



- ✓ Sopharma – Who are we? Brief History, Corporate structure
- ✓ Key & Main markets
- ✓ Product portfolio
- ✓ Sopharma as a CMO
- ✓ Quality management System
- ✓ Manufacturing Sites & Spare Capacities
- ✓ QA/ QC/ R&D
- ✓ Distribution
- ✓ Summary
- ✓ Contacts



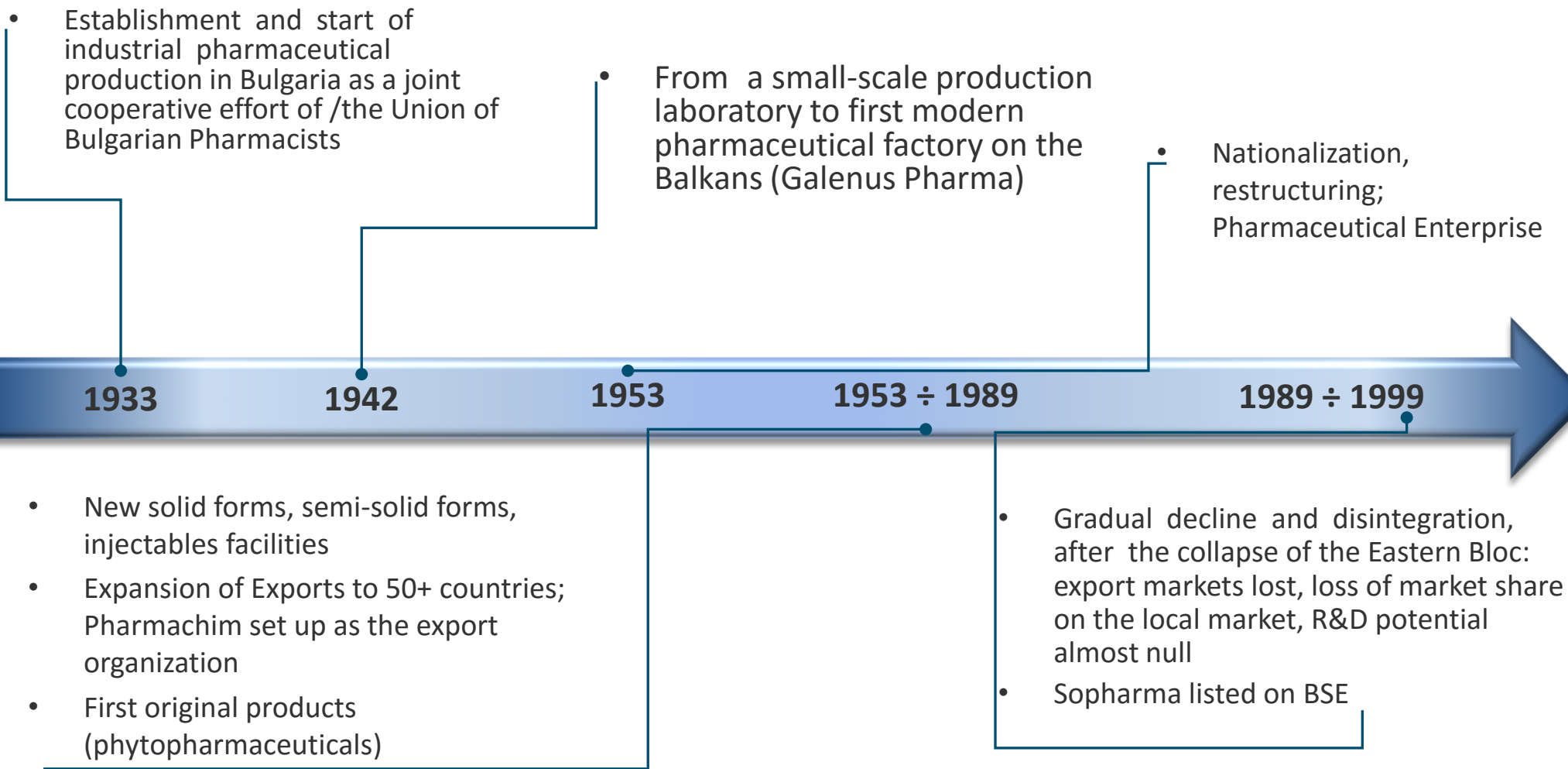
Who Are We?

- ✓ Company with more than 80 years tradition and modern approach for production of human medicines- modern production, European quality standards, corporate social responsibility
- ✓ The Group is a leading, vertically-integrated Bulgarian manufacturer, exporter and distributor of pharmaceuticals and other health related products with a strong presence in Southern and Eastern Europe, offering a wide range of prescription and OTC pharmaceutical products and other health related products and services
- ✓ The Group is active on over 40 markets, on 5 continents
- ✓ 39 subsidiaries, 7 joint-ventures and 2 associate companies in 7 countries





Brief History: The Roots, Rise and Fall



Brief History: A New Beginning

- Privatization – Sopharma becoming a privately held pharmaceutical company
- Clear targets set for transforming the company to a pharmaceutical manufacturer compliant with the internationally approved standards for quality and efficiency (EU cGMP)

- Modernization of existing production facilities
- Export markets rapidly recovered and growing, R&D potential regained
- Acquired five small producers
- New modern pharmaceutical plant Vrabovo opened for production of medicinal products
- Licensed its production facilities according to the European GMP

- Expansion in Bulgaria and on neighbor markets (acquisitions in Bulgaria, Ukraine, Russia, Serbia)

2000

2001 ÷ 2005

2006 ÷ 2008 – to date

2011 ÷ 2013

2013 ÷ 2015

- Listing on Warsaw Stock Exchange
- The Group opened a new additional production facility in Serbia with an annual capacity of 70 million tablets.

- The new state-of-the-art solid-forms factory of Sopharma is operational and won three awards in the construction sector
- The Bulgarian Rose Sevdopolis was delisted and became from a public company to plant which is part of Sopharma PLC
- Medica AD join Sopharma Group



Corporate structure

Board of Directors

Chairman of the Board of Directors
and Executive Director

Deputy-chairman of
the Board of Directors

Independent Members
of the Board

Members of the Board
of Directors

Independent Members
of the Board

Director Business operations,
Strategic and Organizational
development

Director Advertising and Corporate
Communications

Director Quality Management

Representative office of
Sopharma AD in :

Director Cooperation and Licenses

Director Commercial Department

Head of "Quality Assurance"

Chief Financial Officer

Director Marketing

Division "Regulatory Affairs -
Bulgaria and third markets"

Deputy Chief Financial Officer

Director Security

Division "Medical Affairs and
Clinical Trials "

Director Investor Relations

Director Technical matters

Division "European Regulations"

Director Institutional Relations

Director Production matters

Division "Pharmaceutical Products
Safety"

Director "Intellectual property"

