Press Release

SPuMoNI, the European project about Big Data and process modelling for smart industry

A programme for European Coordinated Research on Long-term Information and Communication Technologies (ICT) and ICT-based scientific challenges, CHIST-ERA annually calls for research proposals on key emerging topics. In 2017, the brief was 'Big Data and process modelling for smart industry'.

The call was addressed by a consortium composed by two Industrial partners—PQE Group (Italy) and Istituto De Angeli-Fareva (Italy)—and three Academic Partners—National College of Ireland (Ireland), University of Thessaly (Greece) and Polytechnic University of Valencia (Spain).

The Consortium brings together state-of-the-art expertise and capacity for developing and promoting new approaches for *Smart Pharmaceutical MaNufacturIng (SPuMoNI)* in order to support the Pharmaceutical industry using leading computational and data quality techniques. It combines partners with a track record in pharmaceutical production systems, cloud computing, blockchain technologies, and data quality.

Presented at the CHIST-ERA Projects Seminar as part of the EU Presidency 2019 activities in Bucharest last April, *SPuMoNI* receives financial support from the European Union and is worth over 1.1 M Euro.

SPuMoNI Project

The Pharmaceutical industry is currently producing significant amounts of electronic data through manufacturing lines increasingly automated via pervasive sensors and devices. Manufacturing line data sources are heterogeneous with various embedded systems controlling the different processes involved in the production of medicaments.

Data Integrity and end-to-end traceability have become a key point to be compliant with the different international regulations and guidelines. As an example, in order to release a medicine batch number, it is necessary to ensure that all the data produced is compliant with the ALCOA principles (Attributable, Legible, Contemporaneous, Original and Accurate). Auditable computerised systems are therefore the key to pharma production lines, since the industry is becoming increasingly regulated for product quality and patient health purposes. As systems are continuously generating data in various formats, data must be dynamically analysed to ensure the quality and compliance of the overall process. The main idea of this project is to systematically assess all data produced by computerised production systems in representative pharma environments: (i) design data quality assessment models based on the Data Quality dimensions agreed by the European Institute for Innovation Through Health Data, including rules derived from regulatory documents; and, (ii) identify behaviour patterns of data probability distributions over time and among the manufacturing sources to identify outliers, i.e. data behavioural patterns which can violate ALCOA premises.

To this end, there will be a semi-autonomous data quality control decision support system aiding pharma manufacturing companies to reduce the effort of analysing compliance data. Finally, a system prototype demonstration in an operational environment (Technology Readiness Level 7) will be evaluated using industry-grade real pharmaceutical manufacturing data sets and streams coupled with best pharma industry practices.

Quotes from the Consortium

"We (PQE Group) are very glad to be the coordinator of this important international project with a great responsibility in terms of data governance. For this reason, we are defining the rules that this data has to follow in order to be compliant with different global regulations. SPuMoNI is a great challenge and we will do the best to achieve our goals."
Mariola Mier, LATAM Director & Partner at PQE Group

"The SPuMoNI consortium proposes to use the latest software systems, frameworks and standards such as Blockchain, combining them with intelligent data quality control models. These activities will lead to innovations, keeping competitive production qualitatively at the world level required in IDA, and therefore in Italy."
David Cerrai, Istituto De Angeli IS & Logistics Director

"I strongly believe SPuMoNI will further cement our position in technology-driven innovation for enterprises in Ireland and abroad"
Dr Adriana E. Chis, NCI computing lecturer

"I'm really proud that the Cloud Competency Centre's core strengths of cloud computing and data analytics can be used within SPuMoNI to advance data provenance and compliance in the pharma industry"
Dr Horacio González-Vélez, Head of the NCI's Cloud Competency Centre

"NCI punches above its weight in the area of research, and a project like this is a boon not just for the funding it brings, but for the forward-looking, real-world work that is done here in the College to realise it."
Gina Quin, president of The National College of Ireland (NCI)

"SPuMoNI provides another excellent opportunity to put our intelligent software technology into real-world practice and solve long lasting problems."
Prof Anthony Karageorgos, Associate Professor at the University of Thessaly (UTH), Head of the Applied Informatics Laboratory

"I really enjoy to be a part of a highly motivated team of software engineers at UTH, aiming to develop software for supporting important needs of pharma manufacturing enterprises. Collaborating with SPuMoNi partners will provide us the opportunity to gain a lot from their knowledge and expertise."
Prof Vassilis C. Gerogiannis, Member of the Management Board of the Entrepreneurship and Innovation Research Institute, University of Thessaly

"UTH always gives priority to projects developing cutting edge innovative technologies to industrial settings, and SPuMoNI is a project that significantly strengthens our long-term tradition in this respect."
Prof Ioanna Laliotou, Vice Rector of Research and Lifelong Learning, University of Thessaly

