Curriculum Vitae

Personal information

Maja Lusina Kregar

Work experience

Quality Assessor, Principal Advisor for Documentation Assessment
Nov 2018 – present
HALMED (Croatian Agency for Medicinal Products and Medical Devices), Croatia

- Assessment of CTD Module 3 (Quality) ducumentation in marketing authorisation applications - national, DCP and CP procedures
- Assessment of variations
- Scientific advice
- Member of QWP ESEC
- Participation in QWP drafting groups for regulatory guidelines

Assistant Professor
Mar 2022 – present
Faculty of Medicine, University of Rijeka, Croatia
Nominal title (without employment)

- Teaching students of the Pharmacy study programme (MPharm)
- Teaching topics: analytical development, pharmaceutical development, stability testing, quality control, regulatory guidelines, pharmaceopoeias, CTD documentation

Principal Scientist, R&D Analytical Project Leader
Jul 2013 – Nov 2018
PLIVA Croatia Ltd., Croatia (member of TEVA Group)

- Leading the analytical R&D team from early drug product development to regulatory submission and approval
- Development of new generic drug products for various markets
- Pharmaceutical development, analytical development, biopharmaceutical characterization

Researcher Analyst; Senior Researcher Analyst
Dec 2000 – Jul 2013
PLIVA Croatia Ltd., Croatia

- Analytical development in generic R&D: analytical method development and validation, analytical support in formulation development, preparing and reviewing registration documentation for new product submissions
- Dissolution testing
- Stability testing of drug substances and drug products

Education and training

Formal education

PhD in Pharmaceutical Sciences
Dec 2000 – Feb 2016

Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia

- Thesis title: Development of an in vitro release test for topical microparticle systems

Master of Pharmacy
Sep 1995 – Sep 2000
Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia

Training / Professional Development

- Clinical trials evaluation (on site training), ANSM, 14 Apr 2025, Paris, France
- 10th BBBB Conference on Pharmaceutical Sciences, EUFEPS, 12-14 Sep 2024, Tartu, Estonia
- European Federation of Pharmaceutical Scientists Annual Meeting, EUFEPS, 31 May - 02 Jun 2023, Lisbon, Portugal
- Developing clinically relevant dissolution specifications for oral drug products, Academy of Pharmaceutical Sciences, Jan - Aug 2021, online course
- A-Z of sterile products manufacture, NSF International, 12-16 Apr 2021, online course
- Global registration and life cycle management for APIs, ECA and Concept Heidelberg, 10-12 Mar 2020, Vienna, Austria
- Quality – Drug substance and drug product, Atrium and University of Copenhagen, 04-06 Nov 2019, Copenhagen, Denmark
- Quality by design (QbD) in pharmaceutical development, University of Copenhagen, 19-23 Aug 2019, Copenhagen, Denmark
- Parenteral Products, European Continuing Education College, 22-23 Nov 2016, Zagreb, Croatia
- Modified release for solids and parenterals, CfPA, 16-17 Jun 2014, Zagreb, Croatia
- Modified release for parenteral products, Diane J. Burgess, 10-11 Apr 2014, Zagreb, Croatia
- Stability testing: Regulatory considerations for worldwide submissions, Pharmaceutical Training International, 06-07 Nov 2013, Zagreb, Croatia
- Dissolution Course, Vivian Gray and Nikoletta Fotaki, 23-24 May 2013, Zagreb, Croatia
- Application of Surfactants for Formulation of Aqueous Drug Suspensions, The Center for Professional Advancement, 09-10 Nov 2011, Zagreb, Croatia
- Workshop on dissolution, biowaivers and bioequivalence, American Association of Pharmaceutical Scientists, 03-04 Oct 2011, Zagreb, Croatia
- Practical HPLC Method Development, Crawford Scientific, 24-25 Jun 2008, Wythenshawe, UK
- Workshop on BE, BCS and Beyond, American Association of Pharmaceutical Scientists, 21-23 May 2007, North Bethesda, USA
- International regulatory workshop on bioequivalence and dissolution, FIP, EUFEPS, AAPS, 19-20 Oct 2006, Budapest, Hungary
- Stability Testing in Pharmaceutical Industry, European Compliance Academy and Concept Heidelberg, 28-29 Nov 2002, Barcelona, Spain

