

Curriculum vitae, Cristiana Campa

1. Summary

For most of her career, Cristiana Campa worked on characterization and development strategies for (bio)pharmaceuticals. She has gained this 20+ years' experience first as a researcher and technical team manager in academy and company settings, then as Head of Analytical Development in Technical Development- Italy, at Novartis Vaccines (now GSK Vaccines), position covered until 2015.

Since 2012, she has been a technical lead for the implementation of Quality by Design (QbD) at Novartis Vaccines, working across several CMC functions and sites in Europe and US. Due to this experience, in 2015-2017 she has been leading the QbD integration efforts, aimed at the definition of a global, integrated Quality by Design approach at GSK Vaccines, after acquisition of Novartis Vaccines by GSK.

She has then been appointed as Head of Science and Development practices in Technical R&D, GSK Vaccines, with oversight on QbD implementation, Knowledge Management, and product development roadmaps, covering all Technical R&D sites (Europe and US).

She subsequently moved to her current role of Global Technical R&D Advisor, mostly focused support of innovative CMC development strategies within GSK Vaccines and across different GSK modalities. She is involved in external advocacy in the CMC space, including (i) the EFPIA MQEG PRIME COVID CMC team; (ii) the Vaccines Europe (VE)/ IFPMA CMC adaptive pathways group (former CMC COVID team), where she acts as chair; (iii) the EFPIA/ VE ICH Q2(R2)/ Q14 team (until 2022); (iv) the EFPIA/ VE ICH Q6 EFPIA team, where she acts as team lead. She is also actively involved in some technical conferences and workshops supporting dialogue between industry and regulators, as speaker or as part of the scientific committees. Since January 2023, she is a member of the Board of Directors at Parenteral Drug Association (PDA).

More details are reported below.

2. Work experience

- **June 2018- today: Global Technical R&D Advisor**

Providing scientific support to CMC development teams across global Technical R&D organization on development strategies, scientific and technological innovation; focus is on vaccines, with strong engagement on cross- modality integration of CMC strategies within GSK, covering small molecules, biotherapeutics, and vaccines (e.g., for Quality by Design, acceleration strategies, specifications setting). Nominated GSK Vaccines Fellow in 2019, and Senior Fellow in 2023.

- **July 2017- May 2018: Head of Science and Development practices in Technical R&D, GSK Vaccines**

QbD implementation, Knowledge Management, and development roadmaps focused on Chemistry, Manufacturing and Controls (CMC), for GSK Vaccines.

- **September 2015- June 2017: Head of Quality by Design (QbD) Integration at GSK Vaccines and Lead of Analytical workstream**

Leader of a global team in Technical Research & Development, with members in different GSK Vaccines sites; scope of the work was the definition of an integrated Quality by Design approach for product and process development at GSK Vaccines, after acquisition of Novartis Vaccines by GSK. In addition to acting as QbD Integration head, Cristiana had direct responsibility on the team of experts defining analytical strategy following QbD principles.

- **March 2013- August 2015: Head of Analytical Development, Technical Development, Siena, at Novartis Vaccines (GSK Vaccines since March 2015)**

Department Head of the organization responsible for the development, validation and transfer of analytical methods for release/ stability of glycoconjugate and protein vaccines (toxicology and clinical phases, up to launch), covering both physicochemical studies and bioassays & immunoassays, In Technical Development,

GSK Vaccines, Italy. The team was also responsible for specifications setting and additional characterization of antigens at drug substance and drug product level.

- **February 2012- February 2013: Technical Lead in Technical Development and Manufacturing Science & Technology Quality by Design / Product & Process Development Roadmap Global Implementation Team at Novartis Vaccines**

Support for QbD implementation in Technical Development, providing indications about how to apply QbD principles & framework within current development projects, and supporting the definition of the approach for QbD gap assessment for commercial products/ processes, at global level (Siena (Italy), Marburg (Germany), Liverpool (UK) and Holly Springs (US) sites).

