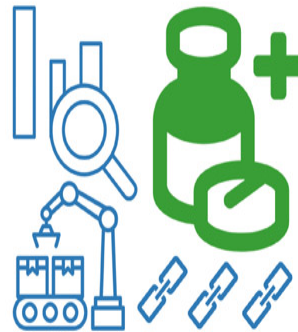


Intelligent Data Analytics

Data Quality

End-to-End Verification



SPuMoNI

Smart Pharmaceutical MaNuFacturing



chist-era



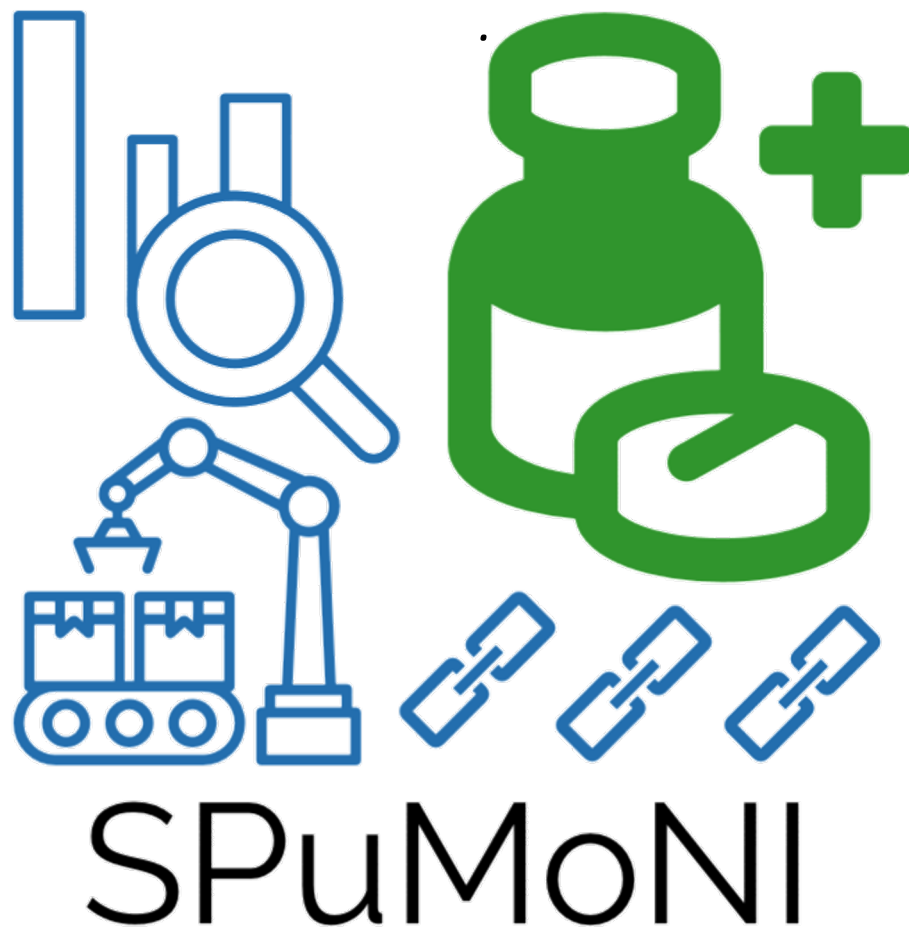
SPuMoNI: Smart Pharmaceutical MaNufacturing

The SPuMoNI project

Horacio González-Vélez

Cloud Competency Centre, NCI
Praha (VIRTUAL)

April 2021



This project is supported by the European Commission
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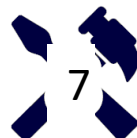
SPuMoNI Project



Months
project



Partners



Work
packages

1.1



Million
budget

- **Call CHIST-ERA 2017:** Big data and process modelling for smart industry (BDSI)
- **SPuMoNI** is 36 months research project funded by European Commission under the CHiST-ERA programme for European Coordinated Research on Long-term Information and Communication Technologies (ICT) and ICT-based scientific challenges
- Focus on developing a **semi-autonomous data quality control decision support system** aiding pharma manufacturing companies in analysing compliance data to ensure the quality and compliance of the overall pharma manufacturing process.