Director Coordination of production

Human Resources

Chief of Production department

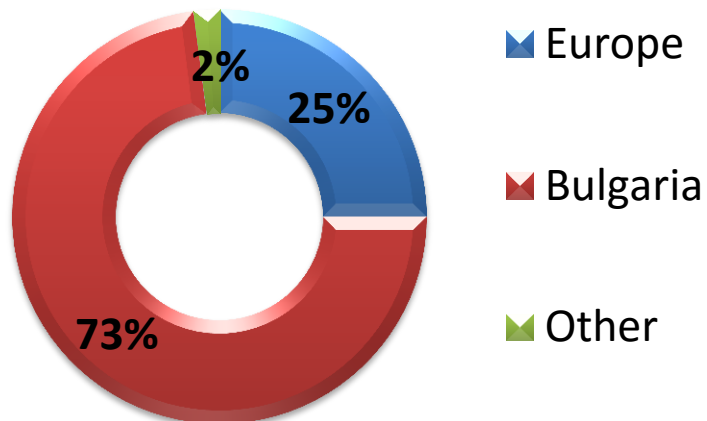
Chief Accountant

- Russia
- Ukraine
- Poland
- Kazakhstan
- Baltic states and Belarus
 - Turkey
- Azerbaidjan
- Georgia
- Armenia
- Tunisia
- USA
- Serbia
- China
- Israel & Palestinian territories

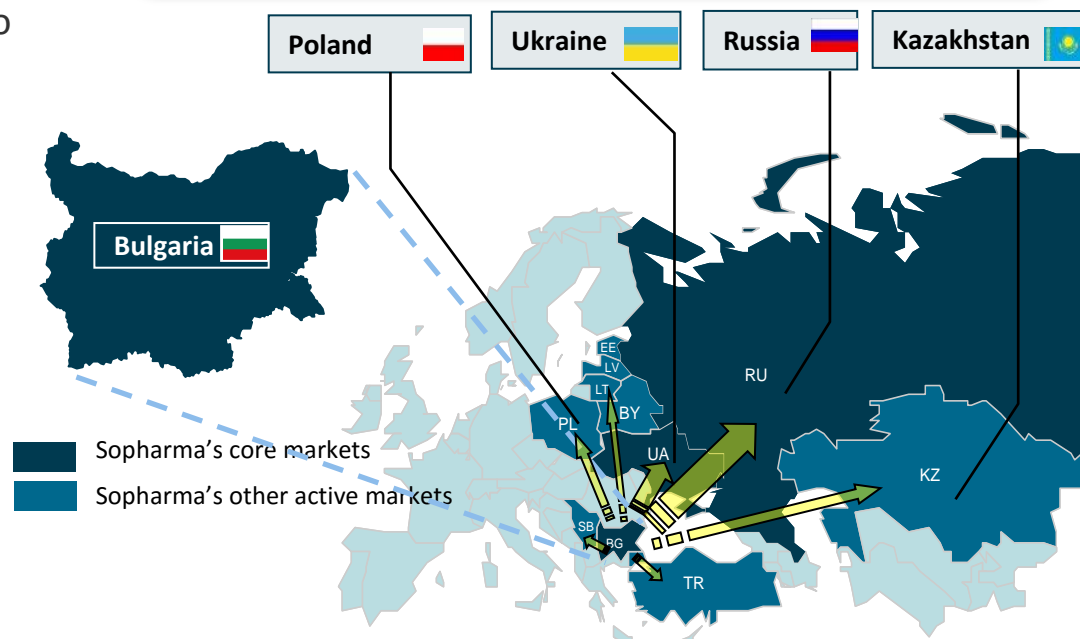
Key & Main Markets

- ✓ The Group is active on over 40 markets, the key markets apart from Bulgaria are: Russia, Ukraine, Kazakhstan and Poland
- ✓ Bulgaria is the main market accounting for 73% of its sales revenues in 2016, increasing by 3% compared to the same period of 2015
- ✓ Russia and Ukraine being the most significant export markets of the Group representing respectively 6.4% and 5.9% of its revenue in 2016
- ✓ Looking ahead, expected sales of finished products growth due to stabilization in Russia and Ukraine markets

Revenue breakdown by geographic region in 2016

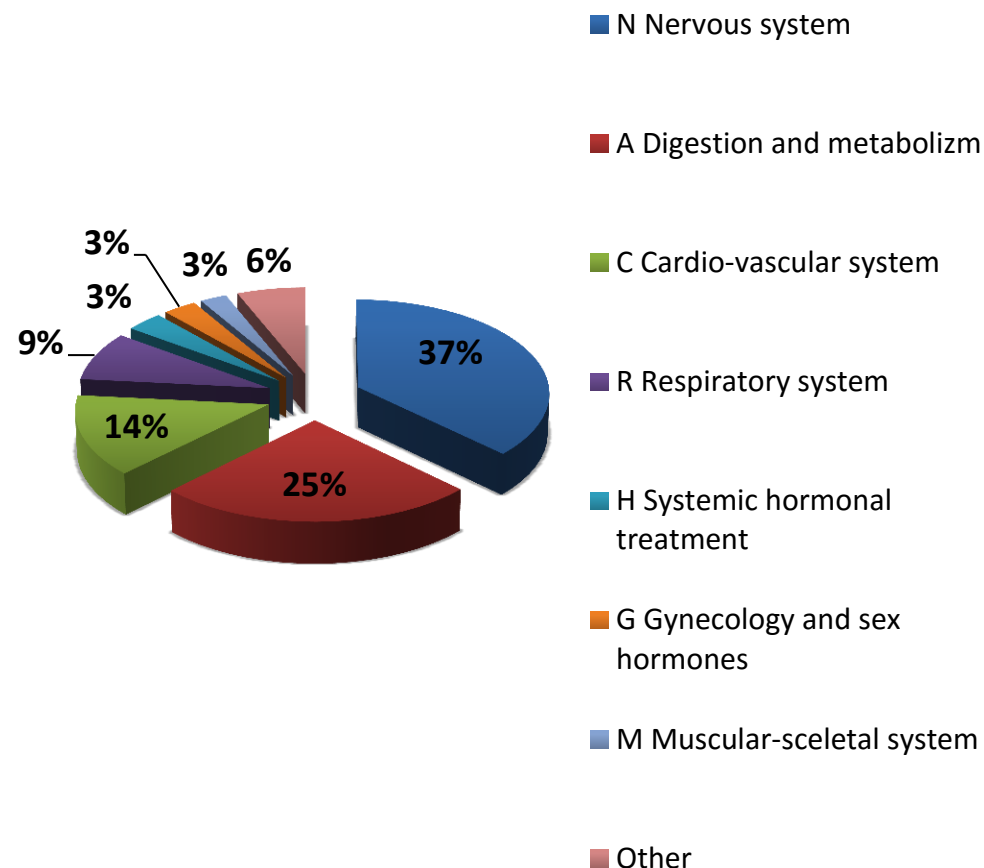


Key markets for Sopharma AD



- ✓ More than 210 products in the portfolio mainly in the form of tablets and ampoules
- ✓ The strength of Company's product brands, both original products, including own phyto-based products, and branded generics supported by their quality and efficacy provide a competitive advantage as in the pharmaceutical sector recognition and a good reputation are of key importance
- ✓ Very strong position in the domestic market
- ✓ Leading position of the Group on the Bulgarian hospital market – high volume sales, liberal payment schedule, low risk
- ✓ Partner of choice for cooperation with large international pharma companies (current relationships with GSK, Novartis, Janssen-Cilag, Wyeth)

