

Mirella Zaffuto

Project Manager at LA-SER Group

zaffuto.mirella@gmail.com

Summary

Excellent quantitative and analytical skills , mindful of the bigger picture as well as the smaller details, positive and professional approach to problem solving, quick learner and being able to gain understanding of different discipline, receptive to new challenges, tenacious, proactive, enthusiastic , energetic ,critical thinker and possess a hybrid skill set that spans both clinical-regulatory affairs and Health Economics-Health Policy.

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Therapeutic Areas of Expertise: Asthma and COPD, Chronic Severe Pain, Oncology Companion Diagnostics , Innovative Molecular Diagnostics in Microbiology, Radiotherapy, HIV / AIDS, Parkinson's Disease, Myelodysplastic Syndrome, Osteoporosis, Pneumococcal Vaccine, Prostate Cancer Therapies, Severe Depression, Idiopathic Thrombocytopenic Purpura, Leg Restless Syndrome.

Specialties: Pharmaceutical and Medical Devices Market Access Strategies, Primary and Secondary Research, Stakeholder Analysis, SWOT-Landscape Analysis and Evaluation, Pricing & Reimbursement and HTA Activities at National, Regional and Local Level, Budget Impact Analysis, Value Communications, Data Collection Models, Algorithm for attribution of therapeutic innovation, Italian Model to evaluate appropriateness and effectiveness of drugs, Pharmacoeconomics, Health Policy Analysis at National and Regional Level

Experience

Project Manager at LA-SER Research at LA-SER Group

January 2013 - Present (1 month)

Auditor at SIFEIT

April 2011 - Present (1 year 10 months)

SIFEIT -Società Italiana per Studi di Economia ed Etica sul Farmaco e sugli Interventi Terapeutici

Health Economics, Market Access, P&R Contractor Manager at LA-SER Analytica at LA-SER Group

October 2012 - January 2013 (4 months)

Advisor within the Global Market Access Network for a Consulting firm at Consulting Firm (confidential)

August 2012 - December 2012 (5 months)

Health Economist, Market Access & Value Communications Senior Regional Consultant at Independent

June 2012 - December 2012 (7 months)

- Real-Time PCR Applications:Regulatory Aspect, Analysis of Reimbursement Procedures at Regional Level and Market Access Strategies at Local Level.
 - Roadmap to Pricing and Reimbursement.
 - Primary and Secondary Research.
 - Payers,Service of Clinical Engineering and Superintendents - Treasurers of hospitals (Provveditori-Ekonomi delle aziende ospedaliere) research and mapping.
 - KOL interviews and workshops.
 - Market Research and Analysis on Opportunities and Challenges.
 - Data collection for pharmacoeconomic models.
 - Research and Analysis of HTA for Medicines, Medical Devices, Oncology Companion Diagnostics-CDx,Vaccines.
 - New product support and analysis :Analysis of Funding's procedures and Purchase's systems of drugs, medical devices, personalized medicine and predictive/prognostic biomarkers (as EGFR, K-RAS, BRAF V600) , inhaled respiratory medication-novel DP-MDI device at Regional and Local level.
 - Value propositions.
 - Publications (manuscripts, posters and abstracts).
- 1 recommendation available upon request*

Health Economist and Market Access Freelance Consultant at Temas S.r.l.-A Quintiles Company

October 2011 - June 2012 (9 months)

- # Review of Client's Needs to develop cost-effective solution with Pre-registration and post-registration Market Access Activities for identification of strategic levers that maximize the perceived value of product to healthcare decision-makers at national, regional and local levels,
- # Perform Landscape analysis and in-depth assessment of funding and purchasing process ,
- # Payer research to collect qualitative and quantitative data useful in order to prepare a global value dossier,
- # Conduct Primary Research:Selection of Sites, preparation of questionnaires for Italian discussions guide or adaptation of questionnaires for European discussions guide, telephone's interviews and face-to-face interviews at the Key Opinion Leader (Physicians, Medical Directors , General Manager of Hospitals,

Clinical Engineers, Supervisors of Health Funding),

Map and identify stakeholders at different level of government (national/regional/ local, both payers and influencers),

Planning and Organising a Workshops with key figures involved at various ways in the process of funding and purchase decision, that can help in designing the best strategies to enter or to improve the product Market access,

Synthesize findings from interviews and workshop ,

Perform strategic planning using a SWOT analysis,

Summary of market challenges,

Action plan for overcoming the market access and commercial hurdles,

Identify and prepare a Value Communications to the right audience who can influence reimbursement and funding decisions through the appropriate medium and relationships ,

Preliminary Meeting with HTA Agencies to discuss about the requirements for support HTA Client's submissions,

Confirm/revise and development of the key message that synthesizes the decision process and help to achieve/improve the access and the use of product(Drug, Tests, Medical Devices) for each payer type,
2 recommendations available upon request

Responsible for Pharmacoeconomic Working Group SSFA at Società di Scienze Farmacologiche Applicate

February 2008 - September 2010 (2 years 8 months)

- Presentation of the Group's activities on the SSFA webpage
- Speaker at Seminars on pharmacoeconomic topics
- Publication of Pharmacoeconomic articles in the Journal of SSFA
- Poster presentation "The economic value of the bisphosphonate drug (BFS) for the prevention and treatment of fractures (FX) osteoporotic: a review of the literature on compliance and persistence (C & P)" at the National Congress SSFA , 2008

Contract Professor in Legislation and Drug Registration at Università degli Studi di Ferrara, Faculty of Pharmacy

February 2003 - June 2010 (7 years 5 months)

I am full responsibility for the organization of the course, from the academic program to the evaluation of students .

