Curriculum Vitae

Personal Information

Name: **Regina Brůhová Michalčíková**

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Nationality: **Czech**

Date of birth: **27. April 1988**

Higher education

▪ 2012 - present	PhD study: Physical Chemistry **Charles University in Prague** Faculty of Science Passed exams including Cambridge English: Advanced (CAE), Physical Chemistry, Analytical Mass Spectrometry Passed final PhD state examination in physical chemistry, 12 October 2015 Dissertation thesis title: New mass spectrometric methods for trace gas analysis of human breath
▪ 2010 – 2012	MSc study: Environmental chemistry **Charles University in Prague** Faculty of Science Diploma thesis title: Formation of nucleobases from formamid initiated by high-power density energy events
▪ 2007 – 2010	BSc study Environmental chemistry **Charles University in Prague** Faculty of Science Bachelor thesis title: Determination of enantiomers of amino acids by HPLC

Work Experience

▪ 5/2018-present (during maternity leave)	Triamed s.r.o./T.M.E Solutions s.r.o. **Medical and Scientific support** ▪ Cooperation with individual pharmaceutical companies (LEO Pharma s.r.o., Ferring Pharmaceuticals CZ s.r.o., Mylan Pharmaceuticals s.r.o.) in the matter of: o Preparation of the scientific articles for peer reviewed journals o Preparation of scientific information materials o Preparation and managing of the non-interventional studies (NIS set-up, preparation of relevant materials, submissons, negotiation with authorities and medical entities (ethical committees etc.), negotiation with HCPs)
▪ 8/2016-present	Roche s.r.o., Prague, Czech Republic **Local Quality Responsible** ▪ Independent responsibility for implementation of global quality standards to the local environment, ▪ Ensuring that all GxP governed activities and documentation are delivered

according to the highest standards of quality and efficiency (focus mainly on GCP/GVP)
- Promoting quality and compliance excellence within the local affiliate by embedding quality principles throughout the organization
- Conducting of professional trainings for all internal stakeholders and responsibility to keep skill level and knowledge up-to-date
- Maintaining and updating highly organized records within internal database
- Close cooperation with HQ of the company, cross-functional communication across all involved departments of the company
- Participating on the international projects
- Conducting of the regular Quality Management Reviews
- Leading of the Local Quality and Compliance Office (the cross-functional governance and decision-making Committee for compliance and quality topics and processes related issues at the affiliate level)
- Organization of the regular Quality Boards on local level (informing Leadership Team about the QA related topics and local situation)
- Keeping oversight with regard to GxP Service Providers
- Deviations and CAPA management
- Implementation of new tools for improvement of the Quality Management System
- Audit and Inspection support and management (experience with the State Institute for Drug Control Inspections – Marketing, Pharmacovigilance, Distribution; GCP/GVP audits, FDA BioEquivalence inspection)

- 10/2013 – 7/2016 Astellas Pharma s.r.o., Prague, Czech Republic

Quality Assurance Manager, DSO Back-up / Medical Department

- Management of Quality Assurance activities in the Czech Republic/Slovakia.

The details of the role are available below.

+ Addition of the Drug Safety Officer agenda:

Maintenance of the local PV System:

- Management of the local PV system and related PV Quality Management System in accordance with local and regional PV regulations and with Astellas Global, Regional and local policies and procedures
- Ensure that local procedures for all PV activities are in place and kept up to date
- Monitor, review, and implement PV regulations for the country/region and communicate any changes to DSO Management, EU-QPPV, the Regional PV Office and/or other local business functions, as applicable
- Ensure a mechanism is in place for 24/7 availability to enable appropriate handling of potential urgent safety issues by the affiliate
- Participate in PV audits/inspections at the affiliate and assist in developing CAPAs in response to findings/observations with guidance from DSO Management and the QA department
- Facilitate early detection of potential safety issues and subsequent timely reporting to the relevant Regional stakeholders (e.g. in Europe the EU-QPPV has to be included)
- Forward communications from local competent authorities to the Regional PV office and work with the Regional PV Office and local Regulatory Affairs to ensure appropriate response are presented to local competent authorities, where applicable
- Participate in the development of safety monitoring and reporting plans for local clinical trials
- Maintain oversight of locally outsourced PV activities
- Ensure local initiatives such as company sponsored websites and other digital media, registries, and marketing initiatives are reviewed for compliance with PV requirements and Astellas PV procedures

- Ensure local post marketing programs (e.g. Post Authorization Studies [PAS] or market research, post marketing surveillance [PMS]) protocols are reviewed for compliance with PV requirements, as applicable
- Initiate and manage local activities related to the implementation of risk minimization plans, if applicable
- Perform other PV-related activities as requested by the DSO manager

PV Awareness Training:

