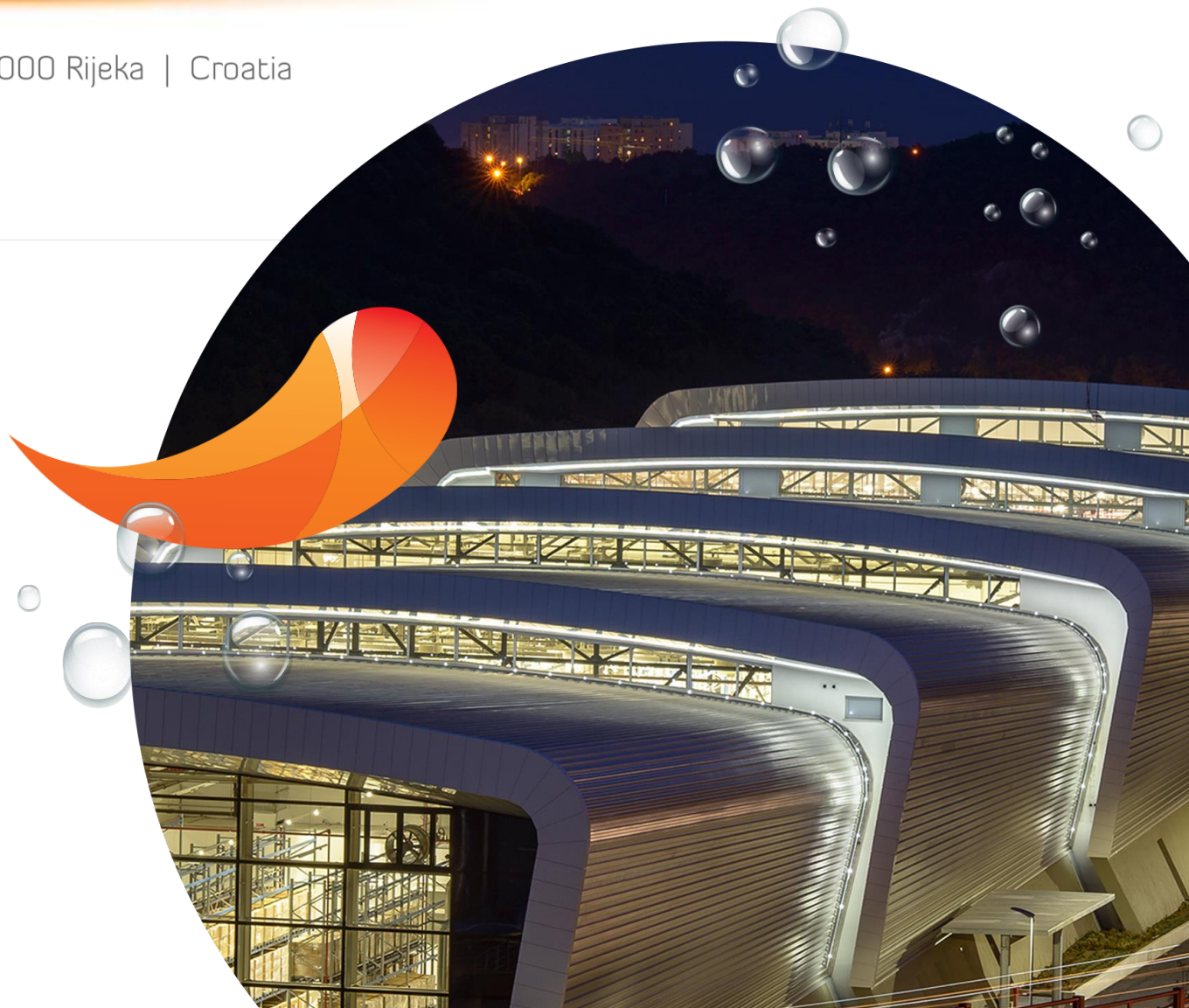
