EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Curriculum Vitae

## PERSONAL INFORMATION

Paolo Porcelli

## WORK EXPERIENCE

July 2004- Present

### GVP Senior Inspector, BEMA Assessor, GCP and GMP API Inspector in training

Italian Medicines Agency (AIFA) (Italy)

Senior Inspector for PhV inspections (since 2010); GCP and GMP API Inspector in training (since 2018); BEMA Assessor (Benchmarking of European Medicines Agencies - since 2017); management of issues related to the theft, loss and diversion of medicines from the legal supply chain from a public health angle (2018-2020); EMA's Pharmacovigilance Inspectors Working Group Alternate (2010 2019); Senior assessor of the PSUR and manager of renewals of marketing authorisation (2005 - 2010). GVP Inspections Office from April 2020 to present, Inspections and Certifications Department from December 2017 to April 2020, GVP Inspections Office from June 2016 to December 2017, GCP and GVP Inspectorate from April 2013 to June 2016, Pharmacovigilance Inspections Unit from March2010 to March 2013 and Pharmacovigilance Office from November 2005 to March 2010.

June 2001-October 2003

### Pharmacist

Farmacap (Italy)

Pharmacist with full time permanent contract. Recruitment by open competition based on qualifications and examination

January 2001-February 2004

### Technical Director of pharmaceutical distributor with contract Collaboration

BOMI 2000 SPA (Italy)

Ensure compliance with Legislative Decree 185/95 and Legislative Decree 538/92 (in particular Article 6). Preparation of programs of business administration and supervision of activities in logistics, distribution and materials management.Attendance at meetings with officials of departments concerned. Compliance with pharmacovigilance

June 1999-March 2000

### Sales representative

Dompè SPA (Italy)

Medical representatives, in Rome for Pharmaceutical Company, with fixed-term contract

July 1997-May 1999

### Pharmacist

Pharmacies (Italy)

Pharmacist in different pharmacies in Rome

## EDUCATION AND TRAINING

November 1991-March 1997

### University degree in Pharmacy

School of Pharmacy, University of Rome (Italy)

Physics, hygiene, general and inorganic chemistry, medicinal chemistry and toxicology exercises I, pharmaceutical botany, human anatomy, general physiology I, food science, organic chemistry, medicinal chemistry and toxicology exercises II, Medicinal Chemistry I, Chemistry toxicology, general physiology II, exercises Medicinal Chemistry III, biological chemistry, technology and legislation farmaceuutica, applied pharmacology, pharmacognosy and pharmacology pharmaceutical, medicinal chemistry and toxicology II

September 2000-December 2004

### Pharma D. (Pharmacologist)

School of Medicine and Surgery, University of Rome (Italy)

General and molecular pharmacology, pharmacokinetics, pharmacoeconomics, and pharmacoepidemiology / pharmacovigilance.

Pre-clinical and clinical evaluation of drugs for regulatory purposes, clinical trials of drugs and organization of services of medical pharmacology

November 2009-June 2010

### Master post graduate: Preclinical and clinical drug development: technical,

scientific, regulatory and ethical"

Università Cattolica del Sacro Cuore Agostino Gemelli di Roma (Italy)

Drug discovery, toxicity testing, legal and ethical aspects, statistics and data processing, pharmaceutical development, clinical trials, drug safety, regulatory affairs, information and promotion, pharmacoeconomics, medical departments in the industry

December 2004- **Master in Pharmacoeconomics**

School of Medicine, University of Rome (Italy)

Basis, principles and concepts of pharmacoeconomics and related disciplines

March 2007- Present **Costant EMA Pharmacovigilance Inspectors Whork Group (PhV IWG) Training Course**

European Medicine Acengy (EMA) and National Competent Authorities (NCAs) (United Kingdom)

1. 10/2017 EMA  European Medicines Agency,
2. 10/2016 BfARm - Federal Institute for Drugs and Medical Devices,
3. 11/2015 EMA  European Medicines Agency,
4. 10/2014 AIFA (ITALIAN MEDICINES AGENCY),
5. 04/2012 Danish Health and Medicines Authority,
6. 11/2010 FAMHP  Federal Agency for Medicines and Health Products - Brussels (BE),
7. 11/2009 AFSSAPS - Agence française de sécurité sanitaire des produits de santé - Paris (FR),
8. 03/2007 MHRA - Medicines and Healthcare products Regulatory Agency (UK)

2012- Present **Costant learning course in Pharmacovigilance**

European Medicine Acengy (EMA), Italian Medicine Acengy (AIFA), National Health Institute (ISS) ()

