



SpuMoNI

BEST INTERNATIONAL
COLLABORATION PROJECT



National
College of
Ireland

The Smart Pharmaceutical Manufacturing Project – **SPuMoNI**

harnesses the potential of state-of-the-art
technologies for the pharmaceutical industry.

SPuMoNI is funded by [CHIST-ERA](#)

a Horizon Europe consortium of research funding organisations in Europe and beyond, supporting use-inspired basic research in Information and Communication Technologies (ICT) or at the interface between ICT and other domains.

In Ireland, SPuMoNI is funded by the Irish Research Council from April 2019 to December 2022 under the Call Topic: Big data and process modelling for smart industry (BDSI), Call 2017.

SPuMoNI comprises two pharma industrial partners — PQE Group and FAREVA's Istituto De Angeli — and three academic institutions: the Universitat Politècnica de València, Spain; the University of Thessaly, Greece; and National College of Ireland.

Team

PQE Group is a Contract Quality Organisation and a Complete Quality Solution provider in the Life Science Industry, with a strong, international performance record in supporting small, medium and large size companies to meet and exceed international compliance standards, including FDA, EMA, WHO, TGA, SFDA, ANVISA, INVIMA, GILS.

Istituto De Angeli manufactures and processes drugs in pharmaceutical preparations for both humans and veterinary use, offering a full solution for production at any scale, small or large, through rigorously controlled processing to suitable packaging, providing clients with a finished product ready to be marketed.

Both [PQE Group](#) and Istituto De Angeli have pharma multinationals as customers with significant operations in Ireland.

Universitat Politècnica de València (UPV), founded in 1968, is Spain's [leading technological university](#), home to around 28,000 students, dedicated to teaching and to research that is relevant and has a positive impact on society, both nationally and internationally.

University of Thessaly (UTH)

founded in 1984, with over 41,000 students at under- and post-graduate level, is deeply invested in high-quality scientific research as essential for the transmission and discovery of knowledge.

National College of Ireland (NCI)

is an Irish not-for-profit, state-aided higher education institution founded in 1951. NCI has some 6,500 students in full and part-time undergraduate and postgraduate programmes including doctoral degrees, with over 2,000 registered in computing degrees. In 2016, NCI became the first institution outside of the Institute of Technology sector to offer higher education apprenticeships.

NCI participated in SPuMoNI via [The Cloud Competency Centre \(CCC\)](#). From its inception within the School of Computing in 2012, CCC has brought forth tangible high-impact synergies across the world. With an emerging researcher base, CCC remains committed to bridging high-performance computing, distributed ledger technologies, data analytics, and parallel processing with ongoing business and economic developments to produce quality research outputs and collaborations with academic institutions, funding agencies, and companies. CCC also offers three 90-credit MSc programmes in Cloud Computing, in Data Analytics, and in FinTech. In line with NCI's overarching mission of widening access to education and the official agenda to build knowledge economy skills, CCC places a strong emphasis on leading aspects of teaching, applied research, and commercialisation in these three programmes including company-based and blended-learning activities.



National College of Ireland
Cloud Competency Centre



Students in NCI's Cloud Competency Centre



The SPuMoNI team, including (first on left) **Horacio González Vélez**, Head of the Cloud Competency Centre at NCI (further research)

(fourth from right) **Adriana E. Chis** Lecturer & Programme Director at National College of Ireland (further research)

(second from right) **Fatima Leal**, Assistant Professor at Universidade Portucalense (UPT) and former Postdoctoral Research Associate at National College of Ireland.

What does SPuMoNI do?

The Falsified Medicines Directive "[introduces harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled.](#)" Such obligatory safety features, legal framework, and record-keeping requirements have arguably imposed stricter controls for manufacturing of medicaments, and this is the challenge SPuMoNI responded to.

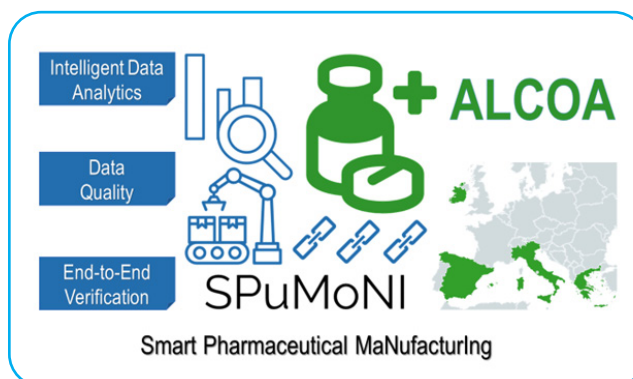
Although the pharmaceutical industry has consistently improved manufacturing processes in compliance with good manufacturing practices, documented deviations from good practices, including the continued falsification of medicines, continue. Disclosure risk assessment techniques in pharma manufacturing typically depend on background knowledge, the behaviour of intruders, and the specific value of the data. Often, only heuristic arguments are used, without numerical assessment.

