

CURRICULUM VITAE DR. CLAUDIA CUSAN

Dr. Claudia Cusan

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PROFILE

- European Registered Toxicologist
- PhD in Pharmaceutical Science
- Master Degree in Pharmaceutical Science and Technology
- Registered Italian Pharmacist
- Registered at AIBO (Associazione Italiana Business Operators in Food Contact)
- Registered at SITOX (the Italian Association of Toxicology)
- Member of External Committee for reviewing the courses of the master's degree in Pharmaceutical Chemistry at University of Trieste
- Founder of S&C BEST Srl

CURRENT ACTIVITIES

2017 – Current: Founder and Vice-President and of S&C BEST Srl (Portogruaro, Italy)

(BEST = Biotecnologie, Enzimi, Servizi Tossicologici)

Consultancy company active specialized in toxicology and biotechnology, active with training courses, innovation and technology transfer



S&C BEST Srl is one of the few companies member of Eurotox Corporate Program

Key toxicological services

- Performing Hazard and Risk Assessment for substances in different applications, as: biomedical devices, food contact materials, performant materials, pharma, cosmetics, industrial chemicals, occupational hygiene.
- Calculating Safe Threshold values within different competences areas as: Specific Migration Limits for Food Contact Materials, Occupational Exposure Limits, Wipe Test Limits, Derived No-Effect Level, Virtual Safe Dose, Permitted Daily Exposure, Acceptable Daily Intake, Tolerable Intake, Toxicological Screening Limits, Estimated Exposure Dose.
- Preparation of Biological Evaluation Plan and Biological Evaluation Report and Technical files for biomedical devices for EU and US submissions, Evaluation of Leachables and Extractables from medical devices and from packaging for different applications (medical devices, pharma, cosmetics, food contact materials), preparation of EU-REACH dossiers, Product Information File for cosmetic registrations, EFSA food contact petitions. Some of those activities performed in collaboration with Regulatory Affairs
- Toxicological studies monitoring responsible in contact with Testing facilities.
- Spokesperson in toxicological meeting within REACH registrant consortia
- Providing training and coaching on toxicology and risk assessment.
- Supporting customers efforts and ambitions in the area of Sustainability and Occupational Safety.
- Providing advises on new products or applications, based on hazard, risk and products sustainability.
- Providing strategic and tailor made advise to the Business on relevant topics, as: Endocrine Disruptors, Nanoparticles, Substances of concern.

CAREER HISTORY

2013 – 2017: Corporate Expert in Product Stewardship and Toxicology at DSM Corporate Operations & Responsible Care (Heerlen, NL)

Corporate Responsible for Global DSM policies in Product Stewardship - Key achievements and responsibilities:

- Creating compelling vision and direction for Product Stewardship and related Sustainability topics, by:

- Developing, delivering, communicating and rolling out DSM policies, coherently with external regulations, DSM's ambitions, customer expectations, and compatibly with the various Business Groups and business environments, in line with DSM Sustainability programs.
- Anticipating changes in the external regulations, that could lead to risk management or opportunities seeking; coordinating DSM competences and initiating the efforts in shaping and mitigating the (re)action.
- Leading or supporting the development of DSM opinion and position in (potential) issues related new regulations or change in society expectations.
- External orientation in the areas of Product Stewardship and relevant Sustainability topics, by:
 - Lobbying for DSM's on external policy development when relevant, consistent with DSM's values, based on knowledge and relevant external developments, by representing DSM on a variety of external networks (ICCA, Cefic, ECETOC, EPAA, meetings with technical experts from European Commission), in interaction with other companies, regulators and government scientists.
 - As DSM spokesperson in internal and external networks, to ensure adequate exchange of knowledge both within DSM and with external bodies regarding Product Stewardship and Product Safety, and engagement with stakeholder groups.
- Supporting the Business Groups, by:
 - Connecting positively with the Business Groups to coordinate on strategic direction in the area of Sustainability and Product Stewardship.
 - Collaborating with Regulatory Affairs Team, Product Safety Team and Marketing & Sales in the: i) toxicological evaluation and risk assessment of DSM raw materials and products and communication within the supply chain; ii) strategic decision regarding the use / production / phase out of substances; iii) classification of substances. Those activities performed to support different business areas as medical devices, food contact materials, food, chemicals.
 - Ensuring safe use of substances, in collaboration with industrial hygienists.
 - Trainer in internal toxicology and risk assessment courses.
 - Identifying and assessing risks and opportunities in the supply chain, by scientifically and ethically evaluating DSM's / Business groups choices in chemicals management, while balancing sense of urgency, drive for performance, continuous improvement, innovation and business growth.