- **December 2006- February 2012: Analytical Project Manager in Technical Development- Analytical Development at Novartis Vaccines, Siena, Italy**

Operative management of a team of experts working on (i) characterization of bacterial vaccines; (ii) development and validation of analytical methods applied to the cited vaccines. Moreover, support was provided for vaccine manufacturing at development and commercial scale (investigations/ problem solving), and for regulatory filing and questions associated to the approval of vaccines in Italy and foreign countries.

- **September 2002- November 2006: Senior Researcher (2002-2005) and then Laboratory Head (2006) at Bracco Imaging SpA, Laboratori Centro Ricerche Bracco- AREA Science Park- Basovizza Campus-Trieste, Italy**

Operative coordination of two research lines, covering both small molecules and biologics: (i) analytical characterization of contrast agents (iodinated small molecules and gadolinium complexes); (ii) preparation of innovative contrast agents through the study of glycobiology of some pathologies (e.g., tumors), in collaboration with University of Trieste (Department of Biochemistry, Biophysics and Chemistry of the Macromolecules).

3. Certifications

- **8-19 May 2023**

ADVAC – The 23rd Advanced Course of Vaccinology- Les Pensières, Center for Global Health, Veyrier-du-Lac, France

ADVAC is an annual two-week training programme for decision-makers, including academia, industry, governmental and non-governmental agencies. The Course aims to facilitate critical decision-making in vaccinology by providing participants with a comprehensive overview of the various aspects of vaccinology (immunology, vaccine development, clinical trials, regulatory processes, vaccine-specific issues including new vaccines, vaccination strategies and policies, programme implementation, humanitarian emergencies, social, economic, political and ethical issues, financing, and communications...). The Course is organized by Organized by Fondation Mérieux & Université de Genève (<https://www.advac.org/advac/about-us>).

4. Education

- **2000- 2002**

Post- doctoral fellowship in Chemistry, University of Trieste (Italy) and NTNU- Thronheim, Norway

The research work was focused on the chemical and enzymatic synthesis of carbohydrates and glycopolymers; special care was devoted to the structural characterization of these saccharidic compounds by mass spectrometry, capillary electrophoresis, gaschromatography and liquid chromatography.

- **1996-1999**

PhD in Chemistry, University of Salerno, Italy and National Research Center for Environment and Health (now Helmholtz Institute), Munich (Germany)

Development of new analytical methods for the analysis of carbohydrates by high- performance anion exchange chromatography with pulsed amperometric detection, and by capillary electrophoresis. During this period, a new analytical method aimed at the analysis of cyanogenic glycosides by capillary electrophoresis was developed.

- **1989-1995**

Master Degree in Chemistry, University of Basilicata, Italy, and visiting student at University of St. Andrews (Scotland)

Pure chemistry studies (5 years courses), with a final experimental thesis in Analytical Chemistry. The thesis regarded the electrochemical and Electron Spectroscopy for Chemical Analysis (ESCA) study of inorganic films containing ruthenium, and their applications for the analysis of some aldehydes. In the period September-December 1992, visiting undergraduate student ("Erasmus" project) at the University of St. Andrews (Scotland, UK). During this period, the following courses/ exams were taken: from Junior Honours Classes: Spectroscopy, Inorganic Techniques; from Second BSc Classes: Physical Chemistry, Analytical Chemistry Laboratory, Physical Chemistry Laboratory.

5. Membership of Scientific Committees of technical conferences

- Co-Chair of the Scientific Committee of the Parenteral Drug Association (PDA) Europe BioManufacturing Conferences, from 2018 to 2023
- Member of the Scientific Committee of the IABS Workshop on Global Harmonization of Specifications, held in January 2023
- Member of the Scientific Committee of the IABS CMC Statistics Workshop, held in November 2022
- Member of the Scientific Committee of the PDA Innovations in Vaccines, held in June 2021
- Co-Chair for Parenteral Drug Association (PDA) Europe Vaccines Conference 2015 and 2018
- Member of the Organizing Committee for Parenteral Drug Association (PDA) Europe Vaccines Case Study Workshop, Bruxelles, April 2014.

