



Standard Project Funded by Call for Proposals 849/2016 - POR FESR 2014-2020 Friuli Venezia Giulia – Axis 1 Activities 1.3.b – Funded by POR FESR 2014-2020 as per LR 14/2015, art. 1 - Prat. n. 24029 (MIC)

“DIAMANTE “– “IN VIVO” DIAGNOSTICS PRODUCTION

Nuclear Magnetic Resonance (RMN) and X-ray Spectroscopy are undoubtedly the most widely used diagnostic imaging techniques to detect, for example, central nervous system disorders, angiopathies, urinary tract disorders, and visualization of tumors. These techniques use of a Contrast Agents, which, injected into the organs to be examined, produce a sharp and selective image of compromised tissues.

Friuli Venezia Giulia has at Torviscosa one of Europe's most important factory where contrast agents are produced. Their production starts from imported raw materials up to the finished product, or to advanced intermediates to be used in other factories.

The first objective of the DIAMANTE project, carried out in collaboration between Serichim Srl and Caffaro Industrie Spa. is to design processes and plants for the production of these raw materials at Torviscosa, using innovative technologies that guarantee the quality, essential for components of a substance used in humans being, and the environmental compatibility.

Two of the raw materials of interest are used in quantities of hundreds of tonnes per year and do not have GMPs production requirements; one third is required at the level of few tons per year, and must be produced according to precisely defined production and control standards. There will be therefore two different production structures.

The GMP plant will be suitable, as far as size and quality control are concerned, also for the production of some molecules that are used in a new artrosis therapy. These for the production of some products that, studied and patented by a research company operating in Science Park Area in Trieste, are now being launched as medical-surgical

aids for the treatment of arthrosis. The projected new plant, suitable for the production of high-value substances in small quantities, will be able to keep this production in Friuli, locally exploiting the results of research carried out successfully in Trieste.

The result of the DIAMANTE project will be the design of two plants capable of producing with innovative technologies the fundamental components of contrast media and auxiliaries for innovative therapies

Selected molecules are all of the specific interest of major FVG-based companies, which are strongly interested in local production, close to their plants and their research and development centers.

For each of the products being developed, INDUSTRIAL RESEARCH will be carried out with the aim of revising the current chemical manufacturing process by introducing innovative control technologies and methods in the critical steps for final product quality and process eco-sustainability. More in-depth knowledge of the chemical and physical properties of processes' products and intermediates, as well as reaction kinetics obtained using the best available techniques, and the systematic use of process simulation methods, will grant the quality requirements that biomedical production needs.

Some steps of the processes under development will require the use of innovative technologies (some of which are among the AMSs) such as:

- continuous reactions in condensed phase (liquid, and liquid-solid) and gas phase (gas and gas-solid), possibly with the use of microreactors;
- continuous liquid-liquid extraction;
- continuous crystallization
- continuous reactive distillation.

For each of the target molecules on which the plant design will be based, EXPERIMENTAL DEVELOPMENT will be carried out to review known processes (also based on the patents and experience that end users will make available to beneficiaries) to adapt synthetic patterns and implementation of reactions to the use of innovative technologies that will characterize the new plants. The acquired data will be used to build simulation models that will optimize process conditions in order to maximize the yield and quality of the desired products.

Simulation models will also produce sizing data for the calculation of raw material costs and investment valuation.

University of Trieste - Department of Engineering and Architecture (DIA) is involved in the modeling process . The role of the DIA is aimed at modeling the chemical-physical data needed for the processes design and development of innovative equipment. A research grant is foreseen for a young engineer who will, under the supervision of the departmental staff and Serichim experts, work on the following activities:

- a) Modeling of synthesis unit operations of target products and processing of experimental data to derive the chemical-physical parameters to be included in simulation models.
- b) Selection of crystallization process models useful for the description and optimization of bio-organic molecules,
- c) Identification of the measurement methods of the thermodynamic, kinetic and crystallographic parameters used by simulation models.
- d) Assistance to Serichim for their implementation and the data measurement.

Revision of traditional processes will lead to some process steps with innovative technologies, some of which will require prototypes for the experimental study. Examples of these prototypes are:

- multiphase continuous reactor for solid / liquid condensed phase reactions;
- reactive distillation column;
- continuous crystallizer.

Each prototype will be used to check the performance of each of the selected process model and for the investment economic evaluation for the possible realization at Torviscosa site.

Serichim Srl will coordinate all project's activities

The expected result of the project coordination is to quickly identify any difficulty or problem that might arise during the project and timely intervene to overcome any issue.

In accordance with the call for information, the public will promptly be informed about the support received by POR FESR FVG and will be given extensive dissemination of the existence of the project and the of results achieved.

A widespread publicity of the benefits of the use the technologies under study will allow Serichim to strengthen its specialization in the new processes study and development of bioactive molecules, and Caffaro Industrie to strengthen its positioning of chemical industry employing stae-of-the-art technologies in the field of intermediates of high added value.

The possibility to generate the interest of other users in DIAMANTE developped technologies will increase for SERICHIM and CAFFARO and for potential capital investors the attactiviness of the investment.