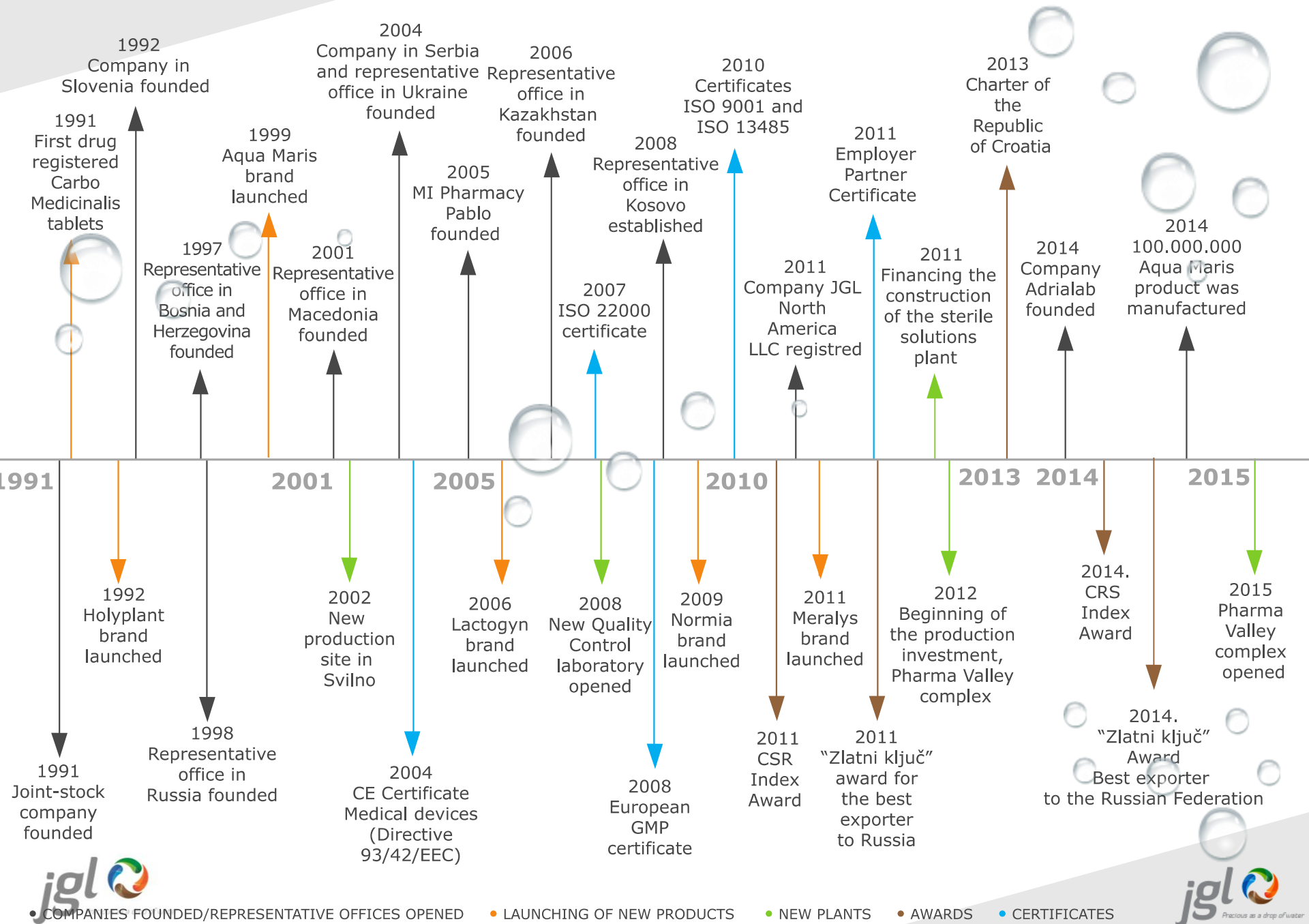