6. Membership of cross- company teams

- 2023- today: member of the Parenteral Drug Association (PDA) Board of Directors
- 2022- today: Lead of the EFPIA/ Vaccines Europe (VE) team on ICH Guideline Q6A/B revision, covering small molecules, biotherapeutics and vaccines
- May 2023- today: Chair of the VE-IFPMA CMC Adaptive Pathways working group (former COVID CMC/GMDP Task Force (COVAX)); in this context, I am also a member of the Steerco of CEPI Templates (Comparability and Process Validation) to support 100 days- mission, and co- leading the Comparability template cross- company team.
- March 2020- April 2023: Member of the VE- IFPMA CMC/GDMP COVID Task Force, and co-lead of a subteam dedicated to stability modeling strategies for vaccines
- March 2020- today: Member of the EFPIA MQEG PRIME COVID CMC team
- 2019-today: Member of the PDA Vaccine Interest group task force, writing PDA Technical Report on Development and Lifecycle Management of Vaccines (see references) and discussing key topics of attention for vaccines CMC development and lifecycle
- Since inception and until 2022: Member of the EFPIA team on ICH Guideline Q2 revision and ICH Guideline Q14 issuing.
- Since inception and until 2022: Co- lead of the Vaccines Europe (VE) team on ICH Guideline Q2 revision and ICH Guideline Q14 issuing.
- 2021-2022: Member of the cross- company IQ (International Consortium for Innovation & Quality in Pharmaceutical Development) team who prepared a case study on analytical strategy for biologics

7. Oral presentations (focus on 2015-today)

- 9 November 2023: “Insights on patient-centric specification setting and implementation for Vaccines” (co-presented with Mathieu Vasselle), ABS 9th Annual Statistics Workshop: Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigm
- 16 October 2023: “Use platform approaches with vaccines to support rapid development and launch”, CASSS CMC Strategy Forum Europe, Stockholm, Sweden
- 16 November 2022: “Overview of Cross-Company CMC discussions related to COVID-19 vaccines”, on behalf of the VE/ IFPMA CMC/ GMDP COVID team, 2022 PDA Asia- Pacific Regulatory conference
- 16 May 2022: “The Use of Stability Modeling to Support Accelerated Vaccine Development & Supply”, Webinar, BioPharm Asia
- 11 November 2021: “CMC Approaches to Support Development and Supply of COVID Vaccines – an overview of cross-company discussions”- on behalf of the VE/ IFPMA CMC/ GMDP COVID team, IABS CMC Statistical Workshop
- 14 October 2021: “Quality by Design: a key enabler of accelerated biopharmaceuticals development”, Process Advances in Pharma, PEC (virtual)
- 29 September 2021: “Quality by Design: An Indispensable Approach to Accelerate BioPharmaceutical Product Development”, PDA/FDA Joint Regulatory Conference (virtual)
- 9 September 2021; “Development of COVID-19 vaccines during this pandemic situation”, Virtual PharmSci, APS International Conference 2021 (virtual)
- 13 July 2021: “Enhanced Approach to Analytical Method Development for Vaccines”, CASSS CMC Forum Summer 2021 (virtual)
- 25 February 2021, “Overview of cross-company CMC discussions related to COVID-19 vaccines”- on behalf of the VE/ IFPMA CMC/ GMDP COVID team, PDA Singapore Chapter Webinar: 2021 Annual General Meeting (virtual)
- 27 January 2021: “Industry Position: Impact of evolving analytical strategies on comparability, specification and National Control Laboratories testing”- on behalf of the VE/ IFPMA CMC/ GMDP COVID team, CMC COVAX Tech Transfer workshop (virtual)
- 25 January 2021; “Overview of Cross-company (Trade Associations) Discussion on CMC Approaches to Support Development and Supply of COVID Vaccines” on behalf of the VE/ IFPMA CMC/GDMP COVID team, WCBP 2021 (virtual)
- 28 September 2020: “Comparability challenges, Industry position”, CMC COVAX Comparability Workshop (virtual)- on behalf of the VE/IFPMA CMC/GDMP COVID team
- 14-16 September 2020: “New PDA Technical Report: strategies for vaccines’ development and lifecycle management” 2020 PDA/FDA Joint Regulatory Conference (virtual)
- 5 December 2019: “ICHQ2 (R2)/Q14 update & Biologics perspective”, JPAG Regulatory hot topics IV, London
- 25- 28 November 2019: trainer and session co- lead at the “Workshop on Supply Chain Management: Quality by Design and Supply Chain Modelling”, organized by Imperial College (UK) and Developing Countries Vaccines Manufactures Network, Hanoi (Vietnam)
- 14 May 2019: “ICH Q2/Q14: Reflections for Vaccines”, CASSS CMC Strategy Forum 2019 Europe, Seville (Spain)
- 26 November 2018: “CMC information to support Vaccine Early Access designation- Composite Case Study from Vaccine Manufacturers (GSK, Janssen, MSD, Pfizer, Takeda)”, EMA /US FDA Workshop on support to quality development in early access approaches, European Medicines Agency, London (UK)

