

## PAULA HEATLEY ROBLES

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Mexican  
Mexican passport and USA  
Visa

**Químico Farmacéutico Biólogo**  
**(Pharmaceutical Biochemist)**  
(ULSA, September 2001)

Health Regulation for Medicinal Products  
Diploma, (UNAM/AFM. September 2006)

Pharmaceutical Administration Diploma,  
(Tecnológico de Monterrey. December 2001)

Digital Photography Diploma,  
(EduMac. November 2019)



### PROFESSIONAL EXPERIENCE

- August 2021 up to date. **MEDICAL WRITER**. Miramar Medcom. Production of health promotional content, clinical research publications, advisory board and consensus reports, marketing materials. Creation of conference abstracts and presentations. Manuscript proofreading. Copywriting.
- July 2007 up to date. **Freelance Specialized Translator. TRANSLATOR**. Spanish-English and vice versa. Translation and Translation Check of Software, Technical, Medical, Chemical and Scientific documents such as production records, audit reports, safety data sheets, analytical methodology, clinical studies protocols and reports, stability studies protocols and reports, Medical articles, between others. Among the main customers are Sanofi Aventis; Sanofi Pasteur; Merck S.A. de C.V.; Ares Trading S.A. (Uruguay) Avivia Pharma; Marie Stops; Laboratorios Exeltis; BioMarin.
- **Regulatory Affairs Consultant for the Pharmaceutical Industry**. Audit in the regulatory area for different laboratories. Dossier Integration for Drugs and Medical Devices. Strategies for the submission of applications for registration.
- August 2016 to November 2017 **Regulatory Affairs Consultant**. BioMarin. Configuration of the Registry Dossier. Monitoring of the status of registration procedures. Internal communication and with Central and South America.
- July 2009 to July 2014. **Regulatory Affairs Consultant for Oncology and biotech drugs**, Merck SA de C.V. Managing documentation related to the Health Registrations of Products for a new registration, renewal or modification. Reviser of translations and translation of medical and technical texts. Coordination of Bioequivalence Studies of the Company
- AstraZeneca S.A. de C.V. **Head of Pharmaceutical Development**. July 2004 to June 2007. Main activities: Development of OTC drugs: liquid, solid and semisolid dosage forms; development of suppliers; processes optimization and transfer; development of Standard Operating Procedures; Dossier integration for drug registration. Technical documentation management (development, quality, production) and medical (medical supplies, research protocols) Evaluation of the technical feasibility of new products or product line to be acquired. Direct work with marketing to strategies, research and market studies, among others. Presentation of projects for obtaining fiscal stimulus CONACYT. Inter-departmental coordination of activities for the introduction of new products
- Médica VRIM S.A. de C.V. **Research and Development Director**. March 2003 to may 2004. Main Activities: Development of the project of a line of supplements, formulation of various products, technical support; development of energy drinks, isotonic drinks and food supplements in liquid form. Coordination of Medical Group, been responsible for the staff, suppliers, etc; Vice Director of Ambulances area. Regulatory Affairs Advisory
- Boehringer Ingelheim-Promeco. Production Technology Chemist (Formulations). March 2002 to February 2003. Main activities: Reformulation of liquid products, suppliers development; optimization and transfer of process; development of Standard Operation Procedures; development of Manufacturing Procedure,

person in charge of the change controls of the plant (liquids), coordination of international projects; in charge of annual capacitation of GMP for the staff.

- Fortitech México. Head of customer service. June 2001 to January 2002.  
Main activities: Link between headquarters in New York and Mexico; logistics of imports of vitamin and mineral premixes, technical support of premixes of vitamins, minerals and special nutrients; sales operations. Major customers: Gerber, Bristol-Myers Squibb, Nestle.

### **TEACHING FUNCTIONS**

- August 2014 – July 2016. Chemistry IV Professor. Centro Universitario Anglo Mexicano.
- August 2013 – July 2014 Chemistry I and Chemistry II Professor. Instituto Piaget. CCH
- basic, intermediate, advanced first aid courses Instructor
- PHTLS (Prehospital Trauma Life Support) Instructor

### **PREHOSPITAL EXPERIENCE.**

- Refresher Course in Advanced Prehospital Care. Metropolitan Institute of Prehospital Care. May 2001.
- Humanitarian Supply Management System. April 2001
- Lifeguard Course. February to August 2000.
- 3rd Workshop handling anhydrous ammonia, Environmental Monitoring and respiratory protection. Mexican Red Cross, through the National School of Urban Rescue. January 16, 1999.
- Electrocardiography Course in Prehospital Medicine. September 1998. Taught by Dr. Gerardo Fernandez Illescas and the TUM Jose Antonio Martinez Gerard, by Advisory and Consulting in Medical Emergency and Rescue.
- EMT, Mexican Red Cross; from September 1997 to date.
- Advanced Course in Prehospital Trauma Life Support (Prehospital Trauma Life Support). Performed on the General Hospital Dr. Manuel Gea Gonzalez, June 1996.

### **Other Courses**

- Scientific and Medical Editing. July 2022.
- 15 Errors in Scientific Writing & How to Fix Them. May 2022.
- Seminar on Development Launch and Management of New Products and services. Strategic Management Inc. Ciudad de México, June 2007.
- Project Manager Intermediate. New Horizons. April 2007
- Market Research. Strategic Management International, Inc. Ciudad de México, January 2007.
- Drug clinical monitoring (Adverse Event Reporting, Pharmacovigilance). November 2006
- 1st Seminar coating immediate release. Colorcón. México. Mayo 2006
- X International Flavours Seminar. David Michael de México. Febrero 2006.
- Finance in operations. April 2005.
- Drug Product Registrations. November 2004.
- Performance Management Workshop. August 2004
- Effective Presentations. Diseño y Proyección Empresariales, S.C. November 2002.
- The most important first. Franklin Covey. April 2002.
- Youth Leadership. Centro Carsolio de Excelencia Motivacional. August 1999.
- Basic Course of Mental Dynamics. Asociación Latinoamericana de Desarrollo Humano. March 1999.
- Short stay within the "Youth to research" doing research program pharmacologically active herbal extracts.
- Course A Saturday with Cosmetic Chemistry. Cosmetologists Chemical Society of Mexico AC October 1998
- Faculty of Chemistry, Department of Language, Universidad Nacional Autónoma de México. French communicative. January 1998
- Faculty of Chemistry, Department of Language, Universidad Nacional Autónoma de México. Spelling and writing course in June 1997
- Emergency Medical Technician. Medical Centre, Universidad Nacional Autónoma de México.