

MUNI | CREATIC

Central European Advanced
Therapy and Immunotherapy Centre



CZECRIN



CZECH CLINICAL RESEARCH
INFRASTRUCTURE NETWORK

Centre of excellence creatic

Faculty of Medicine, Masaryk
University
Brno, Czech Republic

Lenka Součková
Regina Demlová

7.10.2026
Core Facility Day



About creatic

*„CoE CREATIC as the flagship in CEE region, provides excellent research of **gene and somatic cell therapy** to deliver safe, accessible and affordable personalised treatment of life-threatening or chronically debilitating **rare disease patients** that are conventionally considered incurable.“*



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Teaming up with advanced partners



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R&I&D

- excellence in research, development and training in the fields of ATMP gene and cell therapies

- excellence in clinical research, immuno-monitoring and biomarker research

- excellence in biomedical innovation law; IP, data, and technology management; and legally supported RRI framework

Research support

- centre management
- human resources
- data management

- education and training

- stakeholder engagement
- knowledge valorisation



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER Part 1



in connection with manufacturing authorisation no 17692/2/INS/06, last variation no suks125048/2015 issued on 26.10.2015 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: Section 57 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals), as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12.11.2015, it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC¹.

¹ These requirements fulfil the GMP recommendations of WHO.

Part 2

☒ Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile Products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.4 Small volume liquids

1.1.3 Batch certification

1.3 Biological medicinal products

1.3.1 Biological medicinal products (list of product types)

1.3.1.3 Cell therapy products

1.3.2 Batch certification (list of product types)

1.3.2.3 Cell therapy products

1.5 Packaging

1.5.2 Secondary packing

1.6 Quality control testing

1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate:

1.3.1.3 Cell therapy products –

- autologous and alogenuous investigational medicinal products based on in vitro cultivation of immunocompetent cells
- autologous and alogenuous investigational medicinal products based on cultivation of hematopoietic and non-hematopoietic stem cells and immunocompetent cells including their depletion



40 mil EUR enterprise - building on 10 years excellence

ACIU

- Advanced Cell Immunotherapy Unit
- GMP unit certified by State Institute for Drug Control
- Current stage: technological setting serves to produce cell-based investigational therapies (DC, MSCs, MSCs on nanofibre)
- 2 existing ATMP cell-based products: **MyDendrix™** (high-risk malignancies), **FlyCellix™** (Epidermolysis Bullosa)
- Both products are currently in Phase I/II clinical trials.

CZECRIN

- LRI – national node of European Clinical Research Infrastructure Network (ECRIN–ERIC)
- Supported by a national network of clinical sites
- Expertise in three main pillars Clinical Trials Centre (CTC), Regulatory & Pharmacoeconomy Unit (RAPHE) and GMP Units
- Senior experts in key areas as regulatory, market access, GCP, clinical trials (including 3 experts with EMA experience as members of the CHMP, PDCO and COMP committees and 2 experts with previous pharma-business senior experience).
- Education and Training in designing clinical trials: CZECRIN Academy

MUNI | CREATIC

Central European Advanced
Therapy and Immunotherapy Centre

What is our mission AND VISION

Our Mission

To translate cutting-edge biomedical science into safe, effective, and sustainable therapies by combining **scientific excellence with regulatory and health system integration and innovation**, focusing on indications where commercial incentives are weak but patient need is high.

Our Vision:

By 2030, CREATIC will be **Central Europe's trusted ATMP Gateway**, recognised across Central Europe as a benchmark model for equitable translation, delivering a pipeline of therapies, spin-offs, and societal value.

A Key Hub for Central Europe

Located at a strategic point in **Central Europe**, CREATIC integrates academic, research, and clinical expertise, fostering collaboration across the region to accelerate the development and deployment of advanced therapies.



OUR FOCUS - Advanced Therapy Medicinal Products (ATMP)



CZECRIN



gene therapy
medicinal products



somatic cell therapy
medicinal products



tissue-engineered
products



combined ATMP
(medical device)

- 🎯 Targeting the origin of disease (wide variety of diseases, inc. rare genetic)
- 🎯 Personalised
- 🎯 Mostly single dose
- 🎯 Regulation (EC) 1394/2007

CoE CREATIC EXPERTISES AND CAPACITIES



Research programmes

- Advancing Innovation in Cell & Gene Therapies
- Strategic Partnerships for Cutting-Edge Research
- Translating Research into Patient Impact

State-of-the-Art Infrastructure for Advanced Therapies

- CREProFa – CREATIC Production Facility
 - Advanced Cell Immunotherapy GMP Unit (ACIU)
 - Gene Advanced Therapy GMP Unit (GATU)
 - Biotechnology Protein GMP Unit (BiGU)
 - QC and R&D Laboratories | Storages & Warehouses

Complex expertise and Services across the life cycle of the products

- Regulatory Affairs (RA) – Knowledge & Expertise
- Data Science– Advanced Analytics & Evidence Generation
- Knowledge Valorization Unit (KEVIN)
- Comprehensive Clinical Trials Services
- Instant access to patients through CZECRIN HUBS accross the country and ECRIN_ERIC EU wide
- Education

State-of-the-Art Infrastructure for Advanced Therapies

□ Comprehensive Facilities:

- Advanced Cell Immunotherapy GMP Unit (ACIU)
- Gene Advanced Therapy GMP Unit (GATU)
- Biotechnology Protein GMP Unit (BiGU)
- QC and R&D Laboratories | Storages & Warehouses

□ Clean Rooms (1,000 sq. m):

- GMP-certified areas with cleanliness classes A, B, C, D & CNC (Controlled Not Classified)

□ GMP Compliance:

- ✓ Validated processes & monitoring
- ✓ High-level qualification of staff
- ✓ Advanced analytical & microbiological methods
- ✓ Cutting-edge equipment and knowledge

Cutting-edge facilities offer a comprehensive environment for advanced cell and gene therapy research, development and GMP production, designed to meet the highest standards of quality and safety.



CZECRIN



Clinical Trials Services

Via CZECRIN expert team CREATIC provides comprehensive services to implement clinical trials and research in the field of medicinal products, diagnostic methods and medical devices following Czech and GCP legislation.

National Clinical Trials Center & Local HUBs

- Coordinated infrastructure supporting initiation, conduct and harmonisation of clinical studies.
- Regional accessibility ensuring equitable patient recruitment and investigator engagement.
- Broad collaboration with the majority of Czech hospitals, ensuring access to diverse patient populations and specialised expertise.

Comprehensive trial planning & execution (Phases I–IV)

- End-to-end services: protocol development, biostatistical design, operational delivery, monitoring, and project management.
- Clinical Trial Regulatory Authority (SÚKL) and Ethics Committee Submission
- Pharmacovigilance for CTs
- Alignment with ICH-GCP and EMA/FDA standards.

Access to ECRIN – ERIC panEU network





CZECRIN

CZECRIN

CZECH CLINICAL RESEARCH
INFRASTRUCTURE NETWORK

Česká národní infrastruktura pro klinický výzkum
Czech Clinical Research Infrastructure Network

Nezávislá, integrovaná národní infrastruktura pro klinický výzkum, která poskytuje koordinovanou podporu pro akademický i smluvní klinický výzkum napříč Českou republikou.

"An independent, integrated national infrastructure for clinical research, providing coordinated support for both academic and contract-based clinical studies across the Czech Republic."

MUNI
MED

MINISTRY OF EDUCATION,
YOUTH AND SPORTSST. ANNE'S
UNIVERSITY
HOSPITAL
BRNO

CZECRIN: From a Large Research Infrastructure to a National Clinical Research Infrastructure

Evolving roles, services and impact for patients, researchers and the Czech healthcare system

CZECRIN



TOGETHER
FOR BETTER
HEALTH



2014 – 2019

Supporting academic clinical trials

- **Building core expertise**, capacities and services
- **Establishing a network** of collaborating centres
- **Supporting non-commercial** clinical trials
- **Integration into the European research environment** (ECRIN-ERIC)

BUILDING THE FOUNDATIONS



2020 – 2025

Developing the national infrastructure

- **Expansion of the national network** of centres and specialised capacities
- **Connecting** clinical centres, expertise and research communities (DONETs)
- **New technologies and areas** (ATMPs, digitalisation, data)
- **Patient and public involvement** (PPI)
- **Stronger European position** and international collaboration

EXPANDING AND CONNECTING



2026 and beyond

National clinical research infrastructure

- **A comprehensive clinical research ecosystem** in the Czech Republic
- **Supporting academic and commercial** clinical research
- **Connecting** healthcare institutions, expertise, data and processes
- **Partner in the implementation** of the Czech National Clinical Trials Strategy 2026–2035
- **Greater impact** on healthcare and patients

