
QMx
QUALIMETRIX
Analytical Laboratories - Quality Control
Connecting Ideas
Bridging data to compile unique products

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QUALIMETRIX

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WHAT WE DO

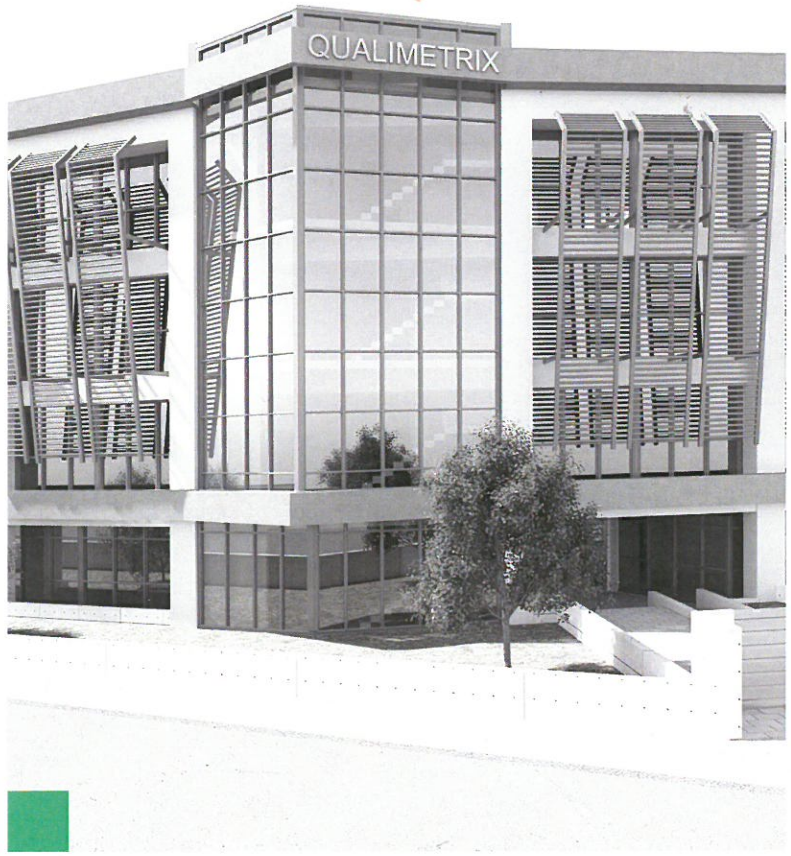
QUALIMETRIX
Analytical Laboratories - Quality Control

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

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 performance consistently taking place in an environment of Good Laboratory (GLP), Good Clinical (GCP) and Good Manufacturing Practices (GMP).

QualiMetriX comprises two active sites: the central laboratory and the innovation center. A third 3000 m^2 site is under construction, which will include six state-of-the-art laboratory units; a sterile area; a high potent lab and a high tech training center. The construction of the third site is expected to be completed within 2019.

The overall structure of the company consists of six scientific and three supporting units.



Scientific

- Quality Control
- Research and Development
- Bioanalysis
- Innovation
- Advanced technologies
- Quality Assurance

Supporting

- Administration
- Business Development
- Technical Support

QualiMetriX is a lifetime project

that was born through years of experience and teamwork and aims to utilize human resources, equipment and expertise for the benefit of the pharmaceutical industry

THE CONTRACT RESEARCH ORGANIZATION

Our ambitions are divided across three levels:

THE TECHNOLOGY

Implementation of state of the art instrumentation and robotic integrated systems in order to build up fully automated procedures which will reduce the manual handling to minimum. In parallel fully integrated and validated computerized systems will be adopted in order to attain an electronical, ultimately paperless, quality management system.