"The technology for big data variability assessment developed at SPuMoni will make auditors and manufacturers even more comprehensive in ensuring the quality of pharmaceutical products"
Juan M Garcia-Gomez, head of Biomedical Data Science Lab. UPV

CONSORTIUM BRIEF DESCRIPTION

PQE Group
Founded in 1998, PQE Group is a consulting company in the pharmaceutical field that has its Headquarters in Reggello (in the province of Florence, Italy) and since 2012 has opened 18 offices worldwide, developing a network of contacts at international level.
Certified ISO 9001 since March 2003, PQE has been characterized as a Complete Quality Solutions Provider for companies operating in the Life Science field, both nationally and internationally. It currently has more than 700 employees distributed in the 22 operational offices in 14 different countries: Italy, Germany, Spain, UK, Switzerland, Poland, Russia, Israel, USA, Mexico, Brazil, India, China and Japan.
As an international group PQE Group delivers projects in more than 25 languages and has supported small, medium and large size companies exceeding compliance standards from the FDA / EMA / WHO / TGA / SFDA / ANVISA / INVIMA / GILS and other local authorities.
PQE Group offers turn-key quality solutions and focuses on offering exceptional cost effectiveness, whilst maintaining the highest quality standards in the market.
Combining the high knowledge acquired in the fields of Processes, Information Technology, Engineering and Quality, PQE Group supports its clients both nationally and internationally in the following areas: Data Integrity Assurance, Computer System Validation, Digital Governance, Qualification of laboratory process equipment and utilities, GxP Compliance, Regulatory Affairs & Pharmacovigilance, Qualification & Engineering, Third Party auditing, Laboratory Excellence Support and Training.

Istituto De Angeli – Fareva
FAREVA is the world's leading subcontractor in the industrial field: it provides research, manufacturing and packaging solutions for cosmetic, make-up, pharmaceutical, industrial and household products. A family-owned enterprise, whose strength lies in its independence.
Istituto De Angeli (IDA) is the pharmaceutical manufacturing company of Fareva located in Reggello (Florence), which has innovation activities and industrial research on internal processes. IDA is a player that makes third-party production activities economically competitive and produces for markets around the world.

National College of Ireland
Located in the heart of International Financial Services Centre in Dublin, the Cloud Competency Centre at the National College of Ireland (NCI) has become a global hub of excellence for teaching and research in Cloud Computing and Data Analytics from its inception in 2012. Aimed to support organisations taking a lead in the global Cloud Computing and Data Analytics space, the Centre provides teaching, research, and entrepreneurship skills through a mutually beneficial collaboration of experts from industry and academia.

The NCI's Cloud Competency Centre is bringing forth tangible high-impact synergies across the world. It is actively collaborating with key educational and industrial partners to continuously enhance their instruction, research, and commercial portfolio beyond the traditional boundaries of academia, funded by the European Commission and local Irish organisations. Further details can be found directly at https://www.ncirl.ie/cloud

University of Thessaly
University of Thessaly with 37 Departments and 8 schools is a University with its own identity and with a prominent position in our national educational system. University of Thessaly provides undergraduate and postgraduate programs and extra-curricular modules in specific research and business fields, for over 43000 students. The main mission of the University of Thessaly is the promotion of scientific knowledge through research and the contribution to the cultural and economic development of the local community and wider society. It is known for its excellent research performance and outstanding scientific achievements, in accordance with the international standards. The excellent equipped Laboratories of the different Departments and Research Units have a number of well-trained researchers to support them. As part of its future goals, University of Thessaly intends to strengthen its cooperation's abroad, increase its human resources, upgrade and utilize existing human resources, attract young scientists and encourage research through the creation of modern research structures, increase infrastructure and utilize its assets and funds from the EU with the research programmes Horizon 2020, RFSR, FP6, FP7, INTERREG and LIFE. The members of the academic and research staff participate in European research networks and numerous innovative research projects in the EC. Today the University of Thessaly has 39.000 undergraduate students, about 3000 postgraduate students and about 1000 PhD students. It also has 610 members of teaching and research staff, 120 members of teaching staff with a temporary teaching contract, 450 members of administrative staff and 100 members of Special Technical Laboratory Staff»

Polytechnic University of Valencia
The Biomedical Data Science Lab (BDSLab) is an interdisciplinary research laboratory of the ITACA institute at Universitat Politècnica de València (UPV) committed to biomedical computer science since its creation in 2000. With more than 19 years of experience, the BDSLab focuses its research on solving real problems from biomedicine by means of advanced machine learning techniques to support health care professionals and the pharmaceutical industry.