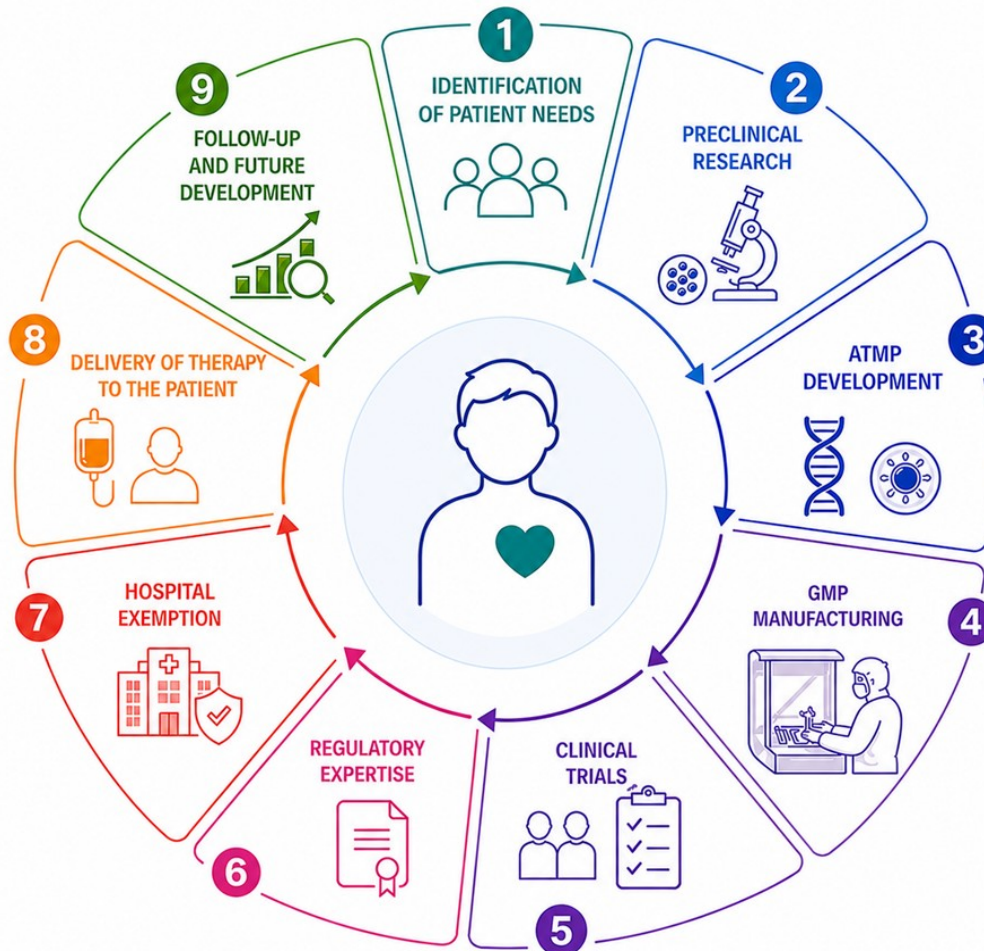
SUSTAINABLE IMPACT



CZECRIN is not only expanding its services. Its role within the Czech clinical research ecosystem is evolving.

One-Stop-Shop Approach

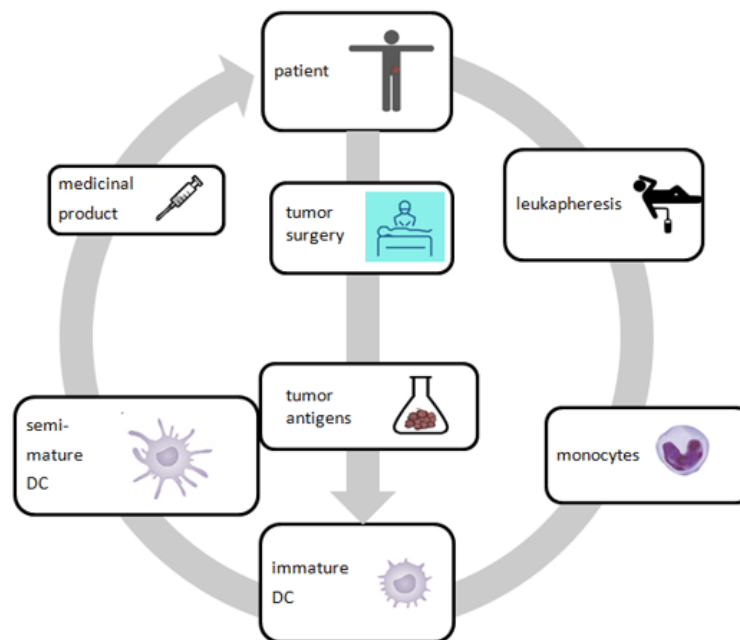
From a patient's need to a personalised treatment solution



Research programmes

Current ATMP for Rare disease: pediatric solid cancer

MyDendrix: cancer antigen-loaded dendritic cells Phase I/II trial



COMBINED ANTITUMOR THERAPY WITH EX VIVO MANIPULATED DENDRITIC CELLS PRODUCING INTERLEUKIN-12 IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS WITH PROGRESSIVE, RECURRENT OR PRIMARILY METASTATIC HIGH-RISK TUMORS

EudraCT number2014-003388-39

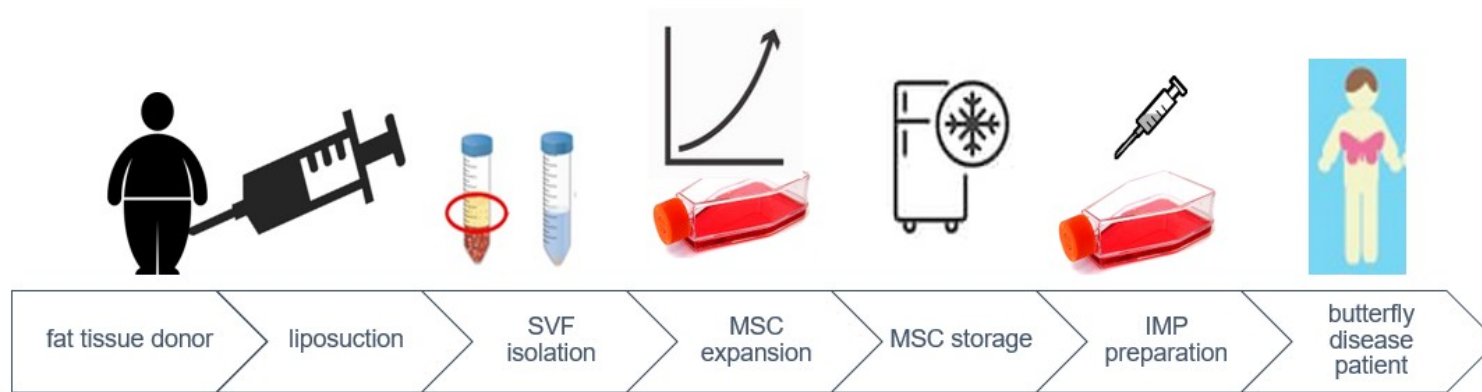
Leader: prof. RNDr. Lenka Zdražilová Dubská, Ph.D.



Research programmes

Current ATMP for Rare disease : epidermolysis bullosa congenita

FlyCellix: adipose tissue-derived MSCs Phase I/II trial



Non-Randomized, Phase 1/2 Safety and Efficacy Clinical Study of Allogenic Adipose tissue-derived Stromal Cells in Patients with Epidermolysis Bullosa

EudraCT number 2020-002936-55

Leader: prof. RNDr. Lenka Zdražilová Dubská, Ph.D.





Knowledge Valorization Unit (KEVIN)

Translating the research activities of the CREATIC into products or services with real economic, social or ethical value

- ☐ Development and production of ATMPs prepared on a non-routine basis according to Regulation (EC) No 1394/2007 („hospital exemption“, HE ATMP)
- ☐ Market access for HE ATMP (fair pricing, reimbursement, sustainable financing)
- ☐ Real availability of medicines for advanced therapies for patients with rare diseases.

Building an intellectual property management strategy to capitalise on the findings of the CREATIC

- ☐ Trade marks for CREATIC products and services
- ☐ Free to operate for R&D
- ☐ Management strategy for intellectual assets

Leader: MSc. Jiří Samek

ROZHODNUTÍ

Státní ústav pro kontrolu léčiv, se sídlem Šrobárova 49/48, 100 00 Praha 10 (dále jen „Ústav“), jako orgán příslušný k rozhodnutí podle § 13 odst. 2 písm. l) zákona č. 378/2007 Sb., o léčivech a změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (dále jen „zákon o léčivech“) **rozhodl** v souladu s § 67 a násl. zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů (dále jen „správní řád“), v řízení o povolení nemocniční výjimky pro léčivé přípravky pro moderní terapie vedeném podle § 49a zákona o léčivech (dále jen „nemocniční výjimka“) o žádosti o povolení nemocniční výjimky pro léčivé přípravky pro moderní terapie společnosti **CREATIC Production Facility, Centrum excellence CREATIC, IČ: 00216224** se sídlem **Lékařská fakulta, Masarykova univerzita se sídlem Kamenice 5, 625 00 Brno**, (dále jen „účastník řízení“) týkající se nemocniční výjimky pro léčivé přípravky pro moderní terapie s názvem autologní dendritické buňky produkující interleukin 12 (dále jen „předmětný přípravek“)

takto:

I.

Ústav v souladu s § 49a zákona o léčivech povoluje nemocniční výjimku pro předmětný léčivý přípravek

down in Directive 2003/94/EC¹,

¹ These requirements fulfil the WHO.

