



‘...always focused on each individual client.’

Who We Are

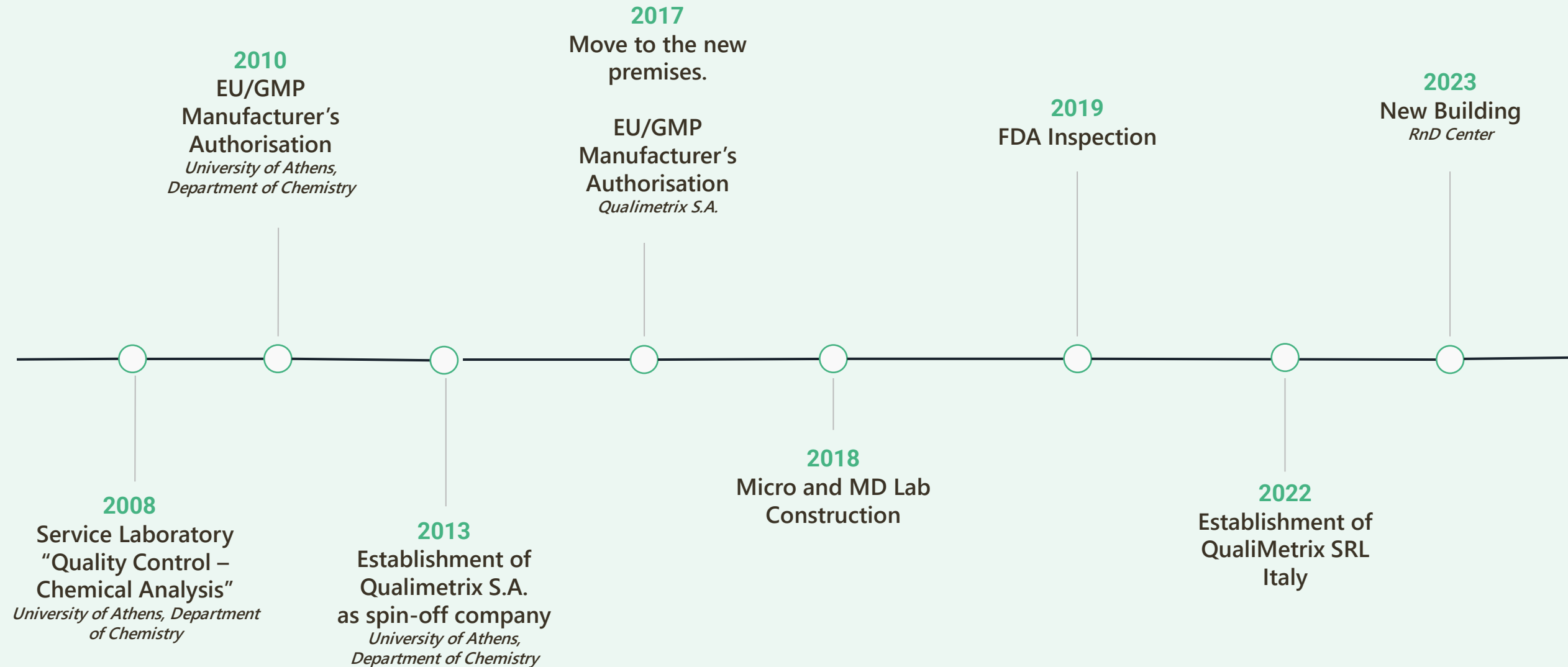
A Contract Research Organization

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



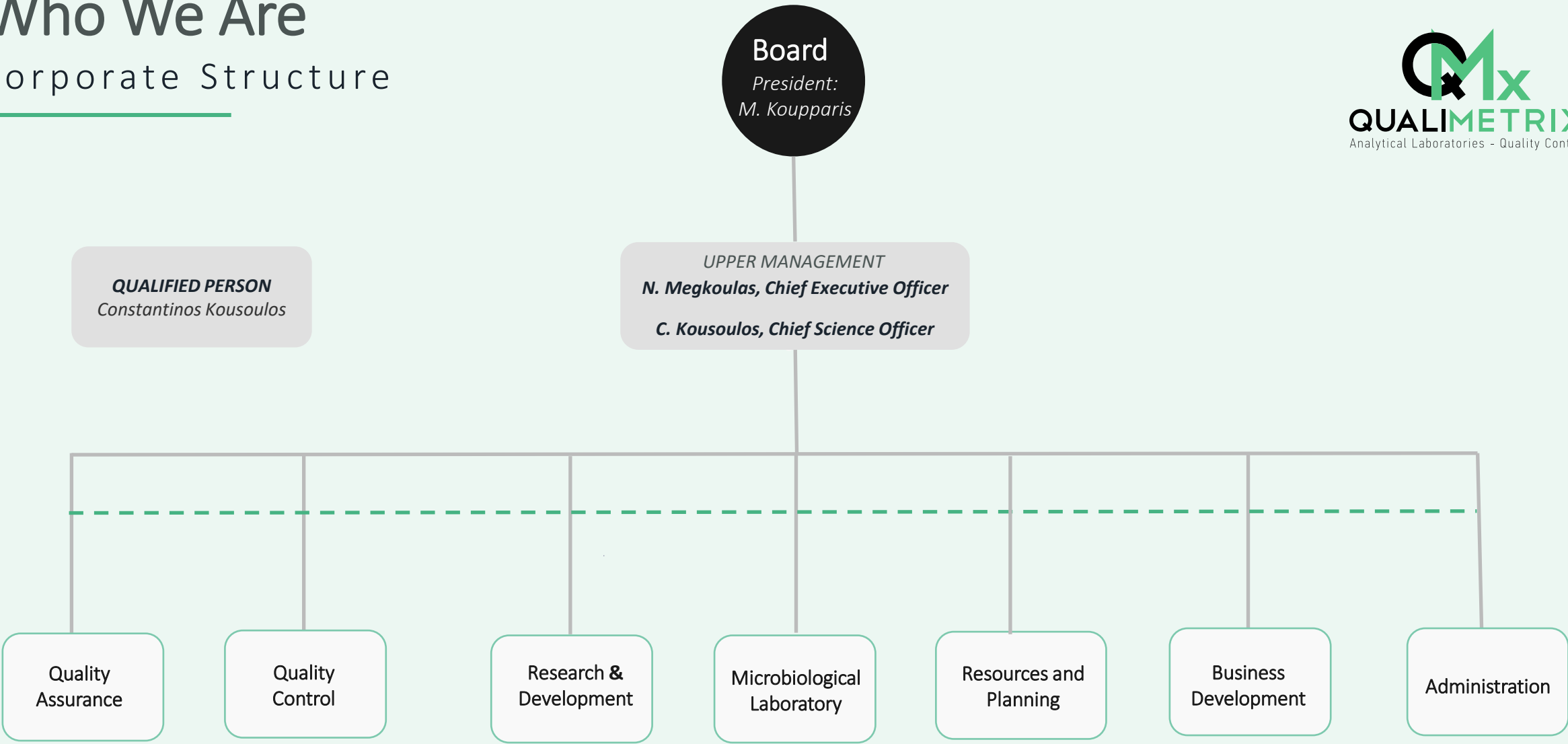
Who We Are

History



Who We Are

Corporate Structure



Who We are

Our Upper Management Team

MICHAEL A. KOUPPARIS

PRESIDENT OF THE BOARD

Partner and co-founder of Qualimetrix. Emeritus 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 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 doctoral research in Pharmaceutical Analysis. Published 20 novel research papers in the International literature, and given numerous of 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/CHMP/QWP); as an assessor (in the National Agency) and as a principal investigator (in the CRO)

