Curriculum Vitae

Betty Polikar, PhD
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Introductive Notes

Betty Polikar (PhD) has a solid experience in innovative drug development and a professional path characterized by early-onset Pharma environment where she developed skills and proficiency in all aspects of the Research and Development area (pre-clinical activities, project design and planning, regulatory profiles, Clinical Operations implementation and Pharmacovigilance obligations). Expert in international-global Team management (direct line and mentoring) she was also involved in global Quality Compliance programs, leading to a specific experience in GCPs and all other applicable guidelines and regulations related to clinical trials (such as, but not limited to, GLP, GMP, GXPs, etc..).
She had the opportunity to run and coordinate Clinical Development programs not only in Western Europe (France, Spain and Portugal, Germany, Netherlands, Sweden, Belgium, Austria, etc) but also in almost all the Eastern Europe Countries (Bulgaria, Rumenia, Czech Republic, Croatia, Russia, Lithuania, Latvia, Ucraine, etc) as well as in MENA, Africa (Sub-saharian Countries and South Africa), Switzerland and United States.
She dealt with international Regualatory Auhorities (FDA and EMA) as well as European Regulatory Authorities and National Regulatory Authorities, both to manage inspections and Scientific Advices and/or Hearings.
She had the opportunity to manage different types of Vendors (international and local CROs, Central Laboratories, International Transport/Logistics Companies, Radiopharmacies, CMOs, etc..) and therefore she had also experienced the management of external teams, when allocated to each study/project. This enabled the ability to interact with different types of organizations, technical backgrounds and different cultural profiles, having the necessity to integrate such groups in the actual organization working with.
She faced interesting challenges related to effective communication flows, implementation of KPIs and metrics, definition and evaluation of the risk in clinical development, definitions of Roles and Responsibilities, oversight of the activities and performance assessments.
Furthermore, Dr. Polikar's experience has been enriched when joining the Academic environment within which the Clinical Trial Center of the Policlinico Gemelli is located. During the last 3 years she had the opportunity to bring the clinical development logics and grammar into the academic world, in supporting the Clinicians with the development of original scientific ideas (i.e.. performing extensive medical writings). She has been involved in many applications to European funded projects (H2020, IMI, PRIN) as a partners or as a subcontractor, her organization has joined clinical national and international networks such as the German Oncologic Network (AIO), the Italian Oncologic Network (AIOM), ECRIN, as well as Patients Associations and Foundations (such as Parent Project, Eupati, Foundation Medicine, etc.).
She is the Team Leader of the implementation Project of the Phase I asset at the Policlinico Gemelli, according to the Italian law (Determina AIFA 809). She is representing the focus point of the Institution towards compliance to GxPs (i.e. GCPs, GLPs, GMPs, etc..).

Current Job Position

July 2017 – up to now
Institution: **Fondazione Policlinico Universitario A. Gemelli**
Location: Rome, Italy
Title: **Head of the CRO Unit of the Clinical Trial Center SpA, a subsidiary of the "Fondazione Policlinico Universitario A. Gemelli"** (under the direct reporting to the President of the "Fondazione Policlinico Universitario A. Gemelli")

November 2015 – July 2017
Institution: **Fondazione Policlinico Universitario A. Gemelli**
Location: Rome, Italy
Title: **Head of the Academic CRO of the Clinical Trial Center**

Professional Experiences

April 2012 – October 2015
Company: **Sigma –Tau, Industrie Farmaceutiche Riunite SpA**
Location: Pomezia (Roma)/Italy
Title: **Head of Clinical Operations, R&D Headquarters**

March 2010 – April 2012
Company: **Acraf SpA - Angelini Research Center**
Location: S.Palomba/Pomezia (Rome)/Italy
Title: **Head of Investigative Clinical Operations, R&D Headquerters**

March 2008 – 28 Feb 2010
Company: **Wyeth Lederle S.p.A. (Wyeth International Research, European R&D Headquarters)**
Location: Aprilia/Latina/Italy
Title: **Regional Study Manager**

December 2006 – February 2008
Company: **Wyeth Lederle S.p.A. (Wyeth International Research, European R&D Headquarters)**

Title: **Project Manager**

September 2003 – November 2006
Company:**Wyeth Lederle S.p.A. (Wyeth International Research, European R&D Headquarters)**
Location: Aprilia/Latina/Italy
Title: Sr. CRA and Regional Responsible and CRO Coordinator for Wyeth Project in the following Therapeutic Areas:
Neuroscience, Cardiology, Transplantation, Oncology, Internal Medicine

November 1999 - August 2003
Company: **Wyeth Lederle S.p.A (Wyeth International Research, European R&D Headquarters).**
Location: Aprilia/Latina/Italy
Title: **CRA (Clinical Research Associate)**

June 1999 – October 1999
Company: Bergamon S.r.l., Rome, Italy
Location: Rome
Title: **Product Manager**

February 1999 – May 1999
Company: ASA S.r.l., Rome, Italy
Location: Rome
Title: Responsible for the organization of national scientific Meetings and Lectures, with international experts.