Partners

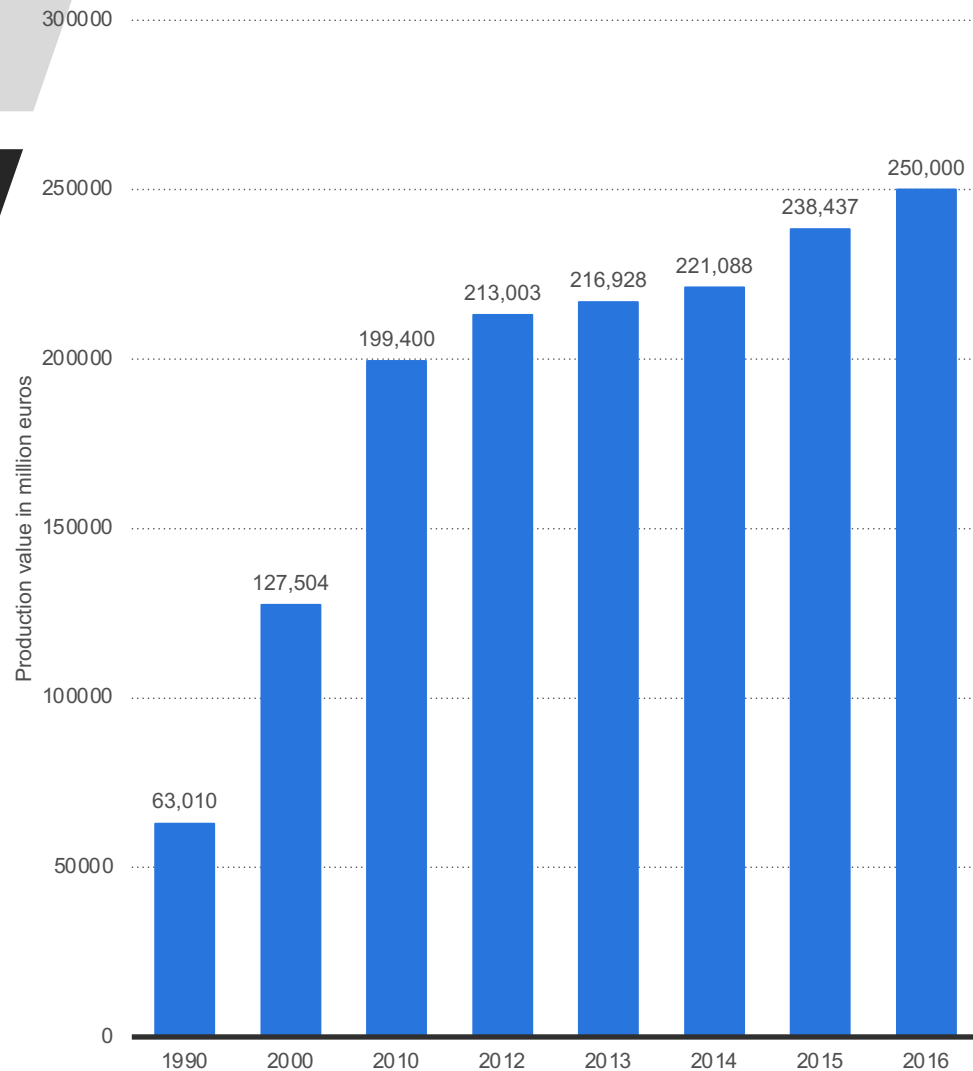


Institution/ Department	Country
PQE	IT
NCI	IE
UTH	GR
IDA Fareva	IT
UPV	ES

With support from IBEC's Technology Ireland Innovation Forum, The Greek Research & Technology Network, and The Panhellenic Union of the Pharmaceutical Industry