THE SCIENCE

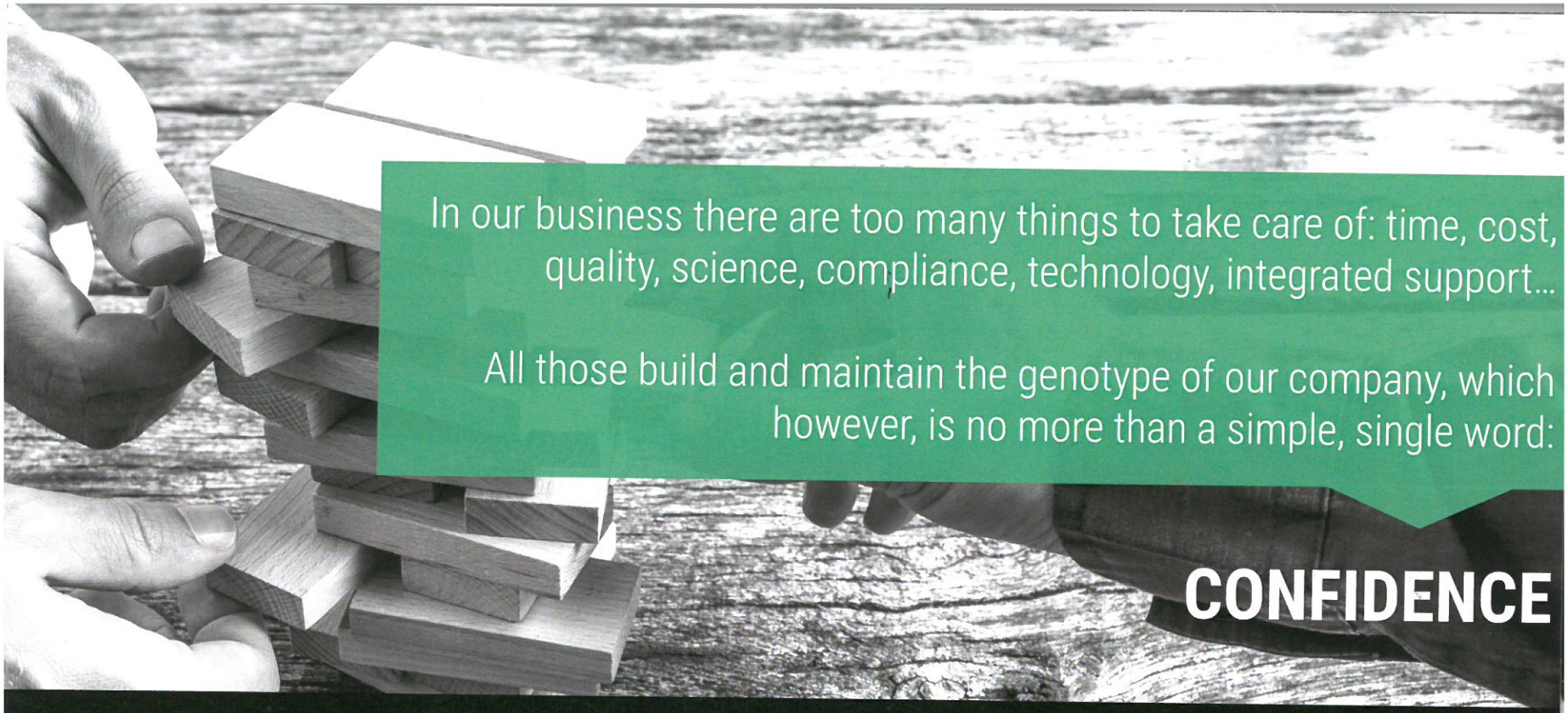
To expand our field of expertise to biotech products and advanced therapies.

THE IMPACT

to the pharmaceutical industry

To complete the construction of the high tech training center and provide training to young as well as senior scientists in the field. The company will act as a cutting edge and open source point, where information and know-how will be available to everyone. The community of QualiMetriX should widen and include fresh scientific brains, which by working in a high level scientific environment should have the opportunity to prove their potential and develop their capabilities, both for the benefit of the CRO as well as for the benefit of the end user; the pharmaceutical industry.

Within the years the company's operation, we have been involved in the approval of hundreds of pharmaceutical products worldwide and a significant number of studies have been performed on behalf of European and Global pharmaceutical companies.



In our business there are too many things to take care of: time, cost, quality, science, compliance, technology, integrated support...

All those build and maintain the genotype of our company, which however, is no more than a simple, single word:

CONFIDENCE

OUR TOP MANAGEMENT TEAM

MICHAEL A. KOUPPARIS

PRESIDENT OF THE BOARD

Partner and co-founder of QualiMetriX. Professor of Analytical Chemistry and Pharmaceutical Analysis. Over 30 years of academic and research experience. Published 174 novel research papers.
Member of the European Pharmacopoeia Committee since 1997 and scientific expert of the World Health Organization (WHO) on the quality control of drugs and the International Pharmacopoeia. Lead Assessor of the National Accreditation System since 1997, conducted assessments in over 300 Testing Laboratories.