JGL PRODUCTION

JGL d.d. | Svilno 20 | 51000 Rijeka | Croatia

www.jgl.hr





• COMPANIES FOUNDED/REPRESENTATIVE OFFICES OPENED
• LAUNCHING OF NEW PRODUCTS
• NEW PLANTS
• AWARDS
• CERTIFICATES



JGL Beginnings



- founded in Rijeka in 1991 as the first private pharmaceutical joint-stock company
- developed from a laboratory for manufacturing and controlling magistral and galenic preparations for the "Jadran" pharmacy
- success lies in the niche strategy – essential drugs of small production
- organic growth based on the development of new products and conquering new markets

JGL Traffic Position



- Rijeka provides the shortest connection between overseas destinations and Central and Central-Eastern Europe, both with respect to land and sea routes.
- The Port of Rijeka is a multi-purpose port facility capable of handling almost any type of cargo.
- Croatia – the 28th member of the European Union.

Fast Organic Growth



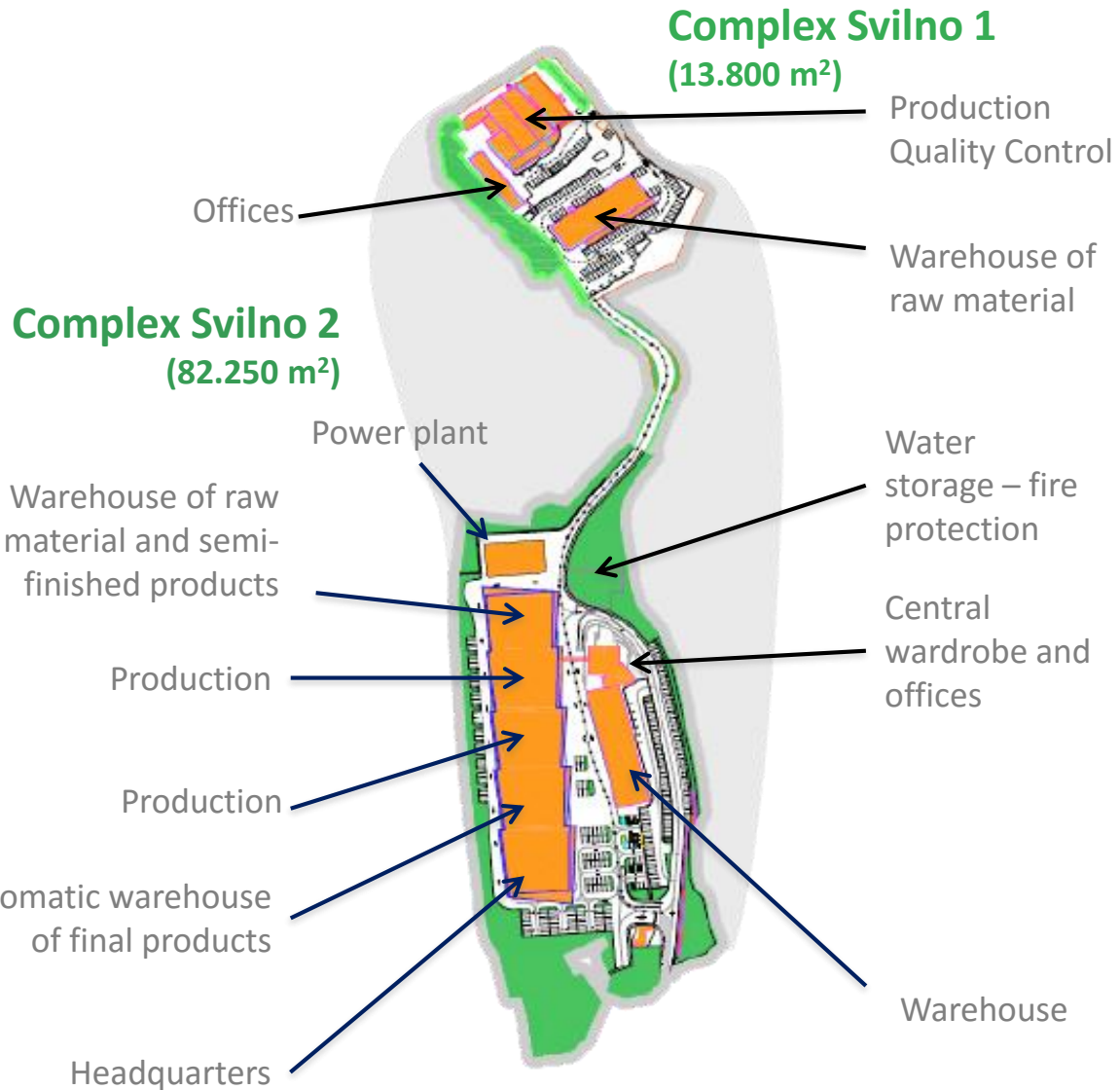
- total revenue of the Group rose from € 200.000 (1991) to € 106.622.000 (2014)
- average annual growth rate is 22 % per annum
- total revenue (JGL) for 2014 is € 84.475.306
- revenue from sales on foreign markets reached € 53.636.464 in 2014, export in the sales structure was 72,50 %





JGL Pharma Valley

- Production site
JGL, Svilno 20
- Production plants
Svilno 1 and Svilno 2
- Plants are connected
with internal road
- Total 96.050 m²



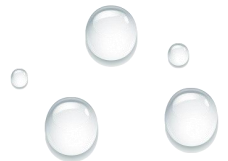
JGL Production

Key strategic technology:

- Sterile liquids – eye drops, sprays and nose drops,
- Bag-on-Valve – *advanced technology approach*.

We also produce:

- Solid oral forms – capsules and tablets,
- Semi solid forms – ointments, creams, gels,
- Non sterile solutions – syrups, dermatological solutions.



