

Evaluation of cytotoxicity, safety and biocompatibility of products of pharmaceutical companies; medical- and dental devices, veterinary dental and cosmetic products; food products and all types implants.



Biotech Research Institute is a structural division of Samara State Medical University (SamSMU), an infrastructural multidisciplinary cluster that implements research, educational and innovative medical areas, as well as production in the field of biotechnology and personalized medicine at the international level. One of the areas of work of the Research Institute "Biotech" of SamSMU is to conduct preclinical studies using the author's two-stage technique on cells in vitro and laboratory animals in vivo. The existing core infrastructure is represented by the following departments:

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Scientific and Research Institute "BioTech" is a structural division of Samara State Medical University (SamSMU), an infrastructural multidisciplinary cluster implementing research, educational and innovative medical directions, as well as fabrication in the field of biotechnology and personalized medicine at the international level.

One of the directions of the SamSMU "Bio-Tech" operations is conducting preclinical studies according to the author's two-stage methodology on cells *in vitro* and laboratory animals *in vivo*. The available specialized infrastructure is represented by the following subdivisions:



Department of Cell Technologies (Cell Biotechnologies):



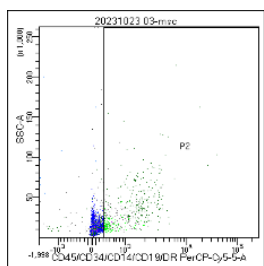
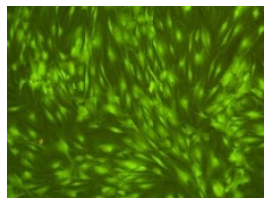
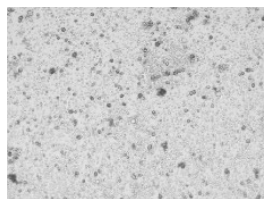
- Laboratory for obtaining primary cell cultures from various sources of human and animal tissues with a cryobank;
- Laboratory for the fabrication of biomedical cell products and cell lines;
- 3D bioprinting laboratory;
- Laboratory for the creation of universal test systems;
- Laboratory for testing drugs, biomaterials and physiotherapeutic factors *in vitro* (GOST RU, ISO, GLP).

Vivarium and preclinical testing department:

- Vivarium;
- Laboratory for testing drugs, biomaterials and physiotherapeutic factors *in vivo* on small, medium and large animals (GOST RU, ISO, GLP);
- Laboratory of fundamental preclinical research (morphological, biochemical, hematological).



In Department of Cell Technologies of the SamSMU «BioTech»:



- Technologies have been developed for obtaining primary cultures (stem, progenitor, differentiated) human and animal cells from different sources - a total of 8 populations from 32 sources.
- A cryobank of cells has been created, which is an analogue of ATCC and functions both in the Master cell bank format with cells from individual donors and frozen at early passages (3-6), and in Working cell bank format with increasing cell culture volume (passage 15-30).
- Our cell lines are characterized, traceable and can be cultured in vitro up to 30 passages, which makes them almost comparable to immortal cells.
- The advantages of our cellular products include a lower price compared to analogues from ATCC. At the same time, the volume of cell material sold in the case of ATCC is 0.5 million cells, in SamSMU "BioTech" - 1-2 million cells.
- We have developed test systems on primary juvenile cells cultures for in vitro comparative evaluation of the efficacy of new biomolecules, biosimilars and generics. We are developing test systems on human blood cells to study pathogenesis and personalized medicine in patients with socially significant diseases of inflammatory genesis (rheumatoid arthritis, gout, psoriasis) and organic pathology of the central nervous system (schizophrenia).
- For the first time in the world, an information-thermodynamic (fractal- entropy) approach to assessing the stability of the impact of external factors on organized cellular systems when analyzing the effectiveness and safety of drugs and other treatment methods (radiation and different physical factors) was introduced.
- The department has created a new cell biological model for research in space medicine.
- Technologies to create unique pioneering products for 3D bioprinting (allogeneic hydrogels and bioinks) and for producing hybrid cell-tissue products have been developed and implemented.



In Department of Preclinical Research of the SamSMU "BioTech" SamSMU:

Developed and implemented in the practice of research activity systems (GOST RU, ISO, GLP) on:

- Two-stage testing of drugs and biomaterials for safety and effectiveness on primary cell cultures (with determination of cell death by morphological and biochemical methods, assessment of proliferative activity and determination of the influence of the studied factor on the adhesive ability of cells), as well as on laboratory animals

(using morphological, biochemical, hematological, radiation (X-ray, CT, micro-CT) and visualization (endoscopy, angiography) methods);



- Assessment of the antitumor effect of chemical, biological agents and physiotherapeutic factors on immortalized cells, including analysis of the stability of the identified effect using an information-thermodynamic (fractal-entropy) approach;
- Analysis of biocompatibility and biointegration (fibro-, chondro-, osseointegration) of implants (dental, orthopedic, surgical) in laboratory animals with assessment of the surface of the product, including the use of the author's package of specially designed software.