250B Industry in Europe

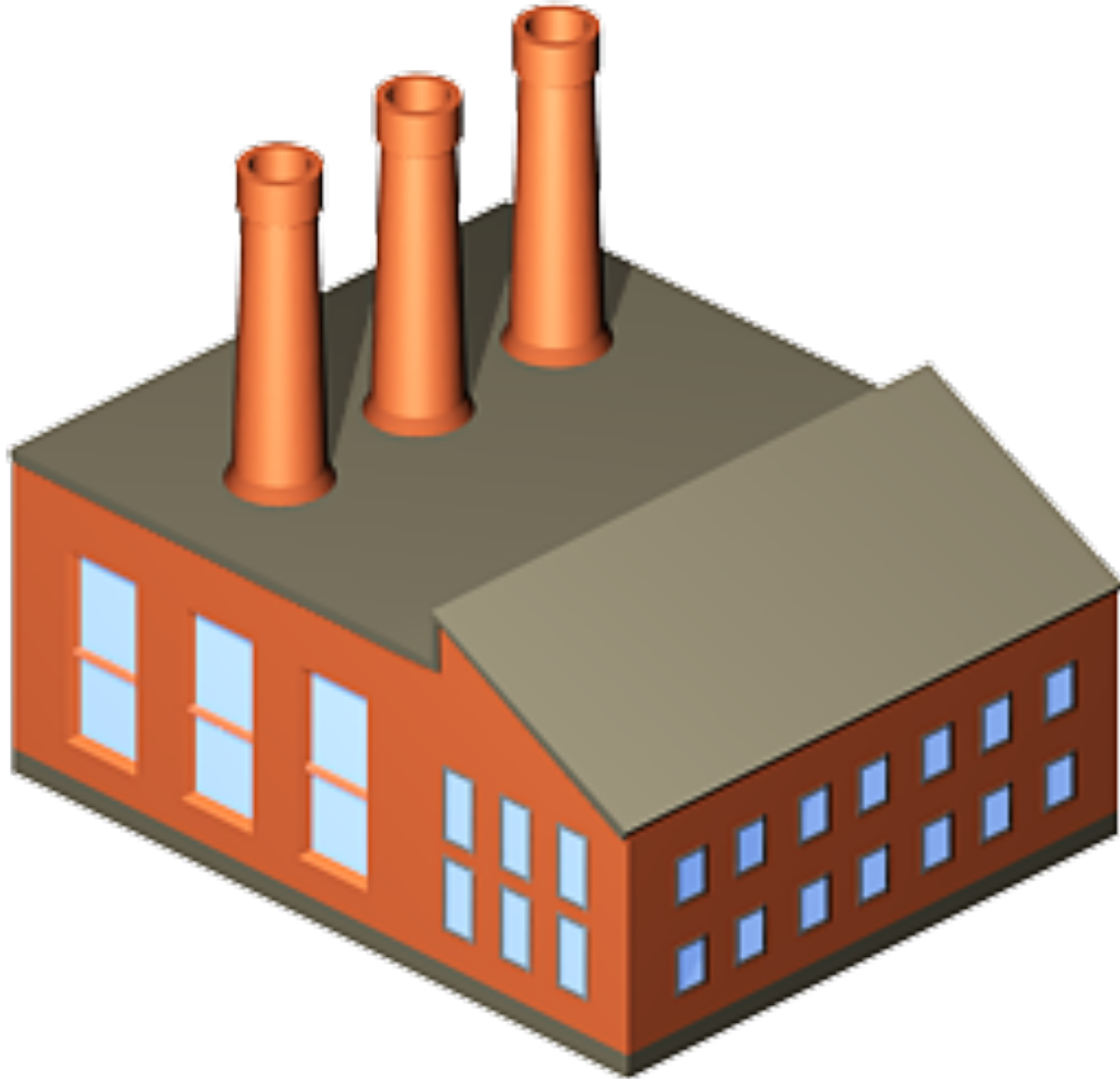
- European pharma manufacturing (production) has quadrupled its value in the past three decades to reach some **250 billion Euro in 2016**, where compliance and risk assessment are critical to maintain its reputation and, ultimately, save lives.



A Plant?

