neotron
pharma

Neotron Pharma is a specialized GMP division dedicated to the Analytical Service for the Pharmaceutical sector on API, Drugs, Excipient and Raw Materials.

Neotron Pharma is the GMP business unit of Neotron Group, a Global Player in the market of analysis and consulting services on food products, supplements, food contact materials (FCM), cosmetics and pharmaceutical products.

Neotron Pharma, following the main International Standards, provides chemical and physical tests and supplies high-level technical support to many Pharma companies in the field of GMP analytical service.

In 2019, Neotron was acquired by the Cotecna Group, one of the world's leading providers of testing, inspection and certification services.

Neotron Group can rely on over 550 members of employees to the main areas of Analytical Testing in 10.000 m^2 of Laboratories.

VISION

NEOTRON VISION IS A WORLD WHERE: The development of technologies and scientific knowledge drives quality improvement of food, drugs and cosmetic products as well as their diffusion into new markets, with new meanings in term of safety, nutritional value, efficacy and disease prevention.

Legislation will be a driver for food safety improvement. As a consequence, the demand for analytical services will increase, both for brand protection and for sense of responsibility and formal purposes. We see two different scenarios: a demand for crises management and specific projects, and a demand for routine controls.

MISSION

THE ROLE NEOTRON INTENDS TO TAKE ON IS THE FOLLOWING: provide state-ofthe-art and robust methods to take under control the supply chain for routine controls, with a strong focus on efficiency and response time. Managing crises, urgencies and specific issue through investment in research, method development, together with a flexible and reactive approach.

OUR VALUES

RELIABILITY

Data reliability is the main asset and it is pursed at any level with a focus on method validation and control.

CONFIDENTIALITY

Confidentiality is ensured at every organization level with utmost attention and controlled procedures.

TRANSPARENCY AND TRUTH

Transparency and truth are essential requirements: our mistakes are acknowledged and an opportunity for improvement.

INNOVATIVE DEVELOPMENT

Scientific and technology improvement is, together with the customer's needs, our "driver" of innovative development.

LONG-TERM VISION

Our choices are guided by a long-term vision and directed at global market.

CERTIFICATIONS, ACCREDITATIONS AND QUALITY SYSTEM

Neotron Pharma offers a complete chemical analysis service for the safety and quality of the entire Pharmaceutical sector: API, Drugs, Excipient, Raw Materials and Packaging.

Thanks to the concentration of know-how and technology, Neotron Pharma guarantees the highest level of quality and reliability of the analytical data, as well as immediate assistance to the customer on any Alert of the Pharma sector, following the main International Standard:

GMP Authorization of Neotron Testing Facility for chemical and physical quality control test

Certificate of registration **FDA (Food and Drugs Administration)** | facilities inspected

Ministry of Health authorization for **veterinary drugs**

Ministry of Health authorization for drugs and **psychotropic substances**

Accreditation in compliance with **ISO/IEC 17025** standard by ACCREDIA (Italian Accreditation Body)

Neotron has been a reference chemical laboratory for the most important Pharma industries for many years.

Thanks to our QA team, the quality of the Pharma division is managed and implemented at 360 degrees, always guaranteeing the customer maximum transparency and reliability of the analytical

ANALYTICAL PORTFOLIO

CONTAMINANTS

Thanks to the experience for over 40 years on the analysis of contaminants on food matrices, it has been possible to translate these analytical skills also in the Pharma department, thus offering support to customers even in the GMP regime. Currently the laboratory approach is based on customer needs, through screening and/or validation activities, paying particular attention to timing and related costs.

NITROSAMINES

Determination of nitrosamine residues, in APIs, excipients and finished products, in accordance with what is reported in the official EMA documents, setting of new nitrosamines and API-excipients interaction studies.

PESTICIDES

Determination of pesticides in raw material as excipients and herbals in accordance with what is described in the general chapter 01/2019: 20813 of the European Pharmacopoeia.

ELEMENTAL IMPURITIES

Determination of Elemental Impurities, in ICP-MS / ICP-OES / AAS in accordance with what is reported in tables 1, 2a, 2b and 3 of ICHQ3D.

PYRROLIZIDINE ALKALOIDS

Determination by HPLC-MSMS of 28 Pyrrolizidine Alkaloids in herbals extracts and finished products.

ANALYTICAL PORTFOLIO

PHARMACOPOEIA METHODS

Neotron Pharma provides a wide range of analytical control according to the main Pharmacopoeia test such as EP, USP, JP, BP, CHP. Lab's approach is to promptly evaluate the tests and monographs requested by the customer, highlighting, with maximum transparency, the feasibility, timing and any consumables necessary to perform the tests.

