

Fair-wind In Your Sails



Corporate Profile

October 2019



Pharmillennium Consulting d.o.o., limited liability company for consulting, services and trade was established in Herceg Novi, Montenegro, June 2000.

- **Scope of Business:**

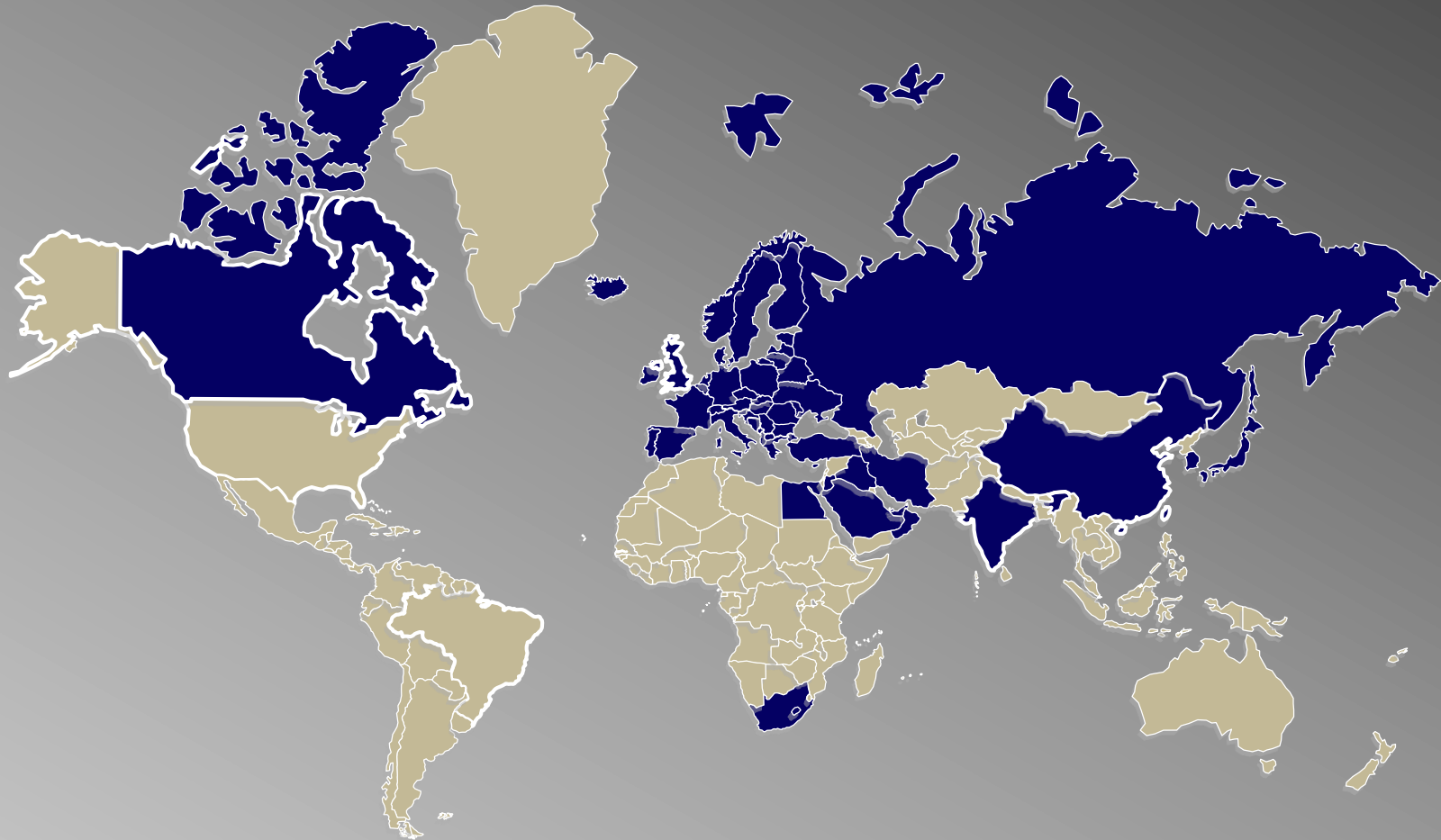
Providing services to customers - manufacturers, MA/License holders, wholesalers, agent companies, QC laboratories, medical institutions and regulatory bodies in the scope of pharmaceuticals, medical devices, food supplements and cosmetics.

