



Center for Comparative Medicine

Tools for Research Support and Development,
with experience and quality.



ICIVET LITORAL

About the Center for Comparative Medicine

“Over 15 years providing technological support for biomedical research”

The general objective of the Center for Comparative Medicine (CMC) at the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral “(Esperanza, Santa Fe, Argentina) is to do research with laboratory animals under international standards of ethics and quality regarding their use and care.

The CMC was established in August 1997 by teachers and researchers interested in the care and use of laboratory animals, primarily for research in veterinary science, medicine and biology. The CMC currently boasts with a total area of approximately 500 m² for production of different laboratory animals, biological testing, quality management and administrative offices. Since March 2013, the CMC has become part of the Instituto de Ciencias Veterinarias del Litoral (Institute of Veterinary Sciences of Litoral) (ICiVet-Litoral), an Institute that belongs to the Scientific and Technical Research Council of Argentina (CONICET).

Activities at the CMC are focused on improving Animal and Human Health, through the provision of laboratory animals and the development of experimental models for improving products and biomedical procedures.

The team includes Veterinarians, Biologists, Biochemists, and graduates in Biodiversity and Biotechnology, as well as technicians specialized in the care of laboratory animals. The team thus covers different areas of the medical sciences such as pathology, microbiology, parasitology, pharmacology, toxicology, ethics and molecular biology, among others.

One of our key missions is to support qualified work for basic research, development, and quality control, for researchers and companies that require it.

As it is well known, laboratory animals are essential for most researchers working in the fields of biology, veterinary and medicine. In addition, laboratory animals are necessary for pharmacological and toxicological tests as well as for everything related to microbiology and physiology. On the other hand, we consider that respecting national and international standards on Ethics in Experimentation and Animal Welfare is essential. The work carried out at the CMC complies with the principles of international guidelines for research involving laboratory animals.



Quality Management

All records of the quality management system are available for on-site audit.

The CMC has implemented a Quality Management System according to the ISO 9001:2008 standards and complies with the requirements of Good Laboratory Practices (GLP). The Quality Management System, which is the result of the policy of quality defined by the Board of Directors of the CMC, includes the organizational structure, functions, activities, resources, staff training and necessary documentation to ensure that the services provided meet the expectations of customers in addition to legal and regulatory requirements related to the activity.

The functioning of the organization under a comprehensive Quality Management System provides control and forecast at the time of providing laboratory animals and carrying out services entrusted by third parties, thus lowering risks of disruptions during their performance and thus leading to an increase in the productivity of the organization and in the fidelity of our customers. In addition, the CMC has very strict and specific procedures to ensure the confidentiality of the relationship with customers.

The CMC also has a measurement and monitoring system that allows the continuous improvement of procedures to detect and analyze possible problematic aspects and thus implement the necessary actions to correct the causes of problems.