Svilno 2 - New Production Site

- State of the art production site
- Bag-on-Valve (BoV) technology
- Production of sterile forms
- Flexibility in packaging process
- Equipmet provided by European suppliers
- Automatic warehouse with rack system and satellite for products and packaging material
- Fully automated processes with In line control



Departments Overview

Facility/department	Size / m2	Year
Svilno 1 Production Sterile Solutions I Non sterile Solutions Semi-solid Forms Solid Oral Forms Packaging	1.077	2006 2006 2010 2007 2007
Svilno 1 Production Sterile Solutions II Packaging	495	2011
Svilno 1 Quality Control	460	2011
Svilno 1 Warehouse; Raw materials	800	2007
Svilno 2 Warehouse; Raw materials and finished products	3.200	2014
Svilno 2 Warehouse; Raw materials and semi-finished products, retention samples, stability chambers, sampling and dispensing area	900	2015
Svilno 2 Production Bag-on-Valve Sterile Solutions	640	2015
Svilno 2 Packaging	2.150	2015
Svilno 2 Warehouse; Finished products, semi-finished products, packaging materials	2.300	2015
Svilno 2 Automated WH Finished products, semi-finished products, packaging materials	2.250	2015

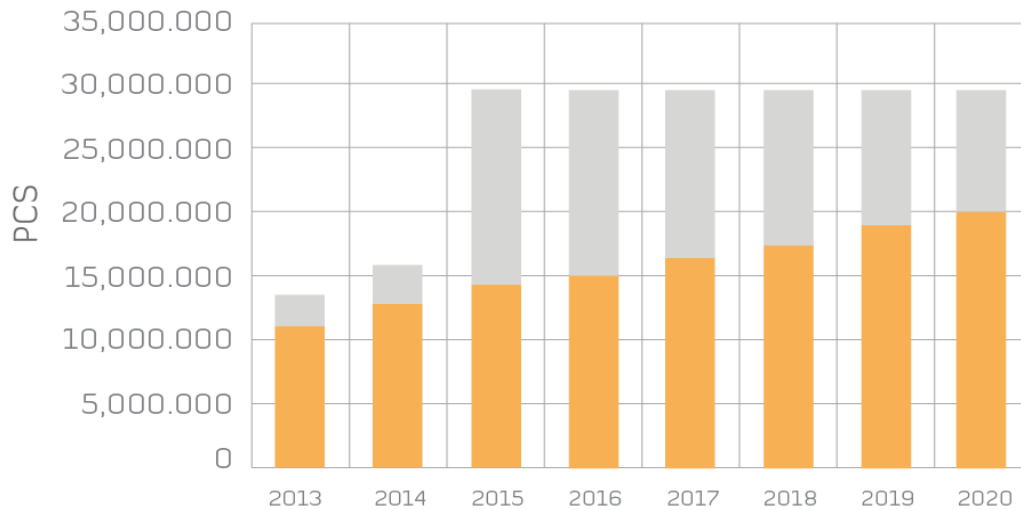




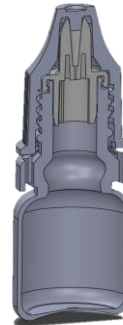
Capacity and Technology Overview

Sterile Eye and Nasal Drops

■ Capacity
■ Plan

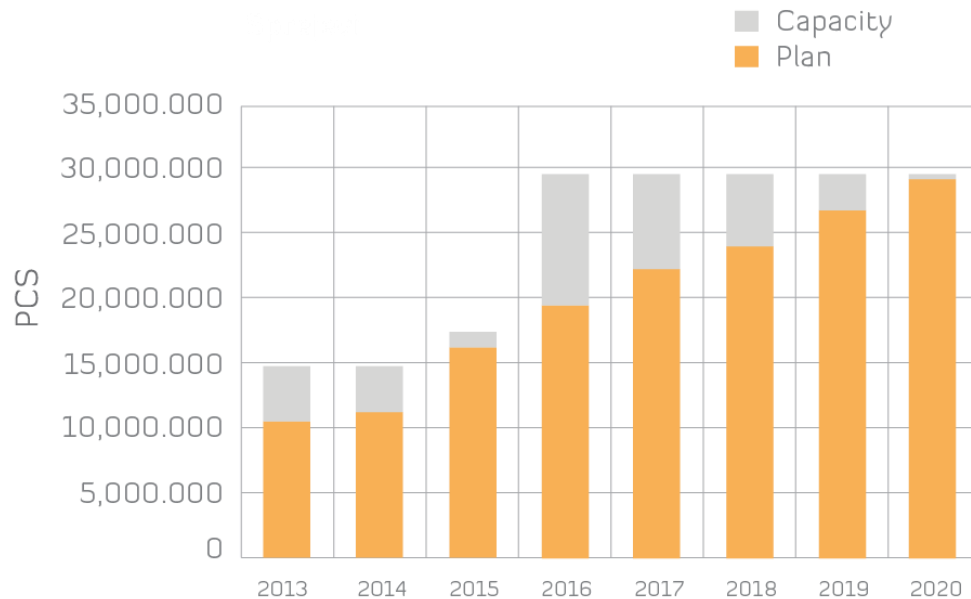


- Batch sizes: 10.000 – 300.000 pcs of dosing units
- Mixing volume: 50 – 3.000 L
- Flexibility in packaging process
- Formats: 2,5 – 20 ml.
- Plastic dropper bottle for multidose use