ASSAY & IMPURITIES

Control of active ingredients and related substances according to a developed and validated method by Neotron or shared by the customer

STRESS TEST STUDY

With specific protocols aligned to customer considering Heat, Oxidative conditions, Acid/Base pH and Photolysis according to ICH Q1B option 1 guidelines

RESIDUAL SOLVENTS

Screening and validation activities for the control of raw materials and finished products as per general chapter 467 of the USP

STABILITY STUDIES

Neotron Pharma is able to perform stability studies and relative storage thanks to the presence of different chambers for climatic zones I, II, IV according to ICH Q1 A (R2)

ANALYTICAL METHOD VALIDATION

Analytical method development and validation workflow

PRELIMINARY STUDY → **METHOD DEVELOPMENT** → **METHOD VALIDATION** → **ROUTINE ANALYSIS or TRANSFER METHOD**

- **METHOD VALIDATION**: Acceptance criteria
- **ROUTINE ANALYSIS or TRANSFER METHOD**: Constant performance monitoring

Before introduction in routine use analytical methods are validated.

ANALYTICAL APPROACH CHOICE

Decision of use/not use instruments and kind of instruments on the basis of method fit for purpose

DEFINITION OF THE ANALYTICAL PROTOCOL AND FEASIBILITY TEST

Definition of all the analytical phases: sample preparation, extraction, purification, detection parameters. Feasibility tests to see if the method works properly

METHOD VALIDATION

Series of tests repetitions and results statistical treatment to evaluate the method performances

PERFORMANCE

VALIDATION PARAMETERS

Linearity · Selectivity · Limit of Quantification/ Detection · Precision · Accuracy · Uncertainty · System Suitability · Stability in Solution · Robustness

ACCEPTANCE CRITERIA

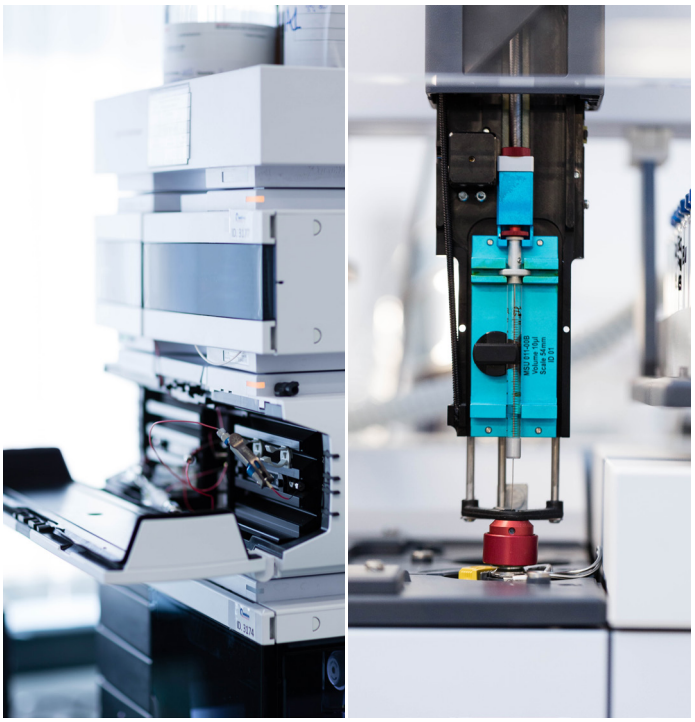
EQUIPMENTS

Regular investments and continuous analytical research and innovation allow Neotron Pharma to be a reference point for pharmaceutical companies at an international level.

WET CHEMISTRY SERVICES

Neotron Pharma has the main analytical equipment necessary for carrying out tests in accordance with the main pharmacopoeias.

Among the main equipment supplied for "Wet chemistry" analysis we find Dissolutor, Disaggregator, Hardness tester, Spectrofotometer, K.F, Densimeter, Viscometer, Mastersizer and many more.



MICRO ANALYTICAL SERVICES

The laboratory has the main instruments dedicated to the validation of Assay / Impurities, Nitrosamines, residual solvents and contaminants divided into the HPLC and GC area.

HPLC area

The laboratory can count on the presence of HPLC and UPLC with the main detectors such as DAD, refractive index, IR, Fluorimeter, Light scattering and MSMS.

To complete the HPLC division we find a tool dedicated to post-column derivatization.

GC area

The laboratory has the main detectors such as FID, ECD, HS-MS, MSMS.