This course is structured in three sections.

- The first section concerns the pharmaceutical legislation and the SSN structure and organization at national, regional and local level.
- The second section regards on the regulatory aspects and procedures for authorization of clinical trials and registration procedures both European and national level.
- The third part deals in -depth about the dimensions of Evaluations from the first section on the characteristics of the drug to the last section on the summary and place in therapy, Pharmacoeconomic techniques, Pricing and Reimbursement Procedures in Italy, assessment's process of Innovation according to the CTS algorithm of AIFA , the mechanisms of risk sharing agreement and the ISPOR European guidelines.

3 recommendations available upon request

CRA/ HE Local Project Coordinator at Kendle International

2006 - 2007 (1 year)

- Act as the main line of communication between the sponsor and the investigator
- Verifying that all research staff, facilities and investigational products have adequate qualifications and resources and these remain adequate throughout
- Responsible for the safety and proper conduct throughout the trial
- Verifying that the investigator follows the approved protocol and all GCP procedures
- Verifying that source data/documents and other trial records are accurate, complete, and maintained
- Adverse events, concomitant medications, and inter current illnesses are reported in accordance with the protocol on the CRFs
- Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator
- Participate in global conference calls and meetings to review progress of ongoing clinical trials.
- Participate at investigator's start-up meeting and Kick-off meetings.

Health Economics & Market Access Free Lance Consultant at PBE consulting SRL

2003 - 2005 (2 years)

Market Access and Health Economic Projects including:

- Value dossiers/ stories
- Literature reviews,
- KOL Interviews,
- Analysis of Landscape,
- Payer Reports
- Appropriate Research alongside Early Phase of Drug Development to determine payer needs, and what evidence to collect in clinical and outcome trials in Phase III and in Late Phase
- Appropriate Research Methodologies to Identify optimal prices,
- Cost of Illness Analysis

1 recommendation available upon request

CRA Administrative/Clinical Contract Specialist at PAREXEL

March 2001 - December 2001 (10 months)

Responsible for the start-up phases, Legal , Economic, Regulatory issues in order to finalize the Clinical Trials Agreement in accordance with the local regulations.

Economist and Management Advisory at FreeLance

June 1989 - February 2000 (10 years 9 months)

- Consultant in Micro and Macro Analysis, SWOT and PEST Analysis,
- Market Research and Analysis of competitors
- Strategic Project Management in different areas to create and implementing the value of client's company.
- Creation of reporting systems and performance measurement tools
- Drawing of business plans
- Definition of Key Performance Indicators (KPI)
- Compilation of balanced scorecards
- Financial statement analysis
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Adjunct Professor of Agro-Food Economics at University of Pavia/Faculty of Economics

June 1988 - December 1993 (5 years 7 months)

This course is designed to teach the fundamental concept involved in the marketing function of Agri-Food Industry.

The focus is on the Market Analysis and Marketing Strategies.

Case studies applied PEST Analysis, SWOT Analysis, Business Plan Framework, Boston Consulting Group (BCG) Matrix and Porter's Value Chain for building a competitive advantage strategies.

Skills & Expertise

Market Access

Pharmacoeconomics

Pricing

Stakeholder Analysis

Health Economics

Analysis

Research

Regulatory Affairs

Clinical Trials

Policy

SWOT analysis

(Expert, 10 years experience)

KOL Identification

(Expert, 10 years experience)

Payer Relations

(Expert, 10 years experience)

Italian Health System at Nazionale and Regional level

Academic Tutoring

Languages

Italian

(Native or bilingual proficiency)

English

(Professional working proficiency)

Publications

Sistemi di finanziamento e acquisto delle tecniche molecolari: i principali fattori che influenzano le decisioni

TEME-Mensile di Tecnica ed Economia Sanitaria April 2012

Authors: Mirella Zaffuto

Innovative technologies: Factors Influencing Financing Decisions in Italian Hospitals

ISPOR 15th Annual European Congress, Berlin November 5, 2012

Authors: Mirella Zaffuto, Anne Postulka, Sonia Allibardi

Education

ISPOR, International Society for Pharmacoeconomics and Outcomes Research

Post-Degree Ispor Short Courses,, Pharmacoeconomic Modeling-Advanced, Copenhagen, 2006 - 2006

University of Pavia/Faculty of Pharmacy

Post-Degree, Specialization in Regulatory Affairs, Faculty of Pharmacia with final mark 50/50, 1999 - 2002

Grade: Regulatory Affairs Professional (RAp)

Activities and Societies: This is the most complete School of Specialization in Pharmaceutical Regulatory Disciplines that providing the skills to 360 degrees on regulatory issues of clinical trials, registration procedures at EMEA and AIFA, pricing and reimbursement procedures and pharmacoeconomic's techniques, structured in courses that have 3 years duration.