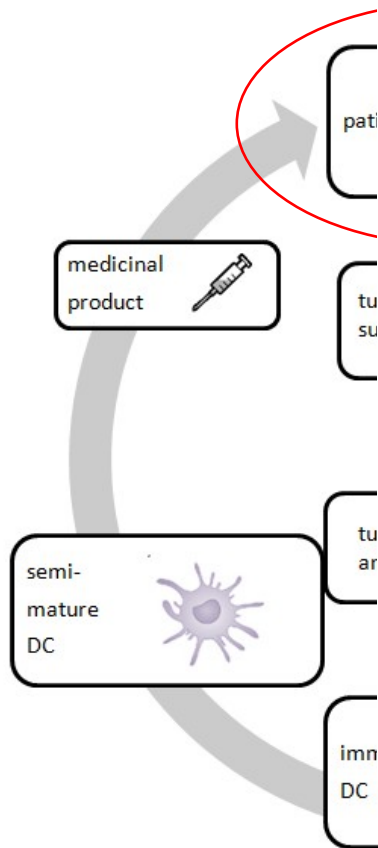
operations for the

st of product types)

Commitment

prescribed in ICH M4Q
User Fee Amendment)

1_Quality/M4Q_R1_.pdf



MyDendrix - Hospital Exemption approved by SÚKL as the first in the Czech Republic (12.3.2026)



STÁTNÍ ÚSTAV PRO KONTROLU LÉČIV	Šrobárova 48 100 41 Praha 10	Telefon: +420 272 185 111 Fax: +420 271 732 377	E-mail: posta@sukl.cz Web: www.sukl.cz
ADRESÁT CREATIC Production Facility, Centrum excellence CREATIC, Lékařská fakulta, Masarykova univerzita, Kamenice 5, 625 00 Brno	ADRESA PRO DORUČENÍ Lékařská fakulta, Masarykova univerzita, Kamenice 5, 625 00 Brno		
Sp. zn. sukls350180/2025	Vyřizuje/linka MUDr. Alice Němcová /817	Datum 12.03.2026	

ROZHODNUTÍ

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Hospital exemption:
a national pathway
for access to ATMPs



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Research programmes

Research Programmes – Expanding ATMPs Expertise

▣ Advancing Innovation in Cell & Gene Therapies

CREATIC strengthens and broadens comprehensive expertise in ATMP research & innovation.

▣ Strategic Partnerships for Cutting-Edge Research

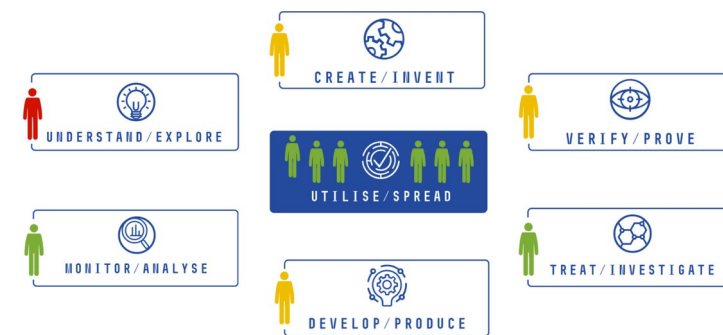
Collaboration with **Fraunhofer IZI**, **ULEI**, and **UCPH** will elevate MU's cell-based ATMP R&D beyond the state-of-the-art.

▣ Translating Research into Patient Impact

A core vision of CREATIC is to deliver research results to patients.

▣ Interdisciplinary Approach

Seven research programmes combining **STM (Science, Technology, Medicine)** and **SSH (Social Sciences & Humanities)** disciplines to drive breakthrough advancements.

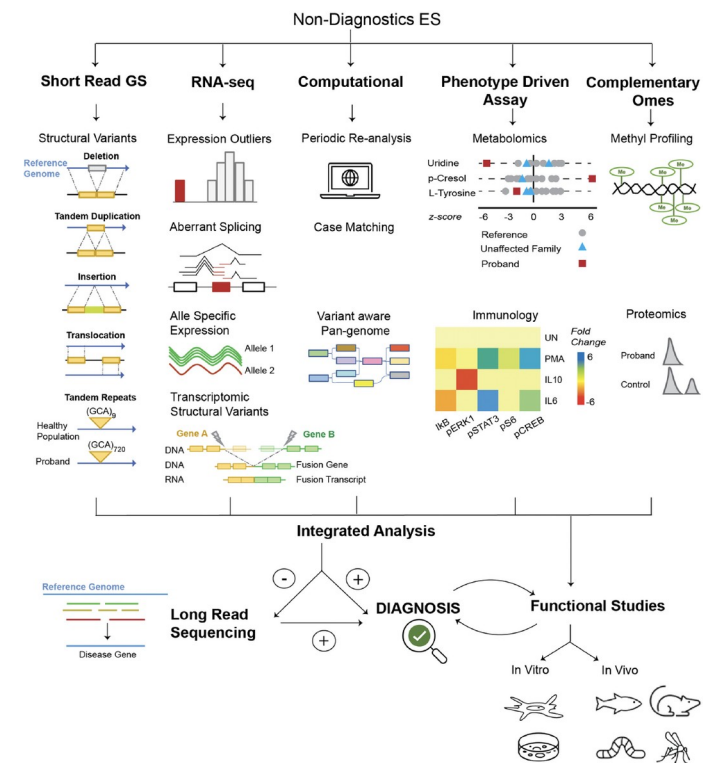


Research programmes

Advanced And Functional Genomics

In addition to **standard genomic and bioinformatic solutions**, as whole-exome (WES) and whole-genome sequencing (WGS), we use approaches for the advanced diagnostics and genomic characterization of the rare and ultra-rare diseases, which are **beyond the state-of-the-art**:

- ☐ Native long-read sequencing,
- ☐ Small and long RNAseq,
- ☐ Methylome analysis,
- ☐ Advanced bioinformatics
- ☐ And computational solutions as case matching.
- ☐ Drug-repurposing testing



Leader: prof. RNDr. Ondřej Slabý, Ph.D.



CENTRE FOR ACCESS TO ADVANCED TREATMENT SUPPORT (CAATS)

Supporting clinicians caring for children with rare and ultra-rare diseases. From comprehensive literature review to finding suitable clinical trials worldwide and facilitating connection with centres of specialised care.

- ☐ **Pharmacological Expertise**

Evaluation of treatment options and ongoing clinical trials to connect patients with appropriate studies and specialised care.

- ☐ **Research Inputs & Collaboration**

Collecting patient and family insights on unmet needs and cooperating with scientific teams (e.g., BIOCEV, CCP, CREATIC).

- ☐ **Education & Patient Engagement**

Providing information, seminars, and training to patients, families, and advocates via CZECRIN Academy and EUPATI.

Leader: PharmD. Adriána Papiež, Ph.D.



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No.	Diagnosis	Aberrant gene	Pathogenic variant/ mutation type	Clinical trial found	Pharmaco- therapy found	Details				
1	a neurodevelopmental disorder associated with a mutation in the GRIN gene	GRIN2B	gain	16	Cohen sy	VPS13B		no	no	
				17	ADCA-DN sy	DNMT1		no	not reviewed	
				18	FOXP1 mutation	FOXP1		no	not reviewed	
2	Pontocerebellar hypoplasia 6	RASR2	info pro	19	de novo variant in the SPTA1 gene	SPTA1	c.146T>C, p.L49P; c.146T>C, p.A867E	no	no	Mitapivat has been studied in adults with HS
3	Autosomal recessive spastic paraplegia, type 56	CYP2U1	info pro	20	CAMK2A mutation	CAMK2A	c.635C>T	not reviewed	yes	memantine as a therapeutic option based on preclinical data
4	FINCA sy	NHLRC2	info pro	21	Intellectual developmental disorder, X-linked 1		IQSEC2 c.2911C>T p.(Arg971Ter)	no	yes	The case reports describe only the treatment of epileptic seizures. Gene therapy is currently under development by Prof. Levy (Technion, Haifa, Israel); preparations are currently underway – to be monitored.
5	ReNU sy	RNU4-2	info pro							
6	Aicardi-Goutières syndrome, type 6	ADAR	c.30 p.(C>G)	22	RENU2 syndrome	RNU2-2:	n.4G>A	yes	no	only observational studies, none with a therapeutic aim
7	DEE91	PPP3CA	c.12 c.26	23	Developmental intellectual disability, type 7	DYRK1A	c.1001A>C (P.Asp334Gly)	no	yes	the theoretical possibility of personalised, targeted oligonucleotide therapy (ASO) under a compassionate use scheme (Consortium 1M1M, University of Tübingen, Germany), as well as L-carnitine supplementation
8	Enamel renal sy	FAM20A	c.12 c.55 2de							
9	CIPA sy	NTRK1	info pro	24	MECP2-associated disorder/atypical Rett syndrome	MECP2	c.746dup p.(Gly250TrpfsTer2 1)	no	yes	Several clinical trials are currently running (including those involving gene therapies), but the patient did not meet the inclusion criteria. Pharmacotherapy: trofinotide is registered with the FDA; the EMA has not yet approved it but is currently reviewing it – a decision is expected in Q3 2026.
10	EPM1	CSTB	exp doc							
11	ASD and vitamin B12	žádný	nor							
12	LMBRD2	LMBRD2	mis	25	Pitt-Hopkins syndrome	TCF4	c.1411C>T	yes	yes	drug repurposing: nicardipine, clemastine, vorinostat; gene therapy in research
13	SPG47	AP4B1	info pro							
14	pyruvate carboxylase deficiency	PC	info pro	26	CIPA sy	NTRK1	information not provided	no	not reviewed	
15	cerebrotendinous xanthomatosis	CYP27A1	info pro	27	ataxia telangiectasia	ATM	c.3320T>C + c.7630-2A>C	no	yes	nikotinamid ribosid, levacetylleucin, triheptanoin
				28	Alazami syndrome	LARP7	c.834dup + c.689dup	no	no	
				29	Developmental and Epileptic Encephalopathy Type 33	EEF1A2	c.424A>G	no	no	





COE CREATIC

- RESEARCH AND DEVELOPMENT OF ATMPs
- NON-COMMERCIAL GMP MANUFACTURING (CREPROFA)
- REGULATORY KNOW-HOW & TECHNOLOGY TRANSFER
- INFRASTRUCTURE FOR CLINICAL TRIALS (CZECRIN)
- KNOWLEDGE VALORIZATION & BUSINESS DEVELOPMENT
- PUBLIC AND PATIENT INVOLVEMENT (PPI)

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MUNI
MED

Surgical Anatomy Center

prof. MUDr. Marek Joukal Ph.D.