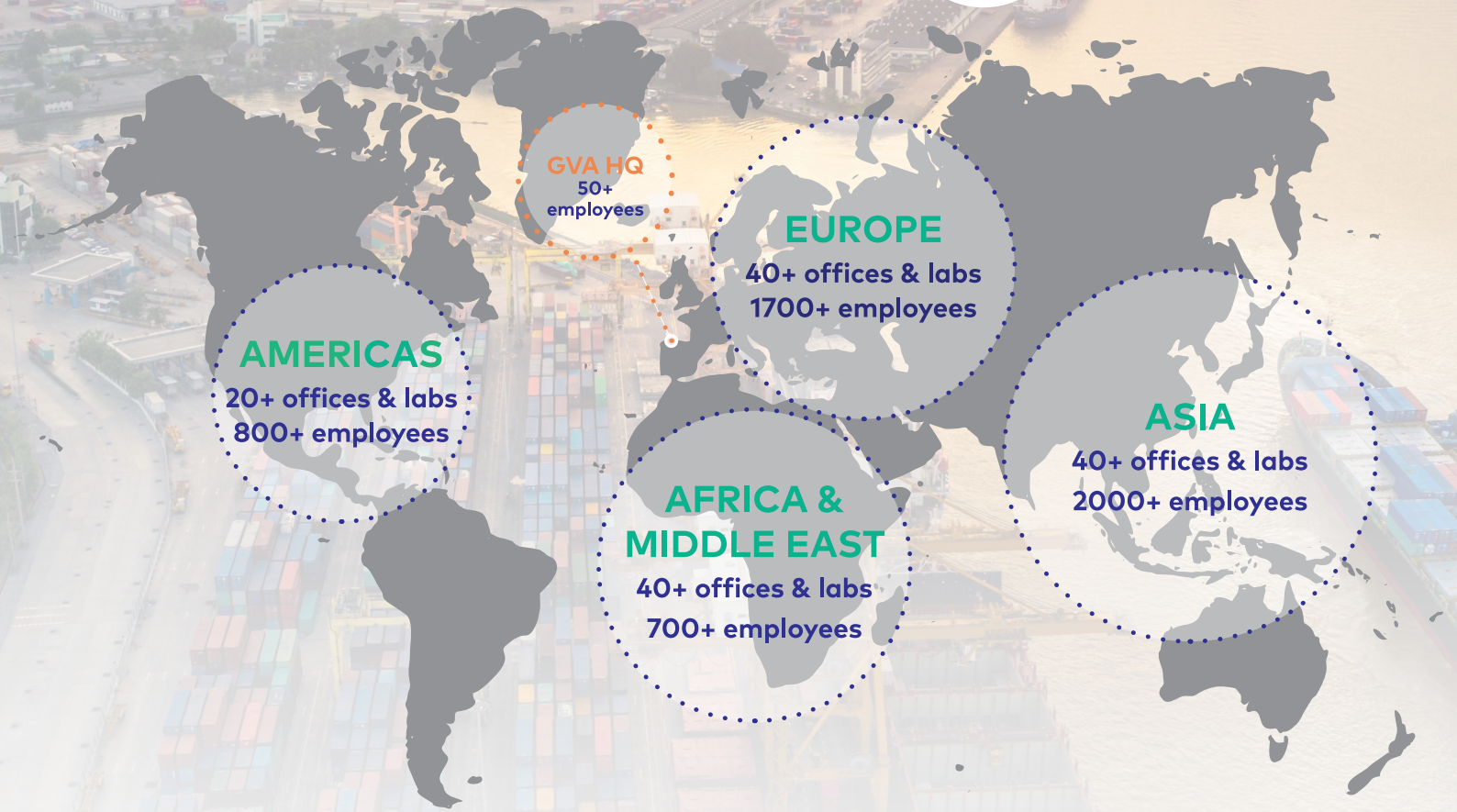
METALS SERVICES

The laboratory has ICP-OES, ICP-MS and AAS which together with the presence of a mineralizer, dedicated to the preparation of the samples, allow Neotron pharma to be reactive to the different customer requests.

COTECNA

Trust for a moving world

Founded in Switzerland in 1974, Cotecna started off as a family business and has now grown to become a world-class international player with over **5,000 employees** in more than **140 offices** across approximately **50 countries**. Today, our trusted network of professionals and certified laboratories applies industry approved standards and provides proven expertise to help clients across five key industries



At a time when supply chains are becoming increasingly complex, we develop ourselves and do everything so that clients can rely on us to control their products. In order to expand our presence in key markets and across core business lines, we pursue strategic acquisitions of exceptional companies in the fields of testing, inspection and certification.

INFO /CONTACTS

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