KAROLINA PAL-KUTAS

GMP/ATMP SPECIALIST ● SCIENTIST ● TOXICOLOGIST

3645 Malyinka, Lillafuredi ut 6. HUNGARY
+36 20 439 69 26
karolina.palkutas@gmail.com

Date of birth: 09th of November 1974
Nationality: Hungarian
Languages: Hungarian, English
Marital Status: Single, no kids

Highly skilled scientific professional with 16 years of experience in pre-clinical toxicology, coordinating study planning, execution, and reporting, with significant expertise in fetal pathology, drug safety, and reproduction toxicology. Demonstrated abilities as a strategic planner able to guide scientific teams in preparing and conducting experiments. Proven ability to establish streamlined operating procedures and experimental methodologies to ensure seamless lab functions. Strong talent for authoring comprehensive, detailed technical, medical, and scientific papers, with several successful publications, presentations, and posters. Knowledgeable in numerous core regulatory and compliance matters.

Recently worked on the field of regenerative medicine and translational science as GMP/ATMP specialist. The main tasks included writing of cGMP-compliant SOPs, contacting regulatory agencies, submitting clinical studies, learning cell-culture techniques and biological assays, overviewing process validations on different fields. Responsible for the H2020 projects' regulatory roadmap mainly in artificial liver 3D printing and artificial pancreas generation. Implementing the Sphericalplate 5D technology for the company Kugelmeiers Ltd. in Switzerland, into the field of regenerative medicine and into the internal Quality Assurance System. Resigned from here as Heaf Of Quality Assurance.

SKILL HIGHLIGHTS

- Study Management
- Repeated dose Toxicology
- Project & Program Management
- GLP
- GMP/ATMP
- CRO
- cGMP-compliant protocols
- Team Building & Leadership
- Scheduling and Forecasting
- Experimental Design
- Peer review of toxicology reports
- Validation (IQ, OQ, PQ, User Requirement)
- Client Relationship Management
- Micronucleus test
- Production validation and testing (GMP)
- Reproductive Toxicology
- Regenerative & Translational science
- Embryology • Visceral Examination • Skeletal Examination • Peer Review of rat and rabbit fetuses
- Cell culture techniques and biological assays
- Study Director
- Reporting
- Communications
- Position Paper
- CAPA
- Drug Safety
- Fetal Pathology
- Comet Assay
- Methodology validation and protocol drafting (GMP)

PROFESSIONAL EXPERIENCES

Mar 2020 – July 2024

GMP/ATMP Specialist

Kugelmeiers Ltd., Erlenbach-Zurich, Switzerland

- Working in regenerative medicine and translational science. Responsible for H2020 projects' regulatory roadmap mainly in artificial liver 3D printing (ORGANTRANS) and artificial pancreas generation (VANGUARD).

- Performing training to consortium members about GMP and ATMPs, drafting process-related cGMP-compliant Standard Operating Procedures (SOPs), flowcharts of manufacturing processes and implementing in-process controls.
- Preparing regulatory dossiers for the approval of therapeutic cell products and medical devices.
- Responsible for method and technology transfer from the research lab to the clinics (cGMP).
- Drafting applications and documents (ethical approval, letter of interest, negotiating regulatory submissions) in the context of preparation for clinical studies.
- Contact with European Medicines Agency (EMA)

Oct 2017- Sep 2019

Laboratory Specialist

University of Zurich, Zurich, Switzerland

- Methodology validation and protocol drafting.
- Writing GMP protocols.
- Undergoing GMP-training at Wyss Zürich.
- Learning cell culture techniques and biological assays.
- Production validation and testing.

Feb 2016- Nov 2016

Senior Study Director

CHARLES RIVER LABORATORIES DEN BOSCH BV, Netherlands

- Planning and executing preclinical reproductive toxicology studies in the DART group.
- Maintain client relationships and communications, OECD 422 studies new study design.
- Combined study designs such as 90-day repeated dose toxicity study with two generation reproductive toxicity study and combined 28-day repeated dose toxicity study with reproductive screening test and Micronucleus test and Comet Assay.

Apr 2009- May 2015

Study Director / Scientific Support/ Fetal Pathologist

HARLAN LABORATORIES LTD., Basel, Switzerland

- Direct planning and execution for GLP preclinical drug safety toxicology studies, including focus on DART studies.
- Consult with clients to determine the optimal study design for regulatory submission.
- Maintain client relationships and communications, coordinating facility tours for external client study monitors as needed.
- Contribute to laboratory operations and functions, including reviewing fetal pathology work. Primary evaluation of teratology studies.
- Streamlined internal operations by redeveloping standard operating procedures.
- Validating a wholly new system, the automatic staining machine for fetuses. Guided all aspects of process adaptation, change management, and staff training to achieve successful integration.
- Maintained high standards for on-time delivery, cost control, resource allocation, and internal health and safety, resulting in process improvements that cut processing time from 4 weeks to 1 week.
- Renowned by clients for providing expert advice and strategic recommendations.
- Management of planning and scheduling of all work in the fetal pathology lab.
- General laboratory management including equipment and stock maintenance.
- Upkeep of personal records and review of others.

