



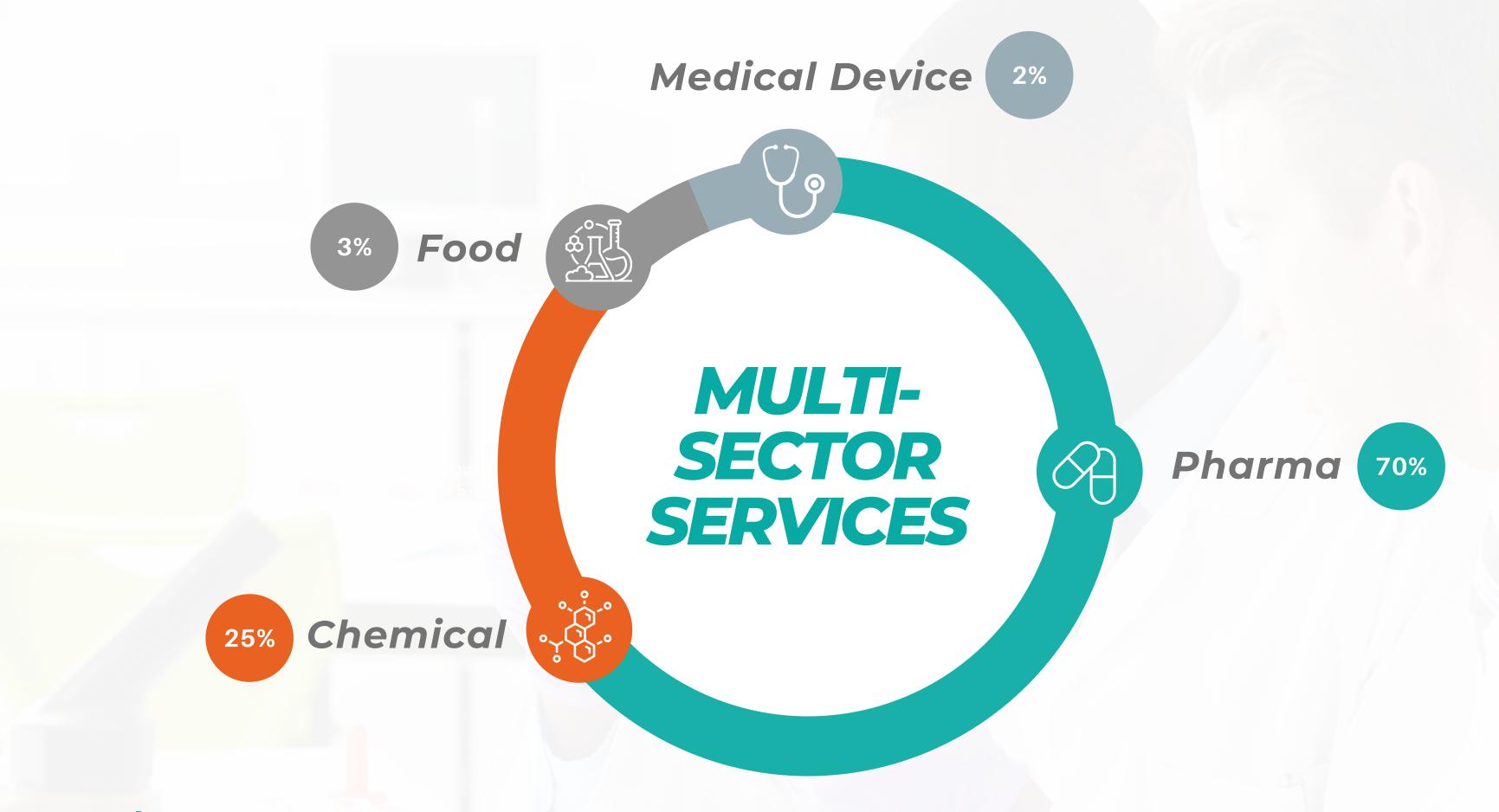
CONTRACT RESEARCH ORGANIZATION

- Founded in 2000
- +4000 studies performed
- Over 200 employees
- GLP Certified since 2003
- In Vivo toxicological studies











WHERE OUR CUSTOMERS COME FROM







OUR ORGANIZATION





- Management of animals facilities
- ISO 9001:2015
- Public and private centers both national & international

ETHICAL ANIMAL TESTING



- Commitment to animal welfare and 3Rs
- Fully compliant with European directives regarding animal welfare
- Environmental enrichement

Replace

Animal studies with non-animal methods

If not possible

Reduce

Animal studies to minimum required and necessary

In addition

Refine

Practices to minimize stress of study animals

GOOD LABORATORY PRACTICE

- Certified since 2003
- Provantis Preclinical Software
- Electronic SOP system for:
 - Rapid access
 - Scheduled and on-demand online revisions
 - On-line training and evaluation of staff



QUALITY ASSURANCE





Evaluada la conformidad de BPL de acuerdo con la Directiva 2004/9/EC y el Real Decreto 2043/1994

and Royal Decree 2043/1994

Otorga el presente

oe with Good Laboratory Practice

CERTIFICADO DE CUMPLIMIENTO DE BUENAS PRÁCTICAS DE LABORATORIO

20/41/BPL057

a la entidad de ensayo / to the test facility

VIVOTECNIA RESEARCH, S.L.