2010 - 2013: Project Manager at DSM Innovative Synthesis (Geleen, NL)

Project management at different levels in diverse and broad project portfolio, with pharma and biomedical applications - Key achievements and responsibilities:

- Financial and project targets responsible. Successful managing of project budget, organization, milestones and results; risk management including mitigation; reporting orally and in writing; preparation of project proposals, including budgeting activities in different teams and business units.
- Effective coordination, steering and organization of multidisciplinary and international teams (up to 14 people, within 4 different locations worldwide).
- Securing robust IP position within the development of new chemo-enzymatic industrial synthesis of antibiotics, for large scale production, including research visits for technology transfer to production.
- Successful technological, economical and safety evaluation of DSM chemical synthetic strategy and comparison with competitors' routes.
- Coordinator of analysts, chemists and production manager's activities in the discussion of quality issues in production batches; active role in the identification of impurities.

2005-2010: Research Scientist at DSM Pharmaceutical Products (Geleen, NL)

Key achievements and responsibilities:

- Assessment of DSM technologies (i.e. fermentation, chemical synthesis, enzymatic synthesis) in the production of peptides with nutraceutical or pharmaceutical applications.
- Identification of nutraceutical peptides with relevant business application, synthesis and development of a new scalable production route.
- Securing IP position (main inventor) within the development of a new chemo-enzymatic strategy towards the synthesis of peptides. This led to the foundation of the DSM spin off company "Enzyep".
- Successful synthesis, development and delivery of innovative monomers to be applied in polymer preparation for drug release and coatings for medical devices.
- Responsible of business cases studies to identify a suitable target compound to proof DSM platform technology.
- Performing lab work as i.e. synthesis of new API or development of a new chemical route for Generics; synthesis of biomedical materials

EDUCATION

2013-Current: Continuous education as Toxicologist

2017-Current: Continuous education as Pharmacist (courses non reported below, available on request)

2018-Current: Continuous education within AIBO

2004: Post doc grant at Pharmaceutical Science Department of University of Trieste, Italy.

2001-2003: PhD Student at Pharmaceutical Science Department of University of Trieste and Biomedical Science Department at University of Padova, Italy.

1994-2000: Master of Science in Pharmaceutical Chemistry and Technology at University of Trieste, Italy, 110/110 cum laude

OTHER RELEVANT INFORMATION and AWARDS

2016: DSM won the DJSI; Product Stewardship (lead by C.Cusan) was determining the success

October 2011: DSM Scientific Publication Award 2011.

2004: Teacher of organic chemistry and pharmaceutical chemistry (evening university courses).

June 2003 - August 2003: 3 months visit researcher at Institut für Pharmakognosie, Karl-Franzens Universität, Graz (Austria)

May 2000: 1 month visit researcher at CNRS of Montpellier (France)

Some of the Recent TRAINING, WORKSHOP, WEBINARS AND CONGRESSES (from 2018)

(The courses related to the Continuous education as Pharmacist are non-reported below, available on request)

2023:

- Seminario Packaging, "Come districarsi tra BPA, Ftalati, PFAS e Microplastiche – Innovazioni e questioni emergenti nella filiera MOCA, Milano, 19 Dicembre 2023
- ISO 10993-17:2023, what's new; Webinar by Eurofins, 30 November 2023
- Seminario AIBO: "Attualità nella filiera del Food Contact", San Marco Evangelista (Caserta) 14-15 November 2023
- ISO 10993-17:2023 update: what you need to know, Webinar by NAMSA, 28 September 2023
- Pharmaceutical impurities: regulatory update and challenges from a toxicologist point of view, Webinar by Eurofins, 27 September 2023
- CEC05 - Particle and Fibre Toxicology course, Ljubljana (Slo), 10 September 2023
- Eurotox 2023: Congress of European Toxicologist; Ljubljana (Slo), 11-13 September 2023
- On demand webinar, TUV ISO 10993- webinar series: ISO 10993-4 aspect of in-vitro hemocompatibility testing (part 6 of 7)
- 11 Congresso scientifico nazionale Food Contact Experts, Baveno, 28-29 June 2023
- SITOX Congress (Italian society of Toxicology), Bologna, 23-24 February 2023
- Online webinar on demand: "Principle for Validation and Reprocessing for Reusable Medical Devices – Cleaning Disinfection, and Sterilization"