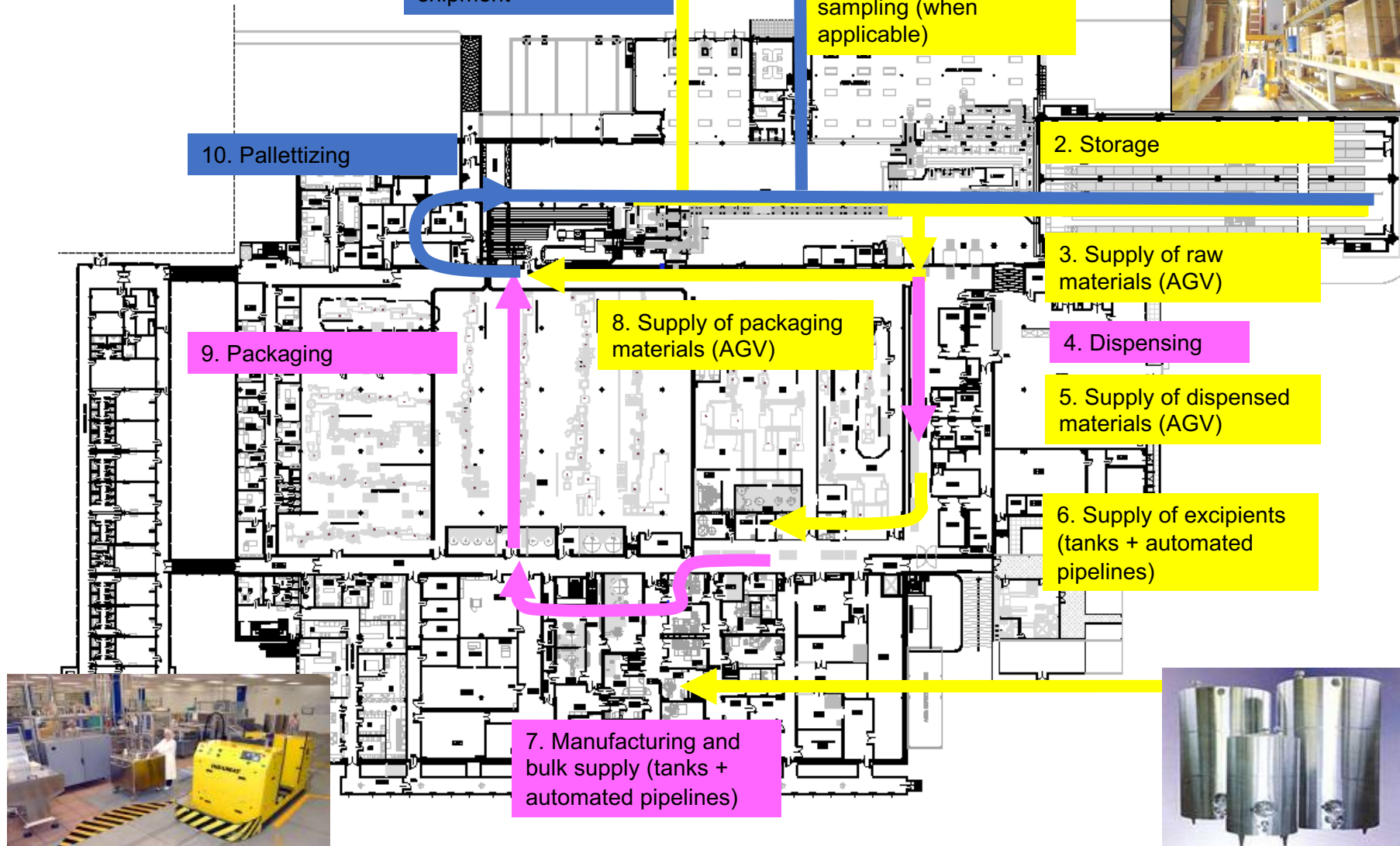


Ahhh– (concept) Plant



Real Plant

MHS IN
PRODUCTION
MHS OUT



- **Pharmaceutical industry** currently producing **significant amounts of 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 medicines.
- **Data Integrity** and **end-to-end traceability** have become a key point to be compliant with the different international regulations and guidelines.



