



Curriculum Vitae

Personal information Malgorzata Skiba

Work experience

1. Employer: Tarchomińskie Zakłady Farmaceutyczne
 - Start date: 121996
 - End date: 122000
 - Position: Specialist in Research and Development Department
 - Activities: 1. Monitoring of workplace hygienic condition. 2. Work with microbial strains. 3. Optimization of the biosynthesis process. 4. Documentation of research work.
 - Country: Poland
2. Employer: Tarchomińskie Zakłady Farmaceutyczne
 - Start date: 012001
 - End date: 122010
 - Position: Specialist in Quality Assurance Department
 - Activities: 1. Implementation of European GMP requirements. 2. Preparation of Standard Operation Procedures. 3. Reviewing projects on sterile and non-sterile areas for compliance with GMP requirements. 4. Performing and documenting of validation: DQ, IQ, OQ, PQ, PV (non-sterile and sterile production). 5. Participation in controlling of changes. 6. Participation in internal and external inspections (in third countries). 7. Conducting internal GMP training.
 - Country: Poland
3. Employer: Tarchomińskie Zakłady Farmaceutyczne
 - Start date: 012011
 - End date: 032014
 - Position: Manager of Validation Department
 - Activities: 1. Implementation of European GMP requirements. 2. Preparation of Standard Operation Procedures. 3. Monitoring of cleanroom parameters. 4. Monitoring of quality parameters of compressed gases. 5. Preparation of protocols with the results of measurements. 6. Performing and documenting of validation: DQ, IQ, OQ, PQ, PV. (non-sterile and sterile production). 7. Conducting internal GMP training.
 - Country: Poland
4. Employer: Main Pharmaceutical Inspectorate
 - Start date: 032014
 - End date:
 - Position: GMP Inspector
 - Activities: 1. Carrying out inspections in production areas of active substances. 2. Carrying out inspections in production areas of medicinal products sterile and non-sterile. 3. Preparation of inspection reports. 4. Sampling of medicinal products for Authorities testing. 5. Preparation of Standard Operation Procedures. 6. Participation in the internal working groups for EMA and PIC/S.
 - Country: Poland

Education and training

1. Subject: Warsaw University of Technology, Department of Chemical and Process Engineering, Specialization: Bioprocess Engineering
 - Start date: 091990
 - End date: 021997
 - Qualification: Master of Science in Chemistry
 - Organisation: Chemical and Bioprocess Engineering
 - Country: Poland
2. Subject: Swissmedic
 - Start date: 052016
 - End date: 052016
 - Qualification: The Swissmedic Training
 - Organisation: How to inspect Data Integrity
 - Country: Switzerland
3. Subject: ISPE
 - Start date: 082016
 - End date: 082016
 - Qualification: ISPE Training Event
 - Organisation: HVAC _ T14
 - Country: Spain
4. Subject: ECA
 - Start date: 112018
 - End date: 112018
 - Qualification: Training
 - Organisation: Isolator Technology Workshop
 - Country: Switzerland
5. Subject: ECA
 - Start date: 112019
 - End date: 112019
 - Qualification: Training
 - Organisation: GMP for vaccine manufacturers
 - Country: Spain
6. Subject: ECA

- Start date: 122020
 - End date: 122020
 - Qualification: Live Online Training
 - Organisation: Fundamentals of Visual Inspection
 - Country:
7. Subject: ECA
- Start date: 032021
 - End date: 032021
 - Qualification: Live Online Training
 - Organisation: GMP and Quality Requirements for Radiopharmaceuticals
 - Country:
8. Subject: PDA
- Start date: 102021
 - End date: 102021
 - Qualification: Live Online Conference
 - Organisation: The 2021 PDA Advanced Therapy Medicinal Products Conference
 - Country:
9. Subject: PIC/S, WHO
- Start date: 122021
 - End date: 122021
 - Qualification: Live Online Conference
 - Organisation: PIC/S Expert Circle Meeting on Control of Cross Contamination in Shared Facilities
 - Country:
10. Subject: PIC/S, MHRA
- Start date: 032022
 - End date: 032022
 - Qualification: Live Online Conference
 - Organisation: PIC/S Expert Circle Meeting on Quality Risk Management
 - Country:
11. Subject: URPLWmiPB (competent authority in Poland)
- Start date: 27052022
 - End date: 27052022
 - Qualification: Training (on-site)
 - Organisation: New guideline on genotoxic contaminants RPLWmiPB
 - Country: Poland
12. Subject: ECA
- Start date: 14022023
 - End date: 14022023
 - Qualification: Live online training
 - Organisation: Single-Use-Disposable - What do you need to know
 - Country:
13. Subject: PIC/S
- Start date: 08112023
 - End date: 10112023
 - Qualification: SEMINAR
 - Organisation: Soft skills that make a good GMP/GDP inspector
 - Country: Thailand

Additional information

[Publications](#)

[Projects](#)

[Memberships](#)

[Other Relevant Information](#)