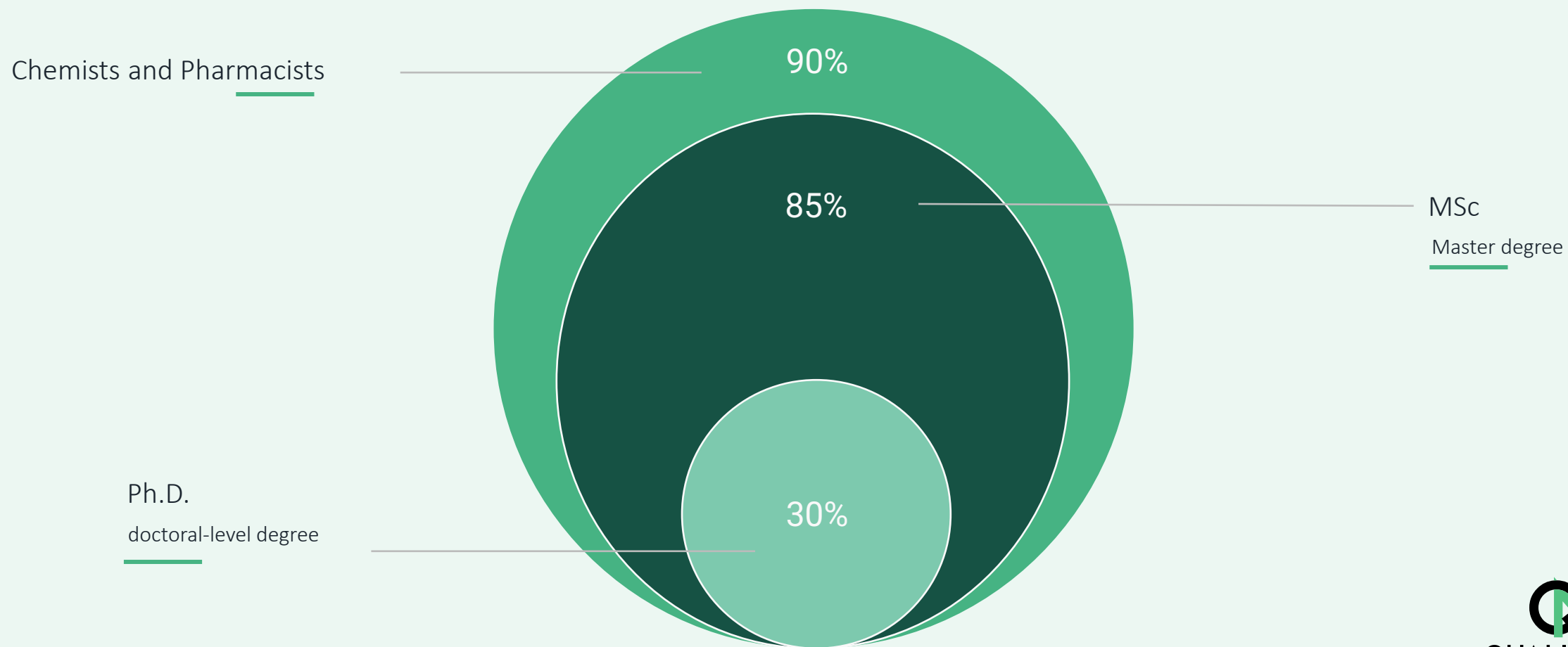
CONSTANTINOS I. KOUSOULOS

CHIEF SCIENCE OFFICER

Pharmacist with an MSc and PhD in Pharmaceutical analysis and 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 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 R&D, Bioanalysis, QC and QA Senior Manager.