NIKOLAOS C. MEGKOULAS

CHIEF EXECUTIVE OFFICER

Partner and co-founder of QualiMetriX. Chemist with an MSc and PhD in Analytical Chemistry and four years of post doctorial research in Pharmaceutical Analysis. Published 20 novel research papers in the international literature, and given numerous presentations in international scientific conferences. Quality expert on chemical pharmaceutical products having served for several years in all parts of the field: as a regulator (in EMA/CHPM/QWP); as an assessor (in the National Agency) and as a principal investigator (in the CRO).

CONSTANTINOS I. KOUSOULOS

CHIEF SCIENCE OFFICER

Pharmacist with an MSc and PhD in Pharmaceutical Analysis / Quality Control. Quality expert on chemical pharmaceutical products with integrated experience in the Pharmaceutical Quality System and products' lifecycle management. He has served as a Quality Assessor in the Agency (initial approval and dossier variations) and as a member of the Laboratory of Human Medicines, a part of the OMCL network, conducting among others the post approval market surveillance. He has successively served all key positions in the field: as an RnD, Bioanalysis, QC and QA Senior Manager.

ACHILLEAS S. MITAKOS

CHIEF OPERATING OFFICER

BSc in Chemistry; MSc in Pharmaceutical Analysis; Executive MBA holder. He joined QualiMetriX in 2015. Began his career as an Analytical R&D Laboratory Manager. In 2005 he joined a Greek Pharmaceutical Company where he successively served as the Analytical Development Manager and then in the Quality Control Operations as the Head of the QA/QC dpt and the Qualified Person. After the acquisition from a US based multinational company he became the Quality Operations Associate Director and the Qualified Person for the newly formed Quality Unit.

OUR SERVICES

INSTRUMENTATION

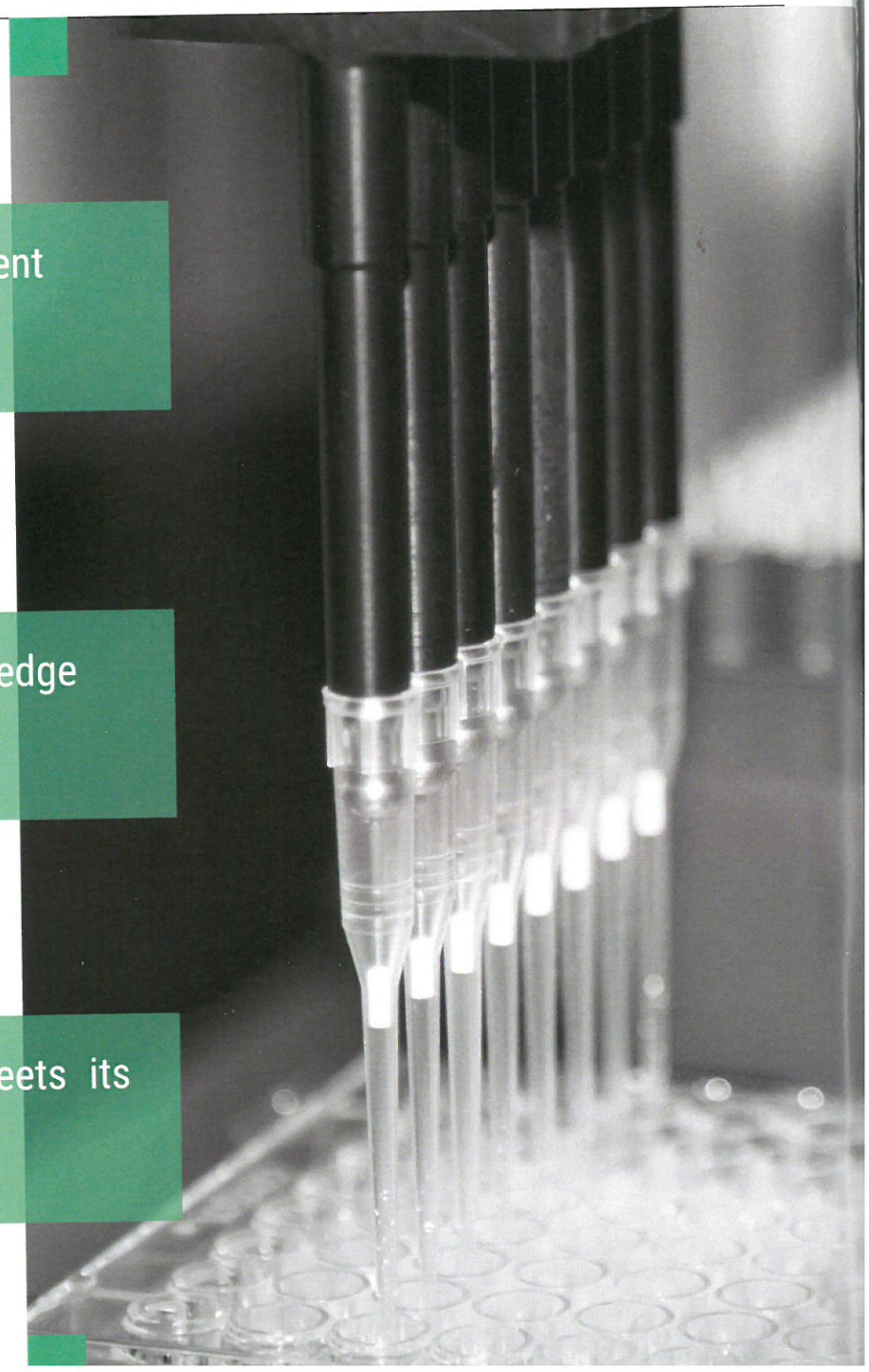
Cutting-edge technology under GMP environment