History of the Surgical Anatomy Center

- The establishment of the center at the Faculty of Medicine of Masaryk University in 2006
- Teaching undergraduate and postgraduate students in the form of courses and workshops focused on theoretical and practical education of non-interventional and interventional procedures in surgery
- Cooperation in the development and testing of new methods and materials for medical use

History of the Surgical Anatomy Center

- Research in the application of clinical anatomy in surgical disciplines
- Other specific research, for example, in the field of conservation of teaching cadavers
- Collection of necropsy tissues for teaching and research
- Teaching specialized educational courses

Organization of courses and workshops



Tuition of specialized education courses

🔗 Embalming, dissection and plastination techniques course



Erasmus+ SCaLPEL

- Focus on general surgery, plastic surgery, neurosurgery and spinal surgery



Cooperation in the development and testing of new methods and materials for medical use

○Gynecology and Obstetrics Clinic UHB, BUT, Medin



Research in the application of clinical anatomy in surgical disciplines



Use of free radial forearm and pronator quadratus muscle flap: Anatomical study and clinical application

Tomas Kempny^{a,b,c,1}, Zuzana Musilova^{d,1}, Martin Knoz^{a,e,*}, Marek Joukal^d, Lipový Břetislav^a, Holoubek Jakub^a, Wolfgang Paul Pöschl^d, Hsu-Tang Cheng^{b,h,i}

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^bMEDICent Clinic, Na Ctvrti 22, 70300 Ostrava, Hrabovka, Czech Republic

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^eClinic of Plastic and Aesthetic surgery, St. Anne's University Hospital, Faculty of Medicine, Pekarska 664/53, 602 00 Brno, Czech Republic

^fDepartment of Oral and Maxillofacial Surgery, Klinikum Wels-Grieskirchen 42, Grieskirchnerstrasse, Wels, Austria

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KEYWORDS
Radial forearm flap (RFF);
Pronator quadratus muscle (PQM);

Summary The authors present an anatomical study and clinical experience with radial forearm flap (RFF) and pronator quadratus muscle (PQM) application in the reconstruction of various body areas. The aim was to describe the anatomical placement and proportions of the PQM, the anatomical location of the major arterial branch of the radial artery supplying the PQM, and the application of this knowledge in clinical practice.

¹Tomas Kempny and Zuzana Musilova contributed equally to this work.

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Letter to the editor

Proximal- or radial-based dorsal capsulotomy? The importance of a proper cadaver study

Une capsulotomie dorsale à base proximale ou radiale?
L'importance d'une étude cadavérique appropriée

Dear editor-in-chief,

We read with great interest the article 'A new capsulotomy-based dorsal approach to the wrist: A cadaver study', where the authors described a modification of the commonly used approach. The new dorsal approach to the wrist joint, suggested by the authors, uses 'U-shaped with proximal base' capsulotomy. The ulnar longitudinal incision is made on the triquetrum bone insertion of the dorsal intercarpal ligament (DICL) and dorsal radiocarpal ligament (DRCL). The radial border is located in the extension of the medial edge of the radial styloid process. Finally, the capsular flap is created with incision along the DICL. The authors considered capsular flap healing more effective by maintaining the vascular supply via the dorsal branches of the anterior interosseous artery. In addition, they described the dorsal radiocarpal arch (DRCA) running along the radiocarpal joint line while the dorsal intercarpal arch (DICA) followed a trajectory parallel to the distal insertion of the DICL. The terminal branches of the anterior interosseous artery were described as having a longitudinal course, anastomosing with both of the arterial arches [1].

However, in their anatomical studies, Mestdagh et al. [2], Gelbermann et al. [3] and Kuhlmann et al. [4] found the DICA to be the largest, formed by the constant dominant branch – ramus carpus dorsalis – which originated from the radial artery in most cases just behind the trapezium. The dorsal carpal branch was the strongest blood vessel contributing to the arcade and contributed the greatest part in the supply to the dorsal capsule of the wrist. The radial part of the DICA provided the supplying branches running upward to the proximal row of the carpal bones. The DRCA was the second largest, and both of the arches were formed by the anastomosis of the terminal branches of the radial, ulnar and anterior interosseous arteries [2–4]. From our experience and from the aforementioned sources, it is clear that the arterial vascular supply to the dorsal portion of the carpal joint capsule is provided by the radial branches of the DICA (Fig. 1). The dorsal carpal branch is the dominant artery running distally or along the course of the DICL. The radial supplying branches run upward and across the DICL. The branches of the radial portion of the DICA are larger, more numerous and more constant than the dorsal branches of the anterior interosseous artery. Therefore, the modified proximal-based capsulotomy suggested by Athlani et al. [1] would not correlate with the position of the blood vessels and would affect the blood supply to the created flap. The radial and distal capsular incisions would interrupt crossing branches originating from the radial portion of the DICA. Due to the small number of specimens,

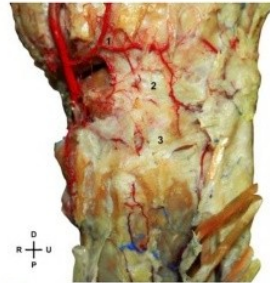


Fig. 1. Blood supply of the dorsal portion of the radiocarpal joint after injection of the radial (red), interosseous (blue) and ulnar (yellow) arteries. 1: dorsal carpal branch; 2: dorsal intercarpal ligament; 3: dorsal radiocarpal ligament.

the cadaver study with vascularization may not be a representative sample of the population. In order to preserve the vascularization of the capsular flap, its vitality and healing capacity, we would suggest capsulotomy with incisions respecting the position of the radial branches of the DICA crossing the DICL.

Conflict of interest

The authors declare that they have no competing interest.

Informed consent

The participant whose image was used in this correspondence had given informed consent for use of their body for medical research.

CRediT authorship contribution statement

Z. Musilova: Conceptualization, Investigation, Writing - original draft, V. Dzetkulicova: Conceptualization, Writing - review & editing, M. Joukal: Supervision, Conceptualization, Writing - review & editing.



Embalming methods research

Anatomical Science International (2023) 98:441–447
<https://doi.org/10.1007/s12565-023-00707-9>

ORIGINAL ARTICLE



Substantial decrease in SARS-CoV-2 RNA after fixation of cadavers intended for anatomical dissection

Kateřina Vymazalová¹ · Omar Šerý^{2,3,4} · Petr Králík³ · Radka Dziedzinská³ · Zuzana Musilová¹ · Jan Frišhons¹ · Tomáš Vojtíšek^{4,5} · Marek Joukal¹

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Abstract

With the onset of the COVID-19 pandemic, a problem arose with classic body donation programmes for obtaining cadavers for anatomical dissections, science and research. The question has emerged whether bodies of individuals who died of COVID-19 or were infected by SARS-CoV-2 could be admitted to Departments of Anatomy. To determine the risk of SARS-CoV-2 transmission to employees or students, the presence and stability of SARS-CoV-2 RNA in cadavers after fixation agents' application and subsequent post-fixation baths over time were examined. The presence of viral RNA in swabs from selected tissues was assessed by the standardized routine RNA isolation protocol and subsequent real-time PCR analysis. To support the results obtained from the tissue swabs, samples of RNA were exposed in vitro to short and long-term exposure to the components of the injection and fixation solutions used for the bodies' conservation. Substantial removal of SARS-CoV-2 RNA was observed in post-mortem tissue following perfusion with 3.5% phenol, 2.2% formaldehyde, 11.8% glycerol and 55% ethanol, and subsequent post-fixation in an ethanol bath. In vitro experiments showed significant effects of formaldehyde on SARS-CoV-2 RNA, while phenol and ethanol showed only negligible effects. We conclude that cadavers subjected to fixation protocols as described here should not pose a considerable risk of SARS-CoV-2 infection while being handled by students and staff and are, therefore, suitable for routine anatomical dissections and teaching.

