

EUROPEAN
CURRICULUM VITAE
FORMAT



PERSONAL INFORMATION

Name Elena Mihaylova Hadjitodorova-Masseva

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Nationality Bulgarian

Date of birth 22/10/1949

WORK EXPERIENCE

- **Dates (from – to)** **08.2010 – present**
Translation and proofreading of medical and pharmaceutical materials
- **Dates (from – to)** **08.2009 – 08.2010**
• Name and address of employer Bulgarian Drug Agency
8, Damyan Gruev Str.,
1303, Sofia, Bulgaria
Drug regulation
Director Regulatory Affairs
• Type of business or sector Management of the Regulatory Affairs Department responsible for validation and assessment of the documentation of the medicinal products in Bulgaria
• Occupation or position held Member of CMDh, second member of the CHMP, EMA
• Main activities and responsibilities
- **Dates (from – to)** **05.2009 – 08.2009**
• Name and address of employer Bulgarian Drug Agency
8, Damyan Gruev Str.,
1303, Sofia, Bulgaria
Drug regulation
Director Biological Products Department
• Type of business or sector Management of the Biological Products Department responsible for validation and assessment of the documentation of the medicinal products of biological origin
• Occupation or position held
• Main activities and responsibilities
- **Dates (from – to)** **02.2008 – 01.2009**
• Name and address of employer Sopharma PLC,
3, Kl. Okhridski Blvd., Sofia 1797
Pharmaceutical industry
Manager Regulatory Standards
• Type of business or sector Implementation and updating of the regulatory standards in the company
• Occupation or position held
• Main activities and responsibilities

- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
 - Occupation or position held
 - Main activities and responsibilities
- 01.2004 – 02.2008**
 Sopharma PLC,
 3, Kl. Okhridski Blvd., Sofia 1797
 Pharmaceutical industry
 Manager Regulatory Affairs
 Management of the MA of the company's products in Bulgaria and abroad
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- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
 - Occupation or position held
 - Main activities and responsibilities
- 10.2000-12.2003**
 Bulgarian Drug Agency
 26, Y. Sakazov Blvd., Sofia 1754
 Drug regulation
 Head, *Assessment of Documentation and Links with the Specialized Committees* Section in the Marketing Authorization of Drugs Department
 Responsible for the assessment of the medical part of the drug dossier and for the technical organization of the work of the specialized drug committees. Within the framework of PERF participated as an observer in the meetings of Safety and Efficacy WPs in EMEA
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- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
 - Occupation or position held
 - Main activities and responsibilities
- 1996-10.2000**
 Bulgarian Drug Agency
 26, Y. Sakazov Blvd., Sofia 1754
 Drug regulation
 Head, *Drug Information & Pharmacovigilance* Dept. including the National Centre for ADRs, the Centre for Drug Information and the Drug Advertising Control unit
 Planned, coordinated and controlled the activities of these centres
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- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
 - Occupation or position held
 - Main activities and responsibilities
- 01.1994-07.1995**
The World Foundation
 6, 11 August Str., Sofia 1754
 NGO
 Secretary of a TEMPUS project *Public Health Disciplines in Bulgaria* with the University of Cambridge as coordinator
 Organisation of postgraduate training of specialists in Public Health (study tours and workshops). Participation in editing of *The World* journal (a journal for medicine, health care and ecology) issued by *The World* Foundation
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- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
 - Occupation or position held
 - Main activities and responsibilities
- 08.1989-12.1993**
 National Drug Institute
 26, Y. Sakazov Blvd., Sofia 1754
 Drug regulation
 Research Fellow in the *National Centre for Adverse Drug Reactions*
 Collecting and assessing ADRs reports within the WHO Programme on ADRs. Participation in the annual meetings of the WHO Centre for ADRs in Uppsala.
 Editor of the information bulletin *Side Effects of Drugs*
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- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
 - Occupation or position held
 - Main activities and responsibilities
- 1984-1986**
 Research Chemical-Pharmaceutical Institute,
 3, Kl. Okhridski Blvd., Sofia 1797
 Pharmaceutical industry
 Research Fellow in the Toxicological Laboratory
 Toxicological studies of drugs
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- **Dates (from – to)**
 - Name and address of employer
 - Type of business or sector
- 1975-1977**
 Hygiene-Epidemiological Inspectorate
 Dupnitsa, Bulgaria
 Public Health