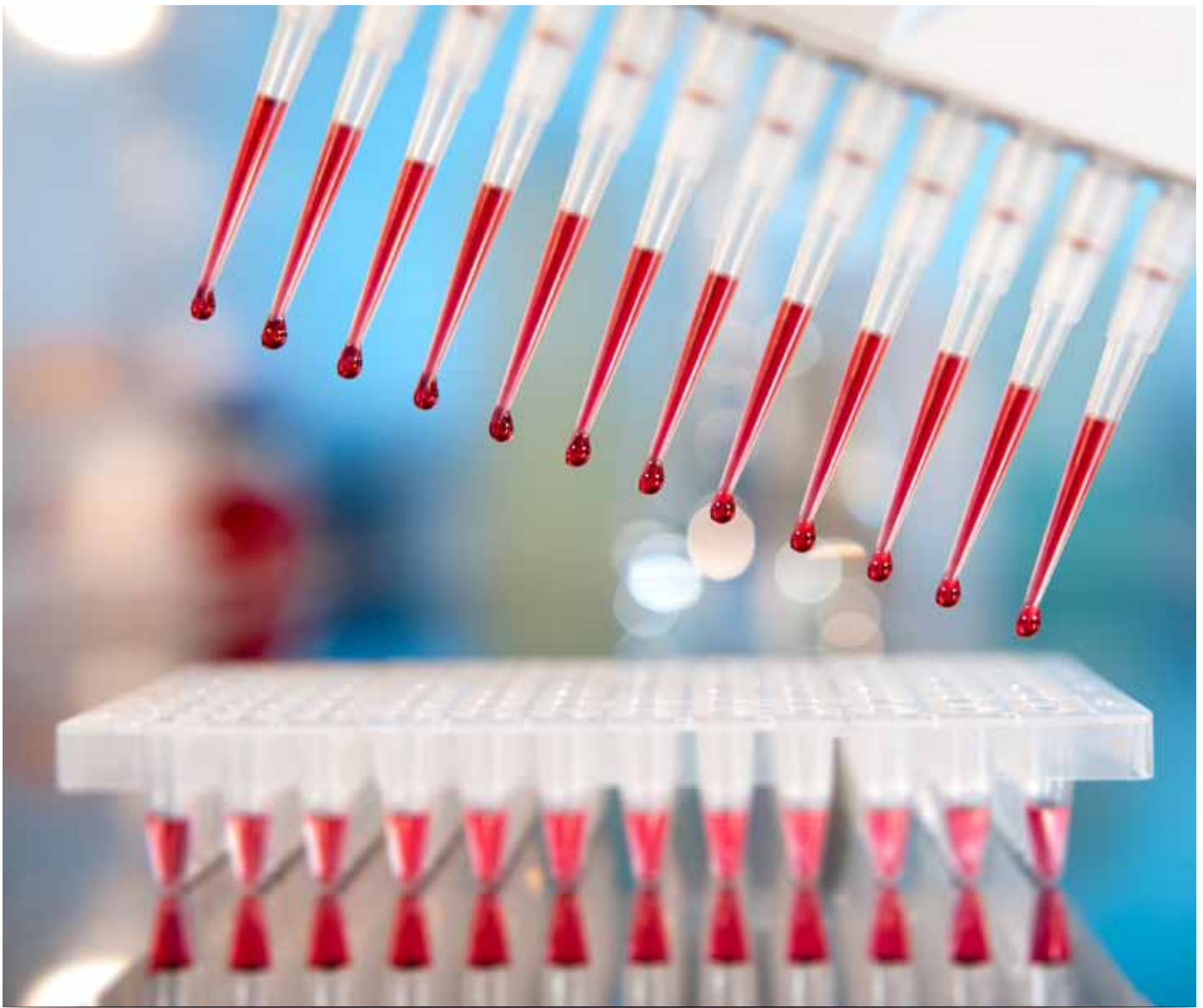
The organizational process includes periodic internal audits to each of the Areas that make up the CMC. In addition, clients make permanent audits to different processes within the CMC, an action that has led to many improvements in these processes.

The Quality Management System of the CMC is reflected on the following documents:

- Quality Manual
- Standard Operating Procedures (SOPs)
- Instruction Manual
- Instructional Charts
- Records

The CMS conducts regular microbiological quality controls of processes and supplies. It also performs microbiological monitoring of laboratory animals by external laboratories. Trained staff of the institution regularly performs clinical monitoring.





ANMAT

In 2007, the CMC adopted compliance with «Good laboratory practices» (GLP), which has been verified by the National Medicine Institute (INAME) of the National Administration of Drugs, Food and Medical Technology (ANMAT-Argentina).

SENASA

Since 2008, the CMC is part of the National Network of Laboratories Authorized by the National Service of Food Quality (SENASA, Argentina), for the supply of animals for laboratory and biological testing.

Good Laboratory Practices (GLP)

The term “Good Laboratory Practice” (GLP) generally refers to a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results as outlined in the OECD Principles of GLP and other national regulations. These include the mode of organization of non-clinical safety studies related to health and the environment as well as the conditions in which these studies are planned, run, controlled, recorded, archived and reported. The GLP apply to all non-clinical studies related to health and environmental safety required by regulators to register or authorize products such as Pharmaceutical products, Chemical pesticides, Biological pesticides, GMOs, Additives, Cosmetic products, Veterinary Medicinal Products and Industrial Chemicals. The CMC is currently in the process of achieving the monitoring of Good Laboratory Practices (GLP) and its recognition by the official Argentine Accreditation Organization (OAA).

Objetives:

The overall goal is an integrated approach to animal research laboratory under international standards

Overall aims.

- To produce high quality laboratory animals in sufficient numbers. To design, advise and execute biomedical assays, guaranteeing a high quality, to meet the requirements of different users.
- To ensure respect for national and international standards on the care and use of experimental animals.

Key aims.

- To encourage the development of basic and applied research on the use of animal models.
- To contribute to the generation of knowledge to improve the health and well-being of humans and animals.
- To provide technological support.
- To constitute a regional reference center and disseminate knowledge that highlights the importance of the use of experimental models in the study of biomedical sciences.
- To ensure respect for national and international standards on the care and use of animals for experimentation and other scientific purposes.
- To contribute to the integral formation of professionals in the Veterinary Sciences.
- To provide infrastructure and support for research and training of human resources within the scope of the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral and researchers from other public and private institutions that require it.