- For example, to release a medicine batch number, it is necessary to ensure that all relevant data is **ALCOA (Attributable, Legible, Contemporaneous, Original and Accurate)** compliant
- **Auditable computerized systems** are therefore key on pharma production lines, since the industry is becoming increasingly regulated for product quality and patient health purposes
- Data must be **dynamically analysed** to ensure the quality and compliance of the overall process



Concept



Intelligent Data
Analytics

Data
Quality



End-to-End
Verification

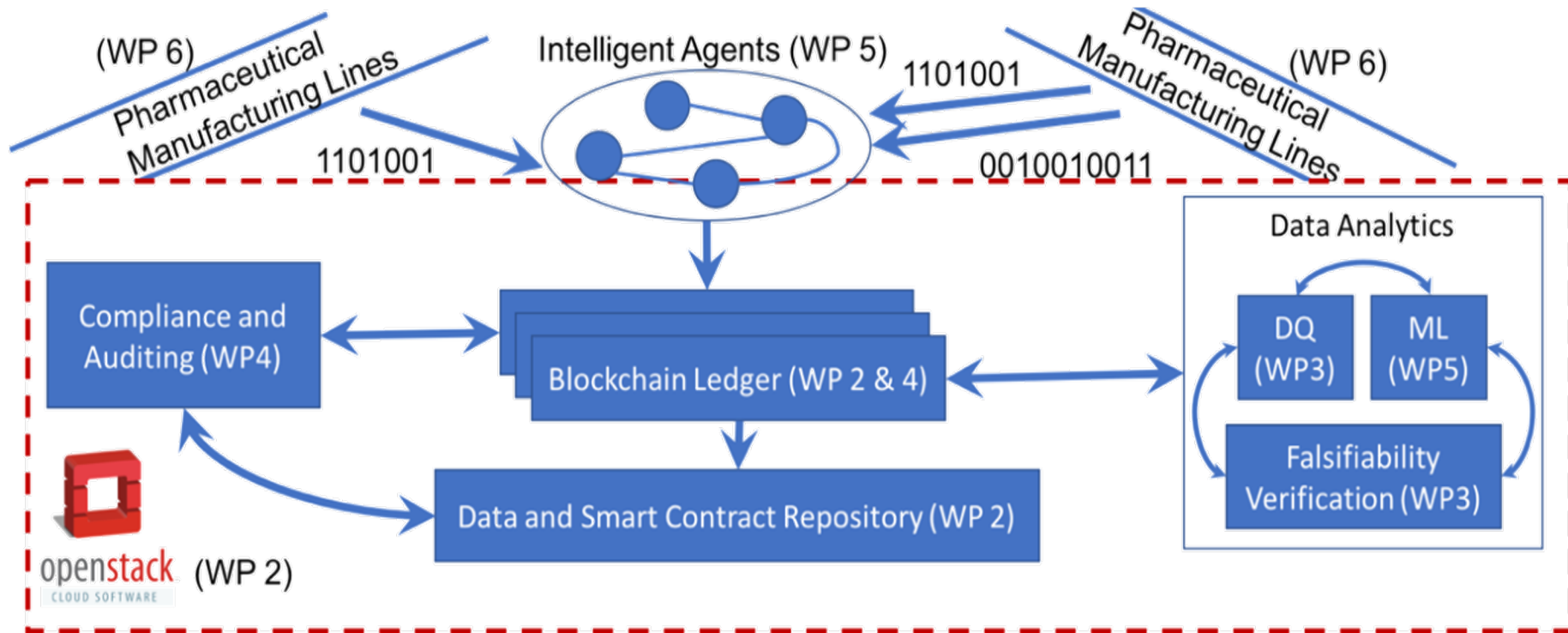
SPuMoNI

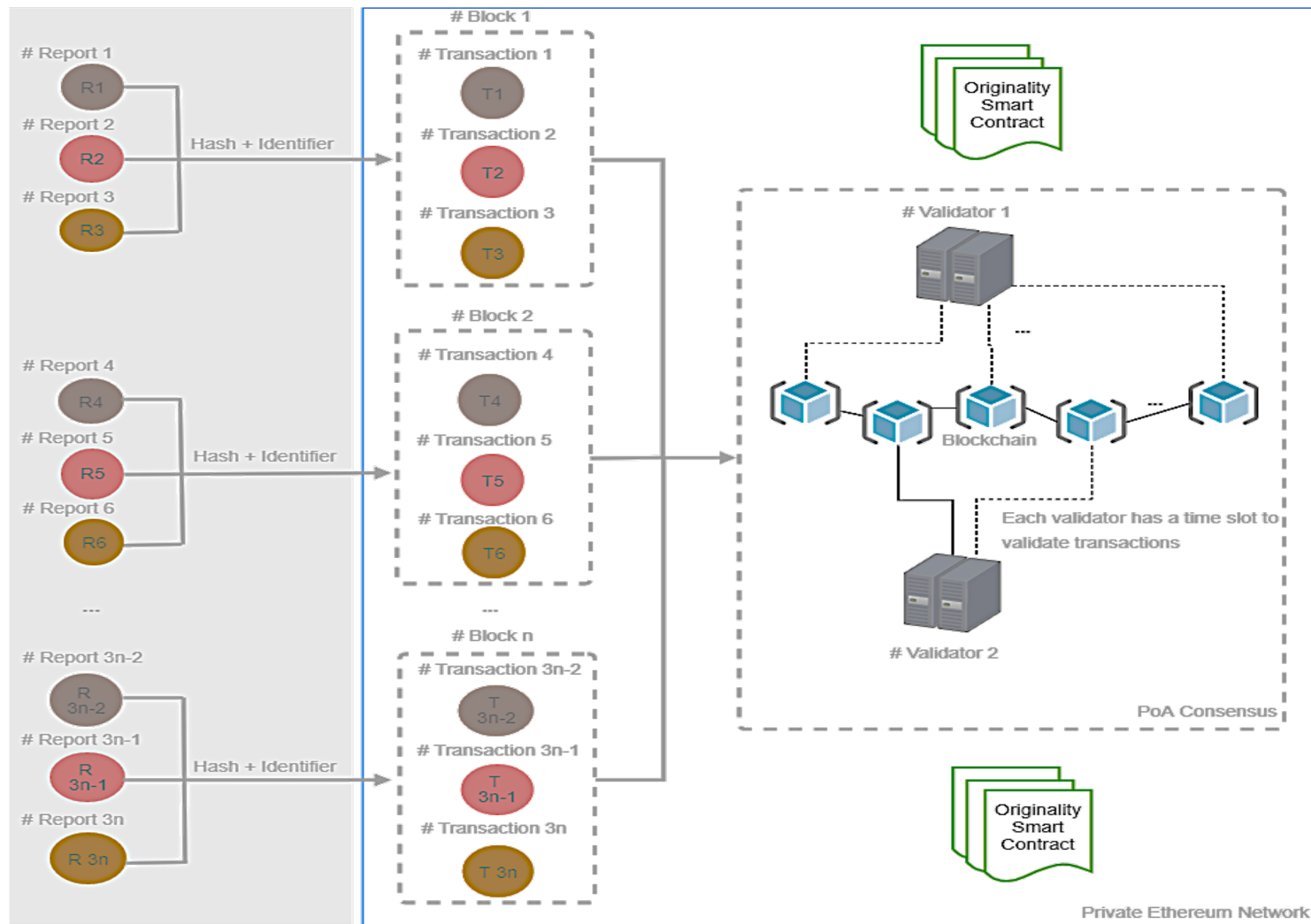
Smart Pharmaceutical MaNufacturing



Approach

- SpuMoni will:
 - systematically **assess all data** produced by computerized production systems in representative pharma environments
 - 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
 - **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
 - Use latest software systems, frameworks and standards such as Blockchain and combine them with **intelligent data quality control models**







ALCOA Report

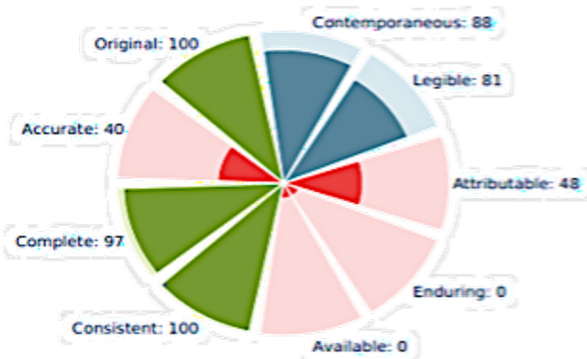


ALCOA Report Analysis

Batch Information				
Batch	Recipe	Recipe version	Order	Product
932130	155696	SU_080-01_P2	32101	155696
Report Timeline				