Keywords Embalming · Dissection · Infections · Coronavirus · Polymerase chain reaction

Further development

- BioBanking – control tissues available for clinical research
- Fully equipped SAC in 2027, testing and research

Thank you for your attention

MUNI
MED

DEPARTMENT OF BIOLOGY

SGT - Shared Genomics Tools

Core facility | Faculty of Medicine, Masaryk University

Zdenek Andrysik

Department of Biology
Faculty of Medicine, Masaryk University

Core Facilities Day Life Science 2026
Masaryk University, Brno, October
7th



andrysik
lab
Molecular
Mechanisms
of Cancer

C G A B G C G
≡ I ≡
G C C O G T T

MUNI
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OF MEDICINE

Key advantages of lentiviral shRNA technology

Stable and Long-Term Silencing:

Unlike transient synthetic small interfering RNAs (siRNAs) that dilute out as cells divide, lentiviral shRNAs integrate into the host genome to provide persistent, long-lasting gene suppression.

Infects Dividing and Non-Dividing Cells:

Lentiviruses actively cross the nuclear membrane, allowing them to transduce stationary, terminally differentiated, or hard-to-transfect cells (such as neurons, primary cells, stem cells, and macrophages).

High Transduction Efficiency:

These vectors achieve high delivery rates across many mammalian cell types, avoiding the high percentage of non-transfected background noise seen with standard chemical transfection methods.

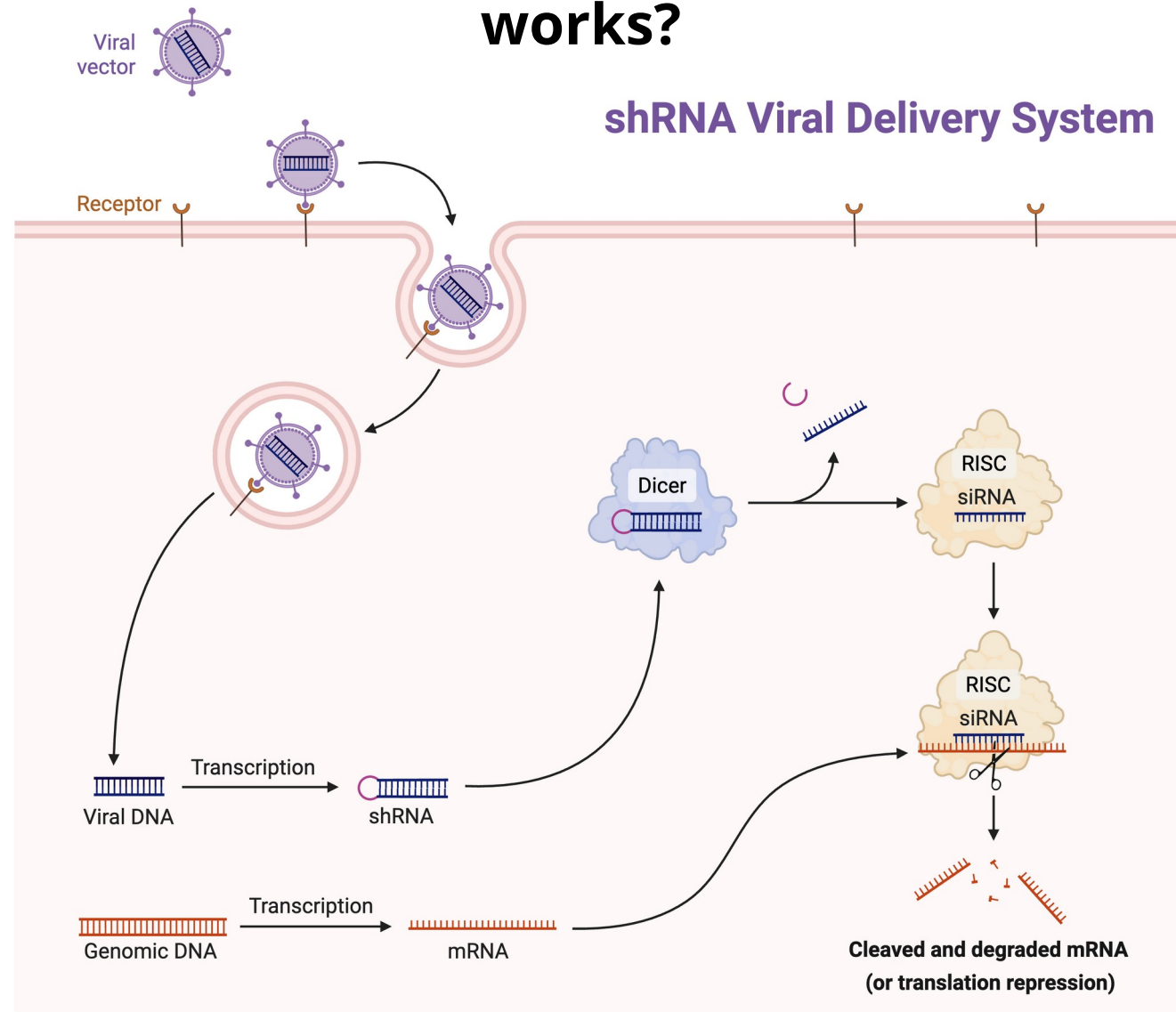
Stable Cell Line Generation:

Permanent genomic integration makes it straightforward to select, expand, and maintain stable knockdown cell populations using antibiotic markers (e.g., puromycin).

Applicability *In Vivo* and in Animal Models: Lentiviral shRNAs can be utilized for animal model research and localized or systemic *in vivo* gene silencing studies.

How it works?

shRNA Viral Delivery System



MISSION shRNA library - origins

The RNAi Consortium (TRC)

Academic & Research Institutions (Boston area & beyond)

The Broad Institute of MIT and Harvard (where the consortium is based)

Whitehead Institute for Biomedical Research

Dana-Farber Cancer Institute

Massachusetts General Hospital

Harvard Medical School

Massachusetts Institute of Technology (MIT)

Washington University in St. Louis

Columbia University

Corporate & International Sponsors

Sigma-Aldrich (now part of Merck, the principal distributor of the library)

Bristol-Myers Squibb

Eli Lilly and Company

Novartis

Academia Sinica (Taiwan)



BROAD
INSTITUTE

MISSION shRNA library – current distributor



Products ▾ 

 CZ |  EN ▾

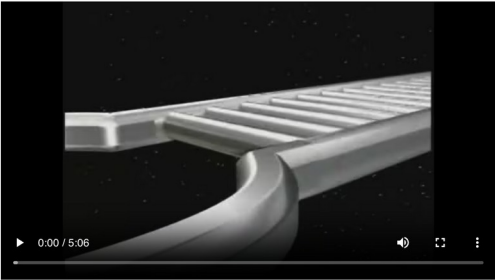
Products ▾Applications ▾Services ▾Resources ▾Support ▾Login / RegisterOrder LookupQuick Order Cart 

Home > [Gene Expression & Silencing](#) > [MISSION® Lentiviral shRNA](#)

MISSION® Lentiviral shRNA

MISSION® Lentiviral shRNA

This tutorial video demonstrates how MISSION® RNAi (RNA interference) experiments leverage the natural RNAi mechanism. MISSION® shRNA reduce the expression of specific target genes by targeting the specific mRNA therefore reducing the corresponding protein expression.



0:00 / 5:06

The RNAi consortium (TRC) comprehensive content

- Largest, most comprehensive shRNA library available, providing unparalleled genome coverage
- Pre-cloned genome-wide libraries: 245,000+ clone shRNA library targeting 20,000+ human and 21,000+ mouse genes

High-throughput manufacturing

- World class high-throughput viral manufacturing including high-titer virus for use *in vivo*

Flexible format options

- Entire libraries, gene panels, pooled libraries, or single gene sets offered in glycerol stock, DNA or viral format

Materials

Product Number	Product Name	Product Description	Pricing
SHIP001	MISSION® Lentiviral Packaging Mix	Production of replication incompetent viral particles	Expand ▾
CSTVRS	MISSION® shRNA	Custom Lentiviral Particles	Expand ▾
SHCLNV	MISSION® shRNA	Lentiviral Particles	Expand ▾
SHCLND	MISSION® shRNA	Purified DNA	Expand ▾
SHCLNG	MISSION® shRNA	Bacterial Stock	Expand ▾

Related Articles

- [Getting Started with MISSION® shRNA](#)
- [shRNAs for Individual Genes](#)
- [General shRNA FAQs](#)
- [Bioluminescent Firefly Luciferase Assays](#)
- [Introduction to Cell Transfection](#)
- [X-tremeGENE™ siRNA Transfection Reagent](#)
- [Reverse Transfection of Plasmid DNA](#)
- [Safe Lentivirus Handling](#)
- [View More >](#)

Related Product Categories

- [Gene Expression & Silencing](#)
- [Escort™ IV Transfection Reagent Protocol](#)
- [Preparation of Cationic Liposomes & Transfection of Cells - Avanti Research™...](#)
- [Protocol for Transducing Mouse Embryonic Fibroblasts \(MEF\) using...](#)
- [X-tremeGENE™ siRNA Transfection Reagent Protocol & Troubleshooting](#)
- [X-tremeGENE™ 9 DNA Transfection Reagent Protocol](#)
- [X-tremeGENE™ HP DNA Transfection Reagent Protocol](#)
- [CRISPR Cas 9 Nuclease RNA-guided Genome Editing](#)