Among the others:

- "Toward Zero Emission, the challenge for Hydrocarbons. International Symposium" (sponsored by Enitecnologie), Palazzo Colonna, Rome, Italy.
- L'EUR nel 2000: "Il Luogo delle Decisioni"
- "The new Centre for Meetings: presentation of a study on the environmental impact" (sponsored by SNAM progetti-Aquater)

1998
Assignee of research fellowship provided by the Fondazione Buzzati-Traverso, further to a national contest, for an individual research project to be developed with Pr. Giulio Cossu, at the at the Department of Medical Istology and Embriology, University *La Sapienza*, Rome , Italy.

1998
Cooperation with Pr. Giulio Cossu for the organization of the meeting titled "Group on the Regulation of Development", S.Miniato, Italy.

September 1997 – December 1997
Assignee of a contract for the purpose of cooperating with Pr. Giulio Cossu, at the Department of Medical Istology and Embriology, University *La Sapienza*, Rome, Italy, with employment of funds and resources offered by the Fondazione Buzzati - Traverso.

1996/1997
Assignee of AIRC (Italian Association for the Research against Cancer) fellowship, further to a national contest, to support an individual research project to be developed at the Laboratory of Molecular Biology, Polo Biologico, CNR (*National Centre for Research*), Rome, Italy.

1996
Cooperation with Dr. Marco Tripodi for the organization of a meeting focused on "Cooperation group for Molecular structure and Gene Expression",Cortona, Italy.

1995/1996
Research Trainee at the Laboratory of Molecular Biology, Polo Biologico, CNR (*National Centre for Research*, Rome, Italy) under the supervision of Dr. Maurizia Caruso, in order to apply for the state examination indicated above.

March 1990/June 1991
Research Trainee at the FIVET Center (*Center for the application of Human Artificial Insemination Techniques*), Policlinico Umberto I, Rome, Italy.

Education

2002
Institution: University "*La Sapienza*"
Location: Rome, Italy
Degree : *Specilization Magna cum Laude in Clinical Pathology (PhD)*

1995/2001
Institution: University "*La Sapienza*"
Location: Rome, Italy
School of Specialization in Clinical Pathology, University La Sapienza, Rome, Italy

1987/1994

Institution: University "*La Sapienza*"
Location: Rome, Italy

Faculty of Biological Sciences: **Degree Magna cum Laude in Biological Sciences**
Experimental thesis discussed under the title of "Regulation of transcription of RB Gene during muscle differentiation"
With respect to the referred thesis, from October 1991 until December 1994, attendance of pre-doctoral fellowship in the Laboratory of Molecular Biology of Dr. Armando Felsani, Cancer Institute, Regina Elena, Rome, Italy.

1987
Institution: Scientific High School *"Istituto Santa Dorotea"*
Location: Rome, Italy

Other Experiences and Competences

Academic Year 2017-2018, Faculty of Biotechnology, University of Tor Vergata (Rome): teacher of the course " Clinical Research", Methodology" , which is mandatory addressed within the specialization of Clinical Research (the course is administered in English). The ownership of the course is shared with the President of AIFA, Dr. Stefano Vella.

May 2018: organizer and speaker at the SSFA/SIMeF seminar entitled: ""Clinical Trial Centre e sperimentazione clinica, l'unione fa la forza?" Grand Hotel Palatino, Rome.

Academic Year 2017-2018 Master on Quality Systems GXP &ISO, Catholic University of Rome. Title of the course: "La Fase I Alla Fondazione Policlinico Agostino Gemelli: l'organizzazione in adeguamento ai sensi della Determina n. 809 del 19 giugno 2015

Academic Year 2017-2018, teacher of the **II level Master titled "International Master Degree in Gynecologic Oncology", Catholic University of Rome, Surgery and Medicine Faculty. Title of the course: "Clinical Trials".**

November 2017: organizer and speaker at the SSFA seminar entitled: "Il paziente al centro, esperienze a confronto". Servier Italian Headquarters, Rome.

