

# Synthetic Chemistry • Small Molecule Contract • Manufacturing



[www.cfpharma.hu](http://www.cfpharma.hu)

## Who we are



**CF Pharma Ltd.**, Hungary is an independent company, being part of the family Schneider owned company group structure, with pharmaceutical intermediate and API (active pharmaceutical ingredient) development and **manufacturing** capabilities of small molecules.



**Patriapharma Ltd.**, Hungary is dedicated to provide **Business development** service within the group.



**Patriapharma Japan**, is the Japanese representative office





**DR. GÉZA SCHNEIDER**, CEO of CF Pharma – attended the Chemical Faculty of Eötvös Loránd University, Budapest where he received his Master degree and from the Faculty of Chemical Engineering of the Technical University of Budapest where received his PhD. From 1966 to 1986 he worked for the Institute of Drug Research where he became Head of the Research of the team. In 1986 he changed for Egis Pharmaceutical Works where he became the Head of Research department. He worked there for 9 years when he undertook CEO position at FIVE COOP – under his leadership this company became the first synthetic source for Melatonin – and later, in 1996 he founded CF Pharma. He has 6 research papers and 18 patents. He was awarded as an excellent inventor in 1985 and became the member of the American Chemical Society in 2008.



**ZITA SCHNEIDER**, CEO of PatriaPharma, and CF Pharma – attended the Chemical Faculty of Eötvös Loránd University, Budapest where she received her Master degree as a chemist. Since she joined the family company in 2003 she worked in various positions: started as QC assistant, then production technologist, head of regulatory affairs, head of quality assurance and later as head of quality. In this last 17 years she participated several GMP related trainings, participated and led internal and external quality audits. Since the establishment of Patriapharma she is also involved in the sales activities. Zita has returned in 2019 from Singapore where she attended INSEAD executive program and strengthened the Asian connections. Since 2020 she is the second generation CEO in the companies.

## Message from our CEOs

“Our approach to ESG reflects our intention to become “a force for good”, to carry-out actions inspired by the genuine concern for others. Our family business although far not the biggest aims to target goals set by the leaders of the pharma industry: minimizing the impact of our operations on the planet, advancing ethics, health, and equity through our business and products.”