Additional information

Publications

Scientific papers

- Jug M, Hafner A, Lovrić J, **Lusina Kregar M**, Pepić I, Vanić Ž, Cetina-Čižmek B, Filipović-Grčić J. An overview of in vitro dissolution/release methods for novel mucosal drug delivery systems. J Pharm Biomed Anal 147 (2018) 350-366
- Jug M, Hafner A, Lovrić J, **Lusina Kregar M**, Pepić I, Vanić Ž, Cetina-Čižmek B, Filipović-Grčić J. In vitro dissolution/release methods for mucosal delivery systems. ADMET DMPK 5(3) (2017) 173-82
- **Lusina Kregar M**, Dürrigl M, Rožman A, Jelčić Ž, Cetina-Čižmek B, Filipović-Grčić J. Development and validation of an in vitro release method for topical particulate delivery systems. Int J Pharm 485 (2015) 201-214
- Dürrigl M, **Lusina Kregar M**, Hafner A, Šegvić Klarić M, Filipović-Grčić J. Mupirocin calcium microencapsulation via spray drying: feed solvent influence on microparticle properties, stability and antimicrobial activity. Drug Dev Ind Pharm 27 (2011) 1402-1414
- **Lusina M**, Cindrić T, Tomaić J, Peko M, Pozaić L, Musulin N. Stability study of losartan/hydrochlorothiazide tablets. Int J Pharm 291 (2005) 127-137

Active participation in scientific conferences

- Jurić Simčić A, Reljić I, Erak I, **Lusina Kregar M**, Cetina-Čižmek B, Hafner A, Filipović-Grčić J. Optimization of the formulation (W/O emulsion) designed for pharmaceutical spray-drying process. EUFEPS Annual Meeting, Athens, Greece, 2018 (poster presentation)
- Jug M, Hafner A, Lovrić J, **Lusina Kregar M**, Pepić I, Vanić Ž, Cetina-Čižmek B, Filipović-Grčić J. In vitro dissolution/release methods for novel mucosal drug delivery systems. 6th World Conference on Physico Chemical Methods in Drug Discovery, Zagreb, Croatia, 2017 (oral presentation)
- **Lusina Kregar M**, Rožman A, Cetina-Čižmek B, Filipović-Grčić J. Influence of process parameters and composition on water content and hygroscopicity of mupirocin microparticles. 10th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Glasgow, UK, 2016 (poster presentation)
- Bartolec M, Pranjić J, Radošević S, **Lusina Kregar M**. Implementation of Analytical Quality by Design approach to RP-HPLC method for dissolution testing. 4th World Conference on Physico Chemical Methods in Drug Discovery and Development, Crveni Otok, Croatia, 2015 (poster presentation)
- **Lusina Kregar M**, Dürrigl M, Rožman A, Jelčić Ž, Cetina-Čižmek B, Filipović-Grčić J. Development of antimicrobial wound dressings: spray dried mupirocin microparticles. 10th Central European Symposium on Pharmaceutical Technology, Portorož, Slovenia, 2014 (poster presentation)
- Dragić T, Jelčić Ž, **Lusina Kregar M**, Mirić S. HPMC matrix tablets swelling properties as a prediction tool for gliclazide release behavior by texture analysis. 7th Central European Symposium on Pharmaceutical Technology and Biodelivery Systems, Ljubljana, Slovenia, 2008 (poster presentation)
- **Lusina M**, Jurlina S, Pozaić Frketić L, Mihoci M. Stability testing of Sildenafil tablets. World Congress of Pharmacy and Pharmaceutical Sciences, 65th Congress of FIP, Cairo, Egypt, 2005 (poster presentation)
- **Lusina M**, Jurlina S, Dumičić A, Dragić T. Stability Testing and Selection of Final Packaging for Pravastatin Tablets. World Congress of Pharmacy and Pharmaceutical Sciences, 64th Congress of FIP, New Orleans, USA, 2004 (poster presentation)
- **Lusina M**, Cindrić T, Tomaić J, Ballian D. Stability Study of Losartan Potassium and Hydrochlorothiazide tablets. 5th Central European Symposium on Pharmaceutical Technology and Biotechnology, Ljubljana, Slovenia, 2003 (poster presentation)

Projects

Memberships

Other Relevant Information

- Member of QWP Support group for revision of ICH Q6 (Specifications)
- Member of QWP Drafting group for Q&A on interpretation of Ph. Eur. 2.2.46 (Adjustment of chromatographic separations test procedures)
- Member of QWP/MWP Drafting group for response to the CMDh request on in-vitro dissolution of modified release products in release media containing alcohol
- Member of EU Expert group on ICH Q2/Q14 (Validation of analytical procedures and Analytical procedure development