RESEARCH & DEVELOPMENT

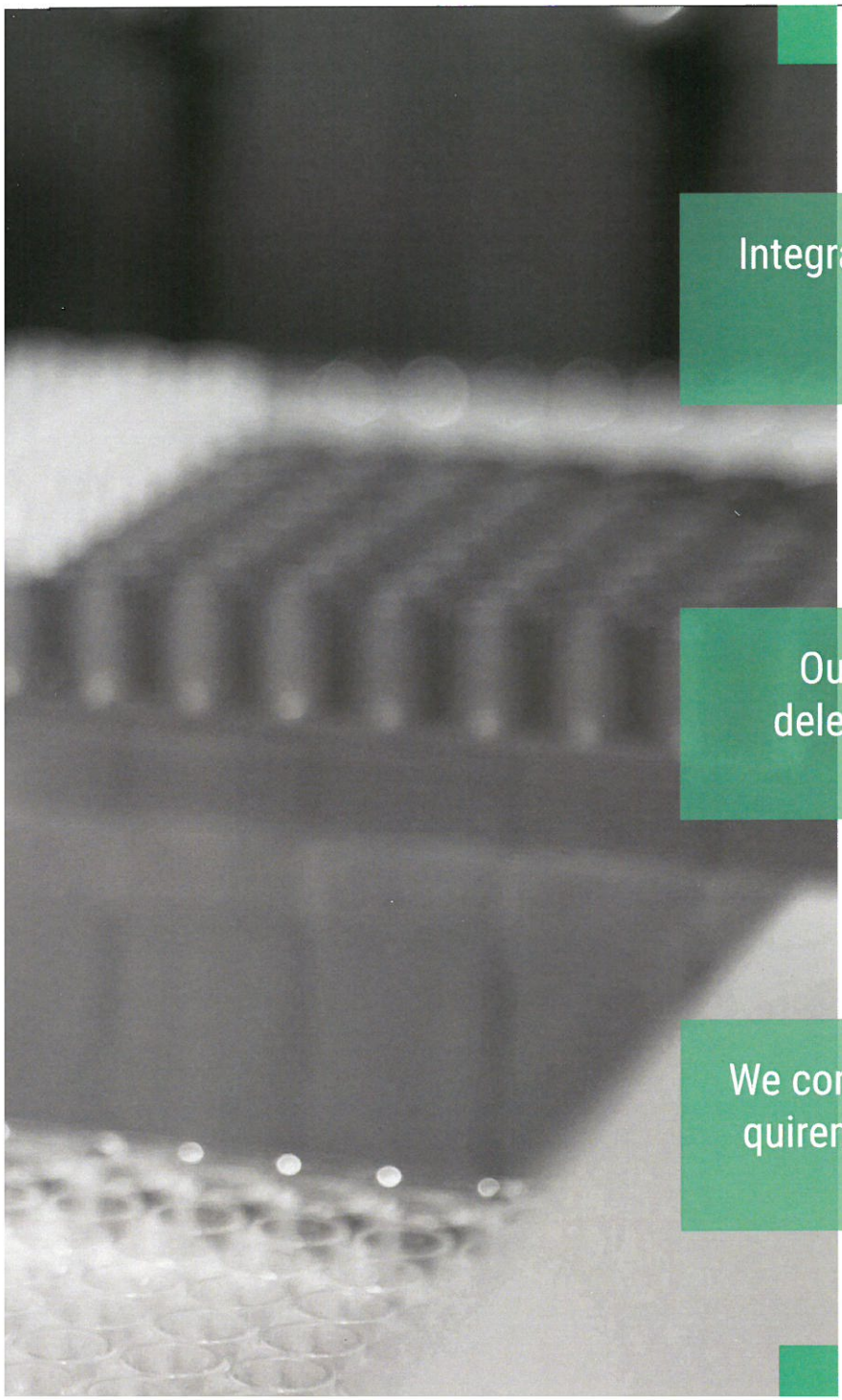
Modern Instrumentation and advanced knowledge in the field of analytical science