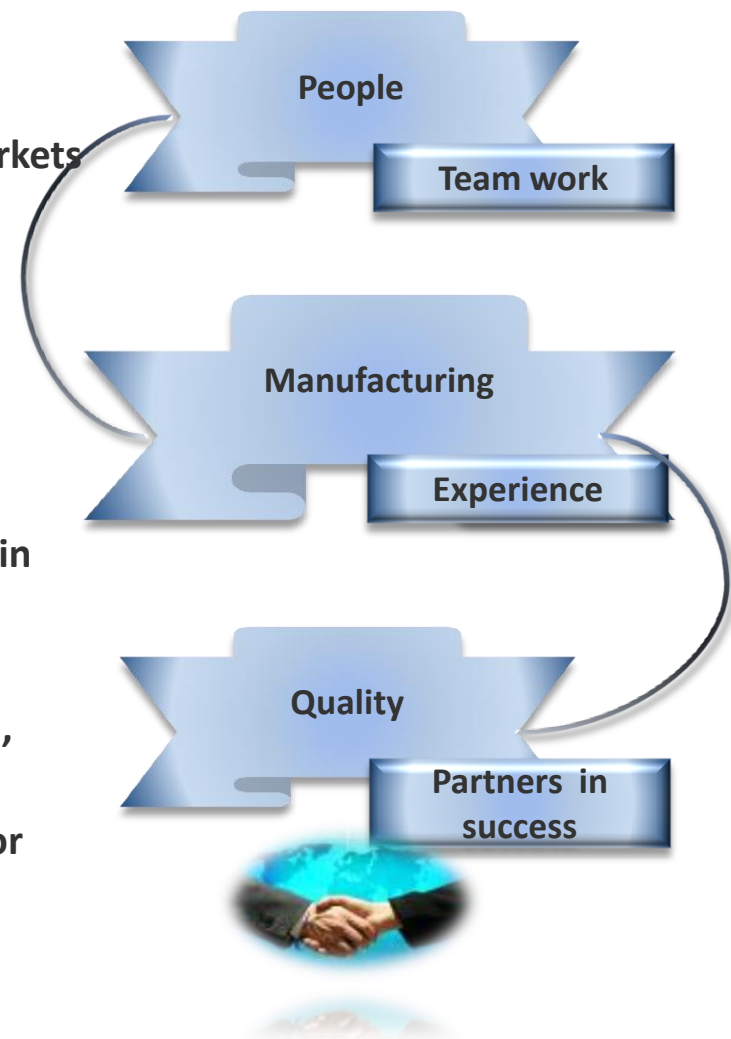
Sopharma's specialization on therapeutic groups



Sopharma as a CMO

- ✓ Our company offers a large variety of CM services:
 - EU-GMP compliant pharmaceutical contract manufacturing,
 - EU primary and secondary packaging services for international markets
 - Development of various dosage forms
 - Technological transfer of customer-developed products
 - Cleaning validation, Process validation
 - EU batch release and batch control

- ✓ Sopharma offers manufacturing of different dosage forms:
 - solid dosage forms (both sugar and film-coating tablets, hard gelatin capsules)
 - semi-solid dosage forms (creams, gels, ointments, suppositories)
 - sterile dosage forms (terminal sterilization and aseptic preparation, BFS technology)
 - non sterile solutions (syrups, oral suspensions, ear drops, liquids for external use)
 - CMO services of medical devices



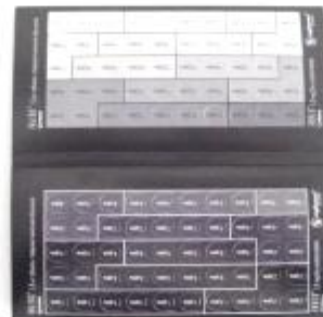
Sopharma as a CMO



How do we look?



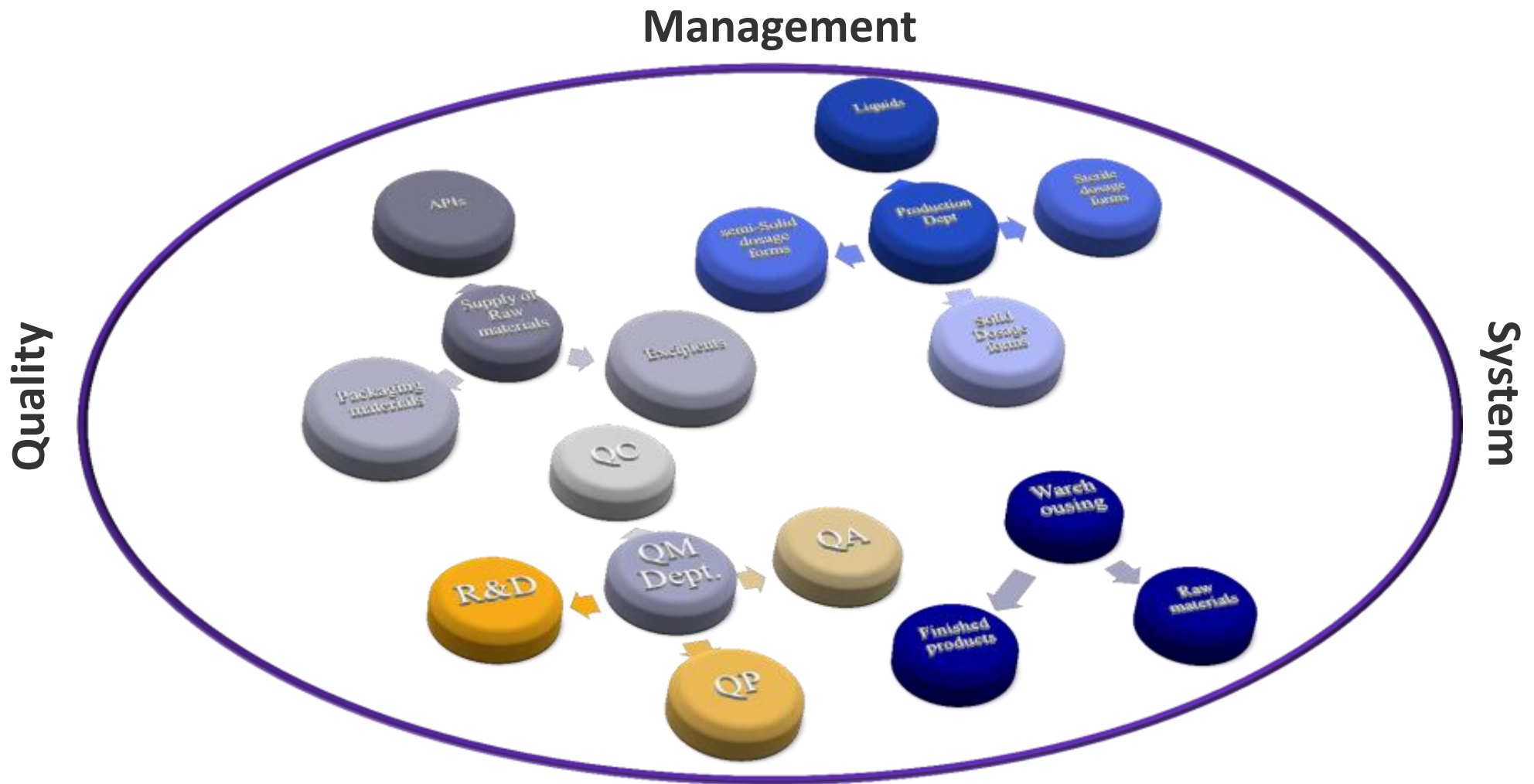
How do we look?