- **Areas of Services:**

Include (but not limited to) – quality systems and standards (GMP, GDP, ISO, etc.) implementation and auditing, registration/licensing documentation development, compilation and management (paper and electronic), business development expertise, market research and RA strategic studies, RA services and submissions, MA/License holding services including QPPV and vigilance services, Batch Release and Testing services in EU, QP services, turn-key manufacturing sites engineering, design and management, pharmaceutical and technology development, contract manufacturing support, HR & Recruiting, etc.

Pharmillennium Consulting d.o.o., Montenegro, has developed corporate structure and network enabling provision of services worldwide.

PHMC (Cyprus) Ltd manages EU and RoW projects



Pharma Concept d.o.o., Serbia, manages WBC (West Balkan or SEE Countries) projects





Recognizing the enlarged needs for knowledge and development, for the last few years we are developing our offer for dedicated, turn-key services to our customers.

By our expertise, practical experience and knowledge, as well as in close cooperation with specialized companies and recognized international experts in the same scope, we are able to provide a wide scope of services and knowledge,

Staying up to date with constant development of applicable international and national standards and regulations is demanding challenge, but also a must for all of us, dealing with pharmaceuticals, medical devices, food supplements and cosmetics.

Strict regulations for every “life cycle” stage of one medicine, medical device, food supplement or cosmetic product are forcing all stakeholders involved, to constantly improve themselves, in order to achieve and maintain the most important requirements for each pharmaceutical product:

Quality, Safety & Efficacy





Head Experts & Management:

- **Mr. Pharm. Predrag Ristić**
 - Pharmillennium Consulting d.o.o., CEO
 - Former Deputy General Manager at the Institute of Pharmacy - Agency for Medicines and Medical Devices of the Republic of Serbia, Head of National Quality Control Laboratory
 - Former Adviser to the Minister of Health and Minister of Agriculture of the Republic of Montenegro
- **MPharm. Specialist in Pharmacy, QP/QC Spec. Dragana Boberity Borojević**
 - PHMC (Cyprus) Ltd , Director
 - Former Head of Registrations Committee at the Institute of Pharmacy/Head of NCL Instrumental Laboratory - Agency for Medicines and Medical Devices of the Republic of Serbia
 - Former Assistant Minister of Health of the Republic of Montenegro, Head of Pharmaceutical Sector
 - Pharmaceutical expert in the scope of the EU GMP, Pharmaceutical Quality Systems, QC, RA, Quality Expert, Business Development Director, Head Project Manager, Lead GMP Auditor at Pharmillennium Consulting d.o.o.
 - QP/QC in Serbia
- **B.Sc.Pharm. Spec. Technology, Spec. QP Miloš Stajković**
 - Pharma Concept d.o.o., Deputy Director, MA Department Head
 - Former Expert Associate - QP at Hemofarm a.d. (Stada Group)
 - Former Senior Expert Associate at Esensa d.o.o.
 - QP in Serbia, RA Expert pharmaceuticals, MDs, supplements



Services:



- Regulatory support in the health care and pharmaceutical sector
- QA, GMP & Validation, GLP, GCP, GDP & GPP and ISO standards implementation, auditing, and certifications
- QP services, Batch Release, Batch Testing in EU
- Computerized Information Systems in medicine and pharmaceuticals
- Development of documentations for registration and licensing of medicinal products (chemical, herbal, biological and biotechnology) and medical devices in EU
- RA services - registration/notification of medicines, medical devices, supplements and cosmetics
- Scientific translating and editing services
- Laboratory engineering, design and contract analytical methods development
- Medical institutions (clinics, ordinations) full support – designing, organisation, HR support
- Engineering, design, turn-key solutions and contract cooperation development of manufacturing sites for pharmaceuticals, supplements and MDs
- Legal advising and corporate legal/administrative consulting services
- Business development and Marketing consulting services
- MAH in EU and EU QPPV
- MIA in EU
- BT & BR in EU

Services in EU:

EU MAH, MIA, QP, QC

- MAH in EU
- MIA in EU - QP Services (API audits), EU Batch Release (BR) Site,
- Batch Testing (BT) Site in EU (with contracted QC laboratories)