November 2017: teacher of the following session: "Real life monitoring simulations" within the "TRAINING DI BASE SULLE GOOD CLINICAL PRACTICE (GCP) E SPERIMENTAZIONI CLINICHE" (Basic Training on Good Clinical Practices and Clinical Trials). Transcelerate certified. Fondazione Policlinico Universitario A. Gemelli, Roma

May 2017: teacher of the following session: "Real life monitoring simulations" within the "TRAINING DI BASE SULLE GOOD CLINICAL PRACTICE (GCP) E SPERIMENTAZIONI CLINICHE" (Basic Training on Good Clinical Practices and Clinical Trials). Transcelerate certified. Fondazione Policlinico Universitario A. Gemelli, Roma

March 2017: teacher of the training session "How to write a Monitoring Report: from planning of tasks to effective communication". Done for the CRAs and Project Managers of Synteract HCR Italia S.r.l. 4 November 2016, Rome, Italy

February 2017: teacher of the training session "Il Sistema Di Qualita' Di Fase I: Applicazione all'Unita' Clinica Di Fase I Di Neuropsichiatria Infantile", within the Phase I Traning Program of the Fondazione Policlinico Universitario A. Gemelli.

January 2017: teacher of the module "La Ricerca Clinica: dall'Assetto Regolatorio Classico all'Evidence Based Medicine within the course of " L'Evoluzione dello Sviluppo Clinico. Project e Data Management nei Progetti di Ricerca". Istituto di Fisiologia Clinica del CNR di Pisa.

Academic Year 2016-2017 Master on Quality Systems GXP &ISO, Catholic University of Rome. Title of the course: "La Fase I Alla Fondazione Policlinico Agostino Gemelli: l'organizzazione in adeguamento ai sensi della Determina n. 809 del 19 giugno 2015

Academic Year 2016-2017, Faculty of Pharmacy, University of Tor Vergata (Rome): teacher of the course "Experimental Methodology in Clinical Research", within the course of "Clinical Trials" , which is addressed as a second level specialized course within the long term Degree Program

Academic Year 2015-2016, Faculty of Pharmacy, University of Tor Vergata (Rome): teacher of the course "Experimental Methodology in Clinical Research", within the course of "Clinical Trials" , which is addressed as a second level specialized course within the long term Degree Program

November 2016:organizer and speaker at the SSFA seminar entitled:" Il flusso del farmaco sperimentale: che succede dietro le quinte", Rome Hotel Royal Santina.

November 2016: teacher of the module "Clinical Trials_Deep Dive" of the Training Course titled "Vascular Pathophysiology Clinical Excellence Trajectory", organized by the Cardiology Department of the Fondazione Policlinico Universitario A. Gemelli, 30 Noveember 2016.

November 2016: teacher of the following training course "Types of clinical trials in Italy and CRO involvement". Done for the CRAs and Project Managers of Synteract HCR Italia S.r.l. 4 November 2016, Rome, Italy

September 2016: teacher of the following module: ""La Fase I al Policlinico Gemelli", within the Phase I Training Program of the Fondazione Policlinico Gemelli. Fondazione Policlinico Universitario A. Gemelli, Roma, 30 September 2016

May 2016: teacher of the following session: "Real life monitoring simulations" within the "TRAINING DI BASE SULLE GOOD CLINICAL PRACTICE (GCP) E SPERIMENTAZIONI CLINICHE" (Basic Training on Good Clinical Practices and Clinical Trials). Transcelerate certified.
Fondazione Policlinico Universitario A. Gemelli, Roma

November 2015: teacher of the following session: "Real life monitoring simulations" within the "TRAINING DI BASE SULLE GOOD CLINICAL PRACTICE (GCP) E SPERIMENTAZIONI CLINICHE" (Basic Training on Good Clinical Practices and Clinical Trials). Transcelerate certified.
Fondazione Policlinico Universitario A. Gemelli, Roma

September 2015: teacher of the following training course :"The monitoring visit and the relevant reporting: how to prevent, document and manage of the serious breaches". Done for the CRAs and Project Managers of Synteract HCR Italia S.r.l. 30 September 2015, Rome, Italy

December 2014: teacher of the following training course: "Regulatory Inspections' Requirements: what is their impact on the monitoring activities of a clinical study?". Done for the CRAs and Project Managers of Synteract HCR Italia S.r.l. 18 December 2014, Rome, Italy

October 2012: teacher of the first level training course titled "La Sperimentazione Clinica nelle Aziende Sanitarie", organized by the Umbria's AZIENDA USL N°2, addressed to the physicians working in the sanitary area of the Umbria Region and covering the training of potential operators for clinical trials, as per the regional requirements in terms of periodic professional updates.

