### Europass Curriculum Vitae

# Personal information

Name and Surname

Addresses

Mobile phone

E-mail

Nationality

Date of birth

041--

Other

WHAT I DO

Since 01 April 2022 today

Since 01 April 2022 today

Since 22 Nov 2019 today



#### SIMONETTA GALLERINI – IMPROVEMENT & SAVING

Fertilizers/Biostimulants Regulatory Affair Senior – Lead Auditor Conformity Assessment CE marking

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simonetta.gallerini@gmail.com

Italy

07 May 1969

F, Driving licence B

Social media: WhatsApp, Telegram, Instagram, Facebook Linkedin profile: www.linkedin.com/in/simonetta-gallerini-90511335

IMPROVEMENT & SAVING of Simonetta Gallerini: www.improvementsaving.com

# Stichting EMCI-EFCI Register, Ammerzoden Netherlands (NB 2832 Notified Body in NANDO EU database)

Indipendent freelance Lead Auditor for Conformity Assessments CE Marking product.

#### Water & Life Lab - Groupe CARSO, Bergamo (Italy)

Laboratory Consultant (freelance) for the accreditation ISO17025

#### European Committee, CEN/CENELEC Management Centre, Brussel

European Standardization at CEN/TC455 Plant Biostimulants (Secretariat held by AFNOR, I'm on behalf of Italy):

- Project Leader "Detection of Vibrio spp." WG3 "Pathogenic and non-pathogenic microorganisms" for the European Standardisation Request M/564.
- Project Leader "Determination of pH in microbial culture media" WG3 "Pathogenic and non-pathogenic microorganisms" for the European Standardisation Request M/564.
- Project Leader "Determination of Chlorides" WG5 "Labelling and denominations" for the European Standardisation Request M/564
- Expert CEN/TC 455 WG4 "Other Safety parameters" for the European Standardisation Request M/564

European Standardization at CEN/TC 260 WG7 "Inorganic Fertilizers and inhibitors" (Secretariat held by DIN Germany, I'm on behalf of Italy):

- Expert member for the European Standardisation Request M/564
- Expert WG "STRUBIAS" for the new European Standardisation Request for industrial waste recovery, recycling of ashes and biochar, to facilitate the Nutrient Circular Economy.

### COMATCH-MALT Consulting GmbH, Berlin

Freelancer consultant for TQM and Six Sigma projects for continuous improvement of company's processes using problem solving tools and statistical metrics. Digitalization processes, QUICK WIN projects, KAIZEN BLITZ projects and long-time projects.

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Since 7 May 2019 today

National and International Committees Since 10 Jan 2022 today

#### Proficiency tests UNI/UNICHIM, Milan

Italian Expert member for the proficiency tests for Italian and European laboratories.

Since 16 May 2019 today

# BRACCO Foundation, European Commission, Gi.U.Li.A. Observatory (www.100esperte.it). https://www.youtube.com/watch?v=ul8xoDPjeDg&feature=youtu.be

European database of 100 women experts evaluated by Scientific Committee "100 women against stereotypes" in STEM Area (Science, Technology, Engineering and Mathematics), women who have dedicated their lives to scientific research obtaining important results in their own careers.

Since Nov 2015 today

#### UNI/CT003 and UNI/CT406, UNI-UNICHIM, Federchimica Milan

Committee Member UNI/CT003 "AgriFood" with the right to vote, UNI Milan,

I represent Italy as expert member in ISO/TC 34 WG26 Plant based-food for standardization,

UNI/CT406 "Fertilizers", with the right to vote for standardization, UNICHIM:

- I'm the Convenor of GL01 for standardization
- I'm an Expert member of GL04

Since Sept 2016 today

#### Board Manager of AICQ Test Laboratories and Calibration Committee, Padua

Italian President in charge for 3 years (2016-2019) and now Board Manager for 3 years (2019-2022).

- Organizational collaboration for the AICQ-ACCREDIA conference held in Padua 13 Nov 2017, "THE NEW ISO 17025: 2017 STANDARD FOR TEST AND CALIBRATION LABORATORIES
- Expert AICQ Working Group (Padua, Oct 2016 Sept 2017) for the review of the international Standard ISO/IEC17025 for the accreditation of testing and calibration laboratories
- Speaker and Scientific Responsible of the Conference held in Bologna 03 May 2017 "PRINCIPLES
  OF GOOD LABORATORY PRACTICE AND CERTIFICATION OF TEST FACILITIES", in
  collaboration with the Italian Ministry of Health and the Italian National Institute of Health

