

PERSONAL INFORMATIONName **Svetlin Sofroniev SPIROV**E-mail **svetlin.spirov@bda.bg**

Nationality Bulgarian

WORK EXPERIENCE

- Dates (from – to) July 2014 – Present
- Name and address of employer Bulgarian Drug Agency
 - Type of business or sector
 - Occupation or position held Secretary General
- Main activities and responsibilities

- Dates (from – to) December 2012 – Present
- Name and address of employer Bulgarian Drug Agency
 - Type of business or sector Medical Devices Directorate
 - Occupation or position held Director
- Main activities and responsibilities

- Dates (from – to) 15.01.2009 – December 2012
- Name and address of employer Bulgarian Drug Agency
 - Type of business or sector Control of Medicinal Products Directorate
 - Occupation or position held Director
- Main activities and responsibilities Management and control of activities in medicinal products manufacturing and import licences; wholesale and retail trade, blocking, withdrawing, and destroying of medicinal products, supply of unauthorized medicinal products, advertisement and clinical trials

- Dates (from – to) 2011
- Name and address of employer PIC/S
 - Type of business or sector BG Association Meeting
 - Occupation or position held Representative
- Main activities and responsibilities

- Dates (from – to) 2011
- Name and address of employer Council of Ministers
 - Type of business or sector Committee for the Positive Medicines List
 - Occupation or position held Member
- Main activities and responsibilities

- Dates (from – to) 2010 – 2011
- Name and address of employer Interpol and National Regulatory Authorities
 - Type of business or sector PANGEA 3 and 4
 - Occupation or position held Representative
- Main activities and responsibilities

- Dates (from – to) 2010 – 2011
 - Name and address of employer Ministry of Health
 - Type of business or sector Higher Pharmaceutical Committee
 - Occupation or position held Member
 - Main activities and responsibilities

- Dates (from – to) 2009 – Present
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector Expert Committee on Approval of Medicinal Products Advertisements
 - Occupation or position held Chair
 - Main activities and responsibilities

- Dates (from – to) 2008 – 15.01.2009
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector Control of Medicinal Products Directorate
 - Occupation or position held Interim Director
 - Main activities and responsibilities

- Dates (from – to) 12.09.2005 – 15.01.2009
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector Legal Division
 - Occupation or position held Head
 - Main activities and responsibilities Legal compliance of the BDA activities; BDA legal services for compliance with national and international law; participation in the development, initiation, and coordination of BDA internal acts, draft contracts, orders, etc.; participation in the preparation and organisation of public auctions; procesual representation at BDA

- Dates (from – to) 2004 – 2012
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector Working Groups on Draft amendments of LMPHM and its Ordinances
 - Occupation or position held Chair and Member
 - Main activities and responsibilities

- Dates (from – to) 01.03.2002 – 12.09.2005
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector
 - Occupation or position held Chief Legal Consultant
 - Main activities and responsibilities

- Dates (from – to) 01.10.2000 – 01.03.2002
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector
 - Occupation or position held Chief Expert
 - Main activities and responsibilities

- Dates (from – to) 20.03.2000 – 01.10.2000
 - Name and address of employer Bulgarian Drug Agency
 - Type of business or sector
 - Occupation or position held Legal Consultant
 - Main activities and responsibilities

EDUCATION AND TRAINING

- Dates (from – to) 22.03.2012 – 23.03.2012
 - Name and type of organisation providing education and training European Directorate for the Quality of Medicines and Health Care
 - Principal subjects/occupational skills covered Certification Procedures in the Medicinal Regulatory Area
 - Title of qualification awarded Training Certificate on Certification Procedures
 - Level in national classification (if appropriate)

- Dates (from – to) 13.04.2011 – 16.04.2011
 - Name and type of organisation providing education and training ERRA – Brussels
 - Principal subjects/occupational skills covered European Pharmaceutical Law
 - Title of qualification awarded Certificate of European Pharmaceutical Law
 - Level in national classification (if appropriate)

- Dates (from – to) 21.06.2011 – 25.06.2011
 - Name and type of organisation providing education and training International Institute of Prevention and Control of Falsified Medicinal Products – Paris, France
 - Principal subjects/occupational skills covered Countering the Traffic of Falsified Medicines
 - Title of qualification awarded Certificate of the International Institute of Prevention and Control of Falsified Medicinal Products
 - Level in national classification (if appropriate)

- Dates (from – to) 15.04.2010 – 16.04.2010
 - Name and type of organisation providing education and training European Directorate for the Quality of Medicines and Health Care
 - Principal subjects/occupational skills covered Preparation and Practice on Implementation of the International Convention on Falsified Medicinal Products and Similar Crimes Presenting a Public Health Hazard
 - Title of qualification awarded Certificate of the European Directorate for the Quality of Medicines and Health Care
 - Level in national classification (if appropriate)

- Dates (from – to) 2010
 - Name and type of organisation providing education and training Medical University – Sofia, Pharmaceutical Department
 - Principal subjects/occupational skills covered Intellectual property legislation in Pharmaceuticals; Good Manufacturing Practice in Pharmaceuticals, and Good Distribution Practice in Pharmaceuticals
 - Title of qualification awarded Certification on Intellectual property legislation in Pharmaceuticals; Certification on Good Manufacturing Practice in Pharmaceuticals; Certification on Good Distribution Practice in Pharmaceuticals
 - Level in national classification (if appropriate)

- Dates (from – to) 20.03.2008 – 21.03.2008
 - Name and type of organisation Ciela AD

providing education and training

- Principal subjects/occupational skills covered

- Title of qualification awarded

- Level in national classification (if appropriate)

- Dates (from – to)

- Name and type of organisation providing education and training

- Principal subjects/occupational skills covered

- Title of qualification awarded

- Level in national classification (if appropriate)

- Dates (from – to)

- Name and type of organisation providing education and training

- Principal subjects/occupational skills covered

- Title of qualification awarded

- Level in national classification (if appropriate)

Civil Procedure

Certification on Civil Procedure

01.03.2007 – 03.03.2007

National Centre “Educational Programs and Projects”

Knowledge on European Procedural Law

Certification for participation in the Workshop on European Procedural Law

1991 – December 1997

St Kliment Ohridski Sofia University, Department of Law,

Civic Law, Criminal Code, Public Law

Lawyer