Università Cattolica del Sacro Cuore/ Faculty of Economics

Post-Degree, Practitioner School of Business Consultant and Qualified Account, 1995 - 1998

Activities and Societies: It is a post-graduate business school to provide an excellent preparation in a typical accounting master's programme for a professional account qualification and a general business career

Università Cattolica del Sacro Cuore

Post-Degree, Economics of the Agricultural and Food System, 1989 - 1990

Activities and Societies: The SMEA Master offers an analytical and integrated vision of principal company functions, and development of the skills necessary to deal with organizational and managerial choices.

University of Pavia/Faculty of Economics

Degree in Business and Economics, Business Administration and Management, General, 1982 - 1988

1 recommendation available upon request

Liceo Scientifico "A.Sciascia" Canicattì (Ag)

Grade: Diploma di Maturità Scientifica

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8 people have recommended Mirella

"We collaborated with Mirella on a global P&R engagement. She was recruited as part of a global expert/payer panel - 26 countries. We found her to be knowledgeable, having great breadth and depth of the Italian healthcare system. She demonstrated an intimate awareness of the healthcare system's "state-of-nation". She was prompt and engaged. Her follow-up was timely and precise. And we sincerely enjoyed our personal interaction. Without hesitation we would recommend her services. Sincerely, Tuhin A. Rahman"

— **Tuhin A. Rahman**, was Mirella's client

"A couple of times I went back in 2012 to Mirella for assessing/discussing some tricky situations coming from my clients and related to Market access/Health Economic field. Thanks to Mirella I was able to come back in a timely manner, providing with a detailed report and good rationale behind some complex scenario. Thanks Mirella, I have appreciated your prompt feedback and the high standard of service delivered."

— **Vincenzo Lopreiato**, was Mirella's client

"“Mirella has a deep knowledge of the Market Access and HTA field and likes to know as much as possible of the client's project in order to give the best possible solution. She's constructive in her critic, always focusing on the client needs. It is very easy to work with her. Mirella is first of all a true lady and a nice person with a solid professional background and good relationship . I recognize her competence and her personal and professional integrity. Mirella is one of the few people in Pharmaceutical field who has a CONCRETE experience of Market access and HTA."

— **Nadia Peviani**, *Founder and Owner, Tamas S.r.l.*, was with another company when working with Mirella at Tamas S.r.l.-A Quintiles Company

"Mirella was my teacher in Legislation and Drug Registration at University of Ferrara, she has a great attitude to teaching and to supporting students to know work world. Thanks to her I have known the clinical researcher world, particularly the world of the CROs, in which I have started to work after the degree."

— **Matteo Barion**, *Student, University of Ferrara*, worked indirectly for Mirella at Università degli Studi di Ferrara, Faculty of Pharmacy

"Professore a contratto presso University of Ferrara Mirella è stata incaricata dalla Facoltà di farmacia dell'Università di Ferrara di un corso denominato "Legislation and Drug Registration", il suo insegnamento è

stato particolarmente apprezzato dagli studenti del corso di laurea in Chimica e Tecnologia Farmaceutiche (CTF) contribuendo alla formazione di questa figura professionale di chimico e tecnologo farmaceutico."

— **severo salvadori**, *Professore, University of Ferrara*, managed Mirella at Università degli Studi di Ferrara, Faculty of Pharmacy

"During the 4th class dr. Mirella Zaffuto was my teacher and thanks to her and her attitude of teaching I have knew the clinical researcher world. She had addressed me in this important field with particular suggestion for my career and future. I wish that young students can find teacher as Dr. Zaffuto that can be groomed their on work world that in Italy is very uncommon."

— **Valentina Poletti**, *Studente, Università degli Studi di Ferrara*, reported to Mirella at Università degli Studi di Ferrara, Faculty of Pharmacy

"I worked with Mirella in the past years, appreciating the contribution of her professional competence, as well as enjoying her positive approach to people and team-working. She is an experienced consultant who could bring excellent knowledge and insight into any project."

— **Patrizia Berto**, *Presidente, PBE consulting SRL*, worked directly with Mirella at PBE consulting SRL

"Mirella was my teacher at the University time and She was the first person where I spoke about clinical trials in the Academic course that She held here . Definitively Mirella was very experienced in her field and knows her market thoroughly. She helped me in the first steps moved into clinical research arena and suggested me important career strategies useful during my professional way. I wish Mirella the best and I am in no doubt that She will make a success of her career."

— **Vincenzo Lopreiato**, *Student, Università degli Studi di Ferrara*, studied with Mirella at University of Ferrara

[Contact Mirella on LinkedIn](#)