# CURRICULUM VITAE: MIRIAM OJEDA LÓPEZ

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## CURRENT SITUATION

Currently employed as freelance, in charge of translating medical documents into spanish & english.

Five years experience: (3 years experience translating medical documents in Pharmaceutical Comp. as Regulatory Affairs Technician + 2 years experience as freelance translator)

Translations made during last 2 years:

- Letters\_clarifications for aemps

- SOP\_transfer of study

- SOP\_protocol deviations

- SOP\_standardized CV and training

- SOP\_pharmacovigilance. Management of the adverse events in trials

- Inner packaging (label)

- Outer packaging (box)

- Package leaflet

- Minimum particulars to appear on small immediate packaging units

- Particulars to appear on the outer packaging

- Summary products characteristics

- Brochure for medical device (for a truly tension-free repair of pelvic organic prolapse)

- Training module\_introduction to clinical research

- Brochure for a leading brand of infant feeding

- SOP for the definition of Job Position

- Brochure\_changing your lifestyle to improve your diabetes

- Economic analysis of recombinant activated factor VII versus plasma-derived activated prothrombin

complex concentrate in mild to moderate bleeds: Haemophilia registry data from the Czech Republic

- Acquired haemophilia\_considerations when using rFVIIa

- Growth Update\_A current awareness bulletin on Growth Hormone

- Important Safety Information\_ Breast implants

- Standard operating procedures\_Selection of Third Party Vendors

- Standard operating procedures\_Management of Misconduct, Fraud and Serious Breaches

- Clinical Study Protocol in the treatment of primary sclerosing cholangitis

- Web\_ for a leading European cell therapy company

- Reports Business & Financial Results

- Letter of the CREC\_clarifications

- Model Patient Information and Informed Consent in hepatitis C

- Clinical Trial Protocol in hepatitis C

- Body mass index for age

- Blood pressure ranges for children

- Medical events of special interest (MESI)

- Monitoring of calcitonin levels

- User Manual for an Optical measuring System

- Oral Stomatitis Daily Questionnaire

- Product monograph for a medicinal product in attention-deficit/hyperactivity disorder

- Treatment individualisation sumposium slide kit

- Sinopsis\_study to investifate the safety and pharmacokinetics of a medicinal product

- Business Update Financial Highlights

- User Manual for a medical measuring device for human eye examination

- Highlights of prescribing information for a medicinal product (extended-release tablets)

- Confidentiality agreement

- Confidentiality / Non-Disclosure Agreement

- Installation instructions for a medical measuring device for human eye examination

- Translation of change traced user manual

- Quick Startup Manual for a medical measuring Device

- Training Protocol for a diagnostic Device

- Brochure\_ How to position the patient and to perform a treatment

- Patient bed, Swivel\_Site Preparation

- Instructions, patient bed, Swivel\_User Manual

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## PROFESSIONAL EXPERIENCE

March 2011- **FREELANCE TRANSLATOR** ALL COUNTRIES

2013 (currently)

February 2008 **PHARMACEUTICAL INDUSTRY**  BARCELONA

- March 2011 **Function: Regulatory Affairs Officer.**

Great experience in International Regulatory Affairs.

Contacting Reference Member State and Concerned Member States.

Preparation and review of documentation (language: english).

Contacting the Health Authorities in each country (Slovenia, Finland, Norway,France...)

Translation and adaptation of National Texts following Referral with the help of translators (languages: Bulgarian, Polish, Slovenian, Finnish, German, Latvian, Lithuanian, Romanian, Dutch, French ...).

Translations for registers from spanish into english for expotation.

Review and translation of documentation from english into Spanish. Responses to questions raised by the regulatory authorities.

2005 – 2007 **NATURHOUSE** VALENCIA

**Function: Dietitian.**

Diet advice in patients with overweight and obesity.

Recommendations of nourishing complements.

2001 – 2004 **EXPERIMENTAL RESEARCH DEPARTMENTS** VALENCIA

**Function: Student Collaborator at University.**

Genetic Human and Microbiology Departments.

## TRAINING

**ACADÉMIC**:

1999 – 2003 **DEGREE IN BIOLOGY** University of Valencia. VALENCIA

2003 - 2005 **DEGREE IN BIOCHEMISTRY** University of Valencia. VALENCIA

**EXTRA-ACADEMIC:**

2007 - 2008  **MASTERS DEGREE IN PHARMACEUTICAL AND PARAPHARMACEUTICAL INDUSTRY** C.E.S.I.F. BARCELONA

2011 - 2013 **MASTERS DEGREE IN GENETIC COUNSELING** POMPEU FABRA UNIVERSITY, BARCELONA. CLINICAL ROTATIONS IN WASHINGTON D.C. UNITED STATES

2005 - 2007 **MASTERS DEGREE IN CLINICAL PHARMACOLOGY** GRUPO SYNTEX

2005 **POSTGRADUATE COURSE: NUTRITION AND DIETITICS** GRUPO SYNTEX

2004 **POSTGRADUATE COURSE: BIOMEDICINE, GENOMICS AND PROTEOMICS**

UNIVERSIDAD COMPLUTENSE MADRID

2005 - 2006 **PEDAGOGICAL APTITUDE COURSE (CAP)- I.C.E.** VALENCIA

1988 - 1998 **PIANO PEDAGOGY CERTIFICATE–Royal Conservatory of Music** ALBACETE

**INFORMÁTICS:** Windows, Microsoft Word, Excel, Acces, PowerPoint, Internet Explorer. MemoQ.

**LANGUAGES**: Spanish Native

English Advanced level

Short-term stays in English speaking countries having a good effect

on my attitude toward learning and using English:

* U.K.: London: english classes (1 month)
* U.S.A.: San Francisco& Las Vegas& NY, for one month: travel&tourism
* U.S.A.: Internship in Genetic Counseling in Washington D.C. (3 months)