# EUROPEAN CURRICULUM VITAE FORMAT

## PERSONAL INFORMATION


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| Name | **MONTAGNO CAPPUCCINELLO, MARCO** |
| Address | **Via Gorizia 23 – Sesto San Giovanni (Mi)** |
| Telephone | |
| E-mail | **m.montagno@chiesi.com** |
| Nationality | Italian |
| Date of birth | 28.02.1966 |


## WORK EXPERIENCE

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| Dates | February 2010 - present |
| • Name and address of employer | Chiesi Farmaceutici S.p.A., Via Palermo 26/A - 43100 Parma, Italy |
| • Type of business or sector | Tel: (39-0521) 2791; Fax (39-0521) 774468; Website: www.chiesi.com |
| • | Pharmaceutical company |
| Occupation or position held | **Director, Global Regulatory Affairs** |
| • Main activities and responsibilities | Full accountability for overseeing global regulatory submissions, management, approvals for the company's portfolio, including the associated communication strategy to all regulatory |

authorities. Engaged to ensure that regulatory practices are fully integrated into pre-clinical, clinical and technical project development, and ensure that all documents submitted to regulatory agencies are appropriately reviewed to ensure they are complete, scientifically accurate, of high quality, in regulatory compliance and presented in a manner that facilitates agency review. Contribution to the creation and implementation of development plans for new projects and full life cycle management products. Incorporation of regulatory strategies and regulatory intelligence designed to maximise the likelihood of successful regulatory applications and regulatory approvals. Global Regulatory function is made of a large corporate group plus almost thirty functionally reporting worldwide affiliates. Experience gained in: MRP, DCP and CP applications for NCEs, fixed dose combinations, abridged products, generics. EU CMDh and CHMP Referrals/Arbitrations (with oral explanations). EU Scientific Advices, pre-IND and pre-NDA US Meetings, CHMP Scientific Advisory Group Meetings, EMA Business Pipeline Meetings, Portfolio Meetings and Pre-submission Meetings at various Health Authorities. Orphan Drug Designations. Paediatric Development Plans. In-licence product evaluations, due diligence processes and inter-companies agreements.

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| Dates | November 1998 – January 2010 |
| • Name and address of employer | Chiesi Farmaceutici S.p.A., Via Palermo 26/A, 43100 Parma, Italy |
| • Type of business or sector | Pharmaceutical company |
| • Occupation or position held | **Regulatory Governance Manager, Corporate Regulatory Affairs** |
| • Main activities and responsibilities | The main tasks of this role within the company were:<br>- Regulatory coordination of all European affiliates, USA and Brazil aiming at planning of the activities consistently with the Group's regulatory strategies<br>- Circulation of regulatory information related to development projects and corporate products<br>- Regulatory intelligence and relationship with the Health Authorities<br>- Management of database and records of corporate regulatory information |

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| • Dates | NOVEMBER 1995 - October 1998 |
| • Name and address of employer | Pharmacia & Upjohn, Milan |
| • Type of business or sector | Pharmaceutical company |
| • Occupation or position held | **Corporate Regulatory Affairs Executive** |
| • Main activities and responsibilities | As Regulatory Coordinator at Pharmacia & Upjohn, in charge for an activity of international regulatory affairs with responsibility by products. Responsibility included either the preparation of the registration dossier documentation of new products and activities of maintenance, updating and variation of existing international authorisations. For products in development, the Regulatory Coordinator was early involved in the Project Team system, in order to approve the experimental protocols, collaborate to the preparation of documentation in conformity with relevant legislation and define the possible strategies, in such a way to speed-up the approval of the products and their commercialisation. |

## EDUCATION AND TRAINING

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| • Dates | SEPTEMBER 1993 - October 1995 |
| • Name and type of organisation providing education and training | Pharmacia & Upjohn, Milan<br>Pharmaceutical company<br>**Internal scholarship**<br>Awarded a two-year fellowship, jointly sponsored by the Italian Government and Industry, to investigate drug delivery for intranasal administration of peptides and proteins. Gained experience in formulations and their characterisation. Experience included traditional and innovative analytical techniques.<br>Six months spent at the Department of Pharmaceutics, The School of Pharmacy, University of London, under the supervision of Dr. Graham Buckton. The project aimed the study of the principles of the bio-adesion mechanisms. The experimental work was published in Pharmaceutical Research 1998 (see the following section about publications). |

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| • Principal subjects/occupational skills covered<br>• Title of qualification awarded | |
| • Dates | November 1986 – July 1993 |
| • Name and type of organisation providing education and training | Pharmacy Faculty, University of Milan, Italy |
| • Principal subjects/occupational skills covered | While studying for this degree, a one-year laboratory project was undertaken at Innovative Formulations/Pharmaceutical Development Pharmacia Farmitalia Carlo Erba, under the supervision of Prof. Andrea Gazzaniga, University of Milan.<br>The aim of this project was to investigate the use of alginates for prolonged release systems of an antitumoral drug. The title of the thesis was: "Alginates evaluation for prolonged release systems of Turosteride", published later on Pharmaceutical Science 1995 (see the following section about publications). |
| • Title of qualification awarded | 5-year Degree in Pharmaceutical Chemistry and Technology |
| • Level in national classification | 5 years' course |

**ADDITIONAL INFORMATION**

Trainer in various internal courses and in Master Programmes in various Italian Universities.

**Publications**

- A.Martini, M.Montagno Cappuccinello et al., "Hydrophilic Matrices as Controlled-release Formulations for a 5alfa-Reductase Inhibitor", Pharmaceutical Sciences 1995, 1: 555-558.

- G.Buckton and M.Montagno Cappuccinello, "Modeling Mucoadhesion by Use of Surface Energy Terms Obtained by the Lewis Acid-Lewis Base Approach: III. An Interaction between Teflon and Carbopol", Pharmaceutical Research, Vol. 15, No. 3, 1998.