Capacity and Technology Overview

Sterile Mechanical Spray and Drops

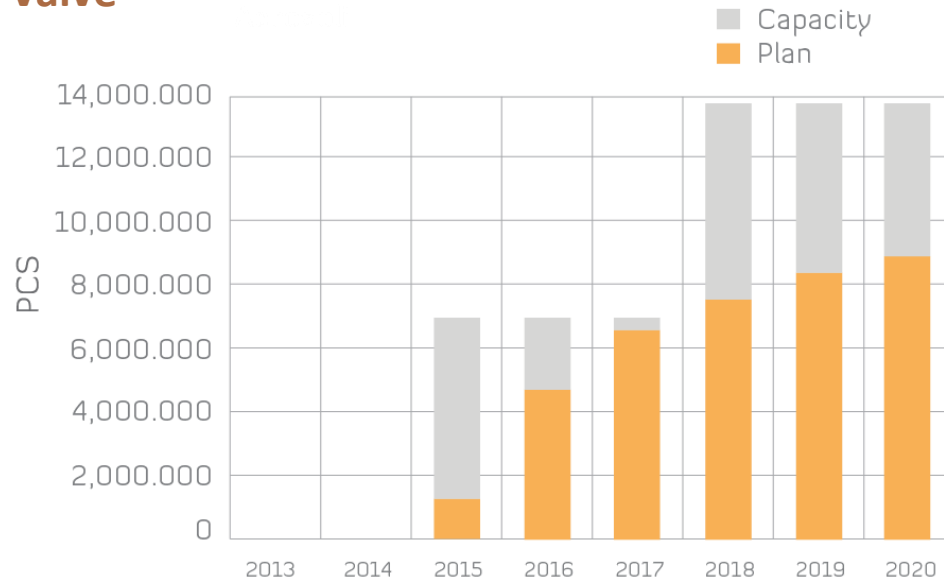


- Batch sizes: 20.000 – 300.000 pcs of dosing units
- Mixing volume: 500 – 3.000 L
- Flexibility in packaging process
- Formats: 10 – 30 ml
- Plastic or glass bottle with snap-on pump for multidose use in form of spray or drop, without preservatives.

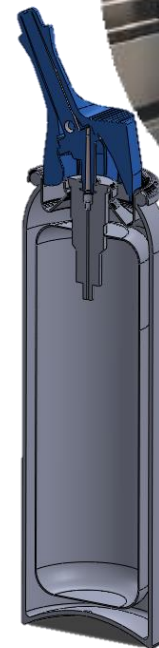


Capacity and Technology Overview

Bag on Valve



- Concept of continuous production
- New technology in JGL
- Batch sizes: min. 5.000 pcs – max. five days continuous process
- Flexibility in packaging process
- Formats: 50 – 150 ml
- BoV – Bag on Valve; product separate from propellant
- High level of microbial reduction without sterilisation



