



Q_Mx
QUALIMETRIX



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QUALIMETRIX
Analytical Laboratories - Quality Control

CONNECTING IDEAS

Bridging data to compile unique products

Contract Laboratory Organization



QualiMetrix is focused on supporting pharmaceutical products throughout their whole lifecycle; from the development of the product to the manufacturing and post marketing stages. Services range from routine to highly complex projects; with full support given to the regulatory requirements and research challenges; and operations consistently taking place in an environment of Good Laboratory (GLP) and Good Manufacturing Practices (GMP).



About Us

QualiMetrix is a lifetime project that was born through years of experience and teamwork and aims to utilize the human resources, equipment and expertise for the benefit of pharmaceutical industry.

QualiMetrix staff comprise highly motivated research experts – graduated specialists with PhD and MSc, experienced in Pharmacy, Chemistry and related Sciences.

How we got here

QualiMetrix was founded in 2013 by a group of senior scientists of chemical and pharmaceutical analysis after years of teamwork and research in the University of Athens. The company established the first building at the beginning of 2017 that has been designed in order to meet all the GMP requirements. In 2018 a second supportive building was established in order to host the microbiological and biological services and also the new extensive stability storage areas.

Currently, a new RnD center is under construction that will add to QualiMetrix additional laboratory space and that will contribute to the expansion of the company.



Confidence

*The genotype
of our company...
a simple,
single word.*

Mission

Our mission is to follow the advancement of science, technology and regulation and to be able to provide to pharmaceutical companies around the world integrated quality services in timely manner.

Vision

The community of QualiMetrix to consist of and embrace the scientific brains and talents, which in the frame of a high level working environment should have the opportunity to prove their potentials and develop their capabilities, both for the benefit of the Organization as well as for the benefit of the end user: the pharmaceutical industry.

Goals

Expand our network at global level; expand our scientific field of operations; challenge and improve the qualitative characteristics of our Organization.



Services

- Quality Control
- Research & Development
- Microbiological and Biological services
- Scientific Advice

Quality Control

Integrated Quality Services throughout the Products' Lifecycle.

- Batch Testing and Release of Final Products
- APIs testing
- Stability Studies
- Post approval (on going) stability studies
- Photostability studies with temperature and humidity control (according to ICH Q1B)
- Validation of analytical methods
- Genotoxic impurities
- Elemental impurities (according to ICH Q3D Guideline)
- Comparative Dissolution Profiles

Research & Development

Modern Instrumentation and the updated knowledge in the field of analytical science.



- Development of analytical methods
- Dissolution development
- Forced degradation studies
- Extractables and leachebles
- Nitrosamines testing
- In Vitro Release and In Vitro Permeation studies
- Structural elucidation of unknown impurities
- Reverse Engineering studies / Investigation of the Reference Product composition
- "Essential similarity" establishment for generic and hybrid applications
- Compatibility studies
- Toxicological evaluation

Microbiological & Biological services

Fully equipped lab for microbiological GMP testing and GLP biological studies.

- Control of microbial burden of non-sterile pharmaceutical products (EP 2.6.12/2.6.13, USP 61/62)
- Bacterial endotoxins test (EP 2.6.14, USP 71)
- Particulate matter analysis (EP 2.9.19, USP 788/789)
- Preservative efficacy testing (EP 5.1.3, USP 51)
- In vitro genotoxicity test (ICH M7) - AMES test
- Biological assays
- Environmental monitoring sample analysis
- Filter validation studies (PDA TR 26, ISO 13408-2:2018)

Scientific Advice

We combine academic knowledge with legislative requirements.
Our services are underpinned by our culture and expertise in regulation.



- Expert Reports
- Data Gap Analysis
- Regulatory Consultation
- Letter of Deficiency Responses / Arbitration Guidance
- EMA or National Agencies' Scientific Advice
- Legal Basis and Regulation Strategy

Instrumentation

Cutting-edge technology under GMP environment.



- HPLC/UPLC – UV/Vis/PDA /PAD/FLD/ELSD/RID/CAD
- Ion Chromatography – Conductivity/PAD
- UPLC-HRMS-LTQ-Orbitrap systems
- LC-MS/MS (Triple Quadrupole)
- GC – MS, GC – MS/MS
- GC – FID/ECD (split- splitless and head space)
- ICP – MS
- USP Vertical Diffusion Cell (Franz Cell)
- Dissolution tester (USP I, II, IV)
- Conductivity meter
- Karl Fischer titrator
- Polarographer
- UV – Vis spectrophotometer
- ATR– Fourier Transform Infrared Spectroscopy System (ATR-FTIR)
- Digital Polarimeter
- PSD Analyser Malver Mastersizer 3000
- XRD
- Microplate reader
- Viscometer
- Force tensiometer
- Cryoscopic Osmometer
- Disintegration tester
- Friability tester
- Hardness tester
- Turbidity meter
- Cytation 5 Cell imaging multimode reader
- Melting Point Tester
- Optical Microscope
- Microwave digestion system
- Solid – phase extraction system
- Stability and Photostability Chambers
- Robotic Liquid Handler System
- Water Activity meter

The above list is indicative, so please contact us in order to gain update information!

Quality Assurance

“Quality is everyone’s responsibility and we never have to stop getting better”

- W. EDWARDS DEMING -

Our laboratories operate under both EMA and US FDA requirements. Biological and in vitro studies follow GLP compliance. Our technical competence is continuously challenged. The reliability of our laboratory’s data is assessed and demonstrated by our regular participation in international Proficiency Testing Schemes (PTS) organized by the EDQM.

- GMP
- MIA
- GLP
- FDA Inspection



Our sites

— Chemical laboratory

GMP Laboratory hosting both QC and RnD activities
579 Mesogeion Ave., 15343, Agia Paraskevi, Athens

— Microbiological / Biological laboratory

GMP/GLP Laboratory site specialized in microbiological activities
and in Vitro testing.
36 Marathonos Ave., 15354 Glyka Nera, Athens

— New RnD center – Under Construction

GMP Laboratory site specialized in Research and Development activities
569 Mesogeion Ave., 15343 Agia Paraskevi, Athens

— QualiMetrix Italy – the Italian entity

QualiMetrix SRL, the Italian entity.
Cassina de' Pecchi (MI) Via Roma 108 Building CD1 Cap 20051





“...always focused on each individual client”





QualiMetrix SA

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