Since Sept 2016 to Oct 2020

#### Italian President on AICQ AgriFood Sector, Milan

- Convenor of Italian Working Group for the European Union Project ENVIRECA-ERASMUS+ "ENVIRECA - GREENING APPRENTICESHIPS IN THE HORECA INDUSTRY" (up to April 2020)
   Scope: map and define Guidelines and current & future Green Skills for apprentices in HORECA sector for environmentally sustainable work practices.
  - Participants: Italy, Sweden, Greece, Bulgaria and Spain
- Creation, validation and teaching of the training course certified by AICQ-SICEV "Auditor/Lead Auditor Quality management system (40 hours) ISO9001 on AgriFood, D.Lgs. n.20 on 23 Feb 2018
- Expert Working Group "The innovations of new ISO 19011:2018", to create the new training course

Since June 2016 today

Senior Member of the Professional Order of Chemists of Piedmont and Valle d'Aosta

Since Jan 2000 to May 2016 Senior Member of the Professional Order of Chemists of Tuscany

Since Sept 2000 to Sept 2016

#### Law Court of Florence

Freelancer technical consultant for waste pollution

#### **Education and training**

26 Nov 2021 Certification of Auditor/Lead Auditor for third parties audits of Quality Management System

AICQ (Italian Association of Quality Culture), Florence

12 July 2019

#### Six Sigma Green Belt certificate n.1323.

Master Lean Six Sigma. International certification of Six Sigma skills. Galgano & Associati Consulting Srl, Milan

24 Oct 2006

**Certification of Internal Auditor of Quality Management System** CSQA Thiene (TV)

12 April 1999

**Chemistry Master Degree, Industrial Organic Chemistry** 

(5 years, 30 exams) University of Florence

Languages

Mother tongue: Italian and French Other languages: English, level B2 certified

### Professional experiences

Since 21 March 2016 to 31 March 2023

### CRO - SAGEA CENTRO DI SAGGIO SRL, Castagnito d'Alba (CN, ITALY) Quality Assurance Manager (GLP, GEP)

Expert of the GLP principles (OECD) as quality assurance in field trials and ecotoxicology trials; expert on Computer Validation System GLP protocols and Data Integrity. Quality control management GEP trials, chemical products, agro-pharmaceuticals products, labelling and MSDS, REACH and CLP Reg., ecology, safety.

Quick Win Six Sigma projects, continuous improvement of processes using problem solving tools and statistical metrics. FMEA Risk Assessment.

Implementation integrated Total Quality Management System GLP-ISO9001-ISO17025-ISO22301.

Training of personnel on Quality System. Teacher "Business organization and QMS" for Agropharma apprentices.

Since 19 May 2008 to 29 Febr 2016

#### BIOCHEMIE LAB Srl, Calenzano (FI)

#### Lead Quality Manager, Quality-Environmental-Safety Integrated System Laboratory Director

ISO9001 and ISO14001 certifications; **n. 157 projects accredited ISO17025** during my job activity: details at www.accredia.com/Biochemielab from rev.21 to rev.37.

Expert of international legislation of REACH and CLP, methods standardization and validation for environmental pollution analysis, ecotox studies, HACCP system, international and national legislation in Food, Food contact materials, Mycotoxins, Plant Protection Products, Organic and Inorganic Fertilizers, Soil, Soil improvers and Growing media, Waters, marine Sediments, Air emissions.

Authorization of Italian Ministry of Agriculture to analyse Fertilizers, Organic Foods, Olive Oils and Extra-virgin Olive Oils for Protected Geographical Indications (PGI) certification, member of International Olive Council. Validation and accreditation ISO17025 of chemical and microbiological methods, management procedures (SOP), training of personnel on Quality System. The long experience of laboratory activities involved the updating of analytical methodologies with the most modern instrumental methodologies.

On April 2014, development, validation and accreditation ISO17025 of a new standard "Evaluation of acute toxicity with Vibrio fischeri in solid phase" (ISO 11348-3:2009 + ICRAM) for the first time in Italy.

Creation, implementation and validation of Computerised QA/QC System and EDD files based on EPA Standard Quality System for interfacing laboratory instruments with LIMS (Laboratory Information Management System) with automatic import of analytical data and quality controls for complete data traceability and quality assurance of analytical data. QAPP Plans. Creation and implementation of electronic Control Charts for continuous monitoring. Creation and implementation of a statistics system applied to evaluate the effectiveness and efficiency of the QMS. Expert of the procedures and processes related to the Accreditation of Laboratories according to the ISO/IEC 17025 and certification ISO 9001 and ISO 14001. High experience in process management implementation.