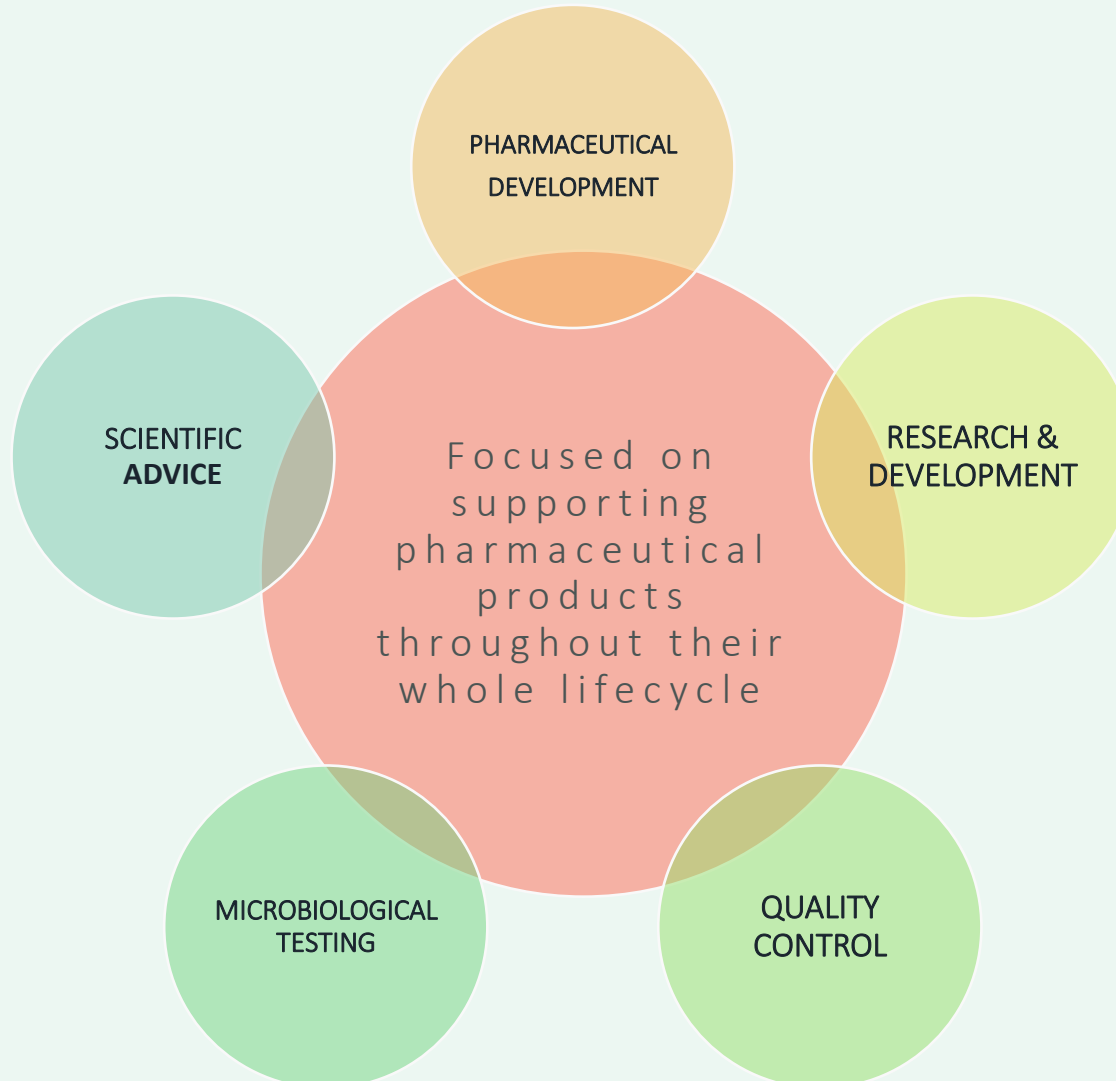
Who We Are

People



Our Services – Pharmaceuticals

Confidence is our core value



Our Services

1

PHARMACEUTICAL DEVELOPMENT

- ✓ Formulation
- ✓ “Essential similarity” establishment for generic and hybrid applications
- ✓ Compatibility Studies
- ✓ Development and optimization of the pharmaceutical composition
- ✓ Development and optimization of the manufacturing process
- ✓ Development of the specifications
- ✓ Studies in the frame of 3.2.P.2

Our Services

2

RESEARCH AND DEVELOPMENT

- ✓ Development of analytical methods
- ✓ Forced Degradation Studies
- ✓ Dissolution development
- ✓ Extractables and Leachables studies for primary packaging and manufacturing materials
- ✓ Skin Permeation studies for locally acting locally applied products (IVR/IVP)
- ✓ Structural elucidation of unknown impurities
- ✓ Toxicological assessment (according to ICH M7)
- ✓ Reverse engineering / Investigation of the reference product composition

Our Services

3

QUALITY CONTROL

- ✓ Validation of analytical methods
- ✓ Elemental impurities (ICH Q3D Guideline)
- ✓ Nitrosamines risk assessment, method development, validation and testing
- ✓ Genotoxic impurities
- ✓ APIs testing
- ✓ Stability studies
- ✓ Stability storage of all zones
- ✓ Photostability with temperature and humidity control (ICH Q1B)
- ✓ Batch testing / Release of final products
- ✓ QP Services (Batch confirmation/Certification for EU Market)
- ✓ On going stability studies

Our Services

4

BATCH TESTING AND RELEASE

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).