2022:

- 3rd Annual Extractables & Leachables Hybrid 2022 Conference, online, 2-3 December 2022
- Webinar: "Optimizing cardiovascular testing for Cardiovascular medical devices", online, 13 October 2022
- International Conference: Food Contact Compliance; Baveno (IT), 27-28 September 2022
- Eurotox 2022: Congress of European Toxicologist; Maastricht (NL), 18-21 September 2022
- CORSO TEORICO-PRATICO Approcci integrati nella valutazione della sicurezza dei prodotti cosmetici (Risk assessment cosmetics), Milano (IT); 11-15 July 2022
- Congress food contact expert 2022, organized online by AIBO, 22 – 23 June 2022
- "Biological Safety Spotlight: Implant Devices. Current requirements and pitfalls explained using case studies" (online)

2021:

- SITOX Congress (Italian society of Toxicology)
- International conference food contact compliance (online)
- Biocompatibility of Raw Materials – What Data Should Your Supplier Provide? (online)
- Substance based medical devices: Regulatory implications under the EU Medical Device Regulation (online)
- La valutazione biologica dei dispositivi medici (two days online with close number of attendees)
- ISO 10993 Evolution: When 17 arrives after 18 (online)
- Biocompatibility Testing of Respiratory Devices as per ISO 18562 – Use of Appropriate Testing and Evaluation Strategies (online)
- ISO 10993-23:2021 (online)

2020:

- AIBO congress (online)
- Bio/Pharmaceutical Package Testing: Avoid Thinking Strictly Inside the Box (online)
- Biocompatibility Testing of Respiratory Devices as per ISO 18562 – Use of Appropriate Testing and Evaluation Strategies (online)
- Biocompatibility testing in medical devices conference (online)
- Genotoxic and elementary impurities conference (online)
- Extractables and leachables - summit 2020 (online)
- Nanomaterial EU MDR – webinar
- Disciplina FDA – Regolamentazione USA per i materiali e oggetti a contatto con gli alimenti
- Changes to EU Safety Data Sheet (SDS) Requirements - Webinar
- Microplastics and Nanomaterials Definitions Regulatory Considerations – webinar
- SITOX Congress (Italian society of Toxicology)

2019:

- Valutazione biologica dei dispositivi medici: corso avanzato
- La classificazione dei dispositivi medici a base di sostanza
- Dispositivi medici borderline
- NIAS, mineral oils, risk assessment and testing, predictive models
- Economia circolare e food contact materials
- Continuing Education Course (CEC) 06: Determining safe exposure limits in occupational toxicology, application to pharmaceuticals
- Le regole della farmacopea EU and packaging a contatto con specialità farmaceutiche e dispositivi medici
- Eurotox 2019: Congress of European Toxicologist

2018:

- Eurotox 2018: Congress of European Toxicologist
- California Prop 65 labelling workshop
- NIAS and mineral oils in food contact materials: regulatory and analytical affairs
- Endocrine Disruptors and alternative methods to animal testing – a scientific and regulatory perspective
- Continuing Education Courses (CEC) 5: Read-across in REACH and its assessment

