



Introduction

2020


Profile



## What is PHARMAGATE?



- International standards for conducting operational activities, speed and mobility in the administration of business processes, flexible infrastructure, broad geography
- Private Company founded in Dec 2011 by members of one family – legal entities located in Ukraine (Kiev), Russia (Moscow), Caucasus region - Georgia (Tbilisi), Asia region - Uzbekistan (Tashkent) and Europe - company HQ in United Kingdom (London)
- Focus profile - wide list of services supporting local and international companies - producers of different medical paramedical goods
- Geography - all CIS and non-CIS countries of the region including EAEU



PHARMAGATE – consultancy, services and optimal solutions for industries producing the following:

- medicinal products
- immunobiological products
- medical devices
- biologically active substances
- food additives
- hygiene products
- veterinary and disinfecting products
- medical equipment
- cosmetic products

PHARMA  
**GATE**  
OPENING PATHS



# Services



## CONSULTING

Advice on local legislation and regulatory features, the development of regulatory policies with the formation of optimal solutions



## REGULATORY AFFAIRS

Approval of your product for its subsequent commercialization, access to all areas that interest you



## PHARMACOVIGILANCE

### SAFETY & QUALITY COMPLIANCE

Identification, assessment, understanding and prevention of adverse reactions or any other problems related to the product



## INSPECTION OF PRODUCTION SITE GMP, ISO

Organization and support of inspection of production sites and authorized for the quality of offices of companies accredited bodies of the region



## PRODUCTS LIFE CYCLE

Obtaining the approval for medical use, management of variations, renewals, conformity assessment, communication with customers



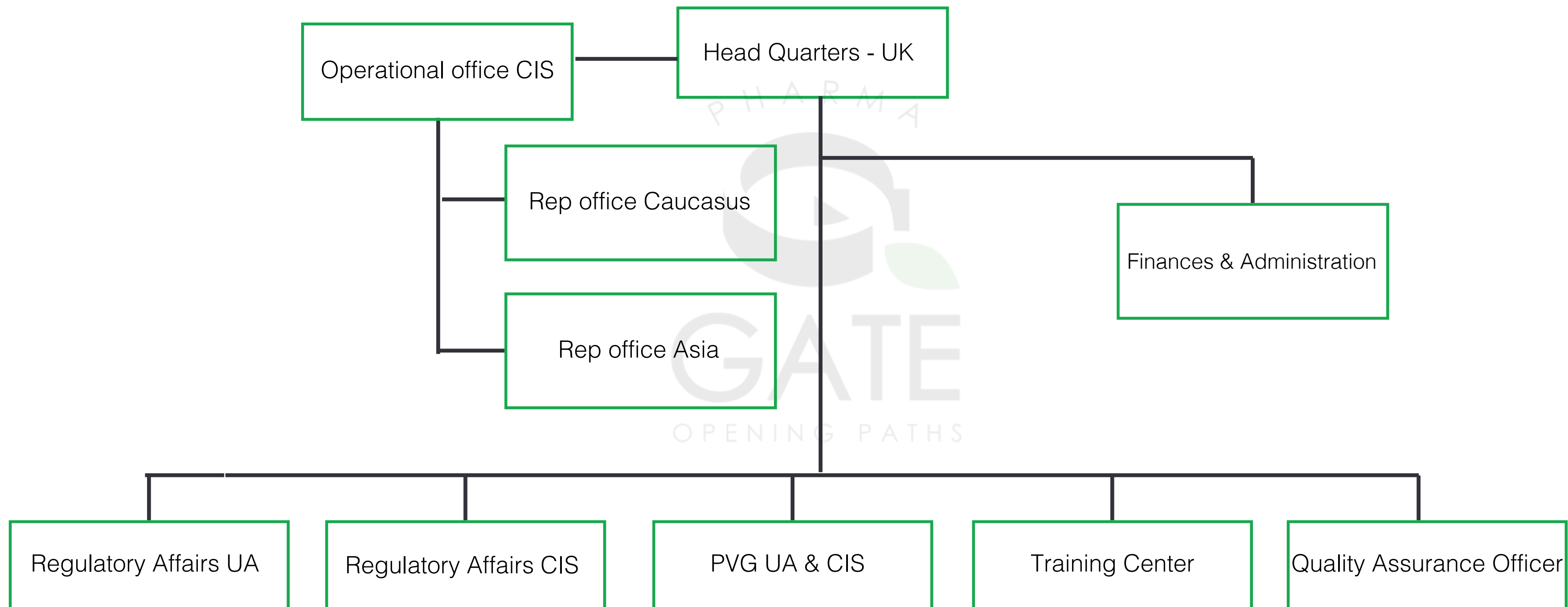
## TRAINING CENTER

Standard programs for open trainings and individual development – for corporate clients on the relevant topics