1. 28-29/11/2019 European Pharmacovigilance congress 2019 (Pharma Education Center)
2. 16/10/2019 Italian Pharmacovigilance Day (LS Academy)
3. 26/03/2019 Giornata di formazione sulla Nuova Rete di Farmacovigilanza (AIFA)
4. 10-11/12/2018 XXVII Seminario Nazionale La valutazione delluso e della sicurezza dei farmaci: esperienze in Italia (Istituto Superiore di Sanità)
5. 29-30/11/2018 EUROPEAN PHARMACOVIGILANCE CONGRESS 2018 (Pharma Education Center)
6. 07/11/2018 Italian Pharmacovigilance Day 2018 (LS Academy  EASYB)
7. 06 - 08/06/2018 58° Simposio AFI "Attività ispettive e punti critici nelle ispezioni di Farmacovigilanza" (AFI - Associazione Farmaceutici Industria)
8. 27/02/2018 "Giornata di studio sulla Farmacovigilanza" (AFI - Associazione Farmaceutici Industria)
9. 13/11/2017 Secondo incontro con gli operatori della farmacovigilanza sulle novità della RNF e di EudraVigilance (AIFA, Ufficio di Farmacovigilanza)
10. 23-24/10/2017 Corso di Farmacovigilanza - novità del sistema di FV e di signal management (AIFA, Ufficio di Farmacovigilanza)
11. 14/03/2014 Good Pharmacovigilance Practice (GPvP) Symposium (MHRA  Medicines and Heakthcare Products Regulatory Agency - Londra (Regno Unito)
12. 30/01/2014 VI Corso di aggiornamento sui farmaci: gli scenari che cambiano Roma (SIF - Società Italiana di Farmacologia, SSFA Società di Scienze Farmacologiche Applicate)
13. 26/01/2013 Corso AIFA per Responsabili di Farmacovigilanza delle ASL (AIFA - Agenzia Italiana del Farmaco)
14. 23/01/2013 Le nuove pratiche di Farmacovigilanza (SSFA Società di Scienze Farmacologiche Applicate)
15. 16/11/2012 Basic EPITT (European Pharmacovigilance Issues Tracking Tool) training course (EMA)

2004- 2011 **Costant learning course in Pharmacovigilance**

European Medicine Acengy (EMA), Italian Medicine Acengy (AIFA), National Health Institute (ISS) ()

1. 10-11/02/2010 Training on the use of EPITT (European Pharmacovigilance Issue Tracking Tool) (EMA)
2. 27-31/10/2008 Corso Avanzato di Farmacovigilanza II Edizione (AIFA, Ufficio di

Farmacovigilanza)

3. 26-30/10/2007 Corso Avanzato di Farmacovigilanza I Edizione (AIFA, Ufficio di Farmacovigilanza)

4. 24/10/2006 Farmacovigilanza aggiornamenti 2006 (AIFA, Ufficio di Farmacovigilanza)

5. 2-3/05/2006 Riconoscimento e segnalazione di reazioni avverse da prodotti di origine naturale (ISS - National Health Institute)

6. 18-24/04/2005 XIII Corso Introduttivo di Farmacoepidemiologia (ISS - National Health Institute)

7. 24/09/2004 Corso di Farmacovigilanza 2004 (AIFA, Ufficio di Farmacovigilanza)

2010- Present

### EudraVigilance and EudraVigilance Data Analysis

European Medicine Acengy (EMA), London (United Kingdom)

Costant learning course in Eudravigilance & EudraVigilance Data Analysis

1. 20/02/2018 The new EVDAS functionalities and EVWEB

2. 15/12/2014 EudraVigilance Data Analysis System

3. 11/11/2013 PhV IWG training on PhV data analysis in 2013

4. 14/11/2012 Phv Inspectors Eudravigilance and EVDAS Training

5. 23/03/2011 Combined EudraVigilance & EudraVigilance Data Analysis System (EVDAS) training for Pharmacovigilance Inspectors

6. 12/02/2010 Training on the use of Attenuated EudraVigilance Data Analysis System (EVDAS)

November 2015- Present

### Costant learning course in Good Clinical Practice (GCP)

Italian Medicine Acengy (AIFA) and others (Italy)

1. 05/11/2019 Simposio GCP 2019 - Dalla ricerca della Qualità alla Qualità della Ricerca (AIFA - Ispezioni GCP)

2. 12/09/2019 Workshop - I Centri di fase I in Italia: il quadro attuale e i futuri scenari (AIFA - Ispezioni GCP)

3. 10/01/2017 Training -Ispezioni presso Centri di Fase I e presso CRO (AIFA, Ufficio Ispezioni GCP)