BoV Advantage



- Protection and no contamination of the products

- 360° use

- Different types of valves



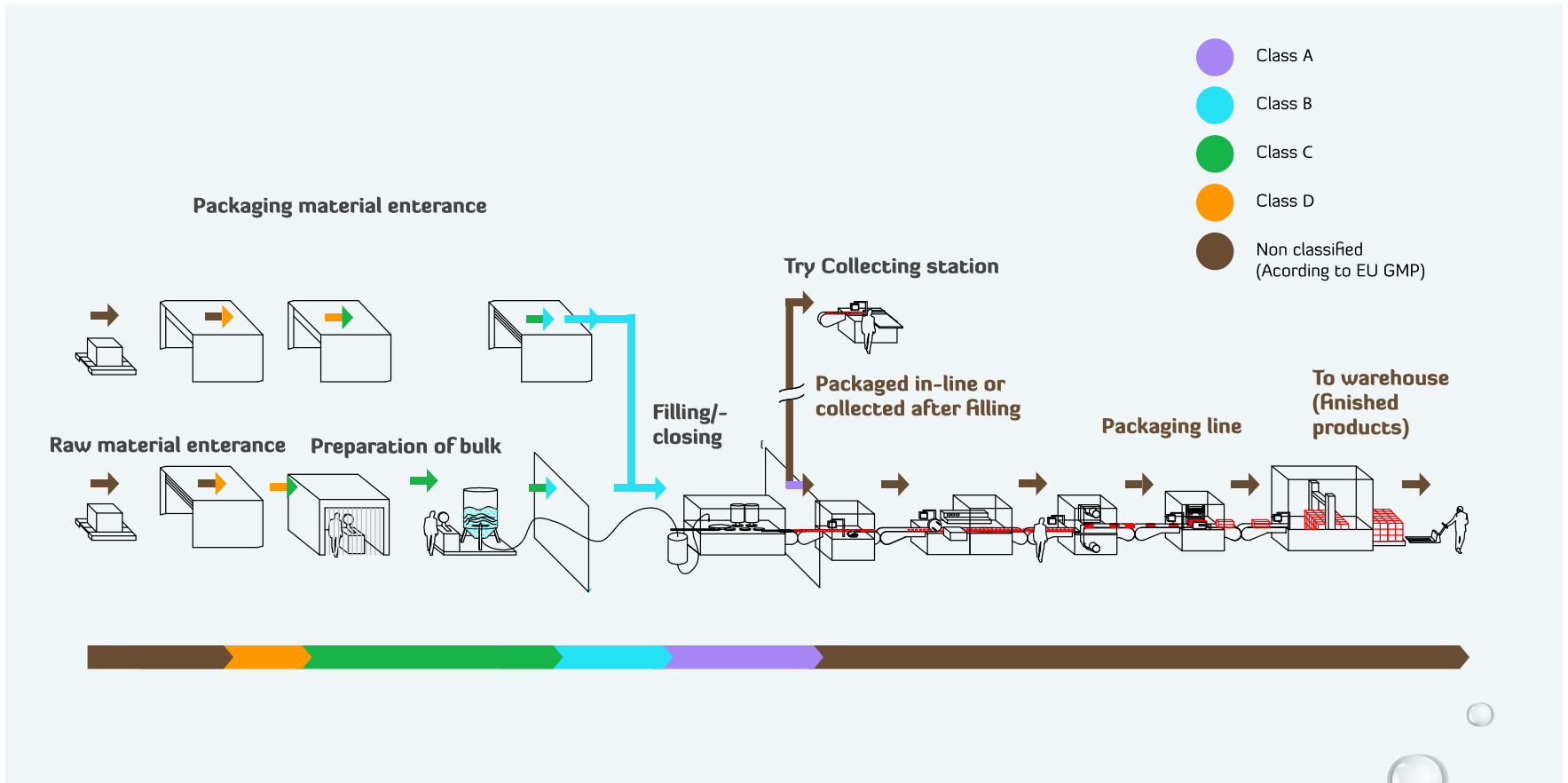
- Variety of actuators



- Product emptying up to 99%

- Environmental friendly propellant – air or nitrogen

Sterile Production Process

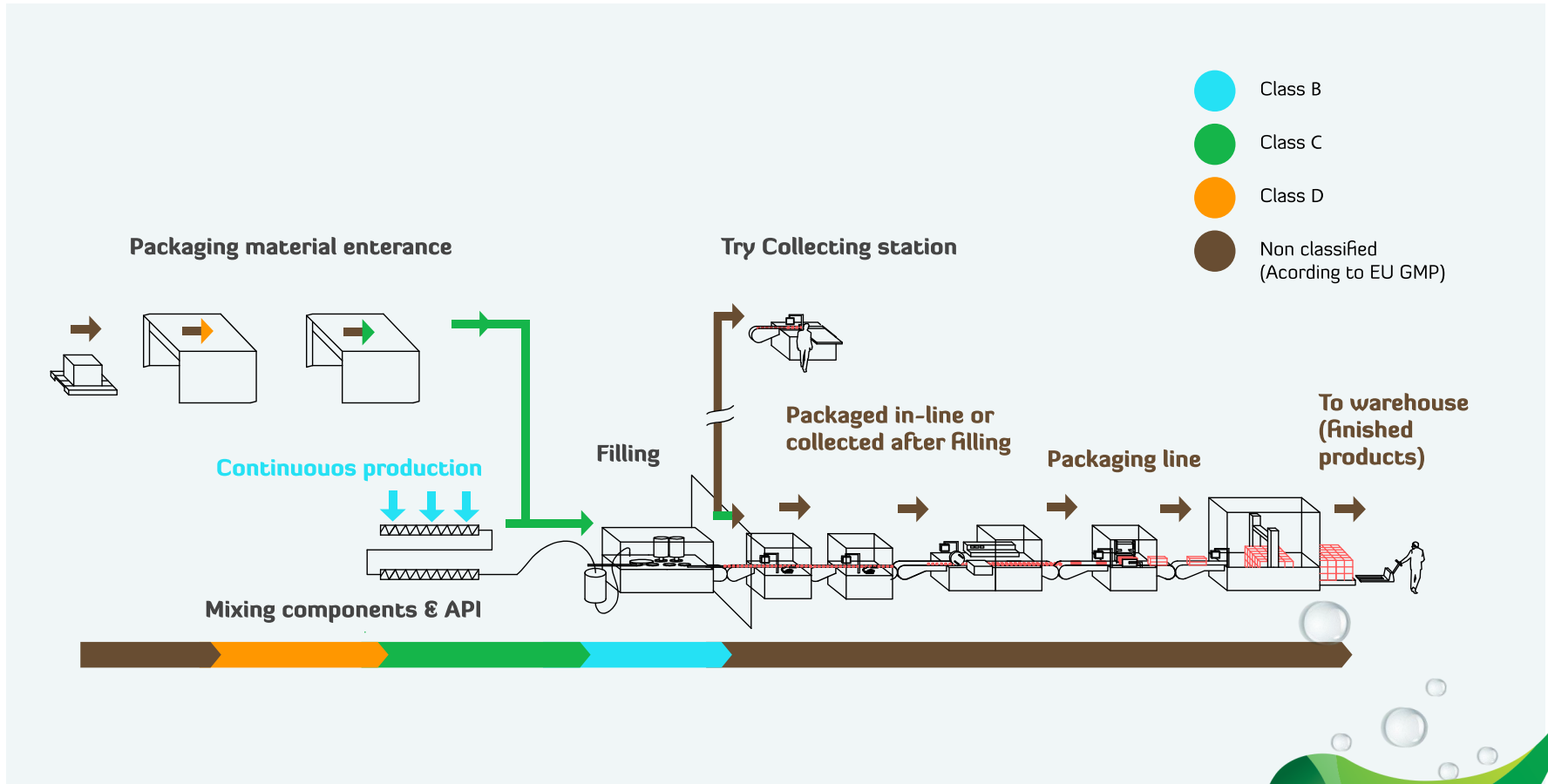


- Sterile processing steps – operate under assurance level 10^{-6}
- Class A (EU GMP) eq. to ISO 5 (BS EN ISO 14644-1) eq. to Class 100 (F.S. 209E)





BoV Process



BoV Process



- **Acciving microbial purity without terminal sterilisation.**
Long shelf life (36M) and low initial bioburden ensured by **ADVANCED TECHNOLOGYCAL PLATFORM:**
 - Sterile filtration,
 - Working and cleaning procedure in line with aseptic production,
 - Sterile primary packaging,
 - Environmental condition class B (according EU GMP),
 - CIP/SIP in place.
- **Continuous production** – bulk preparation by in line mixing system equipped with 2 static mixer for liquids and API. Preparation simultaneously with dosing process.
 - Higher efficiency
 - Higher OEE
 - Decrease total production cost
 - On-line parametric quality control
 - Parametric release



Quality and Certificates

- **EU GMP certificates Part I + relating Annexes**

Croatian Authority; Slovenian Authority, PIC/S member for sterile products, non-sterile products, packaging, QC testing, batch release
Certificates are listed in EudraGMP database