MISSION shRNA library from the Shared Genomics Tools Library highlights

127 911

individual shRNA clones

>20 000

human genes targeted

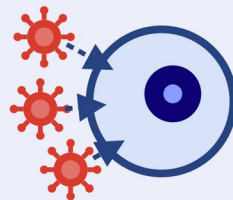
>30%

evaluated clones



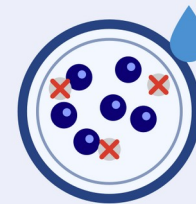
LENTIVIRAL VECTOR

pLKO vector with
a robust shRNA expression



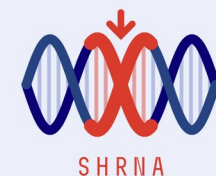
HIGH EFFICIENCY

works in difficult
to transfect lines



PUROMYCIN
RESISTANCE

rapid selection in 2-3 days

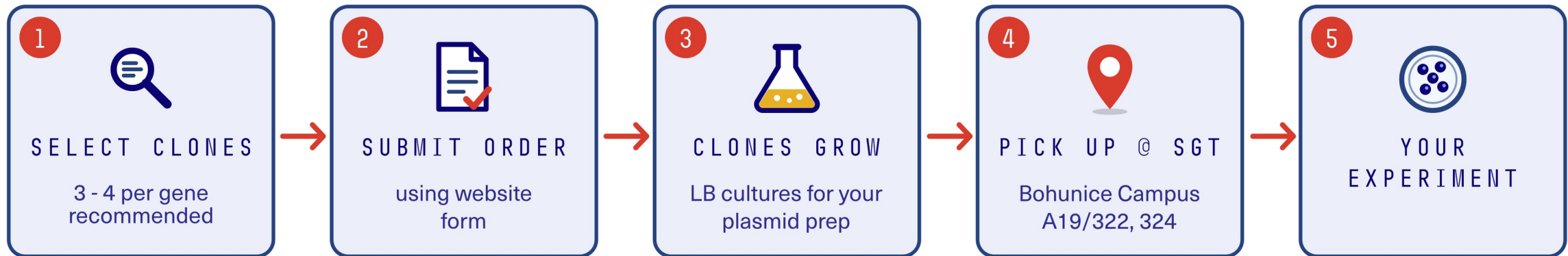


STABLE KNOCKDOWN

shRNA permanently integrated
into the host genome

MISSION shRNA library from the Shared Genomics Tools

Ordering your shRNAs from the SGT

 FAST TURNAROUND COST-EFFECTIVE VALIDATED CLONES NO SHIPPING DELAYS**10 - 14 days**from placing the order
to an expanded KD cell line**363 CZK**introductory price per clone
(LB culture, pick-up on campus)

Shared Genomics Tools

DEPARTMENT OF BIOLOGY CORE FACILITY

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Our mission

At the Shared Genomic Technologies core facility, we provide the scientific community with access to selected molecular biology tools, with a strong focus on minimizing financial costs and ensuring rapid delivery.

Our vision

In the future, we also aim to expand into the custom preparation of genetically modified research models, such as tailored cell lines. Currently, we focus on tools designed to regulate gene expression in mechanistic and functional studies. Our next step is to broaden our portfolio by adding arrayed libraries based on CRISPR and ORF vectors.

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ORDERING YOUR SHRNAS - A STEP-BY-STEP GUIDE

- 1) Go to <https://www.sigmaaldrich.com/CZ/en/semi-configurators/shrna>
- 2) Search for your gene of interest using the search box (eg: *TP53*)

The screenshot displays the Sigma-Aldrich website interface for ordering shRNAs. The top navigation bar includes the Merck logo, a search bar, and links for CZ and EN. The main navigation bar lists Products, Applications, Services, Resources, and Support. The breadcrumb trail shows: Home > Custom Products > RNAi Single Clones > Predesigned shRNA. The page title is "Predesigned shRNA" with a customer service number 420 246 003 200. A green banner states: "Save on 5 or more clones of the same physical material, deeper discounts when you exceed 25". The left sidebar shows a four-step process: Step 1 Product Search, Step 2 Select Clones, Step 3 Specifications, and Step 4 Review & Confirm. The main content area has two tabs: "Manual Search" (selected) and "Upload Queries". Under "Manual Search", there is a "Search Genes" section with the instruction: "Search by Gene Symbol, RefSeq or Gene ID (Enter up to 100 items separated by spaces)". A text input field contains "TP53", which is circled in red. A "Search" button, also circled in red, is located at the bottom right of the input field.

← → ↺ sigmaaldrich.com/CZ/en/semi-configurators/shrna?activeLink=itemSelection

Home > Custom Products > RNAi Single Clones > Predesigned shRNA

Predesigned shRNA

Customer Service | 420 246 003 200

Save on 5 or more clones of the same physical material, deeper discounts when you exceed 25

Step 1
Product Search

Step 2
Select Clones

Step 3
Specifications

Step 4
Review & Confirm

Search Criteria

Search Terms

TP53 ✕

Species

Select a Species

 Human

 Mouse

TRC Version ⓘ

☒ TRC1 ☒ TRC2

TRC Validation

☒ Yes ☒ No

Select shRNA Clones

Showing 1 - 10 of 123 Results

Per Page: 10 ▾ Sort By: TRC Clone ID (Ascending) ▾

☐ TRC Clone ID	Validation	Gene Symbol	Gene ID	Ref Seq	Species	Region	
☐ TRCN0000003753	Validated	TP53	7157	NM_000546	Human	CDS	Details ▾
☐ TRCN0000003754	Validated	TP53	7157	NM_000546	Human	CDS	Details ▾
☐ TRCN0000003755	Validated	TP53	7157	NM_000546	Human	CDS	Details ▾
☐ TRCN0000010814	Validated	TP53	7157	NM_000546	Human	3'UTR	Details ▾
☐ TRCN0000018865	Validated	TP53BP1	7158	NM_005657	Human	3'UTR	Details ▾

Shared Genomics Tools

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Ordering Information

While our online ordering system is being finalized, please place your orders by email. To help us process your request efficiently, include:

- billing and shipping addresses
- shRNA clone details (TRC clone ID number and gene symbol)
- whether you would like control vectors included
- any additional information, such as your PO number

Please email your order request to sgt@med.muni.cz

Libraries are for now available as bacterial **LB stocks ~ 2 ml** for pick-up.

TRC shRNA clones - [a step-by-step guide](#)

TRC1/TRC1.5 Controls Available Upon Request

In addition to target-specific constructs, control plasmids for TRC1 and TRC1.5 systems can also be ordered, including:

- TRC1/TRC1.5 pLKO.1-puro Non-Mammalian shRNA Control Plasmid DNA (SHC002)
- TRC1/TRC1.5 pLKO.1-puro Non-Target shRNA Control Plasmid DNA (SHC016)

Routine orders are processed twice per week. With large orders (over 30 clones) please contact us directly by email to ensure smooth processing of your request. Thank you.

Price List of Services

User Category	Fee per Clone (LB Stock or Agar Stab)
MUNI Users	362.56 CZK (VAT exempt)
External Users	560.00 CZK (VAT included)

Price List of Services

User Category	Fee per Clone (LB Stock or Agar Stab)
MUNI Users	362.56 CZK (VAT exempt)
External Users	560.00 CZK (VAT included)

All fees are listed in CZK. VAT is not applicable to MUNI users. VAT is included for external users.

Non-Redistribution Policy

Individual library components are supplied solely for research use and are not authorized for further redistribution.

Shared Genomics Tools

DEPARTMENT OF BIOLOGY CORE FACILITY

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shRNA Tools

shRNA tools enable targeted gene knockdown through RNA interference (RNAi) allowing researchers to reduce expression of specific genes in mammalian cells, providing a powerful approach for studying gene function, identifying therapeutic targets, and validating signaling pathways. For a comprehensive collection of validated shRNA plasmids and resources, see [Addgene Mammalian shRNA Tools for RNAi](#), [MISSION® Lentiviral shRNA](#) and [General shRNA FAQs](#).

Lentiviral technology

Lentiviral vectors are versatile tools for delivering genetic material into a wide range of cell types. They support applications such as stable gene expression, CRISPR/Cas9-mediated genome editing, and CAR-T cell engineering. For detailed guidance, refer to [Lentiviral Vector Guide](#), [Lentiviral Plasmids](#), [Lentivirus Production Protocols](#) and [CRISPR Guide](#).

Key videos - step-by-step explanations of lentiviral systems and their applications

- [The Basics of the Recombinant Lentivirus System](#) – fundamental concepts and workflow.
- [Lentiviruses: A Versatile Tool for Cell Biology Research](#) – overview of diverse applications.
- [The Basics of Lentivirus Production/Packaging](#) – practical tips and protocols.
- [Lentivirus Transduction Protocol](#) – efficient methods for infecting target cells.
- [Lentivirus Titration](#) - how to determine viral titer

Protocols

Standardized protocols are essential for reproducible results in plasmid preparation, lentivirus production, and transduction. Addgene offers detailed step-by-step protocols and instructional videos to guide researchers through these procedures: [Addgene Protocols](#) | [Addgene Videos](#).