SPuMoNI utilises state-of-the-art technologies to support a smarter industry. These technologies include blockchain, for end-to-end verification of manufacturing data; quality assurance methods, for data integrity compliance; modern artificial intelligence (AI) and data analytics, to smartly extract, transform, and control heterogeneous data sources within the manufacturing processes to better improve big-data quality; and process modelling, for a smarter industry.

Ensuring data integrity is in compliance with the current Good Manufacturing Practice (CGMP) regulations by the US FDA and European Medicines Agency (EMA) means ensuring quality

assessment of batch reports, audit trails, and system registries in terms of the ALCOA+ principles:

- attributable,
- legible,
- contemporaneous,
- original,
- accurate,
- complete,
- consistent,
- accessible, and
- enduring



SPuMoNI has produced an innovative scientific approach to systematically establish and ensure constant proof of the authenticity of pharmaceutical manufacturing data and to develop a user-friendly software tool for pharmaceutical officers, following the [ISPE GAMP](#) (Good Automated Manufacturing Process) validation standards, during both the IT development and the use of a qualified IT infrastructure. Thus this is of immediate impact to the entire pharma manufacturing industry.

Contribution to research

- SPuMoNI has achieved the following significant results in the past three years:
- Collected anonymized datasets with discrete and specific attributes related to environmental conditions of different pharma systems, which are useful for the development of software that already structures data in this fashion
- Issued data integrity guidelines to set the rules on how AI should process data and identify patterns that may lead to compliance issues
- Developed the base AI architecture and further developed additional AI applications for other manufacturing processes related to the pharmaceutical industry, to assess data integrity compliance before validation/deployment
- Enhanced multi-node private blockchain networks to ensure data provenance and compliance in a tamper-proof manner
- Released SPuMoNI guidelines as a template of integrated software/network infrastructure for pharma manufacturing
- Deployed a prototype in an industrially relevant environment

Research has been disseminated through publications in high quality, peer reviewed journals and conferences, including:

1. Simulation, modelling and classification of wiki contributors: Spotting the good, the bad, and the ugly. Silvia García-Méndez, Fátima Leal, Benedita Malheiro, Juan C. Burguillo-Rial, Bruno Veloso, Adriana E. Chis, Horacio González-Vélez: *Simul. Model. Pract. Theory* 120: 102616 (2022).
2. Stream-based explainable recommendations via blockchain profiling. Fátima Leal, Bruno Veloso, Benedita Malheiro, Juan C. Burguillo, Adriana E. Chis, Horacio González-Vélez: *Integr. Comput. Aided Eng.* 29(1): 105-121 (2022).
3. Towards a Computational Approach for the Assessment of Compliance of ALCOA+ Principles in Pharma Industry. M. Dura, A. Sanchez-Garcia, C. Saez, F. Leal, A. E. Chis, H. González-Vélez, and J. M. Garcia-Gomez. In: *Studies in Health Technology and Informatics*, vol. 294, pp. 755-759, 2022. PMID: 35612198.
4. Multi-service model for blockchain networks. F. Leal, A. E. Chis, and H. González-Vélez. In: *Information Processing & Management*, vol. 58, issue 3, pp. 102525, 2021. ISSN: 0306-4573. <https://doi.org/10.1016/j.ipm.2021.102525>
5. Smart Pharmaceutical Manufacturing: Ensuring End-to-End Traceability and Data Integrity in Medicine Production. F. Leal, A. E. Chis, S. Caton, H. González-Vélez, J. M. Garcia-Gomez, M. Dura, A. Sanchez-Garcia, C. Saez, A. Karageorgos, V. C. Gerogiannis, A. Xenakis, E. Lallas, T. Ntounas, E. Vasileiou, G. Mountzouris, B.a Otti, P. Pucci, R. Papini, D. Cerrai, and M. Mier. In: *Big Data Research*, vol. 24, pp. 100172, May. 2021. ISSN 2214-5796, <https://doi.org/10.1016/j.bdr.2020.100172>
6. Performance Evaluation of Private Ethereum Networks. F. Leal, A. E. Chis, and H. González-Vélez. In: *SN Computer Science*, vol. 1, issue 5, 285, 2020. ISSN: 2661-8907.

Contribution to education

Both UPV and UTH share with NCI a belief in the value (indeed, necessity!) of lifelong learning and, particularly relevant to SPuMoNI, are committed to providing students with 'real world' industry experience of the theories they are learning.

In addition to several Postgraduate Capstone Research Projects (MSc dissertations), SPuMoNI has informed teaching and learning in modules such as Blockchain Concepts in the MSc in Cloud Computing programme and Data Intensive Architectures and Scalable Systems Programming in the MSc in Data Analytics programme.

An indirect benefit of SPuMoNI is the development of strong working relationships across three higher education institutes, leading to cross-pollination of interests and ideas, opening up the possibility of future collaboration.



Click image to view video

A collaboration that delivers

Noting the similarity of the acronym of the classic Italian ice cream cake, the playful adoption of 'spumoni' as a project name turned out to be the perfect metaphor – spumoni is only delicious because all its layers combine in perfect partnership.

