

### PERSONAL INFORMATION **Viola Csomor**

#### WORK EXPERIENCE

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February 2015-July 2016

#### **Regulatory Affairs Associate**

Teva Pharmaceutical Works Ltd. (Hungary)

- Preparation of Module 3 sections for sterile liquid products, sterile lyophilized products and eye drops (CMC maintenance)
- Handling of variations in EU, USA and other regions
- Categorization of the variations
- Providing regulatory documentation for variations such as registration of site transfers, changes in manufacturing process, validation documents, variations in testing methods of the active substance or the excipients
- Communication with RA colleagues from other sites or external partners

August 2016-April 2017

#### **Technology & Scientific Affairs Specialist**

Teva Pharmaceutical Works Ltd. (Hungary)

- Manufacturing process validation of small volume parenterals
- Support in routine production process
- Writing of master manufacturing batch records
- Involvement in investigation of deviations connected with manufacturing

May 2017-April 2020

#### **QA Specialist / QA Engineer**

Xellia Pharmaceuticals Ltd. (Hungary)

- Taking part in the organization and preparation for Customer audits and HA inspections
- Learning Management SOP (Learning Management at Xellia, Learning Management with electronic Learning Management System), Administrator role at electronic Learning Management System
- Cleaning Validation SOP management, cleaning validation concept, validation activities (protocol and report preparation)
- Pest Control SOP (Pest Management Program), QA supervision
- Revision and Approval of Equipment qualification documentation
- Taking active part in qualification activities on new built stability climatic chambers
- Revision and Approval of analytical and microbiological method transfer protocols and reports
- Deviation, CAPA, Change Control management and approval

May 2020- Present

#### **Quality Assessor**

National Food Chain Safety Office - Directorate of Veterinary Medicinal Products (Hungary)

Member of Pharmaceutical Department, assessing variations and applications for marketing authorisations of veterinary medicinal products from quality point of view. Participating in National and EU procedures as well.

#### EDUCATION AND TRAINING

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September 2007-June 2012

#### **Gradual education - Pharmacist**

Semmelweis University Faculty of Pharmacy & University of Szeged Faculty of Pharmacy (Hungary)

Thesis: Modern technologies of aseptic manufacturing - TEVA scholarship program

September 2012-August 2014

#### **PhD student**

Semmelweis University Department of Pharmacodynamics (Hungary)

Studies in pharmacokinetics with HPLC-EC, HPLC-UV/DAD analytical methods

September 2015-September 2018

#### **Postgraduate program in Industrial Pharmacology QA Specialist**

Semmelweis University Faculty of Pharmacy (Hungary)

Thesis: Preparation of cleaning validation concept for an API Manufacturing Site

Expertise

Publications

First Author of Article:

HPLC Analysis and Detection of Deprenyl

Viola Csomor, Rudolf Laufer, Zita Postenyi, Huba Kalasz, Ernest Adeghate, Syed M. Nurulain, Kornelia Tekes, A. Adem

Acta Chromatographica

Congressus Pharmaceuticus Hungaricus conference in Budapest

Posters:

- New validated bioanalytical method of determining l-deprenyl with RP-HPLC-EP detection
- Pharmacokinetic analysis of l-deprenyl in rats

Projects

Memberships

Other Relevant Information