Testing of over 1.000 batches/year

All pharmaceutical forms:

- tablets
- capsules
- injectables
- locally applied products
- inhalers

Timelines:

3 weeks for non-sterile products
4 weeks for sterile products

Our Services

5

MICROBIOLOGICAL AND *IN VITRO* TESTING

- ✓ Filter validation studies
 - *Filter compatibility*
 - *Filter integrity*
 - *Filter Extractables*
 - *Viability*
 - *Bacterial Challenge*
- ✓ PET studies
- ✓ BET
- ✓ Microbial burden
- ✓ Container Closure Integrity Test
- ✓ Bioassays
- ✓ Bacterial Reverse Mutation test (AMES)
- ✓ Cytotoxicity
- ✓ Sensitization
- ✓ Irritation
- ✓ Hemocompatibility

Our Services

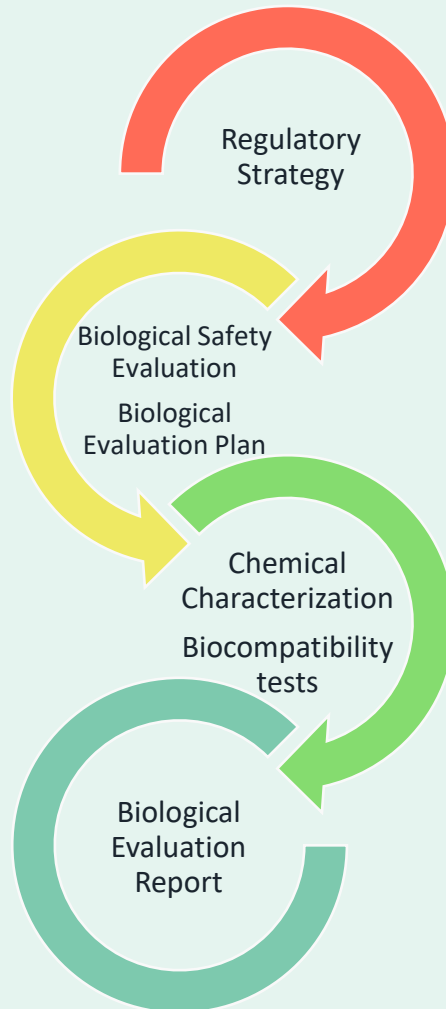
6

SCIENTIFIC ADVICE

- ✓ Expert reports
- ✓ Regulatory consultation
- ✓ EMA or National Agencies' Scientific Advice
- ✓ Data Gap Analysis
- ✓ Letter of deficiencies response / Arbitration guidance
- ✓ Legal basis and regulatory strategy

Our Services

Medical Devices



Our Services

Instrumentation

- ✓ HPLC/UPLC – UV/Vis/PDA/PAD/FLD/ELSD/RID/CAD
- ✓ Ion Chromatography Sys. – Conductivity/PAD
- ✓ UPLC-HRMS-LTQ-Orbitrap
- ✓ 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)
- ✓ Conductivity meter
- ✓ Karl Fischer titrator
- ✓ Polarographer
- ✓ UV – Vis spectrophotometer
- ✓ ATR– Fourier Transform Infrared Spectroscopy System (ATR-FTIR)
- ✓ Digital Polarimeter
- ✓ Robotic Liquid Handler System
- ✓ PSD Analyser Malvern Mastersizer 3000
- ✓ XRD
- ✓ Microplate reader
- ✓ Viscometer
- ✓ Cryoscopic Osmometer
- ✓ Dissolution tester (USP I, II, IV)
- ✓ Disintegration tester
- ✓ Friability tester
- ✓ Hardness tester
- ✓ Turbidity meter
- ✓ Stability and Photostability Chambers
- ✓ Solid – phase extraction system
- ✓ Microwave digestion system
- ✓ Optical Microscope
- ✓ Melting Point Tester
- ✓ Cytation 5 Cell imaging multimode reader

