personal possessions prohibited in the work area?			
2.4.4	Do persons who wear contact lenses in animal rooms also wear goggles or a face shield?			
2.4.5	Are measures taken to avoid accumulation of dust?			
2.4.6	Are walls, floors, ceilings and surfaces non-absorbent and easy to clean and disinfect?			
2.4.7	Are there concave joints between the floor, walls and ceiling?			
2.4.8	Are doors to animal rooms kept closed or locked when experimental animals are present?			
2.4.9	Are all wastes from the animal room appropriately decontaminated, preferably by autoclaving, before disposal?			
2.4.10	Are infected animal carcasses incinerated after being transported from the animal room in leak proof, covered containers?			
2.4.11	Are the personnel trained on how to conduct euthanasia to ensure the safety of the operator and to limit animal suffering?			

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2.5	***Animal Health Monitoring***	**Y**	**N**	**References / Comments**
2.5.1	Is a clinical health-monitoring programme established under the direction of a veterinarian?			
2.5.2	Is there a comprehensive screening programme in place for facilities and animals to detect the presence of unwanted infectious organisms, which can influence the outcome of experiments (i.e. viruses, bacteria and fungi, parasites)?			
2.5.3	Is the genetic background of the animals (genotype) described (qualitative standardisation)?			
2.6	***Housing and Care***	**Y**	**N**	**References / Comments**
2.6.1	Are standards in place for good husbandry and animal welfare?			
2.6.2	Are legal animal welfare regulations assessed regularly?			
2.6.3	Are there staff responsible for the supervision of the welfare and care of the animals?			
2.6.4	Before they are introduced into the premises, are new animals kept separated and tested before they are put together with other animals at the unit (quarantine)?			

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2.7	***Husbandry, Breeding and Genetics***	**Y**	**N**	**References / Comments**
2.7.1	Housing/caging system: are optimal housing equipment and conditions for the animals secured?			
2.7.2	Are the behavioural and socialization needs of the animals met?			
2.7.3	Are the micro- and macro environment monitored with respect to: temperature, relative humidity, ventilation, relative air pressure and air filtration, lighting, noise and other factors?			NOTE: environmental monitoring is covered separately in section 2.2.6.
2.7.4	Are there alarm systems in place for the environmental conditions?			
2.7.5	Nutrition and feeding: Are the requirements and the effects of various aspects of feed and feeding assessed?			
2.7.6	Watering: Are water delivery systems assessed and monitored? Is the water quality assessed and monitored?			
2.7.7	Is breeding performed?			
2.7.8	Are breeding programmes appropriate e.g. number, age, sex, genetic and health quality?			
2.7.9	Is storage of food and litter appropriately performed and monitored?			

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2.8	***Veterinary Medical Care***	**Y**	**N**	**References / Comments**
2.8.1	Is it established that a veterinarian has access to all animals?			
2.8.2	Does the veterinary authority oversee all aspects of animal care and use?			
2.8.3	Does the veterinary authority provide guidance on handling, immobilization, sedation, analgesia, anaesthesia and euthanasia?			
2.8.4	Preventive medicine/animal procurement and transportation: Are policies in place on (i) evaluation of animal suppliers, (ii) lawful animal procurement and transport, (iii) legal quarantine, (iv) separation by species, source and health status, (v) isolation of sick animals and (vi) availability of diagnostic resources for preventive health programs?			