VALIDATION ACTIVITIES

Confirming that a process or a system meets its predefined quality attributes



Our approach for providing routine, as well as sophisticated analytical services involves **"Confidence"** as our core value.



QUALITY CONTROL - POST APPROVAL SERVICES

Integrated Quality Services throughout the products' lifecycle

CLINICAL & NON-CLINICAL STUDIES

Our activities are related to bioanalysis, while we delegate the clinical/ non-clinical part to approved partners worldwide

SCIENTIFIC ADVICE

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

INSTRUMENTATION

Cutting-edge technology under GMP environment. We yearly invest 500,000 euros in new technology (average value). Therefore, the available instrumentation is continuously expanding, while we increase our capacity by maintaining multiple units of the same type.

All systems follow the GMP requirements, such as the annual operational and performance qualifications and the Annex 11 requirements for computerized systems and data integrity.

TECHNIQUES

- HPLC/UPLC – UV/Vis/PDA/PAD/FLD/ELSD/RID/CAD
- NMR – Nuclear Magnetic Resonance
- Ion Chromatography
- Quadrupole LC-ESI/APCI-MS
- LC-MS/MS (triple quadrupole)
- Ion trap LC/MS
- GC – MS
- GC – FID/ECD (split-splitless and head space)
- ICP – MS
- LC-TOF-MS
- USP Vertical Diffusion (Franz Cell)
- Skin Permeation
- Conductometry
- Automatic titrimetry
- Polarography
- Voltammetry
- UV – Vis spectrophotometry
- Atomic Absorption Spectroscopy (Flame; Furnace)
- Infra – Red spectrometry
- Attenuated Total Reflection – Fourier Transform Infrared Spectroscopy (ATR-FTIR)
- Robotic Sample Handling
- Microplate reading
- Surface tension
- Viscometry
- Osmometry
- Dissolution
- Disintegration
- Friability
- Hardness
- Turbidity
- Controlled temperature and humidity storage
- Photostability
- Solid – phase extraction
- Microwave digestion
- Microscopy
- Particles Size Distribution
- X-Ray Diffraction (XRD)
- Water Ultra Purification

! The above list is indicative, so please contact us in order to receive updated information

RESEARCH & DEVELOPMENT

We provide comprehensive analytical support during the development of drug formulations.

Our research and development (R&D) services combine innovative approaches, modern instruments and advanced knowledge in the field of analytical science in order to achieve high performance in terms of selectivity, precision, sensitivity and robustness.

Every method is thoroughly tested to ensure its compliance with regulatory requirements and its ultimate performance and robustness in any laboratory worldwide.

Besides development, method optimization is essential in order to obtain top quality data in a shorter time and at lower cost.