Languages

MOTHER TONGUE:
Italian

OTHER LANGUAGES
English
Reading skills: excellent
Writing skills: excellent
Verbal skills: excellent
French
Reading skills: excellent
Writing skills: good
Verbal skills: excellent

Spanish
Reading skills: excellent
Writing skills: basic
Verbal skills: good

Licenses/Accreditations

2015
Full registration in the National Register of Biologists

1996
Successful state examination for the registration in the National Register of Biologists

Professional Memberships

Member of SIMeF ("Società Italiana di Medicina Farmaceutica", previously named SSFA_Società di Scienze Farmacologiche Applicate) since 2000, **Member of the of the Board of Directors of SIMeF (SSFA) since 2017** and since Jan 2016 **Member of the Working Group of Pharmaceutical Medicine** within the SIMeF (SSFA) organization

Member of the **Scientific Committee of the "Regenerative Medicine Research Center (CROME)"**, the **Catholic University of Sacred Heart (Milan)**. Other Members of the Committee are: Prof. Franco Citterio, Prof. Benedetto Falsini, Prof. Felice Giuliante, Prof. Elisa Gremese, Prof. Giulio Maccauro, Prof. Antonio Gioacchino Spagnolo, Dr. Wanda Lattanzi, Dr. Antonietta Silini, Dr. Luciana Teofili.

Training Courses and Other Events

May 2018	Italian ePharma Day:"Ricerca Clinica 2.0. Aspetti strategici, organizzativi, infrastrutturali e di qualità".16 May 2018, Hotel Melia, Milan.
April 2018	SSFA National Assembly. 10 April 2018, Milan.
March 2018	Workshop on the European Data Protection Regulation (GDPR):"What's new in the pharmaceutical and sanitary environment". Life Science Academy, 6 March 2018, Milan.

November 2017	Workshop organized for the winners of the IIT AIFA National Fundings (for 2016 competition). AIFA location, 13 November 2017, Rome.
June 2017	Assemblea Pubblica di Farmindustria: "Next Generation Pharma Accelerazioni tecnologiche, centralità della persona, governance: l'industria farmaceutica a prova di futuro".21 June 2017, Rome
March 2017	XIV National Congress of SSFA titled : Alle porte del 2020:,la ricerca in Italia tra sostenibilità ed innovazione. 28-29 March 2017, Milan.
February 2017	GRUPPO DI LAVORO RICERCHE CLINICHE AFI: Ispezioni GCP ai centri di fase1, studi early phase e fattibilità locale (GCP Inspections at the Phase I Sites, Early Phase Studies and Local Feasibility) ASST Grande Ospedale Metropolitano Niguarda, 13 February 2017, Milan.
November 2016	"Simposio GVP AIFA sulle ispezioni di Farmacovigilanza" Organized by the Italian Regulatory Authority AIFA and Farmindustria (the Italian Consortium of the Pharmaceutical Companies). 15 November 2016, Rome
June 2016	Assemblea Pubblica di Farmindustria: "Imprese del farmaco e Ricerca.L'innovazione che cambia la vita" (Pharmaceutical Companies and Research. The innovation that changes life). Teatro Argentina, 23 June 2016, Rome.
June 2016	Member of the SSFA (Società di Scienze Farmacologiche applicate) Working Group of the Pharmaceutical Medicine organizing the Conference titled "Terapie avanzate: il vero futuro della medicina? (Advanced Therapies: the real future of medicine?) Fondazione Policlinico Universitario A.Gemelli, 21 June 2016, Rome.
May 2016	Workshop organized for the winners of the IIT AIFA National Fundings (for 2013 competition). AIFA location, Rome.
March 2016	"Sperimentazione Clinica di Fase I in Italia" (Phase I Clinical Trials in Italy). Organized by SIF and SSFA with AIFA participation. CNR Auditorim, 30 March 2016.
Febuary 2016	GIQAR (Gruppo Italiano del Quality Assurance nella Ricerca) Conference: a deep dive into the new European Regulation 536. Istituto di Ricerca Servier 23 February 2016.
January 2016	Member of the SSFA (Società di Scienze Farmacologiche Applicate) Working Group of the Pharmaceutical Medicine, organizing the Conference titled "Uso compassionevole del Farmaco: Il punto di vista degli stakeholders (Compassionate use: the stakeholders perspective). University "La Sapienza of Rome" Roma - AULA D - Plesso Tecce, 28 January 2016.
January 2016	"La Ricerca Clinica parla Europeo: la nuova sfida per Istituzioni ed Imprese" (Clinical Research speaks the European language: new challenges for Institutions and Companies). Organized by the Italian Regulatory Authority AIFA and Farmindustria (the Italian Consortium of the Pharmaceutical Companies), 21 January 2016.
November 2015	Simposio AIFA sulle GCP (AIFA Conference on GCPs). Organized by the Italian Regulatory Authority AIFA, Eventi Fontana di Trevi, 23 November 2015, Rome.
October 2015	"Le Nuove Frontiere nell'immunoterapia Dei Tumori: Realtà e Prospettive" (The new frontiers of tumor immunotherapy: reality and perspectives"). Istituto Superiore di Sanità,16 October 2015, Rome.
September 2015	"Il Nuovo Regolamento Europeo Sulla Sperimentazione Clinica: Aspetti Critici E Opportunità" (The new European Regulation on clinical trials: critical aspects and opportunities). Organized by SIFEIT. Auditorium of the Ministry of Health, 17 September 2015, Rome .
May 2015	"The New EU Regulation on Clinical Trials: Italian status". TFS, 22 May 2016, Rome.
November 2014	"Clinical Research Forum: le nuove sfide per la Ricerca Clinica (the new challenges for clinical research)". PEC (Pharma Education Center). 12 November 2014, Milan, Italy
November 2014	13th Annual PCT- Partnership in Clinical Trials Conference. 4-6 November 2014, Barcelona, Spain.
May 2014	"3rd Healthcare Summit: Sostenibilità e Nuovi Modelli per la Sanità del Futuro (Sustainability and New Models for the future Health System)", 28 May, Rome.
May 2014	**Chair (and Speaker)** of the 4th European "Outsourcing in Clinical Trial" Conference. 21rst and 22nd of May, 2014 –Bruxelles.