Ethics and Welfare

The use of animals in research, teaching, and biological testing, is acceptable only if it contributes effectively to a better understanding of biological principles

Animal experimentation is one of the fundamental pieces in biomedicine, research projects, diagnostic tests and controls for pharmacological products. In its 11th Inter-American Meeting of 1980, the Pan American Health Organization (PAHO) expressed that: «countries which have achieved a breakthrough in the control of human and animal diseases are those that have established entities dedicated to a better development of the Science of Laboratory Animals».

The use of animals in research, teaching and biological testing is acceptable only if it contributes effectively to the understanding of fundamental biological principles or to the development of knowledge that we can reasonably expect to benefit humans or animals.

Animals should be used only when the researcher has already sought for an acceptable alternative. The continuous exchange of knowledge, literature review, and adherence to the principles of «Three Rs» of Russell-Burch (Replacement, Reduction, and Refinement) are other necessary conditions. Researchers who use animals should use the most humanitarian methods available, make that the number used is the smallest possible, and use the appropriate species for valid results.

The works carried out at the CMC comply with the principles of international guidelines for research involving animals. In addition, the CMC has an Advisory Committee of Ethics and Safety, which was created to ensure that the activities that involve the use of animals carried out at the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral are conducted humanely and within the framework of international standards of ethics and biosecurity. Protocols and standard operating procedures held at the CMC are evaluated by this Committee.



Facilities of the CMC

In addition, there is an area of productive biological trials with cages and facilities for the management of large animals during clinical assays.

The CMC has 500 square meters, integrating production areas of different animal species, biological testing, quality management and several outbuildings for administration, maintenance and storage rooms.

All the rooms, including those for both production and biological testing, have automated controls of temperature, illumination and air renewal with high efficiency filtering systems.

The production area has four rooms for breeding and stock, as well as changing rooms, laundries, preparation of materials and an independent storage room.

The area of biological testing has rooms for the maintenance of different species, boxes for the housing, isolation and quarantine of large animals, and laboratories for general procedures and initial processing of samples.

There is also an administrative area, with a meeting room with a video conference system, an archive with a system of protection against fires, and research and development offices. The facilities have security systems that allow the permanent and remote monitoring of all the areas of the CMC by using high resolution cameras, as well as control equipment and environments through specific sensors that ensure the immediate response in case of any kind of emergency. The building is integrated with that of the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral, in direct relation with its Laboratories of High Complexity, which work in association. This allows us to address comprehensively the development of experimental protocols. These fully installed laboratories include:

- Laboratory of Applied Cellular and Molecular Biology
- Laboratory of Clinical Trials
- Laboratory of Pharmacology and Toxicology
- Laboratory of Food Analysis
- Laboratory of Image Analysis
- Laboratory of Microbiology
- Laboratory of Parasitology
- Laboratory of Histology and Pathological Anatomy





The equipment includes:

- A high efficiency filtering air conditioner system.
- Individually Ventilated Cages (IVC systems).
- Animal transfer stations with protection class II.
- Safety cabinets.
- An emergency power system.
- An autoclave.
- A system of automatic monitoring of environmental conditions.
- Ultrasound systems

The analytical equipment includes:

- Equipments for cellular and molecular biology (real time thermocyclers, digital microscopes, etc) for diagnosis and health monitoring.
- An LC-MS/MS system composed of a liquid chromatograph Shimadzu UFLC XR and a Triple Quadrupole Gas Chromatograph Mass Spectrometer AB Sciex Q-Trap 3200.
- A Near Infrared (NIR) Spectrophotometer Shimadzu Prestige.
- A Clinical chemistry autoanalyzer Metrolab 2300 plus.
- A hematology autoanalyzer Mindray BC-2800Vet.
- A cellular and tissue culture laboratory fully equipped for in vitro assays.



Animals

The CMC has its own production of genetically certified mice, rats and rabbits, as well as areas for the maintenance of other species often used in biological tests such as poultry, pigs and cattle.



Rats.
Wistar.

Mice.
BALB/cj.

Rabbits.
New Zealand.



Services offered.



