# Laboratory profile

# Vita Nova Institute - 'new life' with green path to health

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# Mission and topics

Vita Nova Institute was founded on September 5, 2002, as a non-profit civil society, focused on education, science, technology and research in the pharmaceutical field. The institute is located in Hortolândia, within São Paulo state, Brazil.

As a pioneer in Brazil, Vita Nova is a multidisciplinary institution which is focused on pharmaceutical research. It has several research lines including: implementation of innovative analytical methods, discovery of new chemical entities with biological activity, development of new chemical and biotechnological processes and development of new extended-release pharmaceutical formulation. The aim of this research is to minimize costs, maximize results and develop products that improve the quality of life.

Vita Nova has four Scientific Divisions: analytical, organic chemistry, biotechnology and pharmaceutical application. These can be seen arranged in an organization chart in Figure 1, under the Scientific Directory. The Project Management Division, which is under the same directory, is responsible for the professional project management of all projects, integrating technical, regulatory, financial and intellectual property issues. The board of Directors is completed with the Financial

and the Innovation Directors. Moreover, the institute has an Audit Committee, a Corporate Committee and a Scientific Committee, which contribute to the professional management and the scientific direction of the same.

Below are some examples of application in each of Vita Nova's Scientific Divisions.

#### Industrial valorization

Vita Nova Institute has an important partnership with EMS S.A., a generic pharmaceutical company in Brazil, with which it has several projects. Beside this partnership, Vita Nova also has projects in collaboration with a number of research centers and universities in Brazil, aimed at developing new chemical entities with anti-hypertension and anti-inflammatory activities.

# Scientific flashlight in the analytical field

The first innovative result obtained by Vita Nova's Analytical Division, was the development of a new spectroscopic method to determine the amount of amoxicillin in pharmaceutical oral suspensions, using UV-visible absorbance spectra in association with a multivariate calibration method. The validated methodology demonstrated that the model was able to predict the quantity of amoxicillin in oral suspensions in the concentration ranges necessary to fit the regulatory requirements of this specific pharmaceutical product. A good agreement was

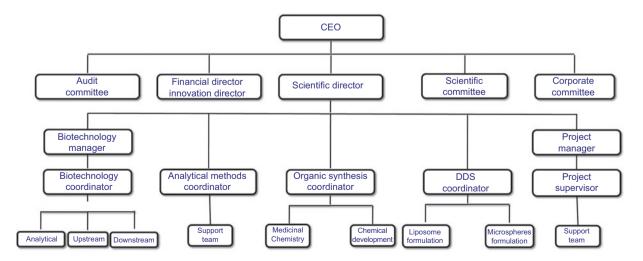


Figure 1 Organization chart of the scientific divisions of Vita Nova Institute.

observed between the new spectroscopic method and the standard chromatography method. The new spectroscopic method allowed a reduction of 66% of costs and 20% of solvents necessary to perform the assay; this is a good example of green processing, which could be used by pharmaceutical companies.

Nowadays, this new method is being used at EMS S.A. and it has also been approved by Brazilian Health Surveillance Agency (ANVISA) as a routine work method for quantification of amoxicillin.

# Scientific flashlight in the medicinal chemistry

The Organic Synthesis Division has been working with medicinal chemistry and chemical development and is continuously developing new technologies aimed at increasing the speed of obtaining lead compounds and decreasing waste in chemical processes.

To study process safety, the Organic Synthesis Division has been using an automatic equipment named MultiMax from Mettler Toledo to collect information regarding the temperature and time reaction (Figure 2).

# Scientific flashlight in the biotechnology field

Vita Nova's Biotechnology Division has the expertise to develop bioprocesses (upstream and downstream) using prokaryotic or eukaryotic systems. Besides that, the group also works on the analytical evaluation of biosimilar candidates, performing the physical-chemical comparisons between the candidate and the reference drug, in order to request marketing authorization of the biosimilar products in Brazil.

# Scientific flashlight in the new formulation field

The Drug Delivery Systems Division has been developing new formulations based on technologies such as microspheres and liposomes, aiming at controlling drug release and/or targeting delivery to circumvent pharmacokinetic obstacles, minimizing drug toxicity and its side effects, and enhancing the bioavailability and therapeutic effect.



Figure 2 Chemical development.