Since 07 Jan 2003 to 15 May 2008

#### ALPHA ECOLOGIA Srl, Florence

#### **Chemistry Lab Manager**

During my job activity, we obtained the ISO17025 Accreditation on 2003 starting with 3 validated methods internal developed.

Then, I developed n. **68 projects** ISO17025 accredited: details at www.accredia.com/AlphaEcologia up to rev.8.

Method development and validation, continuous implementation of the Control Quality Lab as Chemistry Lab Manager. Expert of standards methods and methods validation in the Food sector, in particular Plant Protection Products and Mycotoxins, large supermarket chains food analysis.

Since 02 Jan 2002 to 31 Dec 2002

#### C.T.A. Srl, Florence

Law Court of Florence Consultant Office for environmental pollution, soils, waters, air emissions and land to be reclaimed.

2001

### C.I.R.M.M.P. CONSORZIO INTERUNIVERSITARIO RISONANZE MAGNETICHE DI METALLO PROTEINE, University of Florence

Annual fellowship to develop organic macrocycles compounds in the study of metal-proteins.

CIRMMP manages and partially owns the instruments in CERM, one of the most well-equipped NMR laboratories in the world.

2000

#### A.R.P.A.T., ITALIAN AUTHORITY

Chemistry lab technician for waste and soil analysis

Since July 1999 to Dec 1999

#### UNIVERSITY OF FLORENCE

Stage of 6 months with the aim creation and implementation of clinical research database

#### **SKILLS**

#### Social skill and competences

#### Organisational skill and competences

#### Technical skill and competences

Excellent skill to work in group applied in many situations where it was essential to collaborate between figures covering different positions and from different Countries.

Excellent skill to work in stressful situations, especially related to the relationship with the public during the participation in conferences as a speaker; the deadlines of work activities always respected; work for goals.

Lean Six Sigma Green Belt certificate n.1323.

Lean Six Sigma Projects: QUICK WIN and KAIZEN BLITZ projects. Implementation of Total Quality Management in many companies and management for processes with KPI indicators monitoring of the QMS and Customer Satisfaction.

FMEA Risk Assessment.

Planning of corrective actions and continuous improvement, KAIZEN; Business Model Canvas implementation.

Participation in national (AICQ/UNI/UNICHIM) and international (CEN/TC) Working Groups for the Standards revision or Standards development for chemicals.

High knowledge of GLP Principles and OECD Guidelines, Computer Systems Validation, creation and implementation of QA/QC/EDD files computerised system for LIMS (Laboratory Information Management System) of chemical/pharma companies.

Writing and management of Standard Operating Procedures (SOP), methods validation, management procedures, training of personnel on QMS.

#### Computer skill and lab instrument competences

uHPLC, HPLC DAD and fluorescence Microsoft Office, Microsoft Visio

IC, Ionic Chromatography

Lims, Minitab

UV-VIS Spectrophotometry, ELISA kit GC-MS Ion Trap and single quadrupole 1H-NMR, 31P-NMR, 13C-NMR, 19F-NMR

GC-MS QQQ Triple Quadrupole, ICP-OES, ICP-MS

Agilent QA/QC computerized system (EPA Standard

GC (ECD, FID, NPD), GC-HS Quality System, EDD files) AAS with furnace and flame FT-IR. Potentiometric titrations

#### **Publications**

- For European 100esperte STEM Area, July 2020: https://www.youtube.com/watch?v=ul8xoDPjeDg&feature=youtu.be
- "Quality Assurance 4.0: new challenges and new strategies", Magazine QualitàOnLine and AICQ QUALITA' Magazine, Jan-Feb 2020
- "GLP, Kaizen and Monozukuri Working Group", AICQ QualityOnLine Magazine 04 nov 2016 and AICQ QUALITA' Magazine, Jan-Feb 2017
- "Homogeneous hydrogenation of ketones in the presence of H2Ru(CO)2(PPh3)2", Dalton Transaction, Issue 39, 2007
- "Total Quality Management in the generational transition of Tuscany Companies (Ferragamo model)", Tuscany Region, 2001
- "Homogeneous hydrogenation of ketones in the presence of H2Ru(CO)2(PPh3)2", Applied Organometallic Chemistry, 14, 570-580 (2000)
- Abstract Homogeneous hydrogenation, Book of Abstract on XIII FECHEM International Conference on Organometallic Chemistry, Lisbon 1999

#### **Awards**

2019, DEMETRA DATABASE (Six Sigma Project), creation and implementation of a new GLP Validated Computerised System for specimens management phase in GLP Studies.

