CURRICULUM VITAE

Lidia Strappaveccia born in Rome;

Married with 1 daughter;

1979 **Biology degree** with 110/110 cum laude .University of Rome;

1982 **Specialisation degree in Microbiology**, with 70/70 cum laude. University of Rome;

2017 **Executive Master in finance, administration and management control**. Gema Business school;

2017 On going: Master's Degree in Biotechnology for Environmental Management and Sustainable Agriculture;

1985 English language Proficiency diploma - Trinity College of London;

2014 French language level B1- Accord Ecole de Langues-Paris;

Address 1: Via Adige 20 Roma 00198

Address 2: Via Palazzo 2 Cennina Arezzo

Mobile 3356244905

WORKING EXPERIENCE DURING STUDIES

1976-1979	Daily morning attendance as internal student researcher at the Microbiology Department University of Rome Italy. Research on the antibacterial activity of Lactoferrin.
1976-1980	Daily afternoon attendance as apprentice in the Quality Control Department of ICAR LEO pharmaceutical plant, Rome Italy. Research with Prof Sermonti on genetic selection of Penicillin and Cephalosporin strains.

AFTER DEGREE

1979-1982	**Quality Control Analyst** I.C.L pharmaceutical plant producing β-lactam antibiotics trough fermentation and synthesis, ICAR LEO, Rome Italy.
1981-1982	**Researcher** for higher antibiotic production with strain genetically selected production at I.C.L. Rome Italy.
1982	**Responsible for the start up** of a new department of sterile products lyophilised and solutions, ISF plant, Rome Italy.
1983-1987	**Production Manager for the sterile products**, SKF, Rome Italy.
1988-1992	**Pharmaceutical production Manager** of Smith Kline Beecham, Rome Italy. 85 people and 8 different departments: Injectable liquid, Injectable Lyo, Injectable powder, Oral products, Ointments, Suppositories, Nasal Spray, Packaging.
1992-1994	Members of Smith Kline Beecham European Committee for "Continuous Improvements Program" for the European manufacturing operation cost saving program and processes rationalization.
1992-1994	**Quality Control/Quality Assurance Manager** at Smith Kline Beecham Rome Italy.
1995-1997	**Responsible for the project and the start Up of a new pharmaceutical manufacturing plant and Qualified Person** Biopharma S.r.l., Rome Italy. Lay-out definition, purchasing of instruments for CQ lab and pharmaceutical machines, recruitment of personnel. Training of the people incoming. Organisation of the quality system for the first Authority GMP approval. Start of the production for Third Parties, Injectables and Oral products.
1996-1998	**Technical Director and Qualified Person** Biopharma S.r.l. Customers contacts, new products incoming and transfer technology organisation Registration of generics products in Italy and France. Production of sterile vials and oral products.
1998 -2011	**Technical Director, Qualified Person and Plant Manager** BiopharmaS.r.l. Organisation of the quality system for FDA approval in Biopharma without consultants.
	Start up of Injectalia after the acquisition of ex Alfa Wasserman plant in Pomezia. Reorganisation of personnel and new quality system for obtaining the FDA approval.
	Registration of generics products for USA for Biopharma and Injectalia plants. Production of Interferon by human leucocytes bulk to be filled in ampoules. Production of Heparin syringes, diluent ampoules, Biotech vaccines vials.
	Start up of a new plant in Caserta. Lay out definition, new personnel recruitment, purchasing of production equipment and instrument for CQ .

Organisation of the quality system for obtaining the GMP authorisation and new customer contacts for start up the new packaging activities.

Start Up of Drug On
Acquisition of an ex Abbott Plant (API synthesis) situated in Liestal Basel, Planning of new API pipeline and integration of the quality system. Crystallization of oral API, production of Bulk API for many Customers.

2011-2015 **Technical Vice President and Qualified Person** , Orofino Pharmaceutical Group (320 people)

- Biopharma plant : β-lactam antibiotics finished products injectable and oral in S.Palomba, Rome Italy
- Injectalia plant: sterile products: syringes, vials, ampoules hemoderivates, biotech vaccines. Pomezia, Rome Italy
- K24 Pharmaceuticals plant: secondary packaging, quality control and warehouse. Caserta Italy
- Drug' on plant: chemical synthesis plant (ex Abbott). Basel Switzerland

Organisation of the Corporate system in order to harmonise the philosophy of the Contract Manufacturing Activities.
Organisation of Production, Regulatory, QA, QC, Purchasing, Product Development.
Getting new customer, organise their incoming and the relative transfer.
Maintaining the existing customers assuring the higher level of customers service.

2016- September 2017 **Corporate Business Development Director and Qualified Person**

Organisation and development of new products, new technologies, new customers.
Identify potential clients, research and build relationships with new clients.
Identify new potential products to develop and register..
Plan approaches and work with internal team to develop proposals that speaks to the client's needs, concerns, and objectives.
Plan, organize, direct, control and evaluate the budget and activities associated with new clients/new products/new technologies.
Present new products/technologies/services and enhance existing relationships.