PATENTS

- H.M. Moody, C. Cusan, E.G. IJpeij, "Process for preparing 3'-thiosubstituted cephalosporins employing a penicillin G acylase." PCT Int. Appl. (2012), WO 2012175585 A1 20121227
- H.M. Moody, C. Cusan, E.G. IJpeij, "Enzymatic biosynthesis of a novel crystalline cefoperazone intermediate." PCT Int. Appl. (2012), WO 2012175587 A2 20121227
- P.J.L.M. Quaedflieg, T. Nuijens, C. Cusan, C.H.M. Schepers, "Peptide synthesis using enzymatic activation and coupling." PCT Int. Appl. (2010), 36pp. CODEN: PIXXD2 WO 2010057961 A1 20100527 CAN 152:590454 AN 2010:652006
- P.J.L.M. Quaedflieg, B.J.M. Plum, A. Dias, B. Ritzen, C. Cusan, C.H.M. Schepers, "Enzymatic conjugation of bioactive moieties." PCT Int. Appl. (2009), 30pp. CODEN: PIXXD2 WO 2009101178 A1 20090820 CAN 151:287402 AN 2009:1014713
- P.J.L.M. Quaedflieg, T. Nuijens, C. Cusan, "Chemo-enzymatic synthesis of a c-terminal aryl amide of an amino acid or peptide." PCT Int. Appl. (2009), 32pp. CODEN: PIXXD2 WO 2009080631 A2 20090702 CAN 151:99705 AN 2009:792992
- P.J.L.M. Quaedflieg, T. Nuijens, C. Cusan, H.M. Moody, T.J.G.M. van Dooren, "Chemoenzymatic peptide synthesis via c-terminal ester interconversion." PCT Int. Appl. (2009), 46pp. CODEN: PIXXD2 WO 2009047311 A1 20090416 CAN 150:421311 AN 2009:454304
- P.J.L.M. Quaedflieg, C. Cusan, B. Ritzen, A. Dias, "Selective enzymatic hydrolysis of protected peptide esters." PCT Int. Appl. (2008), 34pp. CODEN: PIXXD2 WO 2008155381 A1 20081224 CAN 150:54398 AN 2008:1533901 CAPLUS

MOST RELEVANT PUBLICATIONS

- J. S. Lee, T. Groothuis, C. Cusan, D. Mink, J. Feijen, "Lysosomally cleavable peptide-containing polymersomes modified with anti-EGFR antibody for systemic cancer chemotherapy." *Biomaterials* (2011), 32(34), 9144-9153
- T. Nuijens, C. Cusan, A.C.H.M. Schepers, J.A.W. Kruijtzter, D.T.S. Rijkers, R.M.J. Liskamp, P.J.L.M. Quaedflieg, "Enzymatic synthesis of activated esters and their subsequent use in enzyme-based peptide synthesis." *Journal of Molecular Catalysis B: Enzymatic* (2011), 71(1-2), 79-84

- C. Bolcato, C. Cusan, G. Pastorin, G. Spalluto, B. Cacciari, K.N. Klotz, E. Morizzo, S. Moro, "Pyrazolo-triazolo-pyrimidines as adenosine receptor antagonists: effect of the N-5 bond type on the affinity and selectivity at the four adenosine receptor subtypes." *Purinergic Signalling* (2008), 4(1), 39-46
- C. Cusan, G. Altinier, S. Sosa, F. Sibilla, F. Bucar, A. Tubaro, M. Prato, G. Spalluto, T. Da Ros; "Anti-inflammatory and anti-oxidant activity of a new class of phenyl-pyrazolone derivatives." *Current Drug Discovery Technology* (2006), 3 (1), 67-73
- S. Moro, M. Bacilieri, B. Cacciari, C. Bolcato, C. Cusan, G. Pastorin, K.-N. Klotz, G. Spalluto; "The application of a 3D-QSAR (*auto*MEP/PLS) approach as an efficient pharmacodynamic-driven filtering method for small-size virtual library: application to a lead optimization of a human A3 adenosine receptor antagonist." *Bioorganic & Medicinal Chemistry* (2006), 14 (14), 4923-32
- P.J.L.M. Quaedflieg, B.R.R. Kesteleijn, P.B.T.P. Wigerinck, N. Goyvaerts, R.J. Vijn, S.S.M. Liebrechts, J.J.H. Kooistra, C. Cusan; "Stereoselective and efficient synthesis of (3R,3aS,6aR)-hexahydrofuro [2,3-b]furan-3-ol." *Organic Letters* (2005), 7 (26), 5917-5920
- D. Penzo, V. Petronilli, A. Angelin, C. Cusan, R. Colonna, L. Scorrano, F. Pagano, M. Prato, F. Di Lisa, P. Bernardi; "Arachidonic Acid released by Phospholipase A₂ activation triggers Ca²⁺-dependent apoptosis through the mitochondrial pathway." *Journal of Biological Chemistry* (2004), 279 (24), 25219-25225
- C. Cusan, T. Da Ros, G. Spalluto, S. Foley, J.-M. Janot, P. Seta, C. Larroque, M.C. Tomasini, T. Antonelli, L. Ferraro, M. Prato, "A new multi-charged C₆₀ derivative: synthesis and biological properties." *European Journal of Organic Chemistry* (2002), 17, 2928-2934