Jan 2008- Feb 2009

Study Manager

HUNTINGDON LIFE SCIENCES LTD, Eye, England, United Kingdom

- Acted as Study Director in one generation studies, and as deputy study director in juvenile toxicology studies. Conducted studies related to animal environmental enrichment and sexual maturation of rats.
- Compiled and prepared historical control data for scientific publication.
- Conducted company training and toxicology induction programs.
- Received commendations from senior management for exceptional performance and quality in the workplace.

Jan 2004- Dec 2007

Study Director

LAB RESEARCH INTERNATIONAL LTD, Veszprem, Hungary

- Launched the fetal pathology and reproduction toxicology lab, validating and establishing all organizational processes, standard operating procedures, lab methodologies, and standards.
- Recruited and trained cross-functional teams of personnel, including study directors, technicians, and support staff.
- Conducted fetal readings. Performed microdissections for visceral examinations and handled fetal skeletal examinations. Authored study plans and reports.
- Elevated staff competencies to achieve a high-functioning work environment through training, coaching, and mentoring.
- Acted as key point of contact for client visits, maintaining exceptional customer relationships.
- Conducted studies on limb bud development in rabbits.
- Developed a poster for scientific publication at the largest congress in the field of toxicology (SOT).

Nov 2000- Dec 2003

Research Assistant / Study Director

TOXICOLOGICAL RESEARCH CENTER, Veszprem, Hungary

- Directed studies on rabbit skin and eye irritation.
- Developed study plans and reports.
- Founded the reproduction toxicology department.
- Conducted visceral and skeletal examinations.

Sep 1999- Nov 2000

Research Assistant

NATIONAL HEALTH CENTER, Budapest, Hungary

- Contributed to oral and dermal administration of rats and rabbits.
- Adapted to the needs of the organization and lab, including learning GLP principles.
- Conducted research into key literature supporting studies.
- Acquired critical skills on positive controls to read fetuses.

EDUCATION & PROFESSIONAL DEVELOPMENT

GMP Lead Auditor online course by Dr. Felix Tobias Kern — **March 2024**

Safety Pharmacology Course Basel, Switzerland — **Feb 2017**
Swiss Society of Toxicology, Postgraduate Certificate

Master of Science in Biology — **Sep 2000 - Jun 2004**
Eotvos Lorand Science University – Budapest, Hungary

Bachelor of Science in Biology & Chemistry — **Sep 1994 - Jun 1997**
Eszterhazy Karoly College – Eger, Hungary

ACHIEVEMENTS

- Cambridge First Certificate in English – Croydon College, London
- Quality Assurance Training on GLP Regulations
- Metrology in GLP Quality Assurance System

- Continuing Education on GLP
- Regulatory Compliance Training for Senior Huntingdon Life Science Staff
- Fetal Examination Training by Ruth Clark
- Embryology Course Edinburgh, UK
- ETS Education
- Provantis 7.0 Reproductive Toxicology
- Toxicology Induction Program, HLS, UK
- UK Industrial Reprotox Discussion Group
- Study Director Training Program, HLS, UK

PROFESSIONAL AFFILIATIONS

European Teratology Society (ETS)
Hungarian Toxicology Society
Swiss Society of Toxicology (SST)
Association of Hungarian Engineers and Architects in Switzerland (MMESE)

PUBLICATIONS & PRESENTATIONS

Lecture: Effect of An Unusual Vehicle – Hungarian Toxicological Society Meeting (2004)
Poster: Effect of An Unusual Vehicle, Citrate Buffer Administered i.v. for the Intrauterine Development of Rabbits and Rats – European Teratology Society Meeting (2005)
Poster: Historical Control Data of Crl(Wi) BR; Wistar Rats, In Embryo-Fetal Development Study – Society of Toxicology (2007), North Carolina, US
Article:"The relevance of Advanced Therapy Medicinal Products in the Field of Transplantation and the Need for Academic Research Access:Overcoming Bottlenecks and Claiming a New Time", Transplant International, 27 September 2023
Manuscript title:"Spheroids composed of reaggregated neonatal procine islets and human endothelial cells accelerate development of normoglycemia in diabetic mice", Journal:Cells, 2025