2017, AICQ Committees and Sectors Prize 2017-2018 Edition, for having actively participated in the Culture of Quality in Italy, both for national events and also in Milan successfully organized by the audience and content

2016, SAGEA INNOVATION AWARD, award for the implementation of Total Quality Management in SAGEA aimed at the pursuit of continuous improvement, KAIZEN

#### **Hobbies**

ACI-SPORT Marshall in car competitions (rally and historic car), trekking, sailing

Participation of Congress or Training course (last years):

New AG International BSWC – Biostimulants World Congress	Milan, Italy	28-30/11, 01/12/2023
New AG International Congress of Fertilizers and Biostimulants	Barcelona, Spain	18-19/04/2023
Speaker Webinar HAPPY BIRTHDAY FERTLIZER, Reg.UE 2019/1009  Happy birthday fertilizers (unichim.it)	Assofertilizzanti/Federchimica- UNICHIM	15 July 2022

Training course for GLP Test Facility operators and Inspectors	Istituto Superiore Sanità- Ministero Salute	December 2021
Auditor/Lead Auditor of third parties audits for Quality Management System, certification	AICQ, Florence	November 2021
English Skills for Public Speaking and Effective Presentations (C1 level)	Language Solution	April 2021
Training course: "Process approach ISO/IEC 17025:2018 for laboratory testing"	University of Study of Padua, AICQ Triveneta with ACCREDIA	February 2021
Scientific Responsible of the 1 <sup>st</sup> Italian Meeting 2020:  "Plant Health Biostimulants, from normative to experimental trials"  Plant Health Biostimulants: dalla normativa alle prove sperimentali - YouTube	SAGEA, FEDERCHIMICA	16 October 2020
English Skills for Public Speaking and Effective Presentations (C1 level)	Language Solution	April 2020
The economic evaluation of business projects	Galgano & Associati	April 2020
New edition of ISO 19011:2018 for the QMS audits	Certiquality	November 2019
Standing meeting: short and effective meetings	Galgano & Associati, Milan	October 2019
Time: instructions for use, Individual development plan, manage conflicts	Quadrifor	July 2018
2° NATIONAL CONVENTION FOR THE IMPLEMENTATION OF THE PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP) Update for Inspectors and Professional Figures belonging to the GLP Test CRO Facilities	ITALIAN MINISTRY OF HEALTH ITALIAN NATIONAL INSTITUTE OF HEALTH	May 2018
Effective communication	SAGEA (Internal training)	Jan-Feb 2018
FSSC22000 v.4.1: REQUIREMENTS AND HOW TO SATISFY THEM"	AICQ, Milan	December 2017
Organizational collaboration at the conference "THE NEW ISO 17025: 2017 STANDARD FOR TEST AND CALIBRATION LABORATORIES"	AICQ-ACCREDIA, Padua	November 2017
Speaker and Scientific Manager for the National Conference "THE PRINCIPLES OF GOOD LABORATORY PRACTICE AND THE CERTIFICATION OF TEST CROS". My presentation: "Quality System integration: GLP, continuous improvement KAIZEN and MONOZUKURI WORKING GROUPS"	AICQ-SAGEA-ITALIAN NATIONAL INSTITUTE OF HEALTH, Bologna	May 2017
III Italian Conference "Activities of the public administration on the control of plant protection products and pesticide residues in food"	ITALIAN MINISTRY OF HEALTH ITALIAN NATIONAL INSTITUTE OF HEALTH	November 2017
Advanced Good Laboratory Practise, GLP	RQA, Cambridge	October 2017
ISO 9001:2015: elements of continuity, novelty and approach to risk	Certiquality, Turin	June 2017
The new standard ISO 9001:2015 and Risk Management	Galgano & Associati, Milan	May 2017
English Conversation	SAGEA Internal course	Jan-March2017
Organizational analysis tools and continuous improvement	IAL-Quadrifor, Milan	December 2016
Enhancement of professional skills: Sales techniques and customer management	ACA Formazione – For.te, Alba (CN)	Oct-Dec 2016
Effectiveness and personal development	Quadrifor	April 2016
Presentation as speaker Italian Conference "Validation of an internal method for a private laboratory: MP015 Determination of histamine in fresh and preserved fish"	ARPA Marche, Pesaro ACCREDIA, ALA Laboratories	November 2013
Presentation as speaker Q-Day, "Quality today in the water analysis laboratory, Accreditation of cuvette test methods for water analysis. The experience for measuring the COD"	HACH LANGE	May 2013
Presentation as speaker "Hydrocarbons in environmental matrices", IDRO 2012. Title: "ISO 16703:2004 and EPA 8015D 2003 two methods compared to determine the parameter C12-C40"	UNI-UNICHIM, Milan	February 2013

END CV