Curriculum Vitae

Personal information

Lidija Makarova

Work experience

1. Employer: Joint Stock Pharmaceutical Company "Grindex"
   - Start date: 091983
   - End date: 052004
   - Position: Senior Chemist_Analyst of Standardization Laboratory, Head of Standardization Laboratory, Head of Regulatory Affairs Department
   - Activities: Standardization Laboratory as Senior chemist_analyst: working out of various analytical procedures and testing documentation, test methods validation, performing of stability studies, working out of documentation for quality control (Standard Operating Procedures, Instructions, In_house Standards and so on), elaboration of Drug Master Files for therapeutically active substances, working out of Chemical_Pharmaceutical Documentation (Part II/Module 3) of Registration documentation and regulatory procedures of medicines. From 1997 _ Head of Standardization Laboratory, :responsible for Laboratory job connected with preparation of registration dossiers – Chemical_Pharmaceutical Documentation, testing of validation performed by other Laboratories, supervising of Stability studies for the finished products, checking of analytical methods standardization. From 1998 _ Head of Regulatory Affairs Department: responsible for preparation of registration dossiers for new registrations, renewals, variations for Baltic Countries, CIS and Eastern Europe countries, planning of registration submissions, as well as supervising of registration process in above mentioned countries.
   - Country: Latvia
2. Employer: _ Latvian State Agency of Medicines
   - Start date: May 2004
   - End date:
   - Current Position: Latvian State Agency of Medicines; Senior Expert of Compliance Evaluation Department
   - Activities: Quality expert responsible for evaluation of Module 3 of marketing authorization submissions within National, DCP and MRP (new registrations, renewals, variations), preparation of Assessment Reports for the finished products and active substances when Latvia is acting as the Reference State in DCP/MRP. Member of ASMF WG since 2011 till 2016. EDQM Expert in CEP procedure since 2012 participating in DCEP Chemical Sessions 3_4 times per year). GDP Inspector from October 2016.
   - Country: Latvia

Education and training

Education:

1)Latvian State University, Master of Analytical Chemistry, 1983

2)Stradina University, Master of Pharmacy, 2004

1. Subject: EMA

- Start date: 12.2007
- End date: 12.2007
- Qualification: Participant
- Organization: Training of Quality Assessors
- Country: United Kingdom

2. Subject: State Agency of Netherlands

- Start date: 03.2010
- End date: 03.2010
- Qualification: Participant
- Organization: EU Assessors Training on “Efficient and Effective Quality Assessment”
- Country: Netherlands

3. Subject: State Agency of Estonia

- Start date: 06.2010
- End date: 06.2010
- Qualification: Participant
- Organization: Integrated Implementation Training Workshop for ICH Q8; Q9 &Q10
- Country: Estonia

4. Subject: EMA

- Start date: 10.2010
- End date: 10.2010
- Qualification: Participant
- Organization: QWP Training on Sterile Manufacture
- Country: United Kingdom

5. Subject: State Agency of Latvia

- Start date: 11.2011
- End date: 11.2011
- Qualification: Speaker
- Organization: Latvian SAM organized quality experts training hold by German Institute's of Drug Products (BfRM)
- Country: Latvia

6. Subject: EDQM

- Start date: 09.2012
- End date: 09.2012
- Qualification: Chemical Expert
- Organisation: EDQM
- Country: France

7. Subject: EDQM

- Start date: 10.2014
- End date: 10.2014
- Qualification: Chemical Expert
- Organisation: 50 Years of Leadership in the Quality of Medicines – Paving the way for the future - International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM)
- Country: France

8. Subject: EDQM

- Start date: 09.2015
- End date: 09.2015
- Qualification: Chemical Expert
- Organization: Chemical Expert Plenary Meeting
- Country: France

9. Subject: EDQM

- Start date: 11.2015
- End date: 11.2015
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

10. Subject: EMA

- Start date: 12.2015
- End date: 12.2015
- Qualification: Chemical Expert
- Organization: EMA HMPC Assessors Training
- Country: United Kingdom

11. Subject: EDQM

- Start date: 03.2016
- End date: 03.2016
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

12. Subject: EDQM

- Start date: 06.2016
- End date: 06.2016
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

13. Subject: EDQM

- Start date: 09.2016
- End date: 09.2016
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

14. Subject: EDQM

- Start date: 02.2017
- End date: 02.2017
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

15. Subject: European Compliance Academy

- Start date: 02.2017
- End date: 02.2017
- Qualification: GDP inspector
- Organization: International Conference "GDP and Real World"
- Country: Germany