Quality Management System



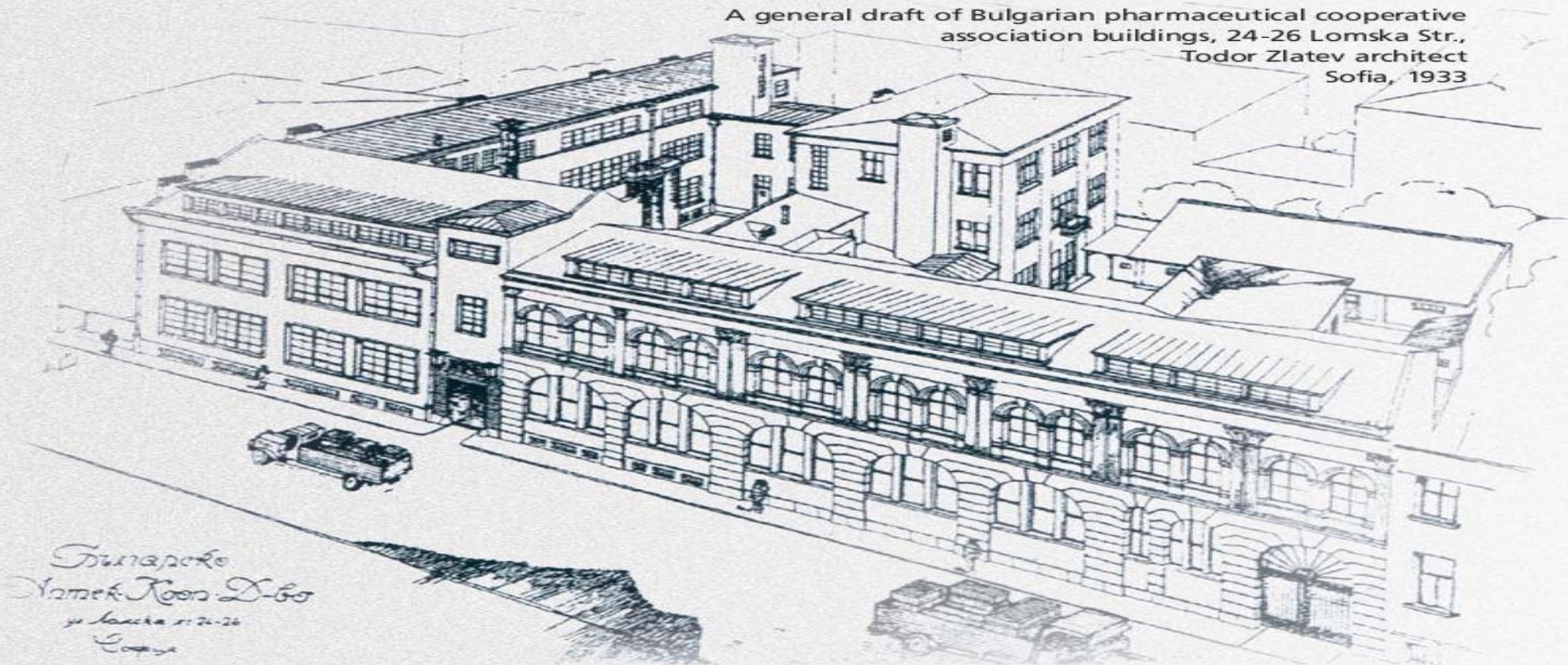
Sopharma's QMS – main elements



Manufacturing sites

Обща скица на сградите на БАКД, ул. Ломска 24-26,
Арх. Тодор Златев
София, 1933 г.

A general draft of Bulgarian pharmaceutical cooperative
association buildings, 24-26 Lomska Str.,
Todor Zlatev architect
Sofia, 1933



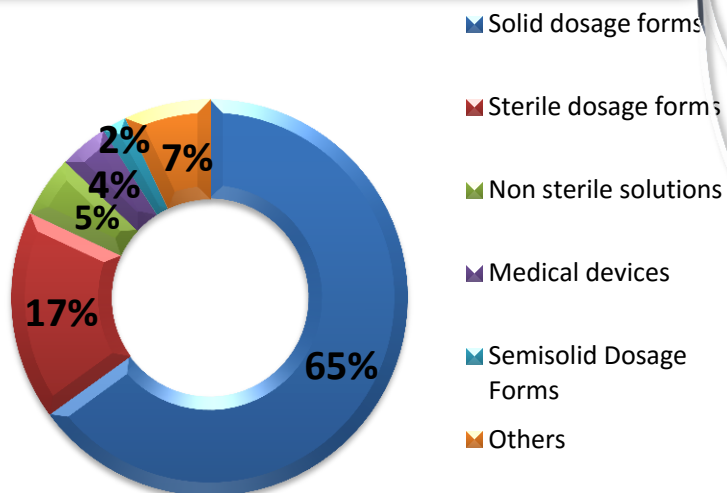
Manufacturing sites

Sopharma Group

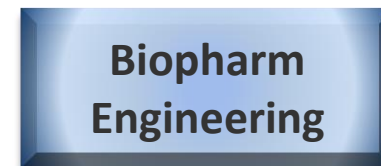
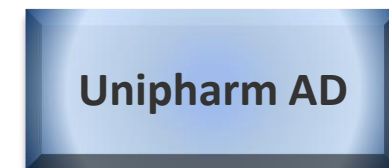
Total headcount: 1834 employees



Revenue breakdown by Finished product sales , 2016



Public companies



* 2016- Tender offering for the shareholders of Unipharm AD (pending approval from the BFSC)



Solid Dosage Forms

Plant Name	EU GMP certificate	Granulation		Compression	Film-coating	Sugar coating	Hard gelatin capsules (size 0 ÷ 4)	Primary packaging Material	IMP License
		High-shear mixer	Fluid bed dryer						
Solid Dosage Forms Plant	•	•	•	•	•	•	• (size 0 ÷ 4)	Al/ Al Al/ PVDC Al/ PVC Al/PCTFE	○
Vrabevo Plant	•	○	•	•	•	•	○	Al/ PVDC Al/ PVC	○
Kazanlak Plant	•	•	•	•	•	•	•	Al/ Al Al/ PVDC Al/ PVC	•
Unipharm	•	•	•	•	•	○	○	Al/ PVDC Al/ PVC	○
Medica Plant	•	•	•	•	•	•	• (size 0 ÷ 1)	Al/PVDC Al/PVC	○
<p>Legend:</p> <p>• Available</p> <p>○ Not available</p>									