**Géza Schneider**  
CEO

**Zita Schneider**  
CEO

## Our strength: people behind the 25 years



# Organizational structure



# Our strengths



EU GMP



Backwards integration



Excellent quality of APIs and intermediates



Drug Master File preparation expertise



High level of regulatory & customer relations management



Lab-to-ton scale comprehensive CMO activities

## ESG

Environmental – Social-Governance culture



Teamwork, family atmosphere



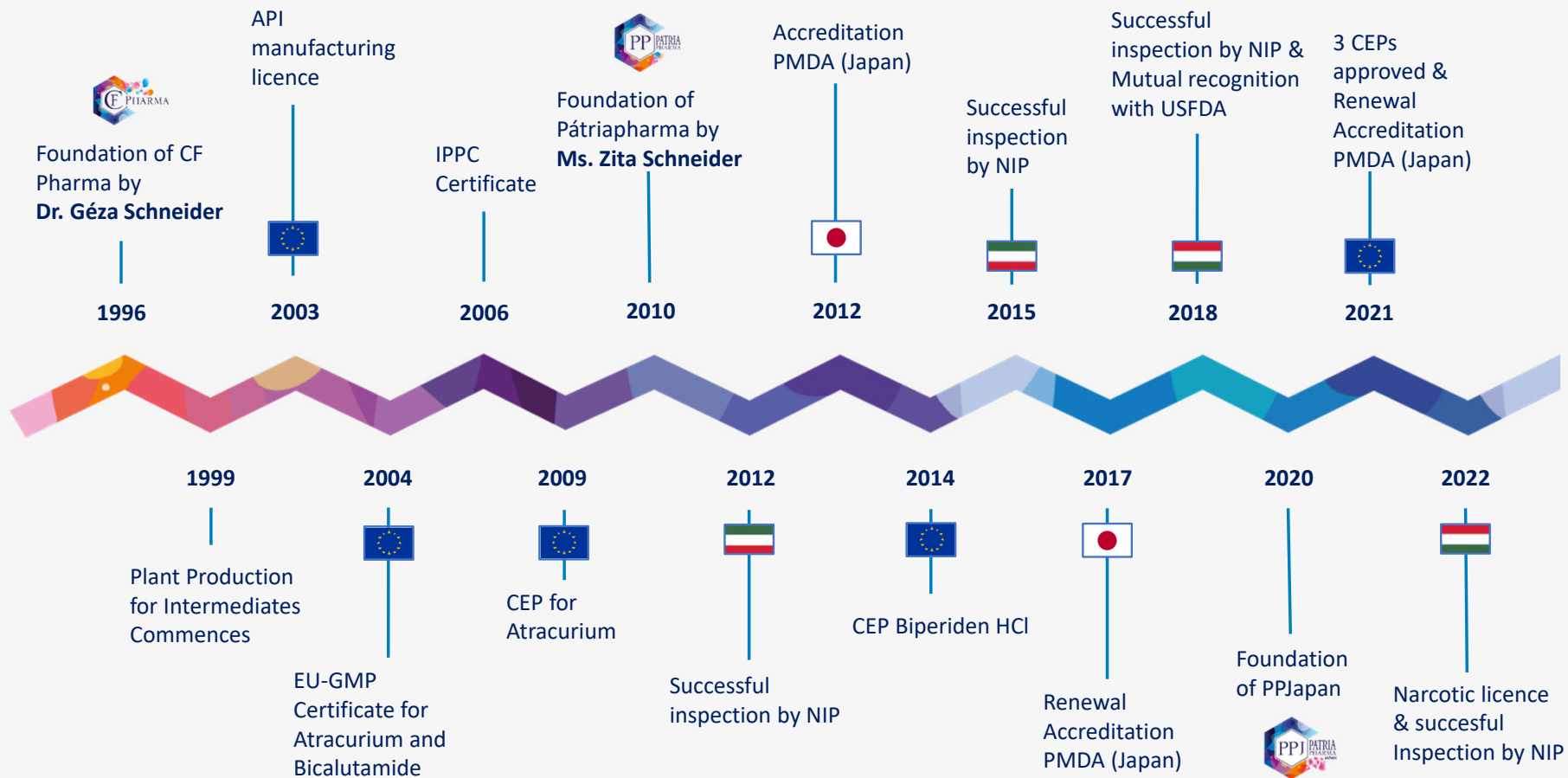
Tailor-made services



# REGULATORY TRACK





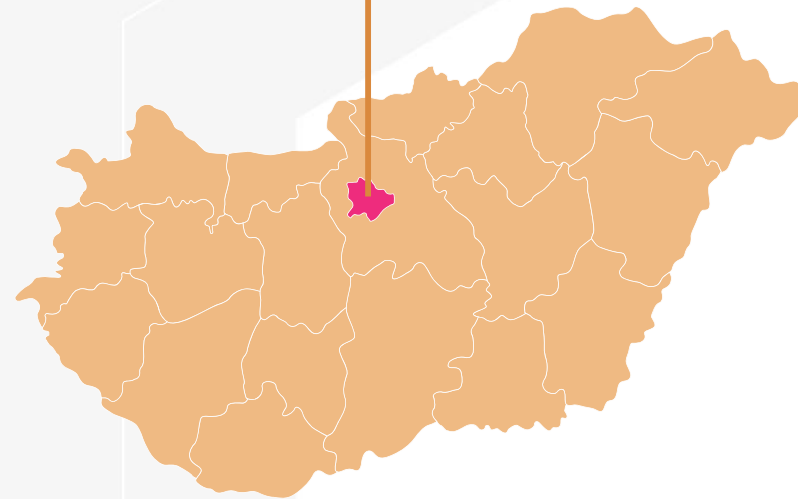
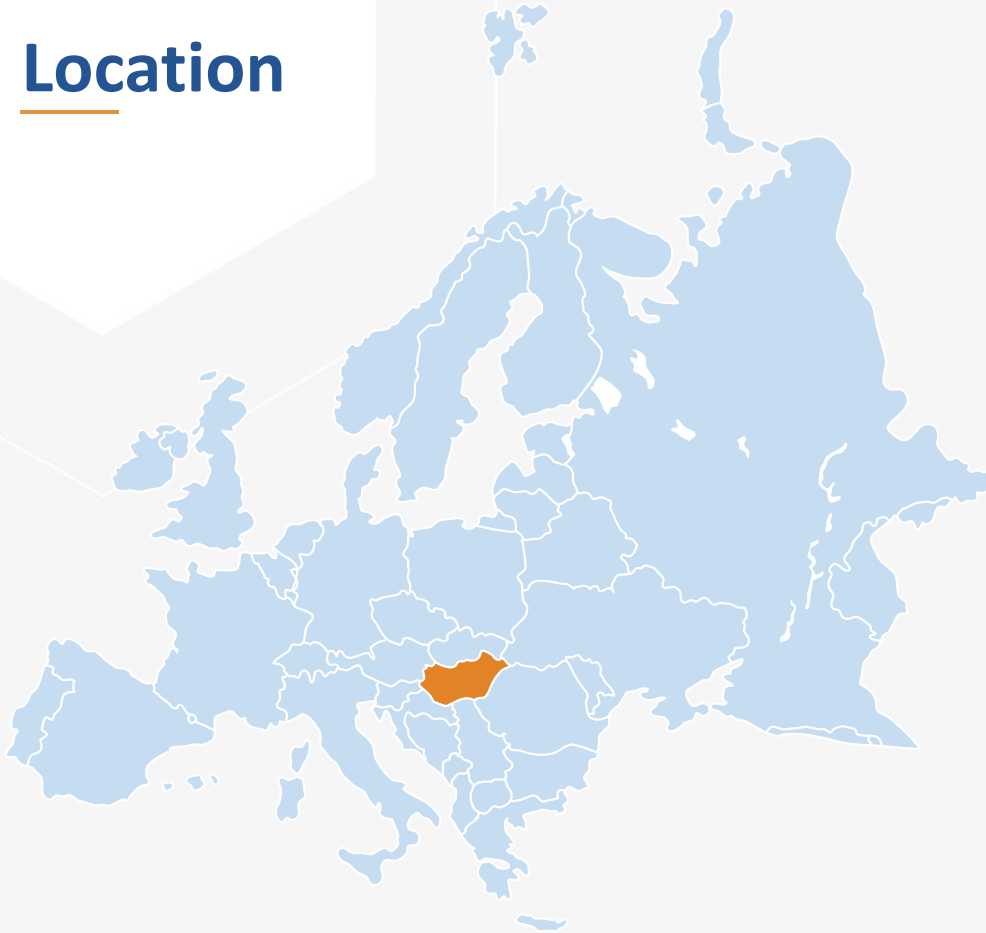


# THE SITE



## Location

- Hungary, Budapest
- H-1097 Budapest, 9th district Kén utca 5.
- 25 mins from international airport



# Our site

AREA OF THE SITE	152 500 m <sup>2</sup>
NUMBER OF PLANTS	1
NUMBER OF CLEAN ROOMS	1
NUMBER OF CONTROLLED AREAS	3
TOTAL REACTOR VOLUME	130 m <sup>3</sup>
R&D LABORATORIES	4
QUALITY CONTROL LABORATORIES	3
AREA FOR EXPANSION	60.000 – 100.000 m <sup>2</sup>



# THE KNOWLEDGE



## Technology

We have strong skills in small molecule chemistry and process development with proven experience in handling complex, hazardous and unique chemistry including controlled substances. This allows us to be a partner of choice in the **research & development of difficult-to-make molecules.**

As a result of R&D activities more than 25 API manufacturing processes have been developed for small and intermediate scale production.

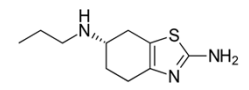
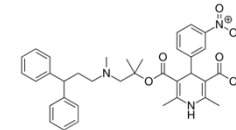
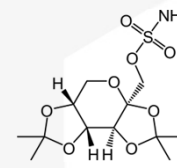
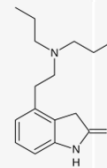
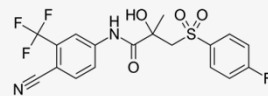