16. Subject: EDQM

- Start date: 06.2017
- End date: 06.2017
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

17. Subject: EDQM

- Start date: 09.2017
- End date: 09.2017
- Qualification: Chemical Expert

- Organization: EDQM Expert Meeting
- Country: Czechia

18. Subject: EMA

- Start date: 10.2018
- End date: 10.2018
- Qualification: GMP/GDP Inspector
- Organization: New GMP Inspectors Training
- Country: United Kingdom

19. Subject: EDQM

- Start date: 12.2017
- End date: 12.2017
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

20. Subject: EDQM

- Start date: 05.2018
- End date: 05.2018
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

21. Subject: EDQM

- Start date: 03.2019
- End date: 03.2019
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

22. Subject: EDQM

- Start date: 05.2019
- End date: 05.2019
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

23. Subject: EDQM

- Start date: 12.2019
- End date: 12.2019
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

24. Subject: EDQM

- Start date: 01.2020
- End date: 01.2020
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

25. Subject: EDQM

- Start date: 02.2021
- End date: 02.2021
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France, remotely

26. Subject: EDQM

- Start date: 10.2021
- End date: 10.2021
- Qualification: Chemical Expert
- Organization: EDQM DCEP Experts Plenary Session
- Country: France, remotely

27. Subject: PIC/S

- Start date: 11.2021
- End date: 11.2021
- Qualification: participant
- Organization: PIC/S
- Country: Remotely

28. Subject: EDQM

- Start date: 03.2022
- End date: 03.2022
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France, remotely

29. Subject: EDQM

- Start date: 05.2022
- End date: 06.2022
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

30. Subject: EDQM

- Start date: 12.2022
- End date: 12.2022

- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

31. Subject: EDQM

- Start date: 02.2023
- End date: 02.2023
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

32. Subject: EDQM

- Start date: 05.2023
- End date: 05.2023
- Qualification: Chemical Expert
- Organization: EDQM
- Country: France

33. Subject: European Compliance Academy - GMP/GDP Forum

- start day: 06.2023.
- end day: 06.2023.
- qualification: participant
- organization: European Compliance Academy
- country: Spain

34. Subject: EDQM

- start day: 10.2023
- end day: 10.2023
- qualification: Chemical Expert
- organization: EDQM
- country: France

35. Subject: EDQM

- start day: 01.2024
- end day: 01.2024
- qualifications: Chemical Expert
- organization: EDQM
- country: France

36. Subject: EDQM

- start day: 05.2024
- end day: 05.2024
- qualification: Chemical Expert
- organization: EDQM
- country: France

37. Subject: EDQM

- start day: 10.2024
- end day: 10.2024
- qualification: Chemical Expert
- organization: EDQM
- country: France

38. Subject: EDQM

- start day: 02.2025
- end day: 02.2025
- qualification: Chemical Expert
- organization: EDQM
- country: France

Additional information

Publications

Projects

Memberships

Other Relevant Information

1) 1993: International Symposium "Purity Determination on Drugs", Stockholm, Sweden 2) 1995: International Seminar "Analytical Validation", London, United Kingd 3) 1996: International Symposium "New Drugs Creation", St_Petersbourg, Russia, Speaker, Paper: "Creation and Analysis of some Pharmaceutical Forms" 4) 2001: International Conference of “European Generic Drug Association”; London, United Kingdom 5) 2002: CADREAC annual conference; Riga ; Latvia 6) 2002: PERF II conference; Tallinn, Estonia 7) 2002: International Conference “Central&Eastern Europe_Regulatory Challenges in the Pharmaceutical Market”; London, United Kingdom 8) 2003: Annual Seminar of Latvian Society of Pharmaceutists, Riga 9) 2004 February: Management of Regulated Documents in Pharmaceutical Industry, Seminar, Riga 10) 2009 September: EursIsYours eCTD review tool’s Users Conference and Open Forum, Nice, France; Speaker: “eCTD reviewing process at the LSAM _ status and next steps” 11) 2010 April: Pharma IQ Conference Successful eCTD Lifecycle Management, London, UK; Speaker: “eCTD reviewing process at the LSAM” 2011 April: eRA 2011 eRegulatory Affairs Conference (including EURS is YOURS User Group Meeting), Peguera, Majorca, Spain 12) 2012 February: EursIsYours eCTD review tool’s Experts Forum, Munchen, Germany 13) From 2011 - a Member of ASMF WG, EMA, London; 14) From 2012 till now- the Quality Assessor of DCEP Procedure of EDQM