- 30 January 2018: “Development of Control Strategy for Vaccine Products”. WCBP 2018, Washington (DC, US)
- 12 October 2016: “Overview of QbD application to vaccines development, with practical examples” World Vaccine Conference Europe, Barcelona (Spain)
- 27 January 2016: “Analytical Control Strategy for Robust Vaccine development”, WCBP 2016, Washington (DC, US)
- 27 January 2015: “A QbD Approach for the Development of a Protein Glycoconjugate Vaccine”, WCBP 2015, Washington (DC, US)

8. Patents

- Method for the preparation of specific antibodies against saccharidic antigens; Inventors: Fulvio Uggeri, Cristiana Campa, Sergio Paoletti, Anna Coslovi, Alfonso Colombatti, Carla Danussi; WO2007147823A1
- Diagnostic and radiotherapeutic contrast agents and process for their preparation; Inventors: Cristiana Campa, Fulvio Uggeri, Sergio Paoletti, Anna Flamigni; WO2008104486

9. Awards

- 2019 Parenteral Drug Association (PDA) Michael S. Korczynski Award (“In recognition of her valuable contributions made toward the development of PDA's international activities”)
- 2020 Parenteral Drug Association (PDA) Europe Service Appreciation Award (“In recognition of contributions to PDA Europe”)

10. Books

Co- editor of the Parenteral Drug Association (PDA) book entitled: “Quality by Design—An Indispensable Approach to Accelerate Biopharmaceutical Product Development” (edited by Amin Khan and Cristiana Campa), covering both vaccines and biotherapeutics, and involving several pharmaceutical companies and institutions (published in March 2021). This book involves several companies and well- recognized academic institutions (Amgen, BioMarin, Eli Lilly, GSK, Imperial College London, Janssen, Novartis, MSD, Sanofi), contributing to the ongoing dialogue for accelerating CMC product development strategies for biotherapeutics and vaccines