Manufacturing sites – production capabilities

Sterile Dosage Forms

Plant Name	EU GMP certificate	Depyrogenization	Terminal sterilization		Aseptic preparation	BFS	Filling volumes	Primary packaging Material	IMP License
			Equipment	Product					
Ampoule plant	●	●	●	●	●	○	1 ÷ 10 ml	Glass ampoules	○
Freeze-dried products plant	●	●	●	○	●	○	1 ÷ 10 ml	Glass ampoules	○
Biopharm Engineering	●	●	●	●	●	●	BFS 0.7 ÷ 500 ml PP Bags 250÷1000ml	PP, PVC, PE, PET	○
Legend: ● Available ○ Not available									

Non sterile solutions

Plant Name	EU GMP certificate	Syrups	Oral suspensions	Ear drops	Liquids for external use	Primary packaging Material	IMP License
Vrabevo Plant	●	●	●	○	○	PET and Glass bottles	○
Unipharm	●	○	○	●	○	Glass vials	○
Medica Plant	●	○	○	○	●	PET, HDPE, PETG and Glass bottles	○
Legend: ● Available ○ Not available							



Semisolid Dosage Forms

Plant Name	EU GMP certificate	Creams	Gels	Ointments	Suppositories	Primary packaging Material	IMP License
Vrabevo Plant	●	●	●	●	○	Al-tubes	○
Unipharm	●	●	●	●	○	Al-tubes	○
Suppositories plant	●	○	○	○	●	Bilayer PVC/ PE	○
Legend:							● Available ○ Not available

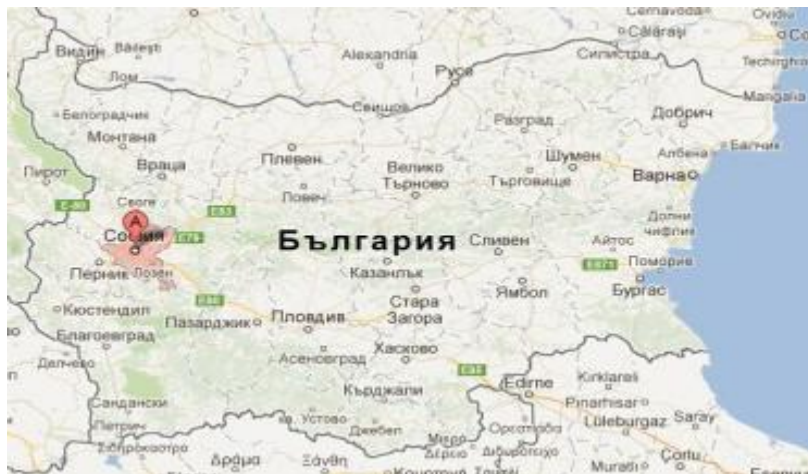
Medical devices

Plant Name	Dressings (sterile and non sterile)	Swabs (sterile and non sterile)	Bandages	Compressing stockings	Elastic support products	First-aid strips and adhesive rolls	Sterile sets for surgical manipulations, first aid kits	Primary packaging Material	EC Certificate; ISO 9001:2008; ISO 13 485:2003
Medica AD	●	●	●	●	●	●	●	Paper/Paper Paper/PP/PA Paper/PP/PE	●
Legend:									● Available ○ Not available





Solid Dosage Forms Plant



Location

Total surface , m²

Employees

**Capacity,
billion units**

Sofia – the capital of
Bulgaria

22 000 m²

255

4bn tablets



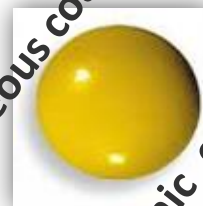
Solid Dosage Forms Plant

We are a customer-focused organization!

* Main manufacturing equipment

- ✓ Fluid bed dryers:
 - ↗ BOSCH-HUETTLIN (nominal volume 527 l) with drying capacity 50÷240 kg/ granulation capacity 50÷210kg
 - ↗ BOSCH-HUETTLIN (nominal volume 937 l) with drying capacity 100÷490 kg/ granulation capacity 100÷375 kg
- ✓ Blenders with capacities 306÷1300 l, 170÷720 l, 102÷433 l. All from L.B. Bohle Maschinen
- ✓ Film-coating drums with capacities 200÷400 kg; 90÷120 kg (Bohle and Manesty)
- ✓ High Shear Mixer (nominal volume 400 l) with capacity 65÷180 kg (BOSCH-HUETTLIN)
- ✓ Tablet presses – FETTE
- ✓ Packaging lines Uhlmann
- ✓ Capsule filling machine MG2 Planeta (capsule's size 0÷4) with capacity 50 000 capsules per hour

Aqueous coating



Organic coating



Sugar-coating



Cross Perforation





Ampoule (sterile dosage forms) Plant



Location

Total surface , m²

Employees

**Capacity,
million units**

Sofia – the capital of
Bulgaria

3 820 m²

219

80 m (two-shift regime)





* Main manufacturing equipment:

- ✓ PW Installation, Aqua PW System , capacity up to 6 t/ h
- ✓ WFI Installation, Gettinge Kemitem, capacity up to 1.5 t/ h
- ✓ Lines for visual inspection + High Voltage Leak Detection(leak detection, pinhole and crack detection) :
 - ↗ AIM 277+Convel: Bosch Eisai + Convel, 2014
 - ↗ AIM 296 + Nika: Eisai, 2007 + Bausch & Ströbel / Nikka Densok , 2007
 - ↗ AIM 296 + KLD: Eisai, 2015 + Bosch, 2015
- ✓ Labeling lines Newman 6VA and Newman VAL 550
- ✓ Secondary packaging lines:
 - ↗ Mediseal, 2015
 - ↗ Soteco , IMA Group
- ✓ Box coding UDA 150S, Metronic

*2015: Reconstructed and
refurbished to double the
capacity!*





* Main manufacturing equipment

➤ Terminal sterilization:

- ✓ Vessels, Schrader, capacity 20 l, 50 l, 100 l, 250 l
- ✓ Washing-depyrogenization-filling-sealing line ALF (RRU+HQL+ALF) , Bosch 2015 for 1, 2, 5 and 10 ml glass ampoules; capacity 1&2 ml– 24 000 units/ h
- ✓ Washing-depyrogenization-filling-sealing line line AVR (RUR+TLQ+AVR) , Bosch 2007; capacity 2 ml glass ampoules – 6 ÷ 16 000 units/ h; 5 ml – up to 12 000 units/ h; 10 ml – up to 9 000units/h
- ✓ Steam sterilization module GEL 91425, Getinge, 3000 l