EXTERNAL ORAL COMMUNICATIONS IN SCIENTIFIC EVENTS

- Lecture at the Packaging seminar, "What do we know on microparticles and their toxicological effects?", Milano, 19 December 2023
- Lecture at University of Trieste, "Toxicological requirements of REACH", Trieste (Italy), 21 November 2023
- Valutazione tossicologica di sostanze potenzialmente pericolose nei MOCA, Seminario AIBO: "Attualità nella filiera del Food Contact", San Marco Evangelista (Caserta) 14-15 November 2023
- Lecture at the Food Contact Experts congress, Baveno, 27-28 June 2023, "Valutazione Tossicologica di NIAS"
- Zoom Webinar (2 hours), "Dispositivi medici: Biological Evaluation Plan e Report, nozioni di tossicologia", 23 March 2023"
- Lecture at University of Trieste (Italy), 12 January 2023, "Medical Devices: from lab development to preclinical studies, what is new in the EU Regulation 2017/745"
- Lecture at University of Trieste (Italy), 14 November 2022, "Toxicological requirements of REACH"
- Lecture at University of Trieste (Italy), 13 January 2022, "Medical Devices: from lab development to preclinical studies, what is new in the EU Regulation 2017/745"
- Lecture at University of Trieste (Italy), 10 November 2021, "Basic principle of REACH and Toxicological requirements"
- Lecture at University of Trieste (Italy), 9 November 2020, "Toxicological requirements within REACH regulation"
- Speaker at Elsevier webinar presentation: "Improve Safety and Toxicological Assessments in Chemical Product Development", 22 April 2020
- Lecture at University of Trieste (Italy), 12 December 2019, "Toxicology in the context of REACH regulation"
- Lecture at University of Trieste (Italy), 2nd October 2019, "L'approccio alla ricerca e sviluppo in un contesto industriale"
- Cyanide Safety Conference, Brussels (Belgium), 13-14 May 2014: "Overview of Cyanide Antidotes"
- Chemical Conference, Lunteren (The Netherlands), 19-21 October 2008: "Enzymatic peptide synthesis using C-terminal tert-butyl ester interconversion"

EXTERNAL POSTER COMMUNICATIONS IN SCIENTIFIC EVENTS

- Poster at the Congress of Italian Toxicologist, Bologna, 23-23 February 2023, "Skin irritation and biomedical devices: the in vitro testing strategy as per ISO 10993-23:2021"
- Poster at the European Congress of Toxicologist, Maastricht, September 2022, "Skin sensitization and biomedical devices: the in vitro testing strategy as per ISO 10993-10:2022"

LANGUAGES

Native Italian speaker, fluent English, basic French and German.

La sottoscritta Dr. Claudia Cusan

consapevole che le dichiarazioni false comportano l'applicazione delle sanzioni penali previste dall'art. 76 del D.P.R. 445/2000, dichiara che le informazioni riportate nel seguente curriculum vitae, sono veritiere.

La sottoscritta, inoltre, autorizza ai sensi del D. lgs. 196 del 30 giugno 2003, al trattamento dei dati personali.

The undersigned Dr. Claudia Cusan

aware that false declarations involve the application of the criminal sanctions provided for by art. 76 of the Presidential Decree 445/2000, declares that the information contained in the following curriculum vitae is true.

Furthermore, the undersigned authorizes pursuant to Legislative Decree 196 of 30 June 2003, to the processing of personal data.

Portogruaro, 31 December 2023