Our services include, but not limited to, the following:

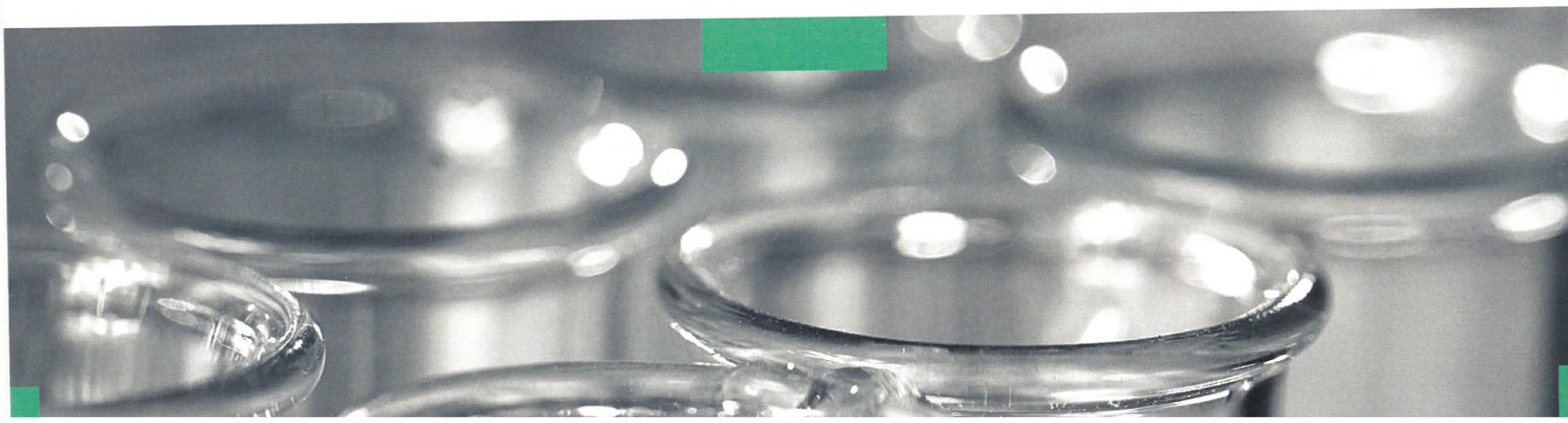
- Development of analytical methods
- Reverse engineering / Investigation of the Reference Product composition
- "Essential similarity" establishment for generic and hybrid applications
- Dissolution development
- Compatibility studies
- Extraction studies for primary packaging and manufacturing materials
- Stability screening of development samples (pre-stability studies)
- Permeation studies
- Structural elucidation of unknown impurities

VALIDATION ACTIVITIES

QualiMetriX provides validation services across a wide range of analytical activities as well as validation of the final product characteristics.

These include, but not limited to, the following

- Validation of analytical methods for batch testing
- Forced degradation studies
- Leachables testing
- Elemental impurities (ICH Q3D guideline)
- Stability studies
- Photostability with temperature and humidity control (according to ICH Q1B)
- Thermal cycling studies
- In use stability studies
- Filter validation
- Cleaning validation
- In process validation



QUALITY CONTROL - POST APPROVAL SERVICES

Full range of quality control services including batch testing and stability studies of the final products and APIs.

Testing forms actually only a part of our services, which concern a systematic approach of the products' post approval management and lifecycle strategy.

Our services include, but not limited to, the following:

✔ Batch Testing/ Release of API's, Excipients, Packaging and Final Product

QualiMetriX is GMP approved to perform routine testing and release of APIs, excipients, packaging and final products (chemical and biological). This activity also involves batch release testing, for products manufactured outside of the EU which are planned for importation and release within the European market (EU testing).

✔ QP services

QP services include the release of Final Products to the market, but also Audits to API and final products manufacturers, third party subcontractors and suppliers.

✔ Post approval (ongoing) stability studies

The stability of a final product should be monitored according to a continuous and appropriate programme that will permit the detection of any stability issue (e.g. changes in levels of degradation products). The purpose of the ongoing stability programme is to monitor the final product and to determine that the final product remains, and can be expected to remain, within specifications under the storage conditions indicated on the label.

✔ Post Approval Management/ Lifecycle strategy

According to the ICH Q10 and Q12 principles, harmonized tools to facilitate prospective changes over the products' lifecycle should be applied. Our services concern a systematic approach to proposing, evaluating, approving, implementing and reviewing changes, such as manufacturing and/or release site; API, excipients and/or packaging supplier; manufacturing process; analytical methods and design space.