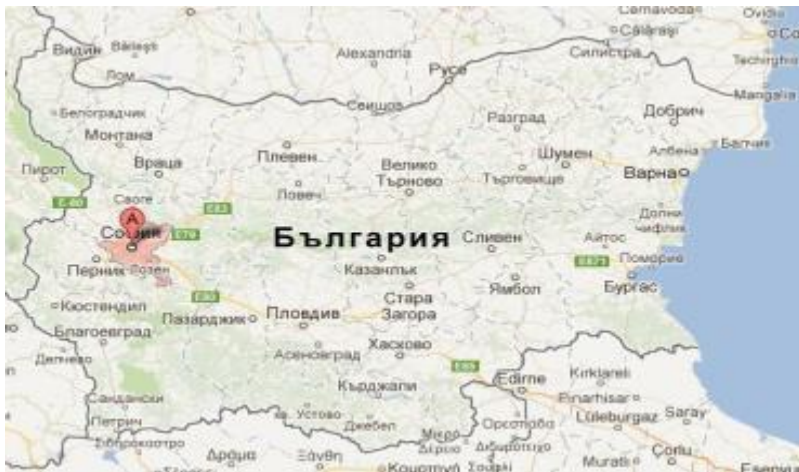
* Main manufacturing equipment

Aseptic Preparation :

- ✓ Vessels, capacity 100 l, 300 l
- ✓ Washing-depyrogenization-filling-sealing line ALF (RRU+HQL+ALF) , Bosch 2007, capacity 1&2ml glass ampoules – up to 24 000 units/ h, 5 ml -up to 15 000 units/ h; 10ml -up to 9 000 units/ h
- ✓ Aseptic sterilization module GE 6613 , Getinge, 500 l & GEL 91425 , Getinge, 3000 l



Lyophilized Products Plant



53



Location

Total surface , m²

Employees

**Capacity,
million units**

Sofia – the capital of
Bulgaria

1 250 m²

50

7.2m ampoules,
4.3m lyophilic
ampoules



* Main manufacturing equipment

- ✓ PW Installation, Aqua PW System
- ✓ WFI Installation, Gettinge Kemitem
- ✓ Vessel Buchi – 15 l, equipped with dosing device, cryostat, pH-meter, thermocouple
- ✓ Vessel, Steridose, capacity 50 l
- ✓ Lyophilizer, Leybold
- ✓ Autoclaves – Tuttnauer



Suppositories Plant



Location

Total surface , m²

Employees

**Capacity,
million units**

Sofia – the capital of
Bulgaria

452 m²

19

15m suppositories



* Main manufacturing equipment

- ✓ Homogenizer Fryma VME-400
- ✓ Vessel 120 l
- ✓ Filling and packaging line Sarong SAAS 15/AP



Vrabevo Plant



Location

Total surface , m²

Employees

**Capacity,
billion and million units**

Lovech district –central
part of Bulgaria; about 150
km
from Sofia

6 987 m²

215

1bn tablets, 20m syrups,
30m ointments



Solid dosage forms manufacturing site

* Main manufacturing equipment

- ✓ Fluid bed dryer Glatt WSG-CD 60 with capacity 40÷120 l
- ✓ Blender Glatt KCM with capacity 40÷100 l
- ✓ Film-coating drum Glatt GCM 175 with capacity 80÷130kg



Semisolid dosage forms manufacturing site

* Main manufacturing equipment

- ✓ Vessels ZOATEC 200 l, 500 l and 700 l
- ✓ Homogenizer up to 700 l
- ✓ Filling and packaging line
NORDENPAC for Al and laminate
tubes with filling head for 5 ÷ 150 ml
and tube's holders with diameter 20
mm



Non Sterile Liquids manufacturing site

* Main manufacturing equipment

- ✓ Vessel Steridose 2 800 l
- ✓ Vessel Rotamil 1 000 l
- ✓ Homogenizer ROMACO FrymaKoruma with capacity 100 l /min suspension
- ✓ Primary packaging line Marchesini ML 661
- ✓ Secondary packaging line Marchesini MA100





Kazanlak Plant: Solid dosage forms, Phyto-APIs & Synthetic products



Location	Dosage form	Total surface , m ²	Employees	Capacity, billion and million units
Kazanlak district – central part of Bulgaria; about 260 km from Sofia	Ointments	1 022 m ²	234	30 m ointments
	Tablets	2 400 m ²		exp. 4bn tablets 100t of substance



Solid dosage forms manufacturing site

* Main manufacturing equipment

- ✓ Fluid bed dryer Glatt WSG-UDP 60 with capacity 40÷100 l
- ✓ Blenders with capacities 40÷100 l, 80÷200 l, 225÷600l
- ✓ Film-coating drums:
 - ↗ Glatt GC 1250 with capacity 80÷150 kg
 - ↗ Glatt GC 1500 with capacity 200÷340 kg
 - ↗ Technicota 400 with capacity 200÷340 kg
- ✓ High Shear Mixer Fielder RMA 400/ 261 VAC with capacity 80÷140 kg
- ✓ Capsule filling machine Macofar MT 80 (capsule's size 0 ÷ 4)



Phyto-APIs manufacturing site

- * The plant is equipped with a production line for manufacturing of APIs

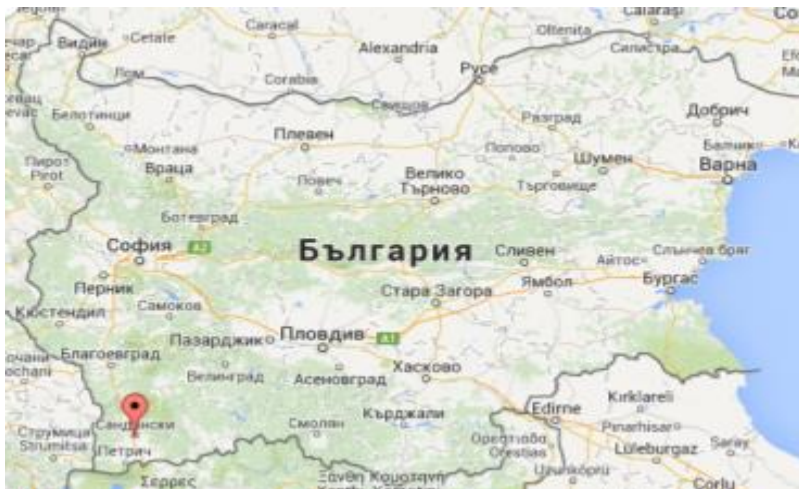


Silymarin



Galantamine





Location	Facilities Area (production +QC + warehouses)	Employees	Capacity, Units
Sandanski – southwest part of Bulgaria; about 160 km from Sofia	9 700 sq. m.	198	Find the slides below; depends on the product



Medical devices manufacturing site

* Main manufacturing equipment

- ✓ Gauze Compress folding machines Bouda with capacity 5 000÷ 7000 pcs/hr
- ✓ Blister machines for sterile products Hammerle with capacity 1 000÷ 1500 pcs/hr
- ✓ Flat Packing machine for sterile products Holweg RV with capacity 1 000÷ 1500 pcs/hr
- ✓ Flow packing machine Tevofarm for bandages with capacity 1000-1200 pcs/hr
- ✓ Weaving machines Jakob Muler
- ✓ Knitting machine Rius Medical 1000
- ✓ Circular knitting machines Lonati
- ✓ Rolling machines for bandages
- ✓ Steam autoclave for medical devices – TBM with capacity 10 m³