La entidad lleva a cabo estudios de Sustancias Químicas y Aditivos Alimentarios, en las áreas de ensayo de: toxicidad (2*), mutagenicidad (3*) y química analítica (8*) en cumplimiento con los principios de BPL, tal como ha establecido la Unión Europea y la OCDE.

The test facility performs studies with Chemical Substances and Food Additives i laboratory, in the areas of expertise: toxicity (2*), mutagenicity (3*) and analytical chemistry (8*) in compliance with GLP principles established by EU and OECD.

D. José Manuel Prieto Barrio

24 de enero de 2020

Fecha de entrada en vigor / Coming into effect: 24/01/2020 Validez hasta / Valid until: 24/01/2021

Fecha de inspección / Date of inspection: 21 y 22/11/2019 Certificada por primera vez el / Certified since: 25/09/2015



(*) áreas de ensayo según Decisión OCDE C(89)87



Fecha inspección: 21, 24 y 25 de octubre de 2019 Validez hasta: 25/10/2021 Valid until: 10/25%/2021

BPL V19.10/44-CM

sanitaria de la Comunidad de Madrid, CERTIFICA que el Sanitary Regulation of Community of Madrid, CERTIFIES aboratorio:

VIVOTECNIA RESEARCH, S.L. C/Santiago Grisolia, 2 28760 TRES CANTOS (MADRID)

- Toxicidad in vitro
- Toxicidad de la reproducción
- 3. Estudios de mutagenicidad
- Mutagenicidad Carcinogenicidad
- - Farmacocinética

 - Administración de producto de ensayo y obtención
 - de especimenes Farmacología de seguridad

Inspection date: 21th 24th and 25th October 2019.

Real Decreto 822/1993, de 28 de mayo, el Real Decreto 42043/1994, de 14 de octubre, la Orden 144-2000 y el Real Decreto 1369/2000 de 19 de julio, D' Elena Mantilla Garcia, Directora General de Inspección y Ordenación Elena Mantilla Garcia, Ceneral Director of Inspection and

VIVOTECNIA RESEARCH, S.L.

28760 TRES CANTOS (MADRID

2. Toxicity studies In vivo toxicit

In vitro toxicity Historuthology

Toxicokinetics

3. Mutarenicity

Safety Pharmacology

Farmacología de seguridad

 formedical products, cosmetics and sanitarian products,
 n medicamentos, cosméticos y productos sanitarios,
 according to the principles of Good Laboratory Practice as umpliendo con los principios B.P.L. tal como ha established by the European Union and the OECD.

ROUTES OF ADMINISTRATION



Routes			De le	
Inhalation			×	X
Oral				
Intravenous				
Subcutaneous				
Intramuscular				
Others				

GENERAL TOXICOLOGY

- DOSE RANGE FINDING (DRF)
- MAXIMUM TOLERATED DOSE (MTD)
- REPEATED DOSE STUDIES
- CARCINOGENICITY STUDIES

GENOTOXICITY & MUTAGENICITY

- AMES TEST
- IN VITRO CHROMOSOME ABERRATION
- MICRONUCLEUS TEST
- CHROMOSOME ABERRATION

REPRODUCTION TOXICOLOGY

- OECD 414
 SEGMENT I
- OECD 416 SEGMENT II
- OECD 421
 SEGMENT III
- OECD 422

SAFETY PHARMACOLOGY

- HERG
- CARDIOVASCULAR ASSESMENT TELEMETRY
- HEAD-OUT PLETHYSMOGRAPHY
- PRIMARY OBSERVATION (IRWIN)

PHARMACOKINETICS

- PHARMACOKINETICS PROFILE IN RODENTS
- PHARMACOKINETIVS PROFILE IN NON-RODENTS

SERVICES STUDY TYPES



BIOANALYSIS UNIT

• SCIEX Triple Quad™ 6500+ LC-MS/MS System

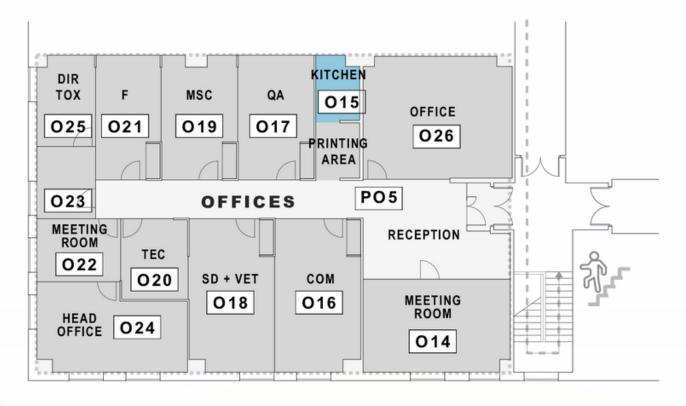
• SCIEX Triple Quad™ 4500 LC-MS/MS System x2