11. Publications

1. C. Campa, A. Lennard, A. Kelly, A. Onur, B. Rellahan, B. Mouterde, E. Blaesing, F. Harte, G. Scheriner, J. Sensius, K. Liebert, M. Popkin, M. Eberle, M. Albarghouthi, M. Stangl, O. Dirat, R. Kock, S. McFadden, S. Linke, S. Hebetreit, T. Buckel, T. Linnemann, V. Auquier, V. Jaitely, W. Hu, EFPIA/Vaccines Europe position paper on ICH Q6 A/B revision (2023), <https://www.vaccineseurope.eu/news/position-papers/efpia-vaccines-europe-position-paper-on-ich-q6-a-b-revision>
2. M.M. Castellanos, H. Gressard, H., X. Li, C. Magagnoli, A. Moriconi, D. Stranges, L. Strodiot, M. Tello Soto, M. Zwierzyna, & C. Campa (2023). “CMC Strategies and Advanced Technologies for Vaccine Development to Boost Acceleration and Pandemic Preparedness. Vaccines”, *Vaccines* (2023), 11(7), 1153.
3. S, Restrepo, J. Jane Halpern, M. Bilanin, C. Campa, C. Hutchens, M. Krishnan, L. Le Palaise, M. McGoldrick, P. Pattnaik, R. Pelt, Pfizer, J. Shanter (2023), PDA Technical Report 89, Strategies for Vaccine Development and Lifecycle Management
4. C. Campa, “Stability assessment for vaccines: recent trends & learnings from accelerated scenarios”, *Vaccine Insights* (2022) 1(5): 281–291
5. M.E. Popkin, M. Goese, D. Wilkinson, S. Finnie, T. Flanagan, C. Campa, A. Clinch, A. Teasdale, A. Lennard, G. Cook, G. Mohan, & M. D. Osborne (2022). “Chemistry Manufacturing and Controls Development, Industry Reflections on Manufacture, and Supply of Pandemic Therapies and Vaccines”. *The AAPS journal*, (2022) 24(6): 101.

6. T. Verch, C. Campa, C. Chéry, R. Frenkel, T. Graul, N. Jaya, B. Nakhle, J. Springall, J. Starkey, J. Wypych, T. Ranheim, "Analytical Quality by Design, Life Cycle Management, and Method Control", *The AAPS Journal* (2022) 24: 34
7. M. McGoldrick, T. Gastineau, D. Wilkinson, C. Campa, N. De Clercq, A. Mallia-Milanes, O. Gernay, J. Krishnan, M. Van Ooij, M. P. Thien, P. J. Mlynarczyk, E. Saltus, P. Juvin, D. Clenet, A. Basso, N. Dellepiane, S. Pagliusi, M. Collaço de Moraes Stávale, V. H. Sivaramakrishnan, S. Desaij, "How to accelerate the supply of vaccines to all populations worldwide? Part I: Initial industry lessons learned and practical overarching proposals leveraging the COVID-19 situation", *Vaccine*. 2022 Feb 23; 40(9): 1215–1222
8. M. McGoldrick, T. Gastineau, D. Wilkinson, C. Campa, N. De Clercq, A. Mallia-Milanes, O. Gernay, J. Krishnan, M. Van Ooij, M. P. Thien, P. J. Mlynarczyk, E. Saltus, P. Juvin, D. Clenet, A. Basso, N. Dellepiane, S. Pagliusi, M. Collaço de Moraes Stávale, V. H. Sivaramakrishnan, S. Desaij, "How to accelerate the supply of vaccines to all populations worldwide? Part II: Initial industry lessons learned and practical overarching proposals leveraging the COVID-19 situation", *Vaccine*. 2022 Feb 23; 40(9): 1223–1230
9. P. Borman, C. Campa, G. Delpierre, E. Hook, P. Jackson, W. Kelly, M. Protz, O. Vandeputte, "Selection of Analytical Technology and Development of Analytical Procedures Using the Analytical Target Profile", *Analytical Chemistry* 94 (2) (2022) 559-570
10. C. Campa, T. Ponce, M. Paludi, J. Weusten, L. Conway, J. Savery, C. Richards, D. Clénet, "Use of Stability Modeling to Support Accelerated Vaccine Development and Supply", *Vaccines* 9 (2021) 1114- .
11. W. Egan, C. Campa, F. Berti, Derek O'Hagan, "Comparability Assessment for Vaccines Development and Lifecycle", Chapter 11 in the book "Quality by Design—An Indispensable Approach to Accelerate Biopharmaceutical Product Development" (edited by Amin Khan and Cristiana Campa), March 2021
12. P. Jackson, P. Hamilton, P. Borman, M. Godfrey, R. Orr, C. Campa, M. Chatfield, F. Norelli, W. Hoyer, T. Schofield, "Using the Analytical Target Profile to Drive the Analytical Method Lifecycle", *Analytical Chemistry*, 91 (2019) 2577–2585.
13. L. Nompari, S. Orlandini, B. Pasquini, C. Campa, M. Rovini, M. Del Bubba, S. Furlanetto, "Quality by design approach in the development of an ultra-high-performance liquid chromatography method for Bexsero meningococcal group B vaccine", *Talanta*, 178 (2018) 552-562
14. A. Gamini, A. Coslovi, M. Toppazzini, I. Rustighi, C. Campa, A. Vetere, and S. Paoletti, "Use of Capillary Electrophoresis for Polysaccharide Studies and Applications" (Chapter 17 in the book "Capillary electrophoresis: methods and protocols, Second Edition" - ed Philippe Schmitt-Kopplin, Humana Press, 2016)
15. M. Toppazzini, A. Coslovi, M. Rossi, A. Flamigni, E. Baiutti, and C. Campa, "Capillary Electrophoresis of Mono- and Oligosaccharides" (Chapter 16 in the book "Capillary electrophoresis: methods and protocols, Second Edition" - ed Philippe Schmitt-Kopplin, Humana Press, 2016)
16. F. Merangolo, S. Giannini, M. Gavini, S. Ricci, C. Campa, "Development of a New Method for Monosaccharide and Sialic Acid Quantification in Sialylated Polysaccharides by HPAEC–PAD", *LCGC Applications of Ion Chromatography*, 2015 9
17. I. Rustighi, I. Donati, M. Ferluga, C. Campa, A. E. Pasqua, M. Rossi, S. Paoletti, "Borate complexes of X-ray iodinated contrast agents: characterization and sorption studies for their removal from aqueous media" *Journal of Hazardous Materials* 205-206 (2012) 10-16
18. V. Carinci, A. Bernardini, C. Campa, C. Magagnoli, F. Beccai S. D'Ascenzi, *Applications of Ion Chromatography for Pharmaceutical and Biological Products*. WILEY (2011) 435.
19. M. Rossi, A. Gamini, C. Campa, "Capillary electrophoresis for monitoring natural and synthetic processes of saccharide- bearing molecules", Chapter 7 in the book "Capillary Electrophoresis of carbohydrates" Humana Press (Ed. N. Volpi) (2010)
20. F. Paoletti, K. Ainger, I. Donat, R. Scardigli, A. Vetere, A. Cattaneo, C. Campa, "Novel fluorescent cycloheximide derivatives for the imaging of protein synthesis" *Biochem Biophys Res Commun*. 396(2) (2010) 258-264

