CURRICULUM VITAE
Marcella Falcone

PERSONAL DETAILS	
Name and Surname:	Marcella Falcone
Address:	
Place and date of birth:	Cosenza (CS) March 20, 1978
Tel. :	
E-mail:	

EDUCATION
Advanced course: The management of medicinal products: regulatory affairs – University of Milan (2010)
Second level master: Pharmacovigilance – University of Milan (2007)
Master's degree : Chemistry and Pharmaceutical Technology – University of Calabria (2006)

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WORK EXPERIENCE

From November 2020 to present

DOC Generici S.r.l. **– Pharmacovigilance Manager/Qualified Person for Pharmacovigilance (QPPV)**

To operate as Qualified Person Responsible for Pharmacovigilance and local Responsible for Pharmacovigilance according to the Italian legislation and European legislation and guidelines. Overall responsibility for establishing and maintaining the Marketing Authorisation Holder's Pharmacovigilance (PV) System, having sufficient authority to influence the performance of the quality system, and to promote, maintain and improve compliance with the legal requirements. Management and coordination of the pharmacovigilance staff.

From June 2019 to November 2020

JSB Solutions Srl. Sesto Fiorentino (FI) **– Pharmacovigilance Manager**

ASSIGNED ROLES

- To manage of the activities within the BU and liaise with the team and management to ensure the compliance of all pharmacovigilance and regualtory projects with client agreement and with local/global regulatory guidelines
- To be involved in training, business development, audits/inspections, client relationship management and line management

From November 2017 to April 2019

PhAST CONSULTING s.r.l., Monza (MB) – **SENIOR PHARMACOVIGILANCE PROJECT MANAGER**

ASSIGNED ROLES

- Qualified Person Responsible for Pharmacovigilance (QPPV)
- Deputy QPPV
- Pharmacovigilance contact person at national level reporting to the QPPV
- Responsible person for Pharmacovigilance of interventional clinical trials
- Trainer (both internal staff and courses for clients)

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MAIN ACTIVITIES

- Registration with EudraVigilance of the Sponsor/MAH for the electronic data interchange of pharmacovigilance information
- Submitting medicinal product data using the extended EudraVigilance medicinal product dictionary (XEVMPD) both for authorised or investigational medicinal products
- RNF management according to new local rules
- Drafting and review of SOPs and WIs in order to ensure compliance with Legal requirements and with corporate SOPs
- Implementing and updating of PSMF
- Drafting and submission of RMPs, including implementation of measures to prevent or minimise risks and the assessment of the effectiveness of those measures
- Signal detection and management: safety surveillance and analysis also from EVDAS
- PSURs /DSURs planning, drafting and notification
- Electronic transmission of ICSRs/SUSARs to EMA
- Drafting and updating of SDEAs with contractual partners and/or CRO
- Training for internal staff and external PhV training to the internal / external Client personnel
- Support to Pharmacovigilance Audit and Inspections

Support for the implementation and maintenance of Medical Device Vigilance System:

- Pre- and post-marketing safety surveillance activities for all classes of medical devices
- Notification of Incidents and field safety corrective actions
- Periodic summary reporting or trend reports

Support for the implementation and maintenance of Cosmetovigilance System:

- Recording, identification and traceability of SUEs
- Notification and transmission of SUEs
- Data collected analysis in order to put in place corrective or preventative measures

From June 2008 to November 2017

PhAST CONSULTING s.r.l., Monza (MB) – **SENIOR SAFETY OFFICER**

ASSIGNED ROLES

- Deputy QPPV
- Pharmacovigilance contact person at national level reporting to the QPPV
- Project leader for assigned pre-marketing Pharmacovigilance activities

- Trainer for Client personnel

MAIN ACTIVITIES

-RNF daily screening in order to retrieve initial and follow-up ADR reports and maintenance of the RNF access tracking sheet
- Collection and processing of ADR reports concerning a medicinal product; follow-up requests; submission of Italian case reports to LHA or AIFA by entering the cases in RNF; maintenance of paper archive and electronic files related to PhV activities; transmission of safety information to Corporate
- Monitoring of medical and scientific literature by using databases (e.g. Medline, Excerpta Medica or Embase), review of local journals and management of EMA's medical literature monitoring
- Collection and management of spontaneous case reports of medical device; Reporting of Incidents to the relevant Competent Authority
- Collection and management of spontaneous case reports of cosmetic product; Reporting of serious undesirable effects to the relevant Competent Authority
Management of SAEs (recording, processing and queries to Investigators)
- Drafting and review of SOPs and WIs
-Periodic review of Authority websites in order to retrieve update of Italian rules or safety concerns regarding medicinal products, medical devices and cosmetics
- Training to internal employees on the processes for reporting safety information
- Electronic transmission of ICSRs/SUSARs to EMA
- PSURs /DSURs planning, drafting and notification
- Drafting and updating of SDEA with contractual partners
- Notification of SUSARs to Competent Authorities and Line Listing of SUSAR to Investigators according to the timelines and modalities described in the law in force