ALCOA+ Scores



ALCOA Report Analysis

Data Integrity Signature	
Hash	46ea4109a0ec7de92a1d1a49032bc2c839a362a688de152892013b80a8123a75
Data Responsible	Spumoni Prototype Data API
Identifier	932130 32101 155696 155696 SU_080-01_P2
Complete Identifier	932130 32101 155696 155696 SU_080-01_P2 1
Number Of Copy	-1
Upload date	1970-01-01 00:00:00
Transaction Blockchain Wallet	No blockchain connection



Main Publications (2nd year)



Big Data Research 24 (2021) 100172



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Contents lists available at [ScienceDirect](#)

Big Data Research

www.elsevier.com/locate/bdr



Smart Pharmaceutical Manufacturing: Ensuring End-to-End Traceability and Data Integrity in Medicine Production [☆]

Fátima Leal ^{a,c}, Adriana E. Chis ^a, Simon Caton ^{b,*}, Horacio González-Vélez ^a, Juan M. García-Gómez ^d, Marta Durá ^d, Angel Sánchez-García ^d, Carlos Sáez ^d, Anthony Karageorgos ^e, Vassilis C. Gerogiannis ^e, Apostolos Xenakis ^e, Efthymios Theodoros Ntounas ^e, Eleni Vasileiou ^e, Georgios Mountzouris ^e, Barbara Otti ^f, Penelope Pucci ^f, Rossano Papini ^f, David Cerrai ^f, Mariola Mier ^g



Information Processing and Management 58 (2021) 102525



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journal homepage: www.elsevier.com/locate/ipm



SN Computer Science (2020) 1:285
<https://doi.org/10.1007/s42979-020-00289-7>

ORIGINAL RESEARCH

Multi-service model for blockchain networks [☆]

Fátima Leal ^{a,b,*}, Adriana E. Chis ^a, Horacio González-Vélez ^a

^a Cloud Competency Centre, School of Computing, National College of Ireland, Dublin, Ireland

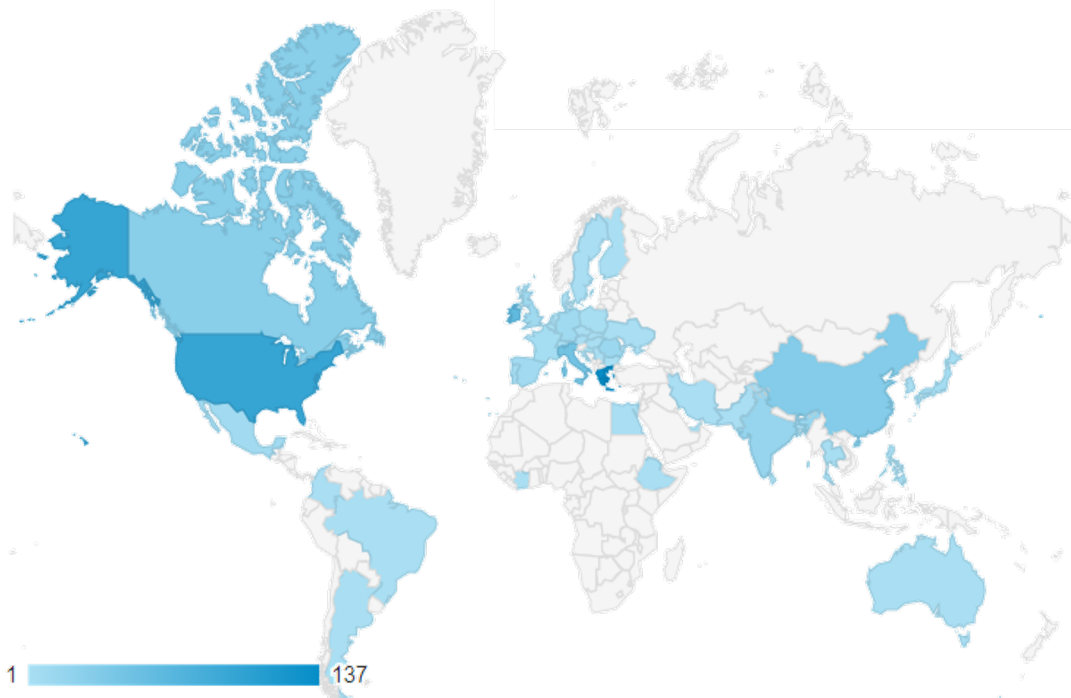
^b REMIT, Universidade Portucalense, Porto, Portugal