For detailed guidance for plasmid handling, see [Creating Bacterial Glycerol Stocks for Long-term Storage of Plasmids](#). In addition, for obtaining a fresh single colony, see [Streaking and Isolating Bacteria on an LB Agar Plate](#). And for preparing an overnight culture, see [Inoculating a Liquid](#)

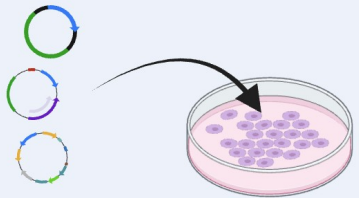
MISSION shRNA library from the Shared Genomics Tools

Wet lab procedure

HEK293T transfection

Plasmids:

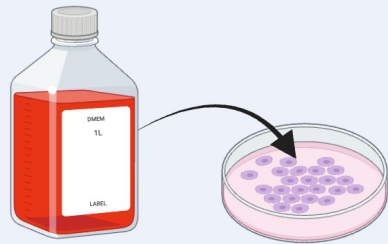
- pLKO.1 (shRNA)
- pMD2.G
- psPAX2



Day 1

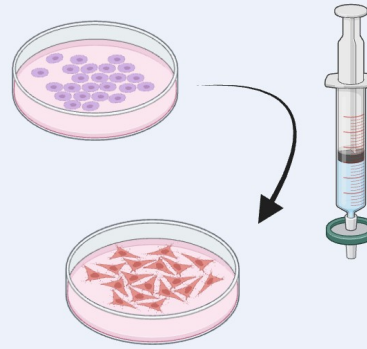
HEK293T fresh media

Virus production start



Day 2

Transduction of target cells



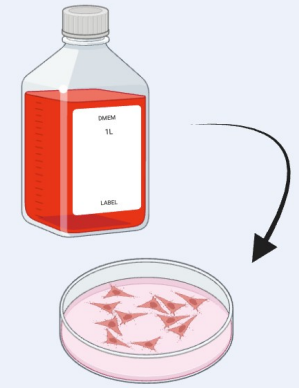
Day 3-4

Puromycin selection



Day 5

Puromycin selection over



Day 8

Contact information and acknowledgement

CONTACT

E-mail:
sgt@med.muni.cz

Web:
[http://biology.med.muni.cz/en/research/
shared-genomics-tools](http://biology.med.muni.cz/en/research/shared-genomics-tools)

Location:
University Campus Bohunice,
A19/322, 324



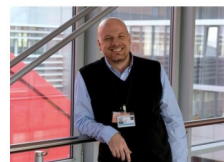
Zdeněk Andrysík



Lenka Sedlaříková

ACKNOWLEDGEMENT

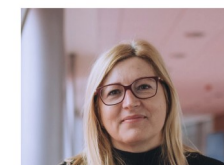
The Shared Genomics Tools core facility was established in response to the growing need for a centralized and shared infrastructure for genomic analyses. Its creation has been made possible through the support and collaboration of many colleagues and institutions, to whom we would like to express our sincere gratitude. In particular, we are deeply grateful to prof. RNDr. Ondřej Slabý, Ph.D., prof. MUDr. Tomáš Kašpárek, Ph.D. and doc. MUDr. Regina Demlová, Ph.D., whose expert guidance, encouragement, and continuous support were crucial in the establishment of this facility. We also gratefully acknowledge the Faculty of Medicine of Masaryk University for its institutional support, without which the Shared Genomics Tools core facility would not have been possible.



Ondřej Slabý



Tomáš Kašpárek



Regina Demlová

**Visit us at the poster #19 presented by Dr.
Sedlaříková!**

MUNI
PHARM

Core Facility Day Life Sciences
09.10.2026

Filosofie řešení výrobní jednotky
v projektu BioPharma Hub

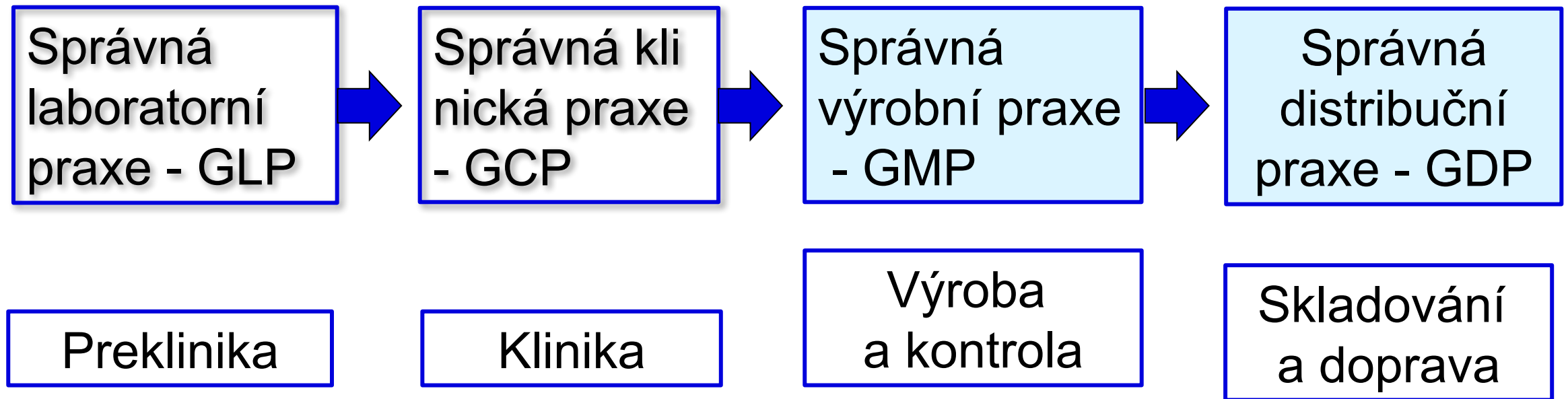
Nový objekt FaF, Campus MUNI,
Brno Bohunice

Centrum spolupráce s průmyslem
CEPRUS

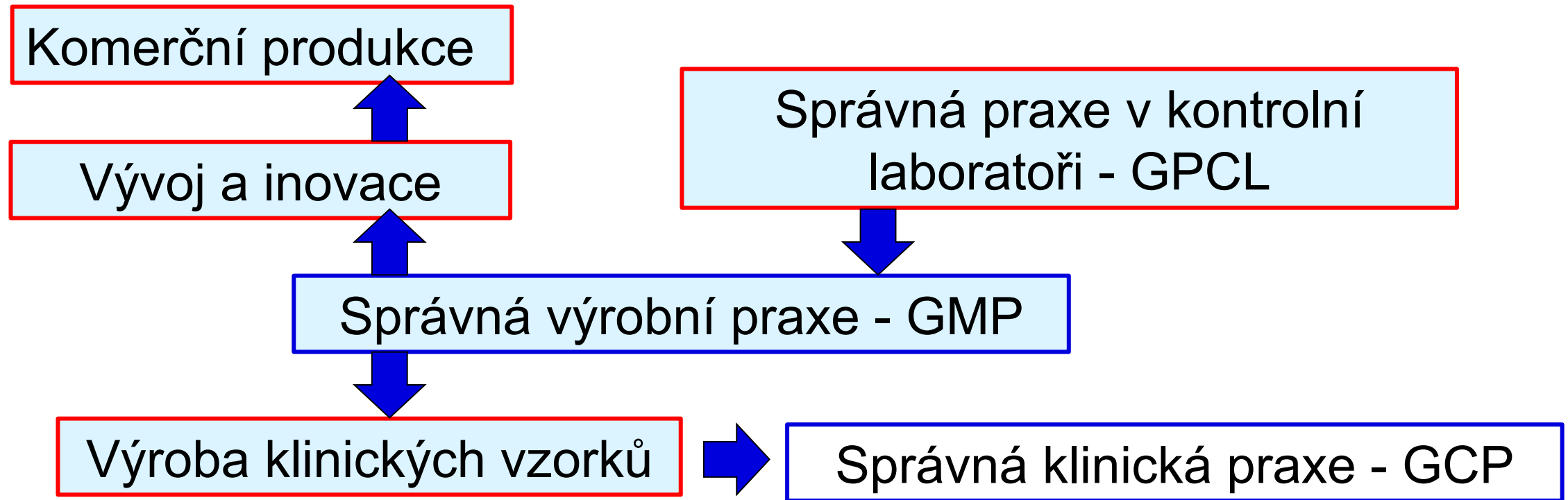
Jan Gajdziok/Jiří Moninec



Zapojení do regulačního schématu 4 GxP výzkumu, klinického testování, výroby a distribuce léčivých přípravků



Vazby správné výrobní praxe - GMP



Filosofie celkového řešení

- Je vybudována plnohodnotná výrobní jednotka
- Výrobní jednotka obsahuje:
 - Prostory pro výrobu pevné dávkové lékové formy
 - Prostory pro sterilní aseptickou výrobu
 - Farmaceutický sklad
 - Pomocné prostory
 - Kontrolní laboratoř
 - Farmaceutický systém jakosti

