

## Curriculum Vitae

Personal information **Malgorzata Berska**

### Work experience

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1. Employer: Chief Pharmaceutical Inspectorate
  - Start date: 122015
  - End date:
  - Position: GMP Inspector, 09.2023 Head of the Unit for Supervision over the Manufacturing of Sterile Products
  - Activities: GMP Inspections
  - Country: Poland
2. Employer: Polfa Warszawa S.A.
  - Start date: 042008
  - End date: 112015
  - Position: Coordinator of Analytical \_ Biological Laboratory, Quality Control Department
  - Activities:

Organising and supervising work of the team in the assesment of the quality of starting materials, packaging, intermediate products, final products and process of production (e.g. Media Fill Test, IPC, cleaning validation), assesment of the received results.

Knowledge of testing methods (microbiological, biochemical, LAL, biological, physico\_chemical), of validation and methods transfer.

Supervising of the data integrity, documentations and archiving.

- Country: Poland
3. Employer: Polfa Tarchomin S.A., Quality Control Department
    - Start date: 091995
    - End date: 032008
    - Position: Senior Specialist
    - Activities:

Biological Laboratory.

Conducting of microbiological, biochemical and biological analysis.

Determination of cross contamination, determination of traces of residues of penicillin.

- Country: Poland

### Education and training

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1. Subject: University of Warsaw, Faculty of Biology
  - Start date: 101990
  - End date: 111995
  - Qualification: Master of Science
  - Organisation:
  - Country: Poland
2. Subject: ECA Academy
  - Start date: 042017
  - End date: 042017
  - Qualification: Training
  - Organisation: Clean Room & HVAC System
  - Country: Germany
3. Subject: ECA Academy
  - Start date: 052017
  - End date: 052017
  - Qualification: Training
  - Organisation: Liophylization
  - Country: Germany
4. Subject: ECA Academy
  - Start date: 062019
  - End date: 062019
  - Qualification: Training
  - Organisation: GMP for Advanced Therapy Medicinal Products (ATMP)
  - Country: Germany
5. Subject: EDQM
  - Start date: 112019
  - End date: 112019
  - Qualification: Training
  - Organisation: CAP Samplers meeting
  - Country: Poland
6. Subject: ECA Academy
  - Start date: 122020
  - End date: 122020
  - Qualification: Training

- Organisation: Risk Assessment in Contamination Control
- Country: Germany
- 7. Subject: ECA Academy
  - Start date: 032021
  - End date: 032021
  - Qualification: Training (online)
  - Organisation: Virus and TSE Safety made simple
  - Country: Germany
- 8. Subject: Parenteral Drug Association
  - Start date: 102021
  - End date: 102021
  - Qualification: 2021 PDA Conference (online)
  - Organisation: 2021 PDA Advanced Therapy Medicinal Products Conference
  - Country: United States
- 9. Subject: WHO and PIC/S
  - Start date: 122021
  - End date: 122021
  - Qualification: Life online Conference
  - Organisation: WHO and PIC/S Expert Circle Meeting on Control of Cross Contamination in Shared Facilities
  - Country:
- 10. Subject: MHRA PIC/S
  - Start date: 032022
  - End date: 032022
  - Qualification: Life online Conference
  - Organisation: PIC/S Expert Circle Meeting on QRM: Virtual Training and Event and Meeting
  - Country:

## Additional information

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[Publications](#)

[Projects](#)

[Memberships](#)

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