From JUN/2007 to MAR/2008
Bayer S.p.A., Milano – **Internship/Consultant**

Pharmacovigilance activities in compliance with corporate requirements and local regulations:
- RNF (Italian PhV database) daily screening
- AEs/ADRs recording (RNF, local literature, consumer/patient) and processing
- Entering into the RNF ADR reports retrieved from literature (only Italian cases)
- AEs/SAEs/SUSARs recording
- SAEs/SUSARs reporting to Sponsor/CA/EC/INV

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- Follow-up requests - Maintenance of paper archive and electronic files related to pharmacovigilance activities

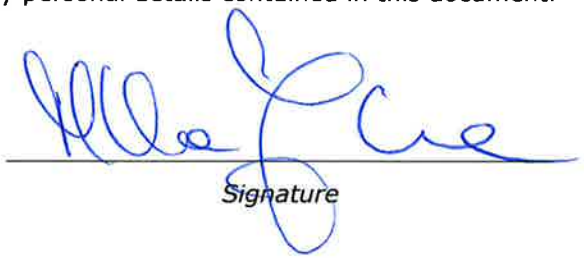
COMPUTER SKILLS
Office, Outlook, main Internet Browsers
Pharmacovigilance Database User: Eudravigilance, SafetyDrugs, ARISg ; Argus Pharmacovigilance System

PERSONAL SKILLS
Organisational/managerial skills : tem working and project management, problem solving

LANGAUGE SKILLS
Italian: Mother Tongue English: Upper intermediate

In compliance with the GDPR and the Italian Legislative Decree no. 196 dated 30/06/2003, I hereby authorize you to use and process my personal details contained in this document.

Date :
02/01/2022
dd / mm / yyyy



Signature

Ministero della Giustizia

Sistema Informativo del Casellario

Certificato del Casellario Giudiziale

(ART. 24 D.P.R. 14/11/2002 N.313)

CERTIFICATO NUMERO: 15005/2022/R

Al nome di:

Cognome	**FALCONE**
Nome	**MARCELLA**
Data di nascita	**20/03/1978**
Luogo di Nascita	**COSENZA (CS) - ITALIA**
Sesso	**F**

sulla richiesta di: INTERESSATO

per uso: RIDUZIONE DELLA META' DELL'IMPOSTA DI BOLLO E DIRITTI: PER ESSERE ESIBITO IN OCCASIONE DI CANDIDATURA ELETTORALE (ART. 1 COMMA 14 LEGGE 3/2019)

Si attesta che nella Banca dati del Casellario giudiziale risulta:

NULLA

ESTRATTO DA: CASELLARIO GIUDIZIALE - PROCURA DELLA REPUBBLICA PRESSO IL TRIBUNALE DI MONZA

MONZA, 29/04/2022 10:52

IL RESPONSABILE DEL SERVIZIO CERTIFICATIVO

Il cancelliere esperto
Marco CORONA

Il presente certificato non può essere prodotto agli organi della pubblica amministrazione o ai privati gestori di pubblici servizi della Repubblica Italiana (art. 40 D.P.R. 28 dicembre 2000, n. 445), fatta salva l'ipotesi in cui sia prodotto nei procedimenti disciplinati dalle norme sull'immigrazione (d.lgs. 25 luglio 1998, n. 286). Il certificato è valido se presentato alle autorità amministrative straniere.

** AVVERTENZA **

Certificato del casellario giudiziale - (ART. 24 D.P.R. 14/11/2002 N.313) - al nome di:

Cognome	Nome	Luogo di Nascita	Data di nascita	Sesso	Paternità	Codice Fiscale
FALCONE	MARCELLA	COSENZA	20/03/1978	F		

Si attesta che nella Banca dati del Casellario Europeo NULLA risulta.