Podmínky Good Manufacturing Practice GMP

- Výrobní jednotka bude inspektována Státním ústavem pro kontrolu léčiv (SÚKL) aby získala povolení k výrobě, kontrole a distribuci léčivých přípravků
 - Musíme předvést funkční:
 - Systém farmaceutické jakosti
 - Výrobu a validaci výroby
 - Technické a pomocné provozy validované
 - Validovaný počítačový systém
 - Funkční systém QC
 - Nejméně tři vyrobené šarže vybraných produktů
 - Odpovědné osoby za výrobu, za kontrolu a kvalifikovanou osobu

Výrobní možnosti a kapacita

➤ Pevná dávkové léková forma

- Šarže cca 5,0 – 10,0 kg
- Tablety, kapsle, prachy
- Alternativně polotuhé formy

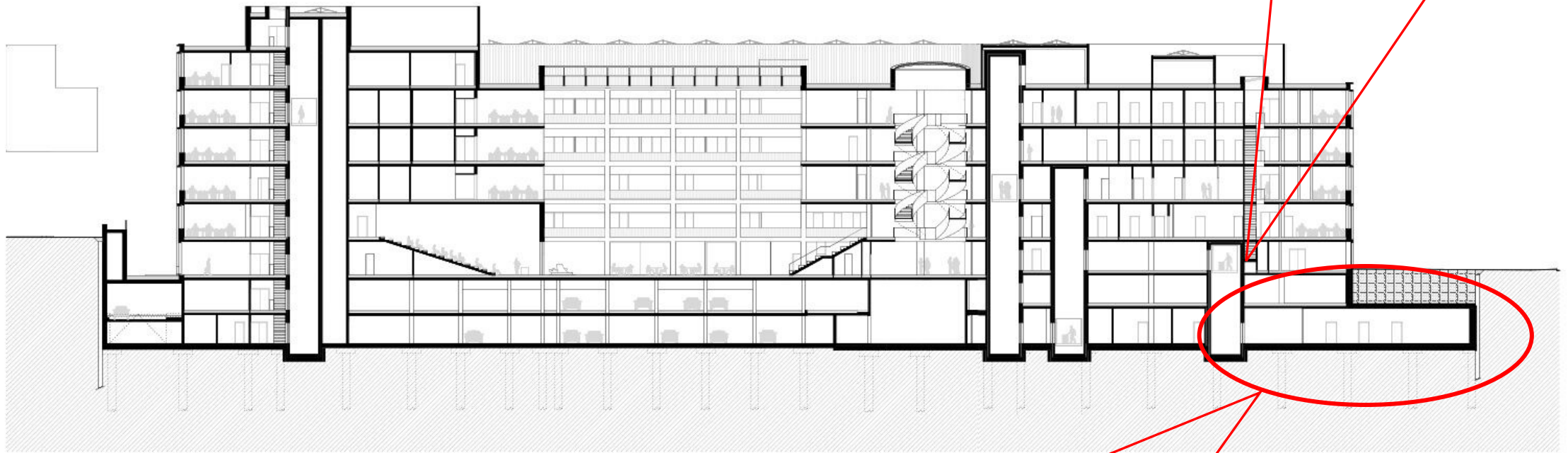
➤ Sterilní formy

- Šarže 5,0 litrů
- Asepticky připravované léčivé přípravky
 - Roztoky, emulze, suspenze,
- Ve formách
 - Injekce, lyofilizované injekce
 - Ampule a lékovky

Technické řešení budovy

1. NP

Laboratoře kontroly jakosti



3. PP

Farmaceutická výroba

Projektové řešení výroby

Farmaceutická výroba



Projektové řešení výroby

Pevná léková forma

Sterilní výroba

LEGENDA:

- třída čistoty A (laminár)
- třída čistoty B
- třída čistoty C
- třída čistoty D
- kontrolovaná zóna K
- 30Pa tlak v místnosti
- MATERIÁL
- PERSONÁL

Č.MÍST-NOSTI	NÁZEV MÍSTNOSTI	PLOCHA (m2)	VÝŠKA MÍSTNOSTI (m)	OBJEM MÍSTNOSTI (m3)	TŘÍDA ČISTOTY	PŘETLAK (Pa)	POČET VÝMĚN (x/hod)
3S100	KORIDOR	31,8	2,5	79,5	K	--	6
3S101	PERSONÁLNÍ PROPUST	5,4	2,5	13,5	D	15	30
3S102	PERSONÁLNÍ PROPUST	5,1	2,5	12,8	C	30	60
3S103	PERSONÁLNÍ PROPUST	5,5	2,5	13,8	B	45	80
3S104	MATERIÁLOVÁ PROPUST	3,3	2,5	8,3	D	25	30
3S105	PERSONÁLNÍ PROPUST	4,3	2,5	10,8	D	15	30
3S106	MATERIÁLOVÁ PROPUST	3,3	2,5	8,3	D	15	30
3S107	SKLAD	33,1	2,4	79,4	K	--	6
3S108	VÝROBNÍ MÍSTNOST KLSLF	44,0	3,0	132,0	B	55	80
3S109	STERILIZACE	13,4	2,5	33,5	D	35	30
3S110	KORIDOR	17,2	2,5	43,0	D	25	30
3S111	KAPSLOVÁNÍ	17,6	4,0	70,4	D	15	30
3S112	SOME PROCES	14,0	4,0	56,0	D	15	30
3S113	TABLETOVÁNÍ	9,4	4,0	37,6	D	15	30
3S114	GRANULACE	12,6	5,0	63,0	D	15	30
3S115	TECHNICKÁ ZÓNA	20,4	2,4	49,0	K	--	6
3S116	TECHNICKÝ KORIDOR	31,0	2,4	74,4	--	--	6
3S117	PERSONÁLNÍ PROPUST	6,8	2,5	17,0	D	15	30
3S118	MATERIÁLOVÁ PROPUST	3,4	2,5	8,5	D	15	30
3S119	MYTÍ	6,5	2,5	16,3	D	25	30
3S120	BALENÍ	6,4	4,0	25,6	D	15	30
3S121	NAVAŽOVÁNÍ	6,8	2,5	17,0	D	15	30
3S122	IPC	4,8	2,5	12,0	D	15	30
3S123	PERSONÁLNÍ PROPUST	2,5	2,5	6,3	D	15	30

Skutečný stav - vnitřní chodba



Skutečný stav - tabletovačka



Skutečný stav - plnička kapslí



Aircondition and control system



Systém farmaceutické jakosti

Založen systém farmaceutické jakosti

- Odpovědnosti
- Řízení rizik a řízení jakosti
- Dokumentační systém

Založen virtuální subjekt pro formování komerčních postupů



Systém farmaceutické jakosti

Odpovědnosti

- Ředitel
- Vedoucí systému jakosti
- Vedoucí kontroly jakosti
- Vedoucí laboratoří
- Kvalifikovaná osoba (Qualified Person – QC)
- Vedoucí výroby – zatím neobsazeno

Připravuje se vstup do komerčního prostředí



Digitální dokumentační systém

- Dokumentační systém je řešen jako důsledně digitální
- Je tvořen řídicími a záznamovými dokumenty v elektronické podobě



**Uživatelský manuál
k Dokumentačnímu systému GMP**

Standardní operační postup
Číslo dokumentu: Axxxx
Verze: V001
Počet příloh: 0

Uživatelský manuál k Dokumentačnímu systému GMP

(The User Manual for GMP Documentation System)

Založen systém kontroly jakosti - QC

- Součástí jednotky jsou laboratoře kontroly jakosti (Quality Control – QC)
 - Fyzikálně chemická laboratoř
 - Mikrobiologická kontrolní laboratoř
- Systém QC je řízen pomocí LIMS (Laboratory Information and Management System)
 - LIMS je důsledně digitální

Farmaceutický sklad

- Součástí celé jednotky je farmaceutický sklad
 - Výchozí látky
 - Obalové materiály
 - „In bulk“ produkty
 - Vzorkování pro propouštění QC
- Zaveden systém FIFO respektive FEFO
- Štítkování pomocí QR kódů



Kvalifikace a validace

Zpracován Řídicí validační plán (VMP)

V rámci stavební dodávky již provedena kvalifikace:

- Čisté prostory a vzduchotechnika
- Řídicí systém DELTA v rámci BMS

Pro jednotlivá zařízení probíhají kvalifikace průběžně

Doplňování vybavení a přístrojů

- Zřízení boxů pro kontrolní mikrobiologickou laboratoř a její vybavení (on going to 02/2026)
- Doplnění strojů a vybavení pro nesterilní výrobu (on going to 12/2026)
- Vybavení pro sterilní výrobu (in discussion)
- Vybavení laboratoří QC (on going)

Příprava komerčních projektů

- První kontrakt pro šarže tablet pro klinické studie (05/2026)
- Optimalizace plnění tvrdých želatinových kapslí (09/2026)
- Smlouvy o spolupráci s klíčovými farmaceutickými společnostmi v ČR a SK
- První kontakty se zahraničím
- Příprava laboratoří QC pro smluvní analýzy

Vize

- Komerční přínos pro MUNI a FaF
- Budování know how výroby a kontroly léčivých přípravků
- Zavedení farmaceutického systému jakosti jako vzor pro edukaci
- Zřízení laboratoří QC jako know how FaF
- Zavedení elektronického systému dokumentace jako vzor pro edukaci
- Základna pro kurzy kvalifikovaných osob (QP)
- Vazba na vývoj a průmysl

Děkuji za pozornost