2018 up to now **Technical Director and Business development Plasmalife srl**

Inspections received by the Authorities as a Qualified Person responsible for the audit

11/1995 AIFA Biopharma
1998 AIFA Biopharma
2001 AIFA Biopharma
2004 AIFA Biopharma

2005 Ministero Della Salute Veterinaria
2007 AIFA Biopharma
02/2009 AIFA Biopharma
07/2009 FDA Injectalia
09/2012 FDA Biopharma
06/2012 FDA Drug'on Basel
01/2014 AIFA Biopharma
02/2014 AIFA – ISS Injectalia
03/2016 AIFA Biopharma
04/2019 Ministero della salute Veterinaria "Il Ceppo"

Inspections received by Customers as a person responsible for the audit

1995 Eli Lilly in Biopharma
1998 Eli Lilly in Biopharma
2000 Pfizer in Biopharma
2002 Pfizer in Biopharma
07/2013 GSK in Biopharma
07/2013 Kedrion in Injectalia
07/2013 Kedrion in K24
10/2013 GSK in Injectalia
06/2014 GSK Biologicals in Injectalia
07/2014 Medimmune Astra Zeneca in Injectalia
02/2015 Thea in Injectalia
05/2015 Phanpharma in Biopharma
01/2016 Medimmune Astra Zeneca in Injectalia
06/2016 Sandoz in Biopharma
06/2016 GSK in Injectalia

Inspections conducted on suppliers as Inspector :

08/2007 Wockardt-Orchid-Aurobindo API INDIA
03/ 2012 Wockardt API INDIA
03/2014 Reig Joufre API SPAIN
04/2014 MSD Sward Dublin FP IRELAND
05/2014 Alfamatic Latina Packaging ITALY
10/2015 Sandoz API AUSTRIA
10/2015 Fermic API SPAIN
10/2015 Dobfar API ITALY
06/2016 Neotron Analytical Lab ITALY
03/2917 IDI FP ITALY
05/2018 Medica Packaging ITALY

Courses and Congress

1981	10/13/8	**"**The rules of metals in infiammatory desease" San Diego la Jolla University
1987	2-3/2	Sviluppo personale e manageriale attraverso il sistema "time manager"
1989	14-15/3	Lyophilisation Technology (Amsterdam)

1991 7-8/2	Cost Accounting course
1991 18-21/3	la gestione economico finanziaria dell'azienda
1991 27/3	La produttività totale
1992 7-8-9/7	Autosviluppo comunicazione e cambiamento in azienda
1992 all the year	Continuous Improvement Program, Facilitator Role
1993 all the year	MRP course
1993 9-10-11/11	Sterile Manufacturing Seminar
1995 2-4/6	IGPA conference
1998 3-5/6	IGPA conference
1999 2-4/6	IGPA conference
1999 1-2/12	IGPA conference "ISPE meet FDA"
2002 20/11	Sterile Drug Product produced by aseptic processing
2009 10/11	Investigators Meeting , centro nazionale AIDS
2011 1/12	I medicinali veterinari
2011 22-24/3	Aseptic Manufacturing Workshop
2011 6/4	Quality risk management Course
2012 14/2	Promuovere la medicina Traslazionale
2012 9/3	Challeges and Opportunities of the Italian Hub of Population Biobank
2013 12/9	la salute attraverso le strutture dedicate alla ricerca biomedica
2013 14/3	L'utilizzo dei medicinali plasmaderivati in Italia
2015 20/5	Info Day I medicinali Veterinari
2015 22-25/6	GSK Global Quality Aseptic Manufacturing Workshop
2016 25/11	Incontro Nazionale delle Persone Qualificate in ambito Farmaceutico
2016/17	Corso Executive Master in Amministrazione, Finanza e Controllo
2016 25/11	Congresso AFI
2017 on going	Master's Degree in Biotech. for Envir. Manag. and Sustainable Agriculture;
2017 13/12	Info day I medicinali Veterinari
2018 19/11	Uso Pratico di Eudravigilance
2018 21/11	Info day I medicinali veterinari
2018 19/07	Incontro sul principali tematiche di tecnica farmaceutica. Ministero Della Salute Veterinaria
From 1995 every year	Partecipation as exhibitor to the CPhI Worldwide, it is the world's leading platform that gathers pharma ingredients product manufacturers, suppliers and buyers. The event covers every step of the pharma supply chain from drug discovery to finished dosage, providing a unique environment for pharma experts to meet, learn, share and drive business throughout the year.

Published works

1980	"Presence of peptides containing alfa aminoadipic acid and valine in P.crysogenum" 6th International Fermentation Symposium, Ontario
1980	"Presence of peptides in fermentation broth of P. crysogenum" 1st international conference on biotechnology, Varna
1997	"An automated biosensor for fast microbial analyses" BCF

Associations

1981	Albo dei Biologi
Dal 1990	associazione AFI
Dal 1993	associazione ASCCA
Dal 2017	associazione Green Peace