Performance Evaluation of Private Ethereum Networks

Fátima Leal ¹  · Adriana E. Chis ¹ · Horacio González-Vélez ¹

Received: 31 July 2020 / Accepted: 5 August 2020 / Published online: 27 August 2020
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MARIOLA MIER

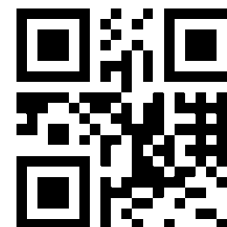
Project coordinator

PQE

m.mier@pqegroup.com

Visit the project's website for more information:

www.spumoni.eu



Or follow project latest news on social network profiles:



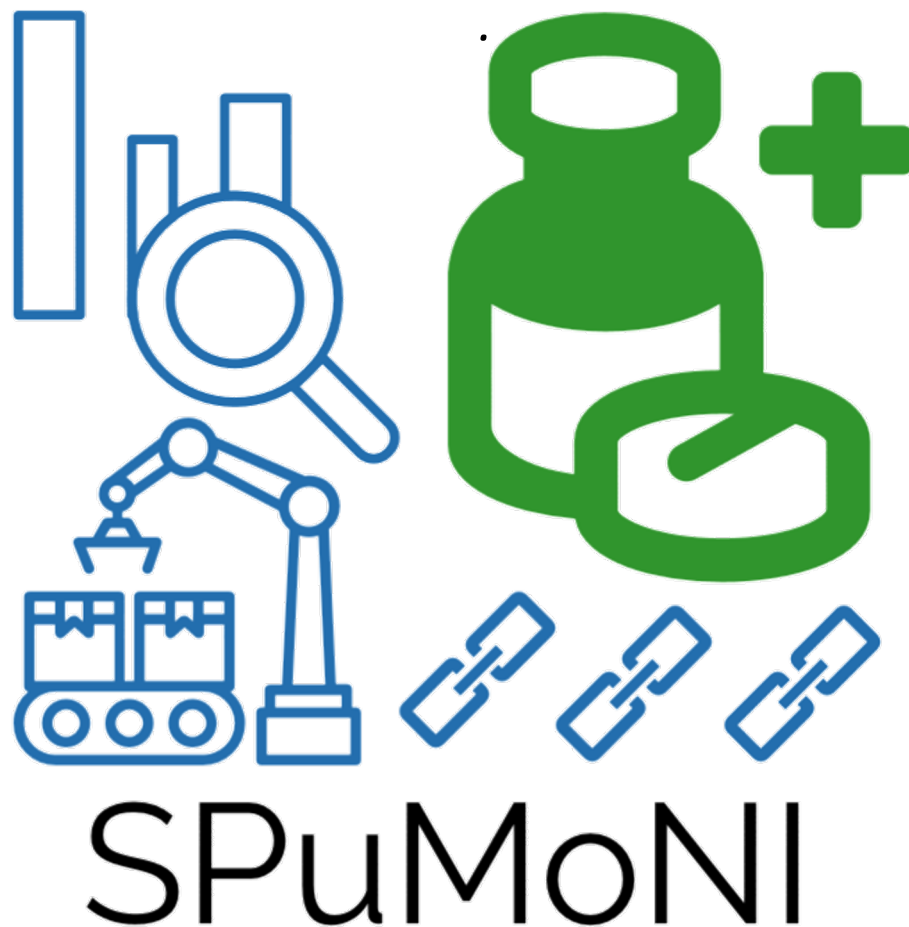
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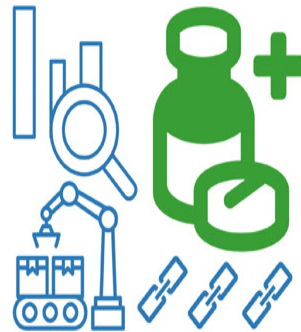
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