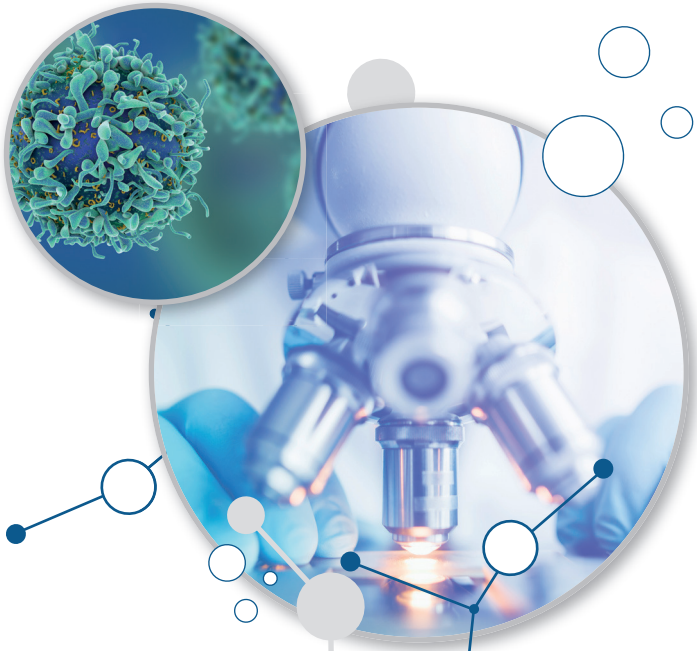
OUR MISSION

The main objective of our organization is to establish and develop a market position as a provider of highly qualified and innovative services for the pharmaceutical, biotechnology and med-tech industries.
We are committed to achieving our mission by providing high quality results and custom-designed solutions.

Our main task in R&D is "to Research new project commitments and Develop them into a long-term partnerships."



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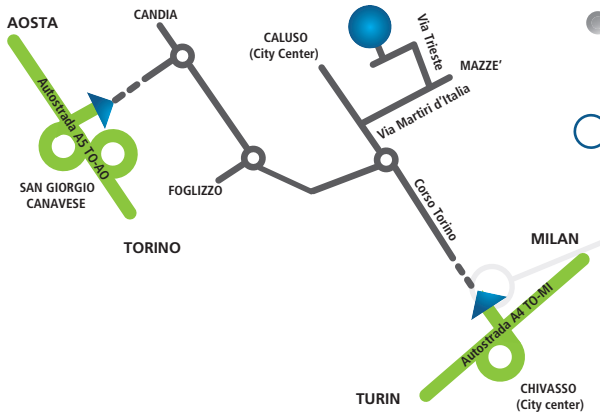
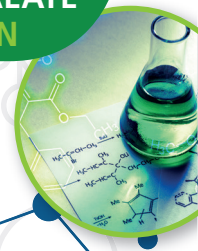


www.gemforlab.com

MDR

MIX DIFFERENT SKILLS AND CREATE YOUR PERFECT SOLUTION

THINKING OUTSIDE THE BOX



MEDICAL DEVICE
BIOLOGICAL EVALUATION

A **medical device** (or its constituent materials) must fulfill its function without causing side effects to the patient.
A set of in vitro methods, run in our laboratories, allow to evaluate the compatibility between the device (or parts of it) and human biological components, all through the development and validation stages.
The proposed tests are in accordance with the guidelines **ISO 10993** and can be performed in accordance with **GLP** quality standards.

CYTOTOXICITY - XTT/MTT ASSAY

The potential adverse effect on cell viability and function caused by the direct or indirect contact with a given medical device can be easily evaluated in vitro, monitoring the vitality and cell lines proliferation, tested by the **XTT** or **MTT** colorimetric assay.

GENOTOXICITY - AMES TEST

One of the key aspects to be evaluated in case of medical devices in contact with a biological system is the potential genotoxic effect on cells, exerted by the constituent material and/or by its leachable components.
An updated version of **AMES test**, suitably adapted to medical devices, allows to identify, in vitro, any alteration of the cell genome consequent to contact with the device.

HEMOCOMPATIBILITY

GEM FORLAB applies a set of methods to comprehensively evaluate the effects of direct or indirect contact of a medical device with blood and/or blood components.

Complement activation

Enzyme-linked immunoassay (ELISA)- mediated detection of the presence in plasma or serum specimens, of factor **SC5b-9**, namely the main marker of native human complement activation and therefore an index of innate immunity activation.

Leukocytes activation

ELISA test for the determination of plasma/serum levels of **polymorphonuclear leukocytes (PMN)-derived Elastase,** allows to evaluate leukocyte activation in a simple and quantitative way.

Hemolysis

Evaluation of the adverse effects of a medical device on erythrocytes, calculating, through the **cyanmethemoglobin** method, the amount of free hemoglobin in plasma/serum specimens.

Coagulation

The determination of **thrombin-antithrombin complex** (TAT) and **beta-thromboglobulin complex** (betaTG) allows the highlight the activation of the coagulative cascade and of platelets following the introduction of a xenomaterial.

INDUSTRIAL
PRODUCT VALIDATION

In addition to the tests required for the biocompatibility of new medical devices, GEM FORLAB provides a package of analytical services for the optimization of production processes and quality control services for batch release.

PYROGEN DETECTION - LAL TEST

The **limulus amebocyte lysate** (LAL) test is used in medical and pharmaceutical research to investigate the presence of endotoxins from Gram-negative bacteria in drugs, medical devices, water and raw materials.

The chromogenic LAL test (for endotoxin detection) has a sensitivity range between 0.01 and 1 EU/ml.

CONTAMINATION DETECTION

The molecular biology laboratory of GEM FORLAB is equipped to detect the presence of a large variety of industrial process contaminants: nucleic acids of fungal, bacterial, viral and human origin, RNAse, DNAse, mycoplasma, host cell proteins and host cell DNA

CONDUCTIVITY

BIOBURDEN