4. 23/11/2015 Symposium GCP (AIFA, Ufficio Attività Ispettive GCP-GVP)

May 2010- Present

### Costant learning course in Quality Assurance

GIQAR Gruppo Italiano Quality Assurance nella Ricerca, Società di Scienze Farmacologiche Applicate (SSFA) and Italian Society of Pharmaceutical Medicine (SIMeF) (Italy)

1. 2018 XXVII Congresso Nazionale GIQAR - Le GXP sulla Strada della Qualità

2. 2017 XXVI Congresso Nazionale GIQAR - Nuove Legislazioni e Tecnologie - La Sfida GXP Continua

3. 2016 XXV CONGRESSO NAZIONALE GIQAR - L'integrità dei dati e l'analisi del rischio e l'impatto GXP

4. 2015 XXIV CONGRESSO NAZIONALE GIQAR - La qualità e le GXP: l'asticella si sposta sempre in alto

5. 2014 XXIII CONGRESSO NAZIONALE GIQAR

6. 2013 XXII CONGRESSO NAZIONALE GIQAR

7. 2010 XIX CONGRESSO NAZIONALE GIQAR

October 2015- Present

### Assessor Benchmarking of European Medicines Agencies (BEMA)

European Medicines Agencies (EMA) (United Kingdom)

1. October 2015 - Benchmarking of European Medicines Agencies (BEMA), established by Heads of Medicines Agencies. Training for newly appointed assessors

2. September 2017 Benchmarking of European Medicines Agencies (BEMA) Seminar

December 2018- Present

### Costant learning course in Good Manufacturing Practice (GMP) for the manufacturing of active pharmaceutical ingredients (APIs)

Italian Medicine Acengy (AIFA) and others (Italy)

1. 11/11/2019 "Corso Interno Aide memoire: ispezione ai produttori di eparina grezza

Case study: criticità legate alla suplly chain di sostanze di origine animale"" (AIFA - Ufficio GMP API)

2. 30/10/2019 Corso Interno Monitoraggio Microbiologico delle cleanroom, Aggiornamento sui metodi di Microbiologia Rapida e Aggiornamento sul rilevamento delle endotossine" (AIFA - Ufficio GMP API)

3. 17-18/10/2019 SCUOLA DI FORMAZIONE FARMINDUSTRIA - Modulo Produzione e Supply Chain (FARMINDUSTRIA)

4. 27/09/2019 "Contaminazione particellare in cleanroom - PW&WFI" (AIFA - Ufficio GMP API)

5. 04/07/2019 Corso Interno Fitoterapici II parte (AIFA - Ufficio GMP API)

6. 21/06/2019 Corso Interno Fitoterapici I parte(AIFA - Ufficio GMP API)

7. 20/06/2019 Corso Interno "Ispezioni GMP ai siti di produzione di sostanze attive ed aspetti generali GMP. Solventi residui e start materials" (AIFA - Ufficio GMP API)

8. 19/06/2019 Corso Interno "Ispezioni GMP ai siti di produzione di prodotto finito e concetti GMP" (AIFA - Ufficio GMP MED)

9. 18/06/2019 Corso Interno "Procedure autorizzative e registrative per la produzione di sostanze attive, Produzione di sostanze attive per scopi sperimentali, Ispezioni GMP ai siti di produzione di gas medicinali (API e PF)" (AIFA - Uffici GMP API & GMP MED)

10. 07/12/2018 Safety features & Supervision of Medicine Traceability Systems (AIFA - Ufficio GMP API)

May 2018- Present

### Costant learning course in Falsified, illegal and stolen medicines

Italian Medicine Acengy (AIFA), Conseil de l'Europe, Società di Scienze Farmacologiche Applicate (SSFA) -Società Italiana di Farmacologia (SIF) - Agenzia Italiana del Farmaco (AIFA) ()

1. 03 - 04/12/2019 "Medicrime Workshop for GMDP and Pharmacy Inspectors (European Directorate for the Quality of Medicines & HealthCare Council of Europe - Conseil de l'Europe)10/05/2018 "Convegno sul Crimine

2. Farmaceutico: Identificazione, Contrasto ed Eliminazione" (Agenzia Italiana del Farmaco, AIFA - Società di Scienze Farmacologiche Applicate, SSFA - Società Italiana di Farmacologia, SIF)

September 2006-September 2006

### Learning course for regulators on MedDRA (Medical Dictionary for Regulatory Activities)

EMEA (European Medicines Agency) - London (UK) (United Kingdom)

Provide a basic understanding of the scope, structure, characteristics, and maintenance of MedDRA, and the relevant regulations concerning its use. In addition, provide an overview of coding with MedDRA and applications of MedDRA in data retrieval and analysis, including use of Standardised MedDRA Queries (SMQs) in safety signal detection and case identification