- Ensure implementation, annual delivery, and documentation of Product Safety Awareness training to affiliate staff (e.g. Medical Information, Sales Rep, receptionists) and if applicable to third party personnel providing PV-related services, and if applicable to other staff within the territory
- Liaise with DSO Management for approval of local training materials used for the PV Awareness Training, if applicable

Product Safety Information handling:

- Ensure spontaneous and solicited reports from the country/region are collected, translated, processed and forwarded to designated Regional PV Office (e.g. DSP, PSP, API-PV) or contractual partners according to required timelines and quality
- Ensure follow-up of Product Safety Information is conducted and documented as required per relevant procedures.
- If applicable perform submission of Individual Case Safety Reports (ICSRs) to national competent authority, concerned ethics committees, investigators and/or contractual partners within the regulatory timelines
- Have a system in place to log and track Product Safety Information
- Ensure filing, storage and archiving of Product Safety Information
- Be aware of the system(s) in place for the handling and tracking of e.g. medical information inquiries and product quality complaints and ensure reconciliation with other Astellas operating units (e.g. Medical Information and Quality Assurance) and contractual partners, as applicable
- Ensure local literature searches for Product Safety Information are conducted according to the relevant procedures.
- Support submission of Periodic Safety Update Reports (PSURs) and other PV documents to local Health Authorities (if applicable)

Compliance:

- Ensure compliance with local and regional PV regulations and Astellas policies/procedures and take corrective and/or preventive actions, when needed
- Ensure timely implementation of new or revised PV-related regulatory requirements in the country/region
- Collaborate with the Regional PV office for process improvement initiatives and corrective and preventive actions identified by the Regional PV office
- Monitor ICSRs compliance and take the necessary corrective and/or preventive actions locally for late reporting
- Report compliance and other PV-related information as requested by DSO management to DSO management

Safety Data Exchange Agreements / Due diligence:

- Review local language contracts for the inclusion of appropriate AE exchange agreement details.
- Liaise with the Regional PV office for the development of Safety Data Exchange Agreements (SDEAs) impacting the country/region
- Ensure qualification of vendors is conducted and periodic audits are requested, in consultation with DSO management and Clinical Quality Assurance (CQA) (e.g. external archiving facility)
- Participate in due diligence activities for local country licensing agreements if

applicable

- 7/2012 – 10/2013 Astellas Pharma s.r.o., Prague, Czech Republic
  Quality Assurance Officer / Medical Department

  - Co-ordination of QA activities in the Czech/Slovak affiliate
  - Maintaining contact with customers and manufacturing sites in relation to QA activities of products which are distributed in the territory
  - Activities connected with a role of Qualified Person (QP) for distribution
  - Preparation of the QA action plan with regard to QA activities to be performed within the fiscal year
  - Conducting of the management review process (including preparation of the Annual Review Report)
  - Artwork Change management, Control of packaging materials of the delivered products
  - Local Change Control Management
  - Management of product quality complaint handling system and risk handling with regard to pharmaceutical technical defects
  - Mock-Recall and Recall activities management
  - Management of locally discovered Deviations
  - Management of CAPAs which emanate from the deviation system, and from other sources, such as audits and inspections
  - Training of affiliate personnel in the requirements of the Quality Management System such as complaint handling procedure, deviation handling procedure etc. and maintaining training records
  - Supporting GMP and GDP Audit schedules, audits of relevant COMs and LSPs with regard to GMP/GDP activities and coordinating of external GMP and GDP Regulatory Inspections
  - Management of the Good Distribution System within territory (GDP operations and the warehouse management)
  - Inspection readiness
  - Self-inspections
  - Coordination of repackaging activities
  - CMO and License Partner Management
  - Preparation and maintenance of Quality /Technical Agreements with Astellas group manufacturing plants and business partners such as local CMOs, LSPs
  - Review of the relevant Product Quality Report/Review
  - Implementation of QA Manual
  - Establishing and maintenance of local SOPs and guidelines reflecting AQAM, Global/Regional SOPs/guidelines and local specific regulatory requirements
  - Cooperation with PV and RA Department and Logistics
  - Communication with Authorities as necessary in regard to QA aspects
  - Co-operation with QAE Department (esp. escalation of any discovered significant quality events)

  + Process Training Manager Role:

  - Coordination of the authoring, review or maintenance of new or revised Quality Documents (support the group to identify needs for local Quality Documents to be written if any, coordinate and/or create new or updated local Quality Documents for Medical Affairs/Medical Department related activities, facilitate stakeholder review and/or contribution of global and/or regionally driven QDs, coordinate periodic review of local QDs).
  - Involvement in review process of regionally or globally driven Medical Affairs Quality Documents.
  - Participation in or contribution to the global or regional work streams for Quality