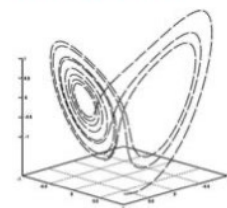


PARTICIPATION IN THE FEDERAL & INTERNATIONAL PROJECTS:

Scientific projects


- As part of the Priority 2030 strategic academic leadership program;
- As part of the National Technology Initiative (NTI) on the end-to-end technology "Bionic Engineering in Medicine";
- As part of the execution of the state task for carrying out scientific work.

приоритет2030⁺
лидерами становятся



Publishing projects

- Special issue "Biopolymers for Regenerative Medicine Applications" profile indexed journal Polymers, MDPI.

 polymers

IMPACT FACTOR 5.0
Indexed in: PubMed
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Значимые публикации

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Design of the study

of medical devices (dental implants) for safety, effectiveness and biointegration
Research is carried out according to the author's two-stage methodology in accordance with GOST RU, ISO and GLP.

Таблица 2-1

Stage	Biological object	Parameters studied	Assessment methods
I. Study in vitro on living cells	Mesenchymal bone marrow stromal cells, dental fibroblasts, epithelial cells*	Cell viability on the surface of the implant (cytotoxicity of the product material)	-Morphological; -Immunomorphological by fluorescence microscopy with fluorophores; -Biochemical with MTT and LDH tests
		Proliferative potency of cells on the surface of the implant	
		Adhesive properties of cells and adhesion to the implant surface	
		Assessment of implant surface cleanliness	Scanning electron microscopy (SEM) and (optional) chemical analysis of the product surface
		Statistical analysis of the results with applying of the author's information-thermodynamic (fractal- entropy) approach to assessing the stability of the influence of external factors on organized cellular systems	
II. Study in vivo on laboratory animals	Rats, rabbits**	Acute and (optional) chronic toxicity of the product material	-Morphological; -Biochemical
		Biocompatibility	-Morphological (histological)
		Biointegration	-Morphological: analysis of mineralized histological preparations - thin sections (slices) containing a fragment of the product and bone tissue, with assessment of the nature of biointegration and confirmation of the cleanliness of the surface of the product

*We use our own identified human cell lines obtained in the Cell Culture Laboratory of the SamSMU "BioTech" from primary material (tissue biopsies from healthy people).

**Rabbits of Soviet chinchilla breed, rats of Wistar stock line are used.

We hope for your interest in this study with productive collaboration and cooperation! Sincerely yours,

Prof. Larisa Volova

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The cost of cytology study is as follows (per study)

Research	Methods used	Cells / Cost			
		Bone marrow MSCs	Tooth pulp MSCs	Gingival mucosa epith. cells	Dental fibroblasts
<ul style="list-style-type: none"> • Cytotoxicity of implant's (sample) material with determination of viable and damaged cells • Cell proliferative activity • Cells' adhesion and viability on the surface of samples • Analysis of precipitated proteins on the surface of samples 	Cultural, biochemical, (MTT, LDH tests), morphological, optical (luminescence microscopy, SEM with examination of the elemental composition of the sample surface), electrophoretic (according to Laemmli).				
<ul style="list-style-type: none"> • Stability of the external factors influence on organized cellular systems 	Author's information-thermodynamic (fractal-entropic) method				

The cost of an animal study is as follows (per study)

Research	Methods used	Animals / Cost		
		Rats	Rabbits	Pigs
Safety and biocompatibility of implant's material	Morphological, morphometric			
Examination of the soft tissue surrounding the implant (implantation in a subcutaneous pocket)	Morphological, morphometric			
Determining the nature of integration of the implant's material with surrounding tissues (by studying thin sections / slices) and percentage of osteo- and fibrointegration	Morphologic, radiation (X- rays, CT scans, etc.), morphometric, visualization (SEM), statistical			
Cost (Russian Ruble)				

Legend: - realizable studies on this animal;

The size of the implanted element for a rabbit should not exceed 0.5-1.5 mm in diameter and 4-5 mm in length. The implantation area is the tibia;

The size of the implantable element for the pig can be matched to the standard manufactured samples. The implantation area is the lower jaw.

Sincerely yours / 곧 답장 받길 기대하겠습니다,

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