Quality Assurance

Certificates

Highest Quality with
Accurate and Timely Results



EU-GMP



FDA
inspection



GLP

Future Projects

R&D Center



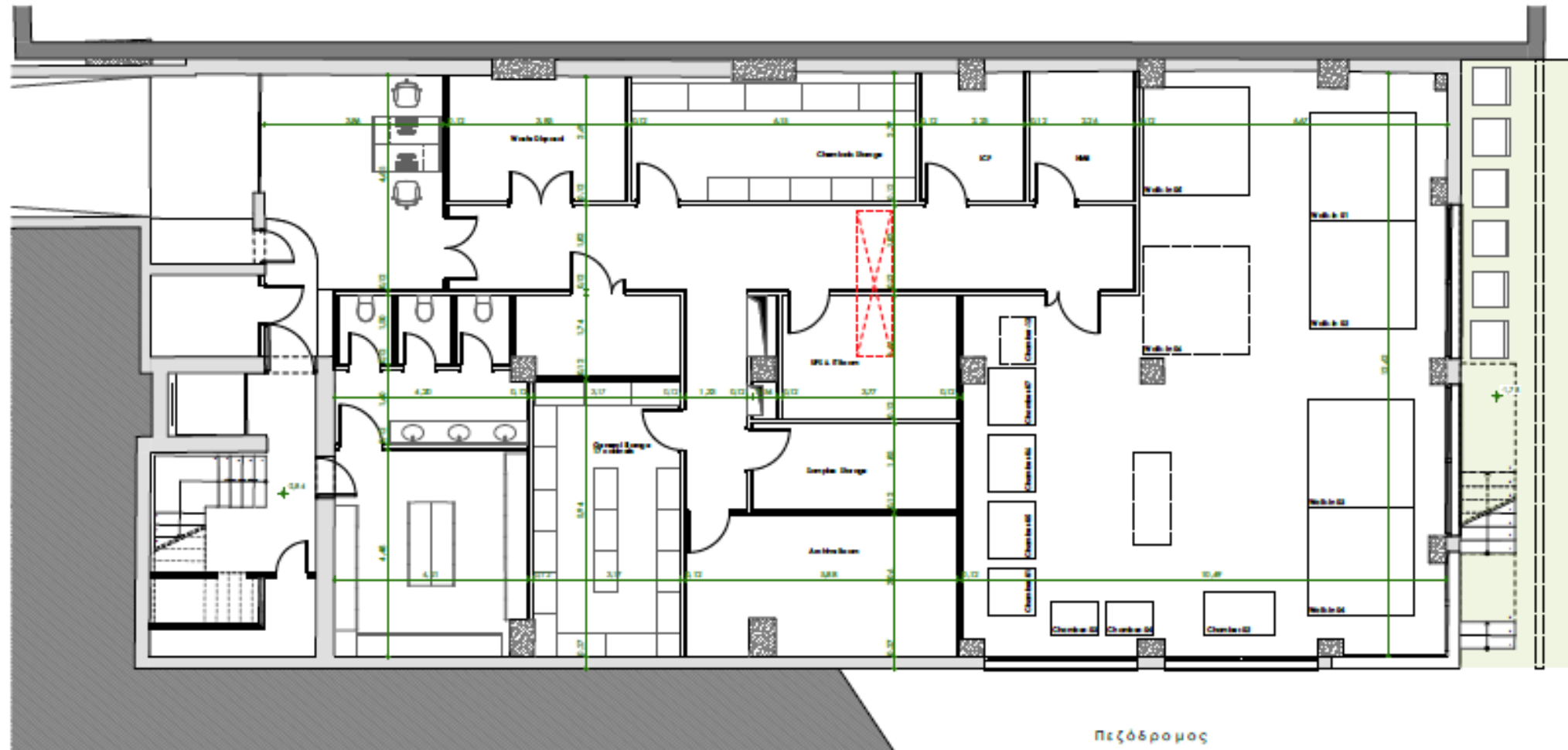
Future Projects

R&D Center



R&D Center

Basement

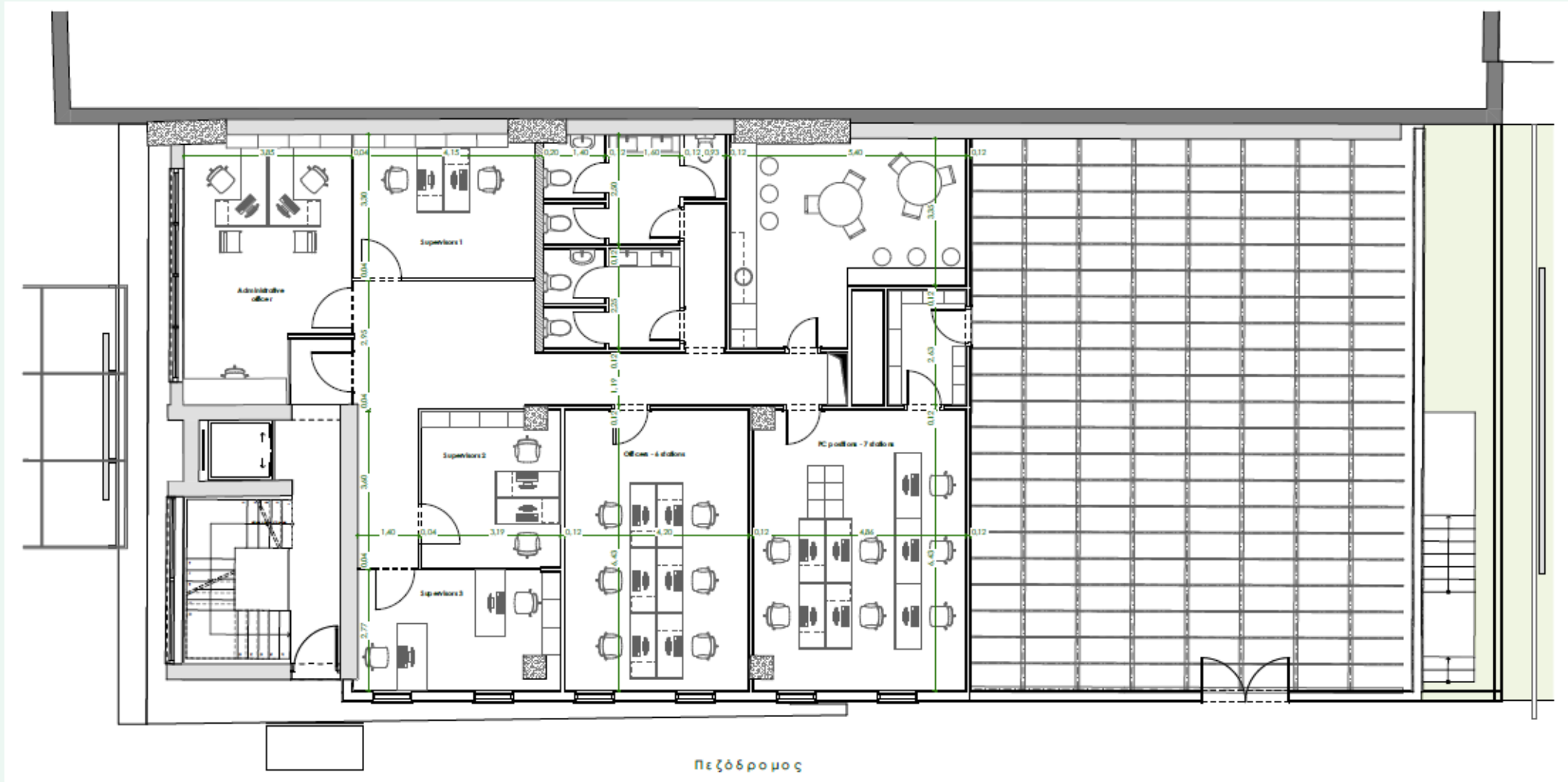