PHARMAGATE is a professional coordinating team with representatives in 13 countries:

- Ukraine
- Russia
- Kazakhstan
- Belarus
- Moldova
- Georgia
- Armenia
- Azerbaijan
- Kyrgyzstan
- Turkmenistan
- Tajikistan
- Uzbekistan
- Mongolia







## Industry expertise

- American Chamber of Commerce (AMCHAM) - Ukraine
- Association of pharmaceutical companies representatives in Georgia (APCRG) - Georgia
- Association of Pharmaceutical Research and Development (APRAD) - Ukraine
- Association of market operators of medical devices (AMOMD) – Ukraine
- Association of perfumery and cosmetics (APCU) - Ukraine
- Association of Foreign Pharmaceutical Producers (AIPM) – Kazakhstan
- Association of medicinal products importers and producers (MP Union) - Armenia
- DRUG INTERNATIONAL ASSOCIATION (DIA), Switzerland

- Abbvie (USA)
- Amgen (USA)
- Alfa Wassermann (Italy)
- Alcaloid ( Macedonia)
- Abdi Ibrahim Ilac (Turkey)
- Actellion (Switzerland)
- Astellas (Japan)
- BC Pharma B.V. (Argentina)
- Baxter AG (Switzerland)
- Berlin-Chemie GmbH (Germany)
- BIOQPHARMA (USA)
- Conrad Swiss (Switzerland)
- Cheplapharma GmbH (Germany)
- Centogen (Germany)
- Dentsply Ltd. (UK)
- Dr.Reddis ( India)
- Fresenius Kabi Deutschland GmbH (Germany)
- Genpact (UK)
- GM Pharmaceuticals Ltd. (Georgia)
- Herbalife Int. ( USA)
- Johnson & Johnson (USA)
- Kyiani ( Sweden)
- Klosterfrau GmbH (Germany)
- Lallemand Pharma AG (Switzerland)
- L.Molteni (Italy)
- Laboratorios Bago (Argentina)
- Merck Co. (Germany)
- MSD ( USA)
- Mega Life science (Australia)
- Mibe GmbH (Germany)
- Montaviit Pharmacoytische (Austria)
- Novartis CH (Switzerland)
- Novonordisk (Denmark)
- NUTRICIA (Netherland)
- PTCBio (USA)
- Pharmselect GmbH (Austria)
- Pohl-Boskamp (Germany)
- Reckitt Benkiser ( UK)
- Santen Oy (Finland)
- Sandoz (Switzerland)
- Sanovel (Turkey)
- Shire ( Switzerland)
- Sobi (Sweden)
- STD Pharmaceutical (UK)
- Schwabe GmbH (Germany)
- Sinovac Biotech (Hong Kong)
- TEVA (Israel)
- US Pharma (USA)
- UCB S.A. (Belgium)
- Weleda AG (Switzerland)
- ZHERMACK (Italy)
- VIVUS (USA)
- Etc.







## PHARMAGATE in figures (2017-2019)

520+  
Variations

80+  
New submissions

110+  
Renewal

35+  
Conformity assessment/  
self-declaration

600+  
Sources for AE screening

15 000+  
ICSRs

75+  
PSURs/ACO/PUR

7500+  
CIOMS



# PhG Quality Assurance

Quality Management System certified – ISO 9001:2008 – 2013, 2016, 2019

Quality Manual – 2,0 version – 2016

## Quality Manual structure

Key Processes	Organizational Processes	Supportive Processes	Operational processes
<ul style="list-style-type: none"><li>• Sales Development</li><li>• Purchasing</li><li>• Customer Support</li></ul>	<ul style="list-style-type: none"><li>• General Management</li><li>• HR management</li><li>• Management IT</li><li>• Measures Marketing</li><li>• Organizational management</li><li>• Quality management</li></ul>	<ul style="list-style-type: none"><li>• Changes management</li><li>• Documentation management</li></ul>	<ul style="list-style-type: none"><li>• Regulatory Affairs</li><li>• Pharmacovigilance</li><li>• Trainings</li><li>• Consulting</li></ul>





# Company Values & Vision



## Practical not merely theoretical

To understand goal of Customer is to sell a product, not to get a formal approval or simply monitored



## Cooperates with Marketing / logistics departments of Customers

To ensure authorized product is marketable and packaging easily produced, supports marketing initiatives for medical marketing excellence



## Follow up support

To assist with regulatory and other related issues that appear during import and sales to market



## SKU harmonization

To arrange multi-language/universal packaging to reduce number of SKU's by handling authorization across territories



## Reasonable rates and fast payback

To keep less expensive service than international CRO's

To cover operational costs easier on behalf of MAH to speed start of market commercial operations



## Contact us

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