Solid dosage forms manufacturing site

* Main manufacturing equipment

- ✓ Fluid bed dryer Aeromatic with capacity 60÷100 l
- ✓ High Shear Mixer Lodge MGT 400P with capacity 100 ÷ 150 l
- ✓ Blender Fuchs Tip B with capacity 100÷200 l
- ✓ Film-coating drums:
 - ↗ Manesty Acela cota 150 with capacity 90÷120 kg
 - ↗ GS HT/M300 with capacity 100÷250 kg
- ✓ Tablet presses – Fette, Ronchi
- ✓ Primary and secondary packaging line Noack
- ✓ Capsule filling machine Zanassi AZ40 (capsule's size 0÷1)

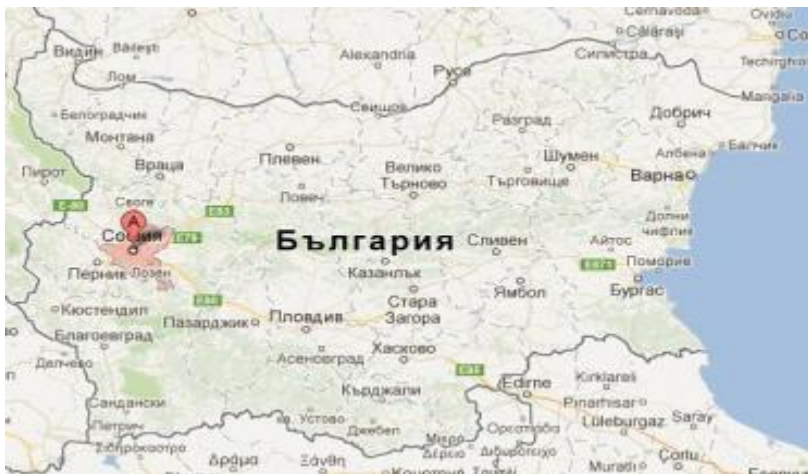


Non Sterile Liquids manufacturing site

* Main manufacturing equipment

- ✓ Vessels with capacities 100 l, 250 l, 800 l
- ✓ Filling machine semiautomatic, with filling volume from 15 to 500 ml and capacity, up to 1000pcs/hr





Location

Total surface , m²

Employees

**Capacity,
million units**

Sofia – the capital of
Bulgaria

846 m²

168

750m tablets



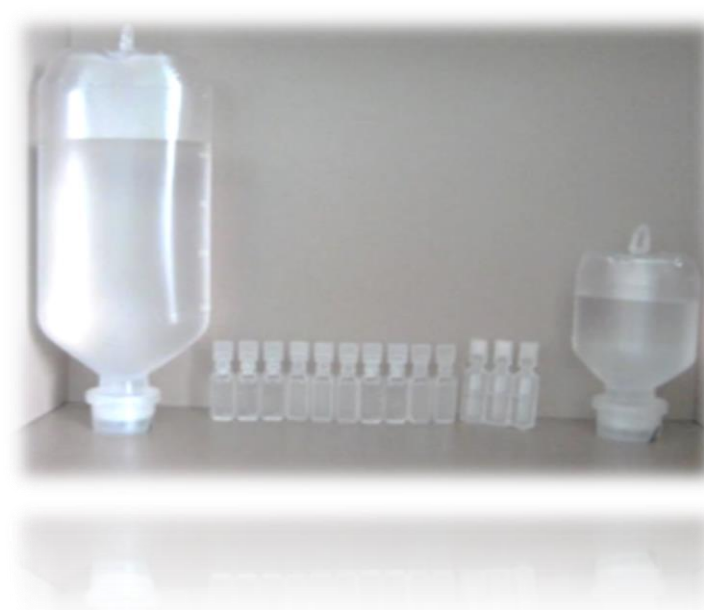
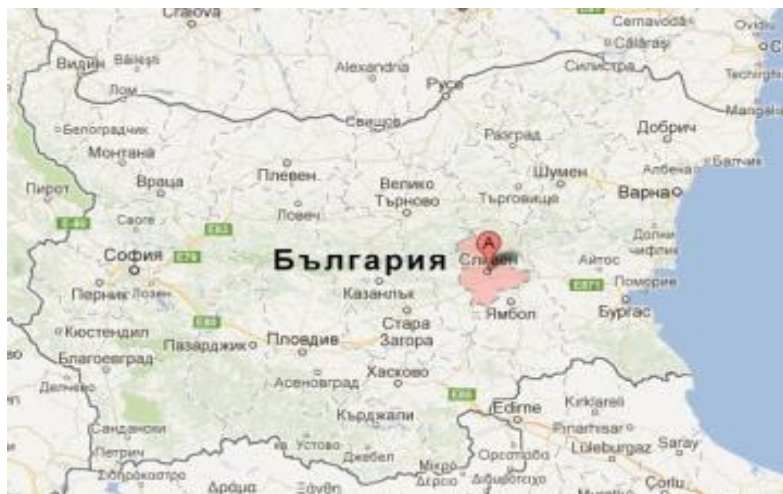
* Main manufacturing equipment

- ✓ Fluid bed dryer Bohle BSF-60 with capacity 40÷100 l
- ✓ Blenders with capacities 60÷160 l, 90÷240 l, 102÷433 l
- ✓ Film-coating drums Bohle with capacities 50÷100 kg
- ✓ High Shear Mixer Pivot P25 with capacity 15÷40 kg
- ✓ Primary packaging line Romaco Noack 623 with capacity 250 blisters per minute
- ✓ Secondary packaging line Romaco Promatic P 91 with online batch number and expired date coding





Biopharm Engineering



Location	Facilities Area (production +QC + warehouses)	Employees	Capacity, Units(ampoules, vial)/ hour
Sliven– eastern part of Bulgaria; about 300 km from Sofia	2 000 sq. m.	114	BFS vials: 12 000 BFS bottles: from 2500 to 3500



* Main manufacturing equipment

- ✓ Line for large volumes i.v. terminally sterilized solutions
- ✓ The new Blow-Fill-Seal Line, Weiler 640 (series ASEP-TECH) is fully operational from 2015 year
- ✓ Capacity:
 - 1ml, 2 ml and 3 ml BFS vials :
~12 000 ampoules/ hour
 - BFS 100 ml bottles:
~ 3000 ÷ 3500 bottles/ hour
 - BFS 250 ml bottles:
~ 3000 bottles/ hour
 - BFS 500 ml bottles:
~ 2500 bottles/ hour