EU PV System, RA

- EU QPPV & Cyprus Local QPPV
- RA Services – RA Strategy, MAA & eCTD compilations, publishing, electronic submissions, full service during MAA procedure, PIL Readability Testing, Variations, Consultations, Scientific Advices

EU Dossier, CRO

- Clinical & Non-clinical EU Experts (M2, M4 & M5 writing/compilations/reviews)
- Quality EU Experts (QOS writing & M3 reviews)
- BE and Clinical Studies - full services in EU

EU GMP

- EU GMP – audits, trainings, implementation & support in CAPA
- EU GMP formal Certification – facilitation in appointing, support in organization, execution and CAPA resolution/management
- PQS/QMS development, trainings, consulting & support
- Qualifications, Validations & Metrology services with accredited laboratory

Market Access

- In/Out-Licensing Support including CTD Dossier Reviews and Verification
- Support in Import, Export (including provision of CPPs), Promotion & Wholesale Distribution with licensed EU partners

Engineering, PM, HR, IT

- Engineering, design, turn-key solutions of EU GMP compliant manufacturing sites and QC laboratories, Project Management, HR and recruiting services
- IT solutions for pharmaceutical companies
- Legal advising and corporate legal/administrative consulting services with licensed partners



Pharmaceutical • Marketing • Consulting

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Reference List of Clients:

- Ministry of Health, Serbia
- Ministry of Health, Montenegro
- Ministry of Agriculture, Montenegro
- Glaxo Ware, UK
- Torlak, OPV Vaccine mfg. site, Serbia
- Hemofarm, Stada, Serbia
- Zdravlje Actavis, Serbia
- Actavis Trading, Malta
- InterEvrogenex, Macedonia
- PharmaS, Croatia
- Alvogen Balkans, Luxembourg
- Alvogen Pharma, Serbia
- Esensa Pharma, Serbia
- Laboratorios Basi, Portugal
- TMC Pharma Services, UK
- Salix Pharmaceuticals, USA
- Bosnalijek, Bosnia
- Clinres Nova, Croatia
- ELC Group, Czech
- CIPLA Ltd, India
- Newlystar Medtech, China
- Jewim Pharmaceuticals, China
- DPBR SA, Switzerland
- WellPharma, Abu Dhabi
- Rasan Pharmaceuticals, Iraq
- D.Med Group, Germany
- Medical Intertrade, Croatia
- ASA Group, Bosnia
- Prevent Group, Germany
- Avicenna Pharma, Turkey
- CSBIO, China
- Panacea Biotech, India
- BC PharmaTech, Cyprus
- Cardinal Health and Cordis, Switzerland, USA
- GryNumberHealth, Lithuania
- UAB Alfa Linija, Lithuania
- Semperit, Austria
- PharmDedict, Bulgaria
- Yaklasim Mak.San. ve Ticaret, Turkey
- PharmaKos, Croatia
- World Medicine, Turkey
- Palmolive/Colgate, Italy
- Unimed Pharm, Korea
- Messer AG, Austria
- Biosensors Europe SA, Switzerland
- Atnahs/Waymade, UK
- Covidien, USA,
- Messer Tehnogas, Serbia,
- Medisport, Italy, Serbia
- Fertiligent, Israel,
- Aytu Bioscience, USA,
- Denta BP Pharm, Serbia,
- MPG, Serbia,
- Cheetah Medical Ltd., Israel,
- Draminski S.A., Poland,
- Ace Medical, Korea,
- Mediserv, Serbia,
- Feel Tech, Korea,
- Across, Korea,
- Magis Health, Serbia,
- Synthon B.V., Netherlands,
- Medbar UK Limited, UAE
- Anik-Atik, Montenegro



Pharmillennium Consulting corporate network and our partners have team of experts covering broad range of specialized knowledge which is necessary in order to provide customers high level of professional and scientific services in all the areas concerned:

- recognized specialists in GMP,
- pharmacology, clinical pharmacy,
- toxicology, medicines control,
- microbiology and virology,
- pharmaceutical technology
- laboratory quality control, batch release,
- experts for the scopes of information and IT services, HR, legal sciences, economy, construction works, etc.





We really believe that we could offer you as much as you need and satisfy you as much as possible.



We wish you to enter the new era of development and success with PHARMILLENNIUM GROUP and our partners.



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