CLINICAL AND NON-CLINICAL STUDIES

We are involved in clinical and non-clinical studies, wherein the analysis of biological samples is needed (e.g. Bioequivalence/ PK studies). Our activities are related to bioanalysis, while we delegate the clinical/ non-clinical part to approved partners worldwide.

Bioanalytical methods are developed and validated according to the EMA guidelines and sponsor's requirements from dedicated and experienced scientists in bioanalytical procedures.

Using state of the art equipment: Robotic Sample Handling, UPLC, GC and LC-MS/MS instruments; all methods are configured according to the complexity of the study, while GLP/ GCP principles are fully implemented.

SCIENTIFIC ADVICE

Qualified experts (former members of the National Agency, EMA and EDQM committees) can provide high level scientific guidance for the Quality, Clinical and Non-Clinical parts throughout the pharmaceutical products' life-cycle.

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


Quality is everyone's responsibility
and we never have to stop getting better
– W. Edwards Deming –

QA DEPARTMENT

HIGHEST QUALITY WITH ACCURATE AND TIMELY RESULTS

Our Quality Assurance department is responsible for offering our clients services of the highest quality with accurate and timely results. The Quality Assurance Department monitors the day to day operations, from the R&D department to the Quality oriented management decisions.

Our laboratories operate under strict quality procedures which meet both GMP and ISO 17025 requirements. The studies are performed by a team of experienced and highly qualified scientists (chemists and pharmacists), all experts in pharmaceutical analysis, who are kept aware of the latest developments through continuous training.

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 EDQM.

GMP

"that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use." (EMA)

A GMP system ensures that every product is produced and controlled according to specific quality standards. The implementation of a GMP system aims to minimize in every aspect of any pharmaceutical production those risks that cannot be eliminated through testing the final product.

To achieve this, every single process must be described in detail in written procedures. The implementation of these procedures also provides documented proof that the correct procedures are followed at all times.

The principles and guidelines for GMP in the European Union are stated in two Directives for medicines for human use and for veterinary use, 2003/94/EC and 91/412/EEC, respectively. GMP Guidelines provide an interpretation of these principles and are supplemented by a series of annexes that may modify or augment the requirements for certain types of products, or provide more specific guidance on a particular topic. Compliance with these principles and guidelines is mandatory within the EEA, while the national authorities of each country are responsible for their enforcement.

QUALIMETRIX

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GOOD MANUFACTURING PRACTICE

GMP

QUALITY PRODUCT

ISO 17025

ISO 17025 is the most important international standard for testing and calibration laboratories.

ISO 17025 applies to all laboratories carrying out tests and/or calibrations, including sampling. These tests may be performed using standard, non-standard or in-house (developed by the laboratory) methods. It specifies the general requirements for the competence of a laboratory to perform the aforementioned tasks/activities.
The accreditation is granted by an accreditation body, in Greece the "Hellenic Accreditation System, E.SY.D." and only after thorough evaluation of the laboratory's Quality Management System as well as actual demonstration of the laboratory's technical competence (premises, instrumentation inspection etc.) When the accreditation is granted, the Scope of Accreditation is also issued. This document is the official listing of all the activities (specific tests, types of tests, technologies, etc.) for which the laboratory has been deemed competent to perform. For chemical testing laboratories, where flexibility is required (regarding the variety of samples, testing methods applied, etc.), it is usually desirable for a "Flexible Scope" to be issued. A flexible scope can only be awarded when the laboratory demonstrates a design/development process of expanding into additional areas not previously undertaken. QuamliMetriX is ISO/IEC accreditated, while "Flexible Scope" has been granted

After the initial accreditation, the accredited laboratories are regularly audited by the responsible Accreditation Body, in order to ensure their continued competence and compliance with the standard.

PTS - EDQM

"a form of external assessment of quality control management systems using inter-laboratory comparisons to determine the performance of individual laboratories in carrying out specific tests or measurements" (EDQM)

EDQM PTS (Proficiency Testing Scheme) studies include basic analytical methods (physicochemical and biological) and the laboratories participation provides an objective means of demostrating the physicochemical data reliability for these methods against the members of the General European OMCL Network (Official Medicines Control Laboratories) as well as other medicines' control laboratories.

EDQM organizes about 5 PTS studies on an annual basis in the physicochemical area and 4 in the biological area. The studies planned for each year are posted on the EDQM website.

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