- ExionLC AD UPLC system x3
- Agilent 1200 series HPLC system
- NanoLC 400 system
- Opentron OT-2 system. Pipetting robot automatizations
- Freezers -80, -20 and +4 degree

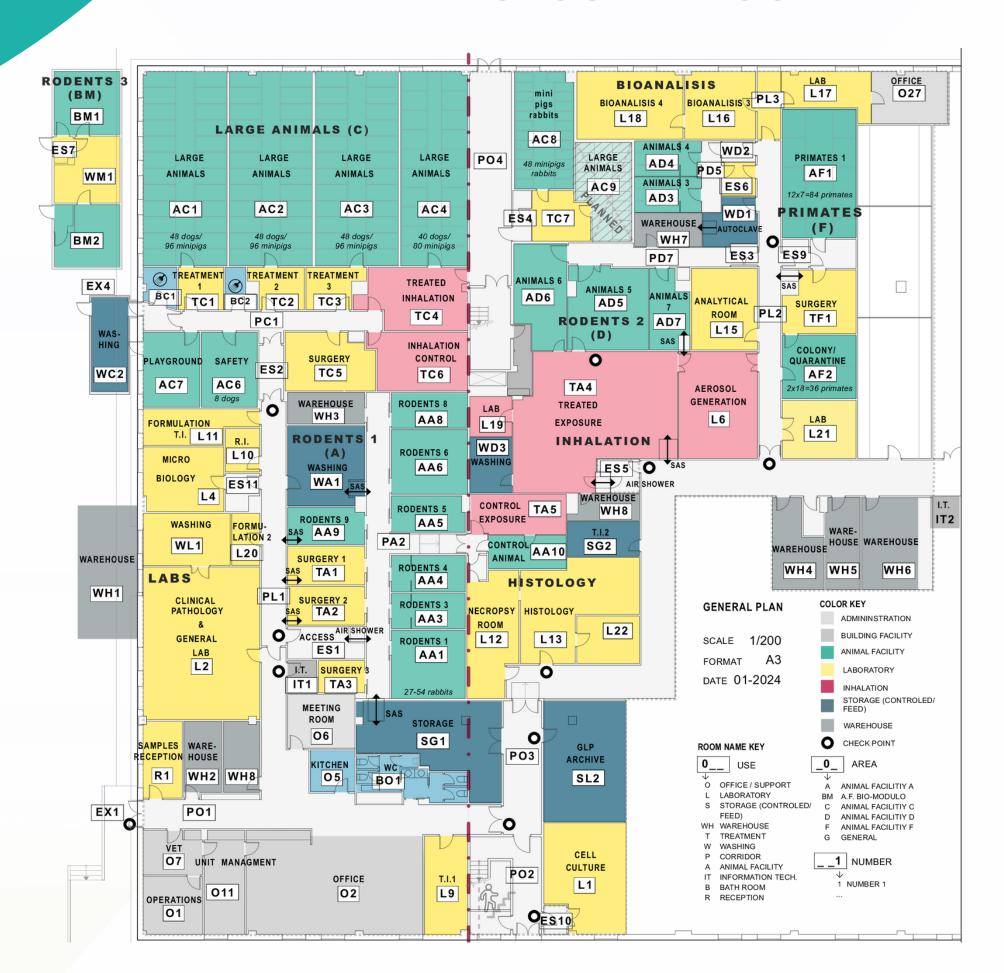


OUR FACILITIES

FIRST FLOOR PLAN



GROUND FLOOR PLAN



RODENTS



• Total capacity in Rats and Mice: 2500

NON-RODENTS



• Total capacity in Rabbits: 48 animals



• Total capacity in Dogs: 184 animals



• Total capacity in Minipigs: 232 animals



• Total capacity in Non-Human Primates: 84 animals

BEST POSSIBLE CONDITIONS

- Delivered by main research animals providers
- Housing according to FELASA standards
- Active enrichment program

ANIMAL CAPABALITIES

STUDY MANAGEMENT A SUCCESSFUL PROCESS

Exercise for your

STUDY

- Study Design Optimization
 - Adapted Scheduling
 - Customized Pricing
 - Contract Signature





- Study Director Assignment
- Activities Scheduling



Study Plan discussion& Signature

- Study Execution
- In life Phase
 - Bionalysis / Formulation Analysis
 - QA Inspection
 - Data Collection & Processing





- Reporting
- Discussion & Finalization
- QA Audited
- Archiving



WHY US?

- 20+ Years of Excellence
- Fast Slots
- 200+ Skilled Professionals
- 4000+ Studies Completed
- Commitment to Quality
- Regulatory Compliance
- Smooth comunication with our SD



HEADQUARTERS



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