Curriculum Vitae
European Format

(Jul 2022 update)

Personal Information - Surname/First name	**Gabaldo Michela**
- Nationality	Italian (hold Italian passport)
- Driving licence	Full clean EU car driving licence

Professional Experience Current Position	July 2022 – Present: **VP, Global ATMP Regulatory Affairs,** EVOTEC, Verona, Italy.
Previous Experiences	July 2021– June 2022: **Head, Translational Project Management & Regulatory Affairs,** SR-TIGET – San Raffaele-Telethon Institute for Gene Therapy/TIGEM, Telethon Foundation, Italy. July 2015 – Jun 2021: **Head, Alliance Management & Regulatory Affairs,** SR-TIGET – San Raffaele-Telethon Institute for Gene Therapy/TIGEM, Telethon Foundation, Italy. December 2014 – June 2015: **Senior Alliance Manager & Regulatory Affairs Manager** within SR-TIGET – Telethon Institute for Gene Therapy Milan, Italy. January 2011 – November 2014: **Alliance Manager** within SR-TIGET – Telethon Institute for Gene Therapy Milan, Italy. October 2010 – January 2011: **Senior Medical Writer** within Global Clinical R&D department at Novartis Vaccines and Diagnostics s.r.l. Siena, Italy. July 2010 – September 2010: **Regulatory Executive** at Aptuit s.r.l (*former* GlaxoSmitkline S.p.A.), Verona, Italy. April 2008 – June 2010: **Principal Regulatory Executive** within Corporate CMC (Chemistry Manufacturing and Control) Global Regulatory Affairs, Pre-Approval at GlaxoSmitkKline S.p.A. Verona, Italy, *with UK line-manager.* October 2005 – March 2008: **Senior Regulatory Executive** permanent position within Corporate CMC Global Regulatory Affairs, New Submissions at GlaxoSmitkKline S.p.A. Verona, Italy, *with UK line-manager*.

August 2003 – September 2005: **Junior Regulatory Executive** within Corporate CMC Global Regulatory Affairs, New Submissions at GlaxoSmitkKline S.p.A. Verona, Italy.

April 2002 – July 2003: **Junior Research Scientist** within Clinical Science and Study Operations group at GlaxoSmitkKline S.p.A.

October 2001 – March 2002: **Junior Research Technician** within Clinical Pharmacology Unit at GlaxoSmitkKline S.p.A.

Secondment Experiences

November 2009 – July 2010: secondment within GlaxoSmithKline, Corporate BioPharm Global Regulatory Affairs, Pre-Approval, Harlow, UK to gain experience of filing Dossiers for Biopharmaceutical products (focus on monoclonal antibodies)

September – December 2005: secondment at GlaxoSmithKline, Corporate CMC Global Regulatory Affairs, Pre-Approval, Ware & Harlow, UK to gain experience of late phase and Major Filings (NDA/MAA) Dossiers for NCEs and FDA PAI inspection readiness.

Educational Experience

2010: **2nd Level "Master** in Regulatory Affairs and Market Access for NCE and Biopharmaceutical Drugs" at the University of Novara, Italy.

2002: Granted **Pharmacist Professional Licence**

2001: Pharmaceutical Chemistry and Technology Degree from Pharmacy School of University of Padua, Italy.

Professional Affiliation

- Member of **ISCT**, International Society for Cell and Gene Therapy, (https://www.isctglobal.org/isct2022/home) - (since 2022)
- Member of the **OD Expert group** (https://od-expertgroup.eu) – (since Apr'20)
- Member of the **RARE-IMPACT consortium** (https://rareimpact.eu/why-rare-impact) – (since Jan'17)
- Member of the **IRDIRC**, International Rare Disease Research Consortium, Therapies Scientific Committee (https://irdirc.org/about-us/people-organisation/scientific-committees/tsc/) - (since Dec'16)
- Member of the **ARM**, Alliance for Regenerative Medicines (https://alliancerm.org), Market Access and Regulatory working groups – (since 2015)
- Member of **ESGCT**, European Society for Gene and Cell Therapy, (https:// https://www.esgct.eu) - (since 2012)
- Member of **TopRA**, The Organisation of Professionals in Regulatory Affairs, UK (https://www.topra.org) - (since 2010)
- Member of **AFI**, Italian Scientific Society of Pharmaceutical Industries (http://www.afiscientifica.it) - (since 2010)

Career Awards

- November 2017 - **Topra Award Winner – Future category** (Acknowledges the role of regulatory scientists in realising the potential of cutting edge technologies)
- March 2017 – **GSK Brilliant Award** in relation to Strimvelis registration and market access – Motivation: *"Because you made things happening"*

Pubblications (co-author)	- Fumagalli F. (2021) "Long-term results of lentiviral haematopoietic stem-cell gene therapy for early-onset metachromatic leukodystrophy" – Lancet - Gentner B. (2021) "First-in-Human Phase I/II Clinical Trial of Hematopoietic Stem & Progenitor Cell Gene Therapy for Hurler Syndrome shows Safety and Extensive Metabolic Correction" - New England Journal of Medicines - Gabaldo M. (2021) "Smoothing the path of advanced therapies", Nature Italy. doi: doi: https://doi.org/10.1038/d43978-021-00064-z - Jonker A.H. et al. (2020) "Boosting delivery of rare disease therapies: the IRDiRC Orphan Drug Development Guidebook", Nature review drug discovery. doi: 10.1038/d41573-020-00060-w. - Stirnadel-Farrant, H. et al. (2018) 'Gene therapy in rare diseases: The benefits and challenges of developing a patient-centric registry for Strimvelis in ADA-SCID', Orphanet Journal of Rare Diseases. doi: 10.1186/s13023-018-0791-9. - Tucci, F. et al. (2018) "Successful treatment with Harvoni® in an ADA-SCID infant with HCV infection allowed gene therapy with Strimvelis®", Hepatology. doi: 10.1002/hep.30160 - Marktel, S. et al. (2018) 'Intrabone hematopoietic stem cell gene therapy for adult and pediatric patients affected by transfusion dependent ß-thalassemia'. doi:10.1038/s41591-018-0301-6 - Sessa, M. et al. (2016) 'Lentiviral haemopoietic stem-cell gene therapy in early-onset metachromatic leukodystrophy: an ad-hoc analysis of a non-randomised, open-label, phase 1/2 trial', The Lancet, 388(10043), pp. 476–487. doi: 10.1016/S0140-6736(16)30374-9.
Participation in meetings/workshops	- Invited speaker / Panel discussant on *ATMP and Orphans innovative drug development* and EU cross-border healthcare in several National, European and international Congresses. - Invited speaker on *orphans, gene therapy EU regulatory framework* and *ATMP EU market access* to a II level Masters held by relevant Italian Universities and Business Schools.
Leadership Skills	– Result oriented and passionate leader with excellent analytical and strategic thinking, skilled in long-term plans, outstanding sense of urgency, great problem solving attitude, proved excellent organizational skills and good reliability confirmed by several "recognition awards" received for the "high commitment and dedication" to the projects; – Design thinking aligned with short/medium/long term organizational strategy, vision and objectives; – Skillful communication attitude; empathic leader talented in building and maintaining relationships at any company level internal and external; – Champion in training and coaching collaborators to maximize their development while focusing on their cultural wealth.
Languages	**Italian:** mother tongue; **English:** Excellent (written/spoken).
IT	Advance knowledge of PC and MAC, Office suite, MS Project, Mind manager, Mural

(I authorize the use of my data - Dlgs 196/2003 and GDPR, Regulation UE 2016/679)