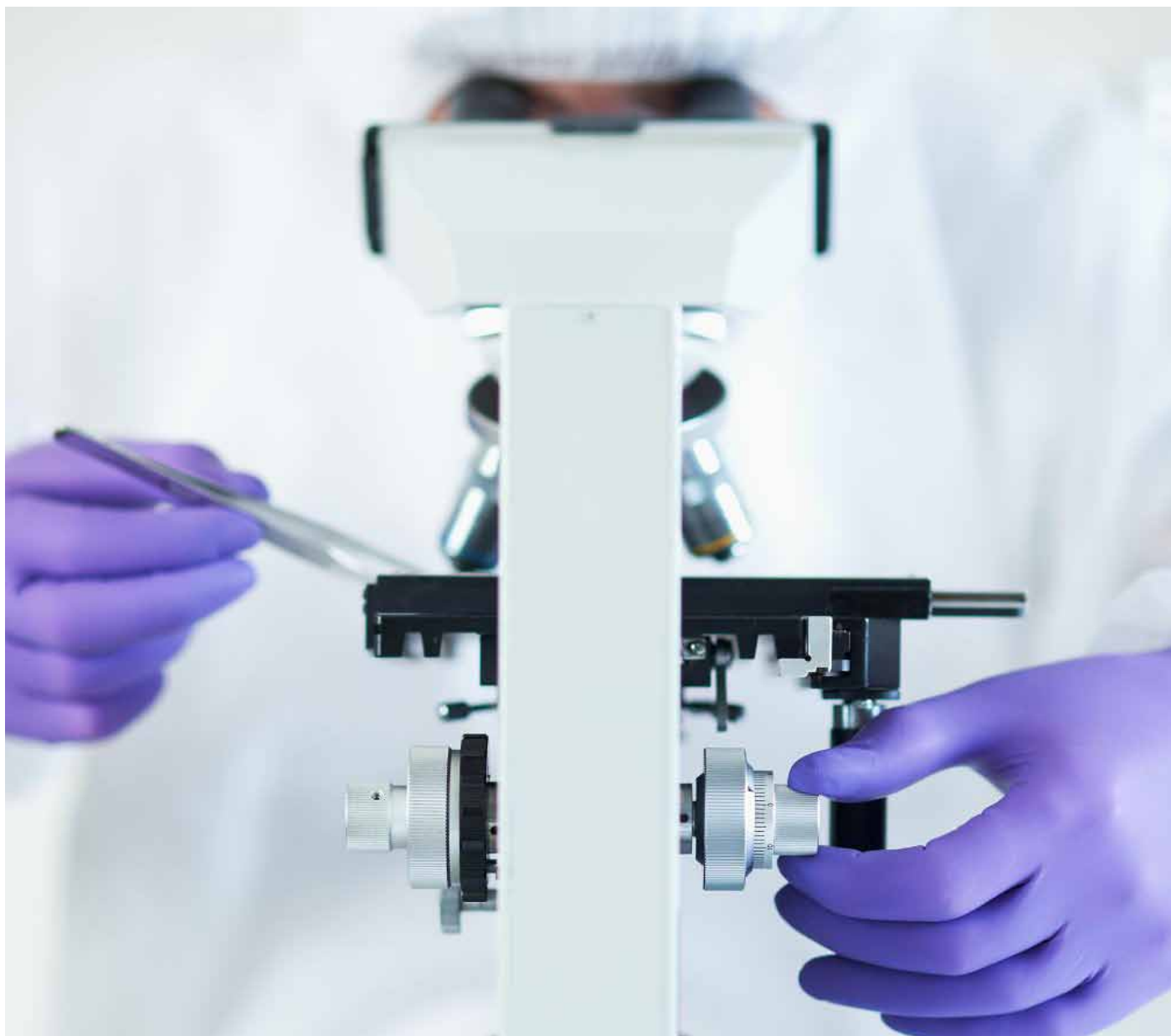
*Services performed by
specific laboratories
of the Faculty of Veteri-
nary Science,
Universidad Nacional
del Litoral.*

The main services provided by the CMC include:

- Provision of laboratory animals,
- Design and implementation of biological tests according to national and international standards (SENASA, ANMAT, OECD, FDA, EPA, Pharmacopoeias, etc),
- Planning and development of preclinical trials of high complexity according to national and international standards (ANMAT, FDA, EMEA),
- Planning and development of clinical trials in farm animals according to national and international standards (SENASA, VICH),
- Development of specific experimental models,
- Provision of biological reagents (serum, plasma, tissues),
- Preparation of polyclonal antibodies,
- Molecular biology techniques,
- Biochemical studies,
- Pharmacological studies,
- Toxicological studies,
- Histopathological studies,
- Immunological studies,
- Experimental surgeries.

In recent years, the CMC has provided services to more than 30 research and development groups rooted in National Universities of Argentina and Research Institutes and to more than 25 companies in the pharmaceutical and health sectors. In addition, it has provided animals for the development of Research and Teaching activities.

The CMC has a Quality Management System in operation, which is in accordance with the ISO 9001:2008 standards. This system includes the organizational structure, functions, activities, resources and documentation to ensure that the services provided meet the expectations of customers in addition to legal and regulatory requirements related to the activity. All records are available to audit on-site.



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