R&D Center

Future Projects

R&D Center

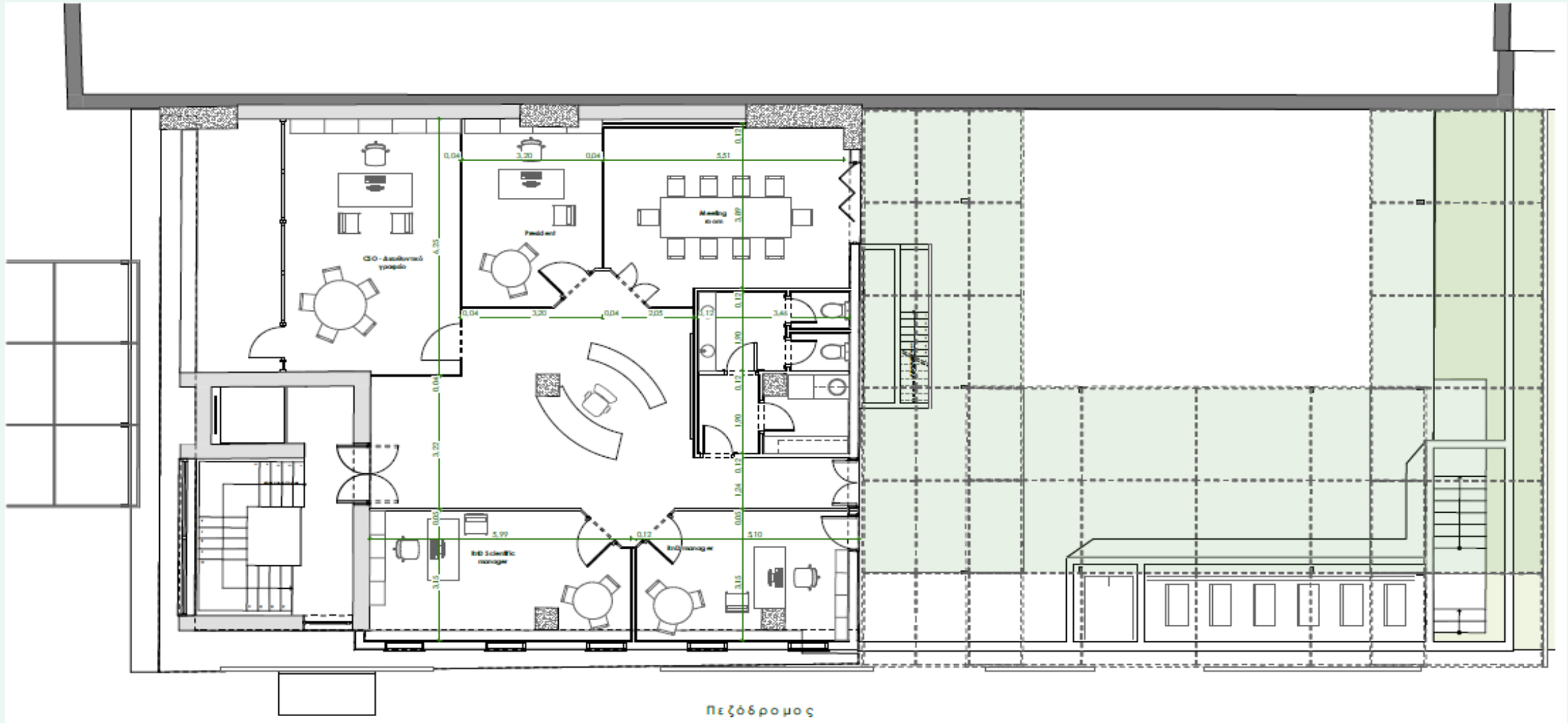
1st Floor



Future Projects

Infrastructure

2nd Floor



Key characteristics of our work



- ✓ One stop lab
- ✓ We undertake the pharmaceutical development from A-Z
- ✓ Flexible – Short and accurate timelines
- ✓ Justified prices
- ✓ Provide support for the study design
- ✓ Assistance during the submission to the authorities

Connecting Ideas

Bridging data to compile unique products.



QUALIMETRIX

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