October 2015-October 2015

### Further training

ISoP International Society of Pharmacovigilance (Czechia)

15th Annual Meeting of the International Society of Pharmacovigilance "Cubism in Pharmacovigilance"

June 2012-June 2012

### Further training

ISoP International Society of Pharmacovigilance (Germany)

New EU Post-Licensing Legislation and Benefit-Risk Management

October 2011-October 2011

### Further training

ISoP International Society of Pharmacovigilance (Turkey)

11th Annual Meeting of ISoP

April 2011-April 2011

### International Society for PHarmcoepidemiology (ISPE)

Further training ()

Mid-Year Meeting International Society for Pharmacoepidemiology (ISPE)

October 2008-October 2008

### 31st Annual Meeting of Representatives of National Centres participating in the WHO Programme for International

WHO - World Health Organization, UMC - Uppsala Monitoring Centre (Sweden)

Impacting patient safety: Adverse drug reaction signal detection - Quantitative and qualitative approaches in screening healthcare data

December 1998-July 1999

### Theoretical and practical course in Allergy and Immunology in Pediatrics

Hospital Medical School of Rome and Lazio Region (Italy)

Prevention, diagnosis and treatment of allergic diseases that arise from childhood. Study of dietary factors, environmental and genetic factors. New drug, vaccines and other measures

December 1997-June 1998

### Theoretical and practical course in pharmacology and pharmaceutical legislation

Hospital Medical School of Rome and Lazio Region (Italy)

Drug activities, preparation and monitoring of dosage forms, national and community pharmaceutical legislation

September 1987-July 1991

### Post secondary school

Liceo Scientifico (Italy)

Post secondary school focusing on scientific training

## ADDITIONAL INFORMATION

Expertise

My expertise mainly is focus on activities related to human even if I have been participated for many years to the EMA's Inspector Working Group.

These are my main activities and responsibilities

- Senior inspector for Pharmacovigilance inspections (since 18.03.2010);

- Good Clinical Practice inspector in training (since 27.05.2019);

- Good Manifactur Practice API inspector in training (since 19.03.2019);

- BEMA assessor (Benchmarking of European Medicines Agencies established by Heads of Medicines Agencies, since 2017);

- Management of issues related to the theft, loss and diversion of medicines from the legal supply chain from a public health angle (2018-2020);

- European expert who can be involved in the Agency's work in the context of the authorisation, supervision and maintenance of medicinal products

for human or veterinary use;

- Italian alternate member at EMA's Pharmacovigilance Inspectors Working Group (PhV IWG) (2010 2019);

- Pharmacovigilance Inspectors Working Group (PhV IWG) liaison with the Eudravigilance Working Group (EV EWG);

- Rapporteur Guideline on good pharmacovigilance practices (GVP). Module I - Pharmacovigilance systems and their quality systems;

- Member of the EMA's subgroup "pandemic vaccines - distant /virtual pharmacovigilance (PhV) inspections of MAHs";

- Member of the EMA's subgroup for the organization of European annual training courses for pharmacovigilance inspectors;

- Lead of the PIC/S Joint Visits Program (JVP) dedicated to GVP -Group 126 (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S);

- Reporter and trainer as an AIFA manager, especially in the field of pharmacovigilance, inspections and quality in numerous conferences, symposia, training courses and university Masters;

- Liaising with Rapporteurs, the Member State competent authorities, pharmaceutical companies and academic centres - In the context of pre inspection all pharmacovigilance activities: signal detection, risk management and networking in pharmacovigilance, management and analysis of data/ information sources including, individual case safety reports (Rete Nazionale di farmacovigilanza and EudraVigilance data), DDPS, PSURs and studies;

- PROJECT TEAM LEADER of general antiinfectives medicines for systemic use (ATC J) (from 2005 to March 2010);

- Assessor of PSUR of general antiinfectives medicines for systemic use (ATC J) (from 2005 to March 2010);

- Responsible for managing the renewal of marketing authorization (from 2005 to June 2010);

- Responsible for designing and operating the online system for renewals of marketing authorizations granted prior to 1991 in collaboration with CINECA (Information Systems and Health-Interuniversity Consortium, Bologna);

- Responsible for planning and management system "date autorizzative" and Check Point Renewals MA in FRONT END AIFA in collaboration with CINECA (Information Systems and Health-Interuniversity Consortium,

Bologna);

- Member of the Board at the AIFA for the evaluation of the Convention on the "Communication on pharmacovigilance of medicinal products" (since 30.01.2009);

- Responsible for organizing secretary and documentation management working group for the establishment of effective anti-AIDS treatment accessibility on Italian soil;

- Responsible for the design and management section of the website AIFA on "Influenza A (H1N1) - vaccines, antivirals and pharmacovigilance;

- Coordination for the verification of non-renewal of marketing authorizations for the updating of

databases and for the preparation of relevant measures to be adopted.