	Documents. ▪ Coordination of training activities at local level (communication of training needs and opportunities between global/regional training and the affiliate, communication/coordination of training of affiliate and external staff, roll out of training on QDs to affiliate staff according to relevant Training role Matrix.
▪ 10/2010 – 7/2012	Astellas Pharma s.r.o., Prague, Czech Republic Assistant to Medical Director &Regulatory Manager / Medical Department Administrative support to Medical Director and Regulatory Manager: ▪ Keeping and coordinating the agendas of Medical Director and Regulatory Manager ▪ Logistics concerning correspondence (draft letters in EN/CZ, correspondence filing) ▪ Assurance of local procedures (order forms, payments, bookings, travel arrangements) ▪ Arranging of departmental meetings + recording minutes of the meetings ▪ Preparing budget lists-expenses, working with SAP program ▪ Maintaining of the Personal File for Medical Department (General folder + Personal folders obtaining Training Records, CVs, Training Programme etc), distribution of the relevant trainings within Medical Department based on instruction from MAE. ▪ Support to Regulatory Manager with preparation of the local documents and submission packages (new registrations, renewals, variations) either in electronic or paper form, control and proof-reading of the Product Information (SPC/PILs) and packaging materials/artworks)
▪ 5/2012-present	J. Heyrovský Institute of Physical Chemistry of the CAS, v. v. i. Prague, Czech Republic Department of Chemistry of Ions in Gasous Phase Postgraduate student, preparation of the thesis
▪ 10/2010 – 5/2012	J. Heyrovský Institute of Physical Chemistry of the CAS, v. v. i. Prague, Czech Republic Department of Spectroscopy Undergraduate student, preparation of the thesis

Publications and Patents
▪ M. Ferus, R. Michalcikova, V. Shestivska, J. Sponer, JE. Sponer, S. Civis: High-Energy Chemistry of Formamide: A Simpler Way for Nucleobase Formation, J. Phys. Chem. A, 118, (2014) 719-736.
▪ R. Bruhova Michalcikova, P. Spanel: A selected ion flow tube study of the ion molecule association reactions of protonated (MH^+) , nitrosonated (MNO^+) and dehydroxidated $(M\text{-}OH)^+$ carboxylic acids (M) with H_2O, Int. J. Mass Spectrom., 368 (2014) 15-22.
▪ M. Ferus, D. Nesvorny, J. Sponer, P. Kubelik, R. Michalcikova, V. Shestivska, JE. Sponer, S. Civis: High-Energy Chemistry of formamide: A unified mechanism of nucleobase formation, PNAS, 112 (3) (2015) 657-662.
▪ R. Bruhova Michalcikova, K.Dryahina, P. Spanel: SIFT-MS quantification of several breath biomarkers of inflammatory bowel disease, IBD: A detailed study of the ion chemistry, Int. J. Mass Spectrom., 396 (2016) 35-41.
▪ R. Bruhova Michalcikova, K.Dryahina, P. Spanel: A detailed study of the ion chemistry of alkenes focusing on heptenes aimed at their SIFT-MS quantification, Int. J. Mass Spectrom., 425 (2018) 16-21.
▪ R. Bruhova Michalcikova, K. Dryahina, D. Smith, P. Spanel, Volatile compounds released by Nalophan; implications to SIFT-MS and other chemical ionisation mass spectrometry analytical methods, Rapid Communication in Mass Spectrometry, In press, 2019, Accepted 13th September 2019.

Conference proceedings and poster presentations
▪ **IABR Summit Vienna 2015** - IABR'S 10th anniversary conference 14-16 Sep 2015 Presentation of results in the form of poster: SIFT-MS quantification of several breath biomarkers of inflammatory bowel disease, IBD: a detailed study of the ion chemistry.

Language skills
▪ English language: advanced (Certificate of Advanced English)
▪ German language: basic

Other skills and competencies
▪ Good experience in the area of audits and inspections (SÚKL inspections in the area of: marketing, pharmacovigilance, distribution, quality, devices; FDA inspection of clinical trials, company audits and audits of 3rd sites)
▪ Auditor training for GDP, GMP, GCP and GVP
▪ IRCA Certified ISO 9001:2015 Lead Auditor
▪ Ability to operate a PC, work with different programs
▪ Ability to work team-oriented and co-operate at all levels of organization, ability to lead and motivate people
▪ Knowledge of relevant EU and local legislation in the relevant areas
▪ Driving licence (category B)
▪ Knowledge of the QP role and possibility to be nominated as a QP.

Hobbies
▪ Science (physical chemistry and medicine)
▪ Sport (horse riding, running)
▪ Literature, traveling, family and friends

Sign off		
Regina B. Michalčíková	**Date: 15.9.2019**	**Signature:**