***All volumes are approximate and should be discussed case by case**



Spare Capacities* - flexible

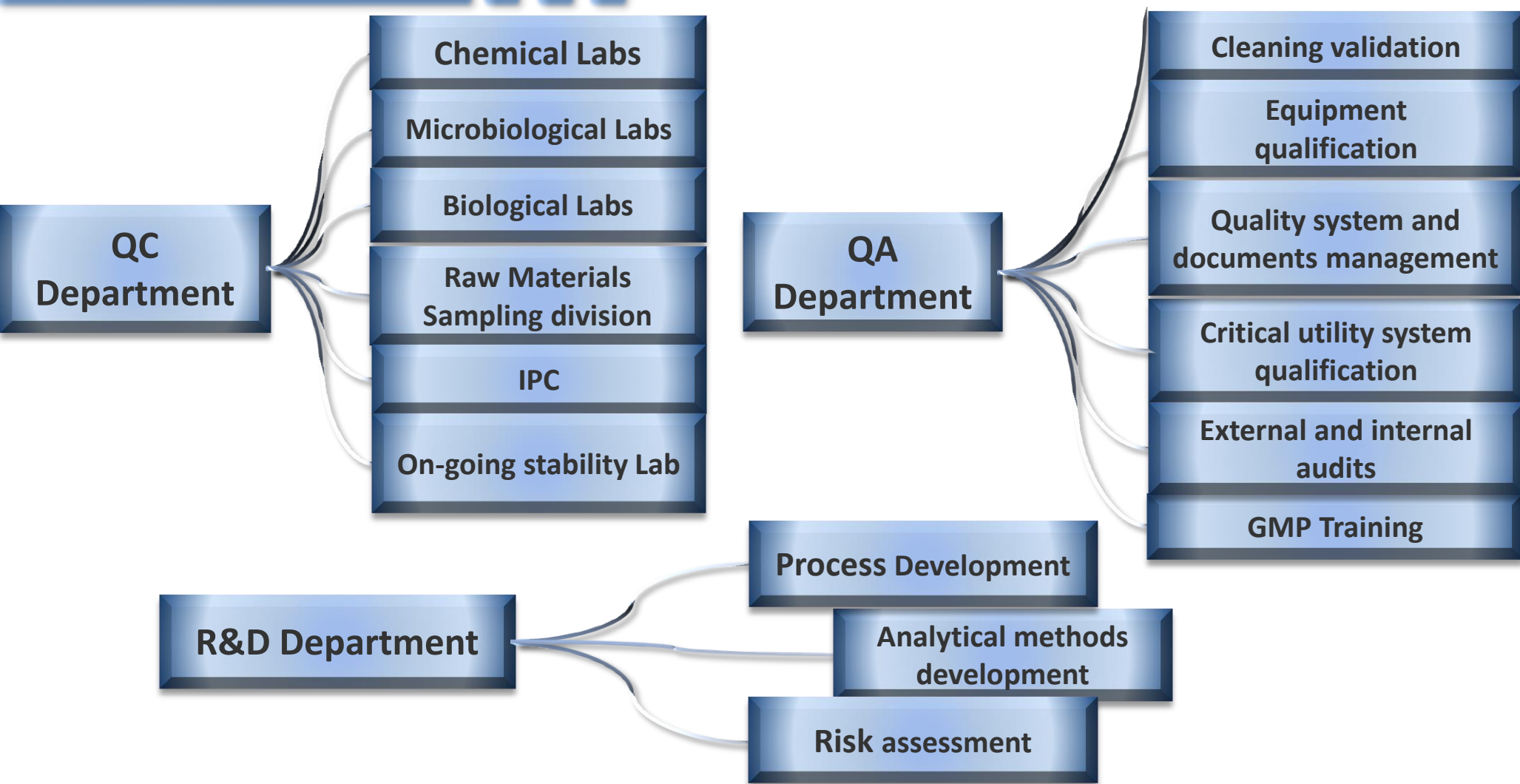
- ✓ **Solid dosage forms:** 1.4 ÷ 1.6 billion units/ year
- ✓ **Semi-solid dosage forms** - 10 million units/ year
- ✓ **Sterile dosage forms:**
 - ↗ Small volumes
 - Terminal sterilization: 16 000 000 units/ year
 - Aseptically prepared: 19 000 000 units/ year
 - ↗ Large BFS volumes:
 - 20 million units/ year (BFS bottles 100 ml; 2 mode shift)
 - 12 million units/ year (BFS bottles 250 ml; 2 mode shift)
 - 7 million units/ year (BFS bottles 500 ml; 2 mode shift)
 - ↗ Small BFS volumes:
 - 120 million units/ year (BFS vials 1 ml, 2 ml and 3 ml; 2 mode shift)

***All volumes are approximate and should be discussed case by case**





QC, QA, R&D Departments



- ✓ 30 + countries receive Sopharma's goods by air transport
- ✓ Georgia, Austria, Albania, Germany, USA, Serbia, Poland, Macedonia, Rumania, Sweden and many others
- ✓ 20 + countries receive Sopharma's goods by land transport
- ✓ Russia, Ukraine, Albania, UK, Greece, Turkey, Latvia, Holland, Czech Republic, Azerbaijan and many others.
- ✓ Sopharma's goods to Korea, Mongolia, Malta by sea transport

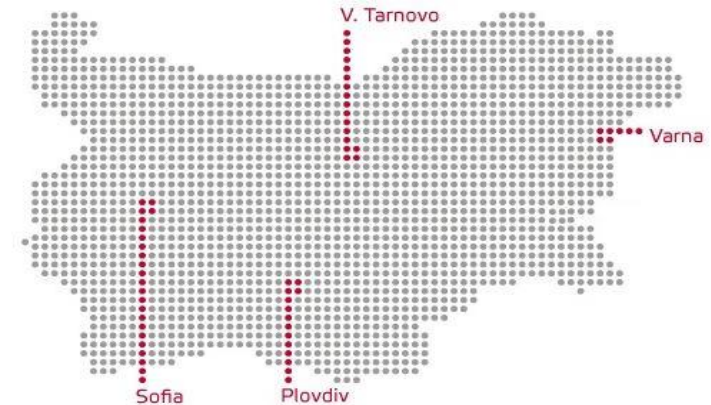


**40 + countries benefit
from Sopharma's logistic
services**



Potential

- ✓ 4 distribution centers
- ✓ 17 500 sq. m. warehouse area
- ✓ 170 sq. m. storage area for thermo susceptible products



New logistic center in Varna

- ✓ Total area: 7 400 sq. m.
- ✓ Warehouse area: 2 800 sq. m.
- ✓ Capacity: 10 000 items



Distribution and wholesaling

- ✓ Main distributor of Sopharma products in Bulgaria, mainly by pre-wholesaling
- ✓ Number one in hospital segment
- ✓ Number one medical equipment supplier
- ✓ Top position in the retail market



- ✓ More than 80 years tradition and modern approach for production of human medicines
- ✓ Sopharma offers manufacturing of tablets, film-coated tablets, sugar-coated tablets, capsules, injectables (terminally sterilized or aseptically prepared), lyophilized products, infusions, syrups, oral suspensions, ointments, cream, gels, suppositories, medical devices, phyto-APIs
- ✓ We provide products manufactured to the highest quality standards backed by prompt storage and delivery
- ✓ Our quality management system provide the backbone of our manufacturing operations
- ✓ Our packaging are designed and printed in our own printing house
- ✓ All of our manufacturing sites are EU GMP
- ✓ The Company's cost structure coupled with the know how and GMP certifications of the majority of its productions facilities enables the Company to offer high quality competitively priced products



Thank you for your time and attention!



sopharma[®]
PHARMACEUTICALS

Ana Lichkova

Manager Contract Manufacturing and New products

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