Publications

BIF (Bollettino dinformazione sui farmaci - bimestrale dell'Agenzia Italiana del Farmaco) - contributo alla realizzazione del numero N. 4 Anno XVI Luglio Agosto 2009

Antibiotici, farmacovigilanza e resistenze batteriche stesura capitolo pubblicato nel Rapporto sulluso degli antibiotici 2009 dellAgenzia Italiana del Farmaco (AIFA) pag.77- 89

Mezzi di contrasto contenenti gadolinio e fibrosi sistemica nefrogenica: lazione regolatoria dellAIFA poster

Istituto Superiore di Sanità - XVIII Seminario Nazionale: La valutazione delluso e della sicurezza dei farmaci: esperienze in Italia. Roma 14 Dicembre 2009

ISTISAN CONGRESSI 09/C14 pag. 62

Donna e farmaci collaborazione alla raccolta dati per la stesura del capitolo pubblicato nel Libro verde La salute della donna dellOsservatorio nazionale sulla salute della donna pag.107- 124

Reazioni anafilattoidi da moxifloxacina stesura articolo pubblicato nel N. 4 - luglio 2007 del bollettino bimestrale di Farmacovigilanza dellAgenzia Italiana del Farmaco (AIFA) REAZIONI

REAZIONI - contributo alla realizzazione del numero N. 2 - aprile 2007 del bollettino bimestrale di Farmacovigilanza dellAgenzia Italiana del Farmaco (AIFA)

Aumento delle segnalazioni di sospette ADRs in Italia poster

Istituto Superiore di Sanità - XVI Seminario Nazionale: La valutazione delluso e della sicurezza dei farmaci: esperienze in Italia. Roma 10-11 Dicembre 2007

ISTISAN CONGRESSI 07/C9 pag. 73

Telithromycin and ocular reactions poster

6th Annual Meeting of the International Society of Pharmacovigilance (ISoP), Liegi, Belgio 11 - 13 Ottobre 2006

Drug Safety 2006, Vol.29, No.10 pag. 997

Analisi dei segnali: ceftriaxone stesura articolo pubblicato nel BIF (Bollettino dinformazione sui farmaci - BIMESTRALE DELL'AGENZIA ITALIANA DEL FARMACO) Anno XIII N.1 2006 pag. 28, 29

Fans tradizionali e rischio cardiovascolare: nella rete nazionale di farmacovigilanza ci sono segnali di allarme? poster

19/22 ottobre 2005 Catania, Congresso SIFO

Giornale Italiano di Farmacia Clinica,18, 3, 2005 pag. 236

"Relazione tra la spesa dei farmaci cardiovascolari in ambito ospedaliero e sul territorio" poster

XXX Congresso Nazionale della Società Italiana di Farmacologia, Genova 2 giugno 2001

Pharmacological research - Drug surveillance, pharmacoepidemiology and pharmacoeconomy, pag. 172

Il mercato delle vitamine, trend di crescita e possibilità di sviluppo pag. 36, 37, 38 Vitaminologia (Rivista Internazionale di Vitaminologia) Vol.17 Luglio Dicembre 2001

Projects

Memberships

Other Relevant Information

1) From 2010 to2016 at Florida University, Università di Roma "La Sapienza", Università di Chieti Pescara, Teacher in masters and specialization schools

2) Since 2001 up today lecturer and teacher in seminars and congresses and speaker in international training sessions such as at Central Drugs Standard Control Organization India, World Health Organization, Italian Medicine Acengy, European Medicines Agency, Danish Health and Medicines Authority, Farmindustria, Associazione Farmaceutici Industria, Assogenerici, Associazione Italiana Infermieri di Camera Operatoria Regione Sardegna, Istituti di Ricovero e Cura a Carattere Scientifico (I.R.C.C.S.) Burlo Garofalo di Trieste, Università di Siena -Regione Toscana, Ordine dei Farmacisti di SIENA - AUSL 7 - Ordine dei Farmacisti di Arezzo - AUSL 8, ASUR Marche Zona territoriale N.5 Jesi, Life Science ACADEMY, easyB, Gruppo Italiano Quality Assurance nella Ricerca, Società di Scienza Farmacologiche Applicate, Pharma Education Center, TEMAS, A Quintiles Company, ARITHMOS SrL