Curriculum vitae
Mariangela Caretto

Name and surname: Mariangela Caretto
Place and date of birth: Lecce, October 14th, 1974
Nationality: Italian

Education and training

January 2003: PhD – Pharmaceutical Sciences – University of Camerino - Italy
November 2000: Degree in Chemical and Pharmaceutical Technology - University of Camerino - Italy
March 1997: Degree in Pharmacy - University of Camerino - Italy
04 Dec 2001 Publication: Journal of Medicinal Chemistry 45 (1) pag. 32-40
"α2-Adrenoreceptors Profile Modulation and High Antinociceptive Activity of (S)-(−)-2-[1-(Biphenyl-2-yloxy)ethyl]-4,5-dihydro-1H-imidazole
2000-2001- some publication and communications during medicinal chemistry congress

Current position, brief description of role, expertise and main tasks performed

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Since October 2020 ACRAF S.p.A GLOBAL RA MANAGER • GLOBAL RA PHARMA
Responsible of the life cycle management of Ontozry (cenobamete) in Europe and of the new MA and life cycle management in UK and Switzerland, following the acquisition of the Company Arvelle by ACRAF S.p.A. Regulatory Lead in the Integration Team Arvelle/ACRAF coordinating a cross-functional team with Global Medical Dept, HTA Dept, Quality Operations, Supply and Tech. Ops. to manage and guarantee business continuity of the product.
Responsible of regulatory activity of some Licensing out products registered in Extra EU Countries by non-Angelini Company.
Regulatory Focal Point and coordinator of the notifications to the CAs of the risk of contamination by Nitrosamine in pharma products with ACRAF S.p.A or an Angelini Group Company as MA holder in Europe and Extra EU Countries, where applicable.
January 2017 – October 2020 ACRAF S.p.A RA Development New Polo Products – International Regulatory Affairs
Regulatory strategy for the registration of new POLO products in Angelini's EU Countries.
Management and coordination of the life cycle management activities of Licensing In products from external Partners: Helsinn Birex Ireland Ltd, Zambon S.p.A, Incyte Bioscience Ltd. registered in the East Europe Angelini Affiliates.
Life Cycle Management (variations, renewal, line extension application) of centralized registration of Latuda (lurasidone HCl).
Responsible of all the regulatory activities of the Generic Business products of Angelini for the Italian Market.

Previous professional experience

JUNE 2013- SEPTEMBER 2016: ACRAF S.P.A Regulatory Affair Manager Generic Business - ITALY
Responsible of all the regulatory activities of the Generic Business products of Angelini for the Italian Market.
Member of the Task Force of Regulatory Affairs of Assogenerici.
JANUARY 2007- JUNE 2013: TUBILUX PHARMA S.P.A Regulatory Affair Manager

Responsible of the registration and the regulatory maintenance (variations, line extension, renewals) of Pharmaceutical Products owned by Tubilux Pharma S.p.A, for Italian and EU markets, registered via National and Decentralized registration procedures.
Preparation of Pharma Dossier in NeeS format.
Preparation of the Technical Files of Medical Devices for ophthalmic use for which Tubilux Pharma S.p.A is "Manufacturer" for Italian, EU and Extra-EU markets.
Notifications of MD Technical File to the Competent Authorities.
Notification of Food Supplement to the Italian Ministry of Health for the Italian Market.
Notification of Food Supplement to the Relevant Competent Authorities for the EU Markets.
JANUARY 2004-JANUARY 2007: Pfizer Italia srl, Via Valbondione, Roma - Regulatory Affairs Advisor
Responsible for the registration and the regulatory maintenance of Pharma products owned by Pfizer Italia for the Italian market for the following therapeutic areas: Central Nervous System, Cardiovascular and Urology.
DECEMBER 2002- DECEMBER 2003: **Pfizer Italia S.r.l. Manufacturing Plant – Borgo San Michele – Latina Italy -** Site Compliance Dept. – Animal Health
Preparation of Module 3 of dossier for the registration and maintenance of Animal Health Products manufactured by Borgo San Michele Plant for Italian and EU Markets.
Collaboration with Quality Assurance Dept., Quality Control Dept, Manufacturing Dept and Regulatory Affairs dept of Pfizer Italia S.r.l. located in Rome.
Experience with QA dept for the approval of the incoming materials used in the productions performed by the Plant.
2 months experience with QC Laboratory on a cleaning validation project via swabbing technic.

Linguistic skills

Mother tongue: Italian

Other languages: English

Reception				**Production**				**Interaction**			
Listening		Reading		Spoken		Written		Spoken		Written	
B2	Independent User	C1	Proficient User	B2	Independent User	B1	Independent User	B2	Independent User	B1	Independent User

I declare that the information contained in this Curriculum Vitae is true and correct.

I declare that I am aware of what affirming the truthfulness of what is represented above entails and of the criminal sanctions as of art. 76 of Presidential Decree n. 455 of 28.12.2000 "Consolidated Act on the laws and regulations on administrative documentation" and in particular of what is provided for in art. 495 of the Penal Code in case of false statements and false claims.

SIGNATURE **Date**

Mariangela Caretto Firmato digitalmente da Mariangela Caretto Data: 2021.10.27 10:14:52 +02'00'

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