- Occupation or position held
- Main activities and responsibilities

Occupational Health Officer
Inspection of the working conditions in the industrial enterprises

EDUCATION AND TRAINING

• Dates (from – to)

1963-1968

- Name and type of organization providing education and training
- Principal subjects/occupational skills covered
- Title of qualification awarded
- Level in national classification (if appropriate)

High English Language School - Sofia
Most of the subjects studied in English

• Dates (from – to)

1968-1975

- Name and type of organization providing education and training
- Principal subjects/occupational skills covered
- Title of qualification awarded
- Level in national classification (if appropriate)

Higher Medical Institute - Sofia
All subjects/occupational skills, required for a medical doctor
Medical doctor
Master's degree

• Dates (from – to)

1978-1984

- Name and type of organization providing education and training
- Principal subjects/occupational skills covered
- Title of qualification awarded
- Level in national classification (if appropriate)

Institute of Obstetrics and Gynecology
Thesis *Teratogenic, embryotoxic and mutagenic effect of the Bulgarian organophosphorous pesticide Chloracetophone*
Doctor of Medicine
PhD

TRAINING COURSES

Assessment of pharmaco-toxicological /preclinical/ documentation – April 2003, EMEA - Safety Working Party, Budapest

European Regulatory Affairs Summer School (24-26.07.2007) Informa UK

Time Management (09.2007)

Chemistry and Pharmacy Section of the EU Registration Dossier with an Emphasis on Stability Testing (30.10.07 – 01.11.07) PTI-Europe; Lector: Andrew Willis

PERSONAL SKILLS AND COMPETENCES

*Acquired in the course of life and career
but not necessarily covered by formal
certificates and diplomas.*

MOTHER TONGUE

Bulgarian

OTHER LANGUAGES

English

- | | |
|------------------|-----------|
| • Reading skills | Excellent |
| • Writing skills | Excellent |
| • Verbal skills | Excellent |

FRENCH

- | | |
|------------------|-----------|
| • Reading skills | Excellent |
| • Writing skills | Excellent |
| • Verbal skills | Excellent |

RUSSIAN

- | | |
|------------------|-----------|
| • Reading skills | Excellent |
| • Writing skills | Excellent |
| • Verbal skills | Excellent |

ITALIAN

- | | |
|------------------|------|
| • Reading skills | Good |
| • Writing skills | GOOD |
| • Verbal skills | GOOD |

GERMAN

- | | |
|------------------|--------------|
| • Reading skills | GOOD |
| • Writing skills | SATISFACTORY |
| • Verbal skills | SATISFACTORY |

SPANISH

- | | |
|------------------|--------------|
| • Reading skills | SATISFACTORY |
| • Writing skills | - |
| • Verbal skills | - |

SOCIAL SKILLS AND COMPETENCES

Living and working with other people, in multicultural environments, in positions where communication is important and situations where teamwork is essential (for example culture and sports), etc.

Ability to work in a team; good communication skills with people of various nationalities, cultures and religions.

ORGANISATIONAL SKILLS AND COMPETENCES

Coordination and administration of people, projects and budgets; at work, in voluntary work (for example culture and sports) and at home, etc.

Good organizational skills
Member of the board of the Community Centre *Nikolay Haytov*
Member of the editorial board of the medical journal *Medical Practice*

TECHNICAL SKILLS AND COMPETENCES

With computers, specific kinds of equipment, machinery, etc.

Microsoft Office, Internet

ARTISTIC SKILLS AND COMPETENCES

Music, writing, design, etc.

Translation of medical literature
Translated medical materials for a number of the biggest pharmaceutical companies for more than 20 years. Translated texts from and into English, French-Bulgarian, French-English, German-Bulgarian, German-English, German-Russian, Russian-English and English-Russian

OTHER SKILLS

AND COMPETENCES

Competences not mentioned above.

Member of MENSA-Bulgaria

DRIVING LICENCE(S)

ADDITIONAL INFORMATION

ANNEXES