February 2014	"Clinical Trial Supply" Europe Conference – 26 and 27 February, 2014.
January 2014	"VI CORSO DI AGGIORNAMENTO SUI FARMACI: gli scenari che cambiano" (SSFA and SIF event) (Sixth Course on Drug Environment Update: changing scenarios). 30 January 2014, Rome.
July 2013	Specialized training sponsored by 'ENEA: "Calibration Activities and Accuracy Verification in Quntitative Imaging", Metro MRT International Project (Metrology for Molecular Radiotherapy). ENEA Headquarters in Rome, 5 July 2014.
June 2013	Refresher Seminar. "New horizons of the Clinical Research" edited by the " Gruppo di lavoro Medicina Farmaceutica della SSFA (Società di Scienze Farmacologiche Applicate)". 27 June 2013, Rome.
May 2013	"3rd Annual Outsourcing in Clinical Trials Europe Conference" 20 and 21 November 2013, Vienna, Austria
December 2012	Training on : "News on Regulatory Compliance : updates of the GxP Regulatory Regulations" Sigma-Tau.
October 2012	"IMD program for UN Industria. Aligning and Engaging People" specialized training course. Rome
January 2012	"PK studies: insights on how to design a pharmacokinetic study and how to use the PK parameters (from pre-clinical to clinical context)"
January 2012	"EMA guideline on bioanalytical method validation: the new issued version (July 2011)"
March 2011	"Compliance and Computer Systems Validation"_ PQE (Pharma Quality Europe)
February 2011	"Creazione del Valore (Creation of Value): from Cost Control to Cost Management" (AngeliniSchool of Management)
December 2010	Training session on the updated version (13.1) of MedRA Dictionary (ACRAF PV)
November 2010	"Quality systems for Pharmacovigilance Management" (ACRAF EU QPPV)
September 2010	"STATISTICS Methods and Applications" (Pr. Alessandro Giuliani_ sponsored by ACRAF)
June 2010	"il Budget per gli Studi Clinici" (IIR_ Istituto Internazionale di Ricerca)
February 2008:	"Problem solving" (sponsored by Wyeth International Research)
November 2007:	"Emotional Intelligence" (Coleman Model) (sponsored by Wyeth International Research)
Dec 2006 - Dec 2007	"New organizational Model: the Matrix"
Dec 2006:	"Project Management". SSFA/SDA Bocconi _ Milan (School of Management)
May 2005:	How to Organize Effective Meetings (sponsored by Wyeth International Research)
April 2004:	English for Effective Presentations (sponsored by Wyeth International Research)
June 2004:	Team Building (sponsored by Wyeth International Research)
September 2002:	Leadership Assessment (sponsored by Wyeth International Research)
March 2002:	*"L'inglese per la ricerca e la divulgazione medico-scientifica".* **"Unione Servizi Roma"**, in collaboration with the **"Unione degli Industriali di Roma"**

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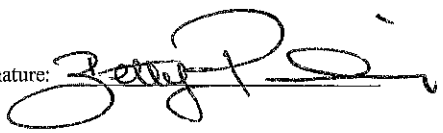
Signature: 

Date: 14 June 2018

14/June/2018