21. C. Magagnoli, A. Bardotti, G. De Conciliis, R. Galasso, M. Tomei, C. Campa, C. Pennatini, M. Cerchioni, B. Fabbri, S. Giannini, G.L. Mattioli, A. Biolchi, S. D'Ascenzi, F. Helling "Structural organization of NadADelta(351-405), a recombinant MenB vaccine component, by its physico-chemical characterization at drug substance level", *Vaccine* 27(15) (2009) 2156-2170
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23. C. Danussi, A. Coslovi, C. Campa, M.T. Mucignat, P. Spessotto, F. Uggeri, S. Paoletti, A. Colombatti "A newly generated functional antibody identifies Tn antigen as a novel determinant in the cancer cell-lymphatic endothelium interaction", *Glycobiology* 19(10) (2009) 1056-1067
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27. F. Abballe, M. Toppazzini, C. Campa, F. Uggeri, S. Paoletti "Study of molar response of dextrans in electrochemical detection", *J. Chromatogr. A*, 1149 (2007) 38-45
28. C. Campa, A. Coslovi, A. Flamigni, M. Rossi "Overview on advances in capillary electrophoresis-mass spectrometry of carbohydrates: A tabulated review" (review), *Electrophoresis*, 27 (2006) 2027-2050
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Autorizzo il trattamento dei dati personali nelle modalità previste dal Regolamento UE 2016/679