

## Curriculum vitae for translations

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### Education:

- **1994-2000:** University Medical School of Pécs

### Former and current jobs:

- **Oct. 2000- Jul. 2002:** Sales representative, Servier Hungaria Kft. (French pharmaceutical company)
- **Aug. 2002- Dec. 2003:** Product manager, Servier Hungaria Kft. (9-week international marketing training program in English)
- **Jan. 2004 - May 2010:** Fellow cardiologist, University of Debrecen, Centre of Medical and Health Sciences, Institute of Cardiology
- **May 2010- Nov 2014:** Specialist in cardiology, University of Debrecen, Centre of Medical and Health Sciences, Institute of Cardiology
- **Dec 2014** – entrepreneur cardiologist in outpatient care and private practices in Debrecen and Budapest
- **Nov 2014** – doing a self-financed training program in cardiovascular MRI at the Cardiovascular Imaging Department, Cardiovascular Center, Semmelweis University, Budapest
- **January 2008-:** freelance medical translator and as of 2009, medical translation agency owner

### Language skills with regard to language exams:

- International advanced exam in English (Cambridge Proficiency in English)
- International intermediate exam in German (Goethe Institut, Zentrale Mittelstufenprüfung)

- Intermediate exam in medical English (University Medical School of Pécs, Department of Medical English)

#### **Computer skills:**

- ECDL (European Computer Driving License) exam
- Advanced user in everyday applications (Microsoft Office)
- Advanced SDL Trados Studio 2017 Freelance (computer-assisted translation tool) user

#### **Work-related language skills:**

- 2005-: Involvement in education of both cardiology and electrocardiography for medical students in English, continuous self-education in cardiology and related topics from web sources and textbooks, all this in English.
- 2006-: Participation in clinical trials at my workplace as a co-investigator (PLATO-Astra Zeneca, IRIS - Servier ICTR), doing all study-related administration and communication in English.
- 2015-: Translation of university lecture notes in ECG for foreign medical students participating in the English training program of the University of Debrecen (appr 300 pages)

#### **Translation experience:**

- 2008-: Official translator working for **ME Trial Masters Kft.** (contract research organization, now a branch of **Zeincro Ltd** in Central-Eastern Europe), the translated documents involve all study-related documentation (discharge summaries, outpatient treatment reports, various medical procedure reports, autopsy reports, death certificates, patient information sheets, informed consent forms, study correspondence such as regulatory authority approvals, cover letters, subject information sheet and informed consent form amendments, etc.) Among clients are included: **Servier Inc., Hoffmann-La Roche Inc., Elpen Pharmaceuticals Co. Inc, Corthera Inc., Falk Pharma GmbH., Zambon Spa., PPM Services**  
**ME Trial Masters Kft.** was one of our biggest partner creating a high proportion of our turnover until 2013, as they ran three large translation projects for **Servier Inc.** involving **large-volume pharmacovigilance translations** (practically all SAEs and

endpoints) related to three major cardiovascular trials (SHIFT, BEAUTIFUL, SIGNIFY) with ivabradine

- 2009-: Official translator working for **Argint International Ltd.** (contract research organization), among clients are: **Actelion Pharmaceuticals Ltd.; Boehringer Ingelheim RCV GmbH.; Pharming Technologies B.V.; PAION GmbH.; Aires Inc.; Cardio3 BioSciences; DermaTools GmbH.; MedImmune Limited (a member of the AstraZeneca family of companies); Karyopharm Therapeutics, Inc.; Daiichi Sankyo Pharma Development; MediWound, Ltd, Viking Therapeutics, Inc.; Idorsia Pharmaceuticals;** Main translation areas: protocol synopses, main or substudy-related subject information sheets, informed consent forms, study correspondence, clinical trial agreements, etc.
- 2011-: Translation partner and approved vendor of **PRA Hungary Ltd. Phase I Unit** (contract research organization), with business partners like **Daiichi Sankyo Development Ltd; Rexahn Pharmaceuticals Ltd.; XencorInc.; Boehringer Ingelheim RCV GmbH; UCB Celltech (a subsidiary company of UCB Pharma SA); F. Hoffmann–La Roche Ltd**
- 2011-: Medical translation reviewer for **Boehringer Ingelheim Hungary Ltd.** (review of translation of linagliptin global training material for Hungarian sales representatives)
- 2012-: Contracted translation partner of **Boehringer Ingelheim Hungary Ltd.** in medical translations related to regulatory affairs (EMA Summary of product characteristics, Patient information leaflet translations), strategic division (eg. new IMPs in oncology and idiopathic pulmonary fibrosis), and marketing materials (eg. for Pradaxa)
- 2012-: Contracted translation partner of **Well PR Ltd.** (Hungarian PR and advertising agency), cooperating in translation jobs related to public or professional medical communication of drugs (eg., Pradaxa, Jentaducto, afatinib, nintedanib, anti-HCV drugs of **Boehringer Ingelheim**), website medical texts of **B.Braun Health**
- 2013-: Contracted translator and approved vendor of **Global Clinical Trial Operations (GCTO), MSD Pharma Hungary Ltd.**, involved in study-related translations of the company
- 2014- Contracted translator for **Eli Lilly and Company**, executing the translation project related to a training material of their newly approved oral antidiabetic agent

(200 pages in diabetology); and, as of 2017; we have an annual contract for pharmacovigilance translations

- 2015- Contracted translation partner of the Hungarian branch of **KCro** (Polish CRO), and being involved in study-related translations. Among sponsor are: **Novartis**, **XBiotech Germany GmbH**
- 2015- Translation partner of **AmVac AG (Swiss vaccine manufacturer)**, executed translation projects: clinical trial project documents for Swiss management as well as related business correspondence with Hungarian subsidiary's manager
- 2016- Translation partner of **GCP Services s.r.o (Czech CRO)**, cooperating in translation projects of study-related documents for Hungarian study sites as well as regulatory correspondence plus study-related legal contracts and agreements
- 2017- **Orion Pharma** – translation of marketing materials for levosimendan (Simdax, acute heart failure medicine)
- 2017- **Wendon Kft.** – subcontractor for a Hungarian translation agency in life sciences translations
- 2017- Translation partner of **Pfizer (Hungarian Affiliate)**, cooperating in translation, transcription, and medical writing projects in anticoagulation (for Eliquis, a DOAC).

Total number of characters translated (*proof-read or reviewed in brackets*) in this field so far: **appr. 25 Million (10 Million)**.

Translations performed both from **HUN** into **ENG** and **ENG** into **HUN**, as required individually. GER-HUN and GER-ENG translations in life sciences are an option; however, my current market has not needed it yet.

**Therapeutic areas** translated so far (including, but not limited to): cardiology, pulmonology, dermatology, immunology, hematology, oncology, gastroenterology, diabetology, neurology, stem cell therapy, pharmacoeconomics, as well as study-related legal texts/administrative proceedings

**Fields of professional interest:**

- Healthcare, life sciences, medicine, cardiology, clinical trials (all phases), pharmacovigilance

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Mikle Robert MD, Company manager