- **ISO 9001:2008 Quality management**

Bureau Veritas Certification

- **DS/EN ISO 13485:2012 Quality management – Medical devices**

Bureau Veritas Certification

- **ISO 22000:2005 Food safety management**

Bureau Veritas Certification

- **CE certificate (93/42/CEE) – Manufacture of medical products**

SIQ, Istituto Superiore di Sanita for sprays, drops, BoV

- **Canadian GMP**

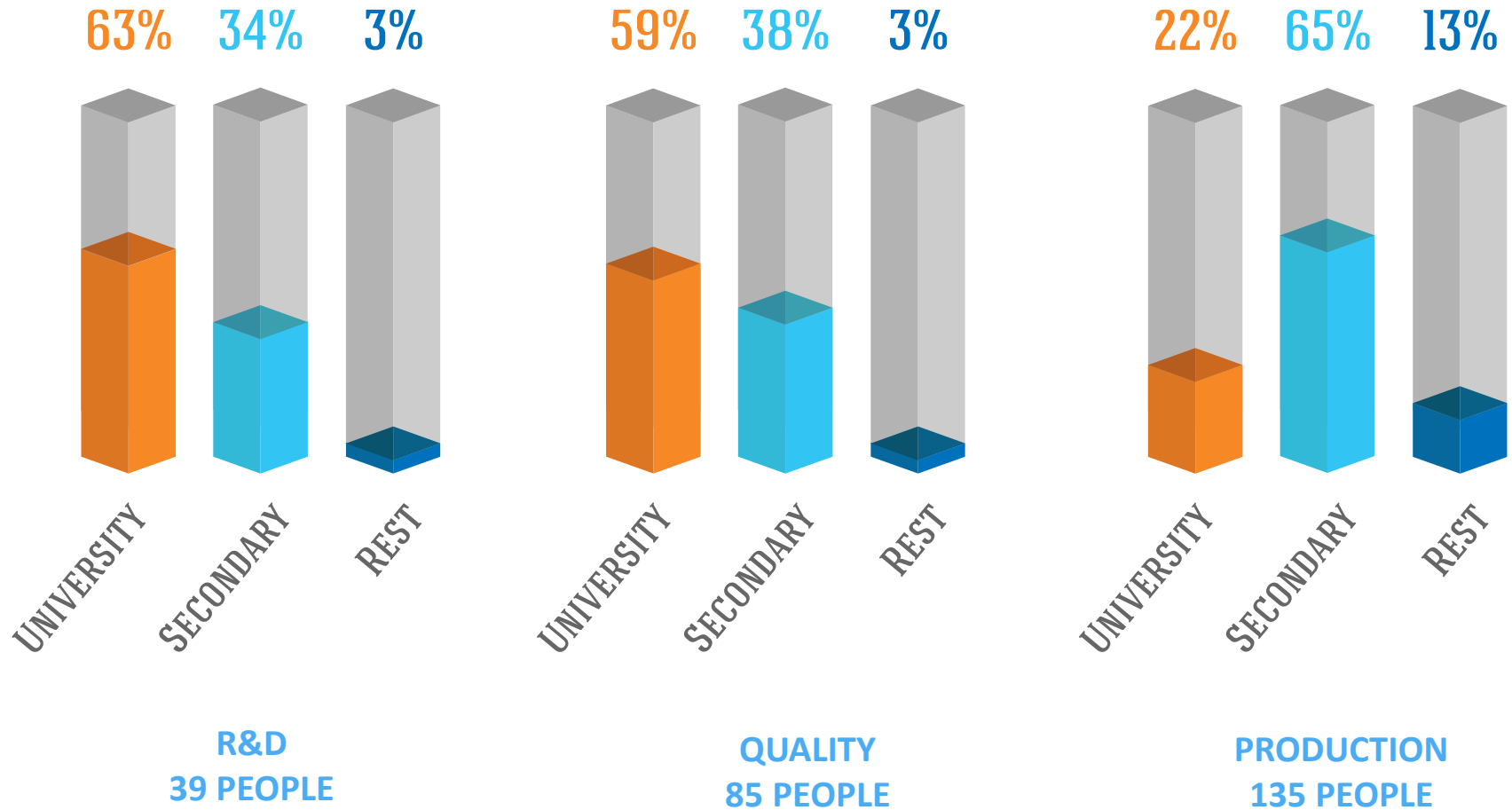
Fabricate, package and test sterile solutions



Inspection/Audit 2015

- Bureau Veritas Certification, ISO 9001:2008
- Bureau Veritas Certification, ISO 22000:2005
- Bureau Veritas Certification, DS/EN ISO 13485:2012
- Takeda, Dubai
- Agency for Medicinal Products and Medical Devices, Slovenia
- PIP, Croatia
- Telstar, Spain for Kernpharma
- Agency for Medicinal Products and Medical Devices, Croatia
- The Competent Authority for Food Supplements, Russia
- Istituto Superiore di Sanita -The Competent Authority for Medicinal Products, Italy
- Agency for Medicinal Products and Medical Devices, Croatia
- Sanitary Inspection of the Croatian - manufacture of food supplements
- Agency for Medicinal Products and Medical Devices, Croatia, Wholesale Distribution of Medical Devices
- GOST R, The Competent Authority for Medicinal Products, Russia
- Ministry of Health, Croatia, Wholesale Distribution
- SIQ -The Competent Authority for Medicinal Products, Slovenia
- Ministry of Health, Belarus

JGL Structure of Employment



They Trust Us



- Partnerships are an integral part of the JGL history and their contribution to our growth is of the essence.
- We create strong relations based on collaboration with partners from all over the world.



Why JGL?

- **Full services** and project management support from R&D to delivery of finish good
- **Excellent logistic** and supply advantage due to position
- **Established pharmaceutical production** with international experience in sterile pharmaceutical forms
- **Flexibility** to upgrade the production capacity
- **Zero market recall** due to aseptic and packaging processes
- **New unique BoV process approach** - microbiological purity without sterilisation, integrity of product, low total production cost





business.development@jgl.hr