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CURRICULUM VITAE

Education:

University degree in pharmacy at Zagreb University;
1998-2003

Grades average: excellent, among 5% of the best students of the College of pharmacy and medicinal biochemistry, University if Zagreb. Study period: 4.5 years.

Employment history:

PharmaVigil d.o.o. – owner and director, JAN2013-present
Services

Pharmaceutics: Regulatory affairs, pharmacovigilance, materiovigilance and pricing and reimbursement for the area of Croatia, Slovenia, Bosnia, Slovakia, Chech Republic, Hungary, Bulgaria, Romania, Turkey, Malta.
Human and veterinary medicinal products, medical devices, food supplements.

References: RB, Ariello, Unimed Pharma, AGFA, Logenex GmbH, Aurobindo Ltd, CSL Ltd, Novartis Vaccine.

Translations of life science texts: EN-CRO, CRO-EN, EN-SER, SER-EN, ENG-FR, FR-ENG, SLO-CRO, CR-SLO, ITA-FR. FR-ITA, EN-BOSNIAN, BOSNIAN-EN

Experience in chemical and pharmaceutical patents: More than 200 000 words (antipsychotics, oncological products, medical devices).

Translation projects (most important ones from 2001 till 2015):

End Clients:

1. **Immatics biotechnologies GmbH, Germany,Ingelheim Boehringer GmbH – patents (cancer vaccinology, immunology), clinical studies, SOPs – (approx. 30 000 words)**
2. **Beckmann Coulter – IVD devices**
3. **Zimmer Inc. – Joint prostheses manuals (approx. 100 000 words)**
4. **Omron – BP monitoring devices (approx. 15 000 words)**
5. **Otsuka Inc. – clinical trial documents (10 000 words)**
6. **Biogen Idec – clinical trial documents (10 000 words)**
7. **LifeScan Inc – glucometeres manuals (5000 -10000 words)**
8. **Pfizer Inc – clinical trials documents (approx. 10 000 words)**
9. **Elly Lily – clinical trial documents/promotive materials (15 000 words)**
10. **Synarc and Wyeth – clinical trials documents (10 000 words)**
11. **GEHC – RTG scanners, CT scanners – around 1 500 000 words**
12. **Nellcor – respirators (adult and neonatal) – 100 000 words**
13. **Beckmann Coulter – IVD devices – around 100 000 words**
14. **QRD documentation – harmonization of PI with QRD templates for more than 200 medicinal products**

References: Moravia IT, Lionbridge, Corporate Translations

Farmavita Regulanet Ltd. September 2009 – december 2012

international project manager and qualified person for pharmacovigilance - dealing with different clients in the area human and veterinary medicinal products, medical devices and food supplements. Pricing and reimbursement activities for generic products. Pharmacovigilance activities for innovative products (narcotics) – for small and medium generic companies.

Elly Lily - pharmacovigilance - subcontracted deputy for SEE+Malta+Cyprus, 2008-2009

- monitoring, collecting, processing and e-submission of the ADRs from the area of SEE via SAP programme (ARGUS) to the national authorities and to the manufacturer (Elly Lily)
- observing local laws and regulations
- implementing ADR monitoring systems for newly established clinical trials
- PSURs/ASRs submissions

Veterina d.d. (Part of Pliva) - Quality assurance associate (GMP and GLP implementation) for veterinary vaccines and oral preparations:

- validation of manufacturing procedures of oral preparations
- daily check-up and revision of production documentation (working and
- maintenance SOPS, control forms)
- dealing with reclamations - annual quality reviews for vaccine products
- solving the OOS results - preparations of documentation for external audits and inspections

Krka d.d., Novo mesto, SI- Regulatory affairs associate SE Europe

- preparation of files for submission to the national authorities in Bulgaria,Romania and Croatia (NtA format for renewals and CTD for new productsnCADREAC
- procedure) both for Rx and OTC products,

- obtaining notifications for cosmetics
- observation of local and EU laws
- solving deficiency letters
- PSUR submissions

Novartis Vaccine, CSL Ltd AU - representative office Zagreb- Drug regulatory affairs and pharmacovigilance – SEE Europe

- local drug regulatory affairs manager for Croatia and Slovenia - biologicals
- submission of documentation (Type I and type II variations, new products, line extension - national registrations) to the local authorities in Zagreb and Ljubljana
- running of MRP procedures in Slovenia - factor IX, subcutaneous immunoglobulines (first on the market)
- local pharmacovigilance activities - retail pharmacist (responsible person for drug storage and distribution)
- observing local and EU laws and regulations

State exam 2004 - volunteer in a hospital pharmacy

Languages:

English – excellent
Turkish – beginner
Spanish and German – intermediate
Serbian and Slovenian – very good

Sterling School of Business English, Ljubljana, Slovenia
SOVA, School of foreign languages Zagreb
Studentski centar zagreb, School of foreign languages

CPE Exam - June 2007, British Council, Zagreb
German and Spanish-intermediate, Slovenian, Serbian -very good, Turkish -intermediate

Additional skills:

PC use in MS office programs, Adobe Acrobat Professional, use of Internet, e-mail, online invoicing systems, document management systems (Sharepoint, KnowledgeTree, Documentum, Citrix, SAP), PhV applications (Argus, PV247),
CAT tools: SDL Trados 2007 and 2014, Wordfast Classic, Wordfast Pro, MemoQ, XTM, Agito, Tstream Editor, Passolo, WorldServer, Microsoft localization tools, Across.

PV driver's licence
ECDL diploma - July 2008

Hobbies:

Swimming, travelling, history, literature, volunteering in children hospitals and shelters

Personal data:

Marital status: single

Additional pharmaceutical education:

1. Croatian mark in the EU – Šibenik, November 2014
2. Croatian Pharmacopoeia – online use, HALMED, March 2014, Zagreb
3. Registration of herbal medicinal products – HALMED, December 2013, Zagreb
4. Registration of herbal preparation, HALMED, December 2014
5. EU 28: science, medicines, health - A regulatory system fit for the future", 6-7 May 2013, Dubrovnik, Croatia
6. New trends in pharmaceutical sciences, Zagreb Faculty of pharmacy, June 2012-11-02
7. Together with HALMED to the EU – December 2012
8. Nutrivigilance and differences between OTC and food supplements, HALMED Zagreb September 2012
9. Materiovigilance in Croatia – HALMED Zagreb, October 2012
4. EVMPD training - EMA, London, january 2012
5. World Drug Safety Congress - London, September 2011
6. 2nd Congress of health ecology, Zagreb 2011
7. Reinforcing patients safety conference- Zagreb, 2011
8. EMA training (Zagreb, August 2010) - Reporting of the individual ICSRs in the EEA-Zagreb, September 2010
9. International subsidiary day -Orion Pharma, Finland, May 2010 - Principles of veterinary pharmacovigilance
10. Risk-sharing and value-based models of pharmacoeconomy, Bratislava, Slovakia - April 2010
11. 1st Croatian congress of pharmacoeconomy with international participitaion Rijeka, Croatia, April 2010
13. Good Pharmacovigilance Practice-Vukovar, Croatia, 2008
14. Good GMP settings - internal education by Veterina Ltd 2006
15. lst Croatian regulatory affairs congress with international participitation-2005
16. Internal regulatory affairs educations - Krka Ltd, Slovenia - 2005
17. International regulatory seminar, Ljubljana, Slovenia, January 2005
18. Internal pharmacovigilance course - Novartis Vaccine. Mainz, Germany - 2004
19. Annual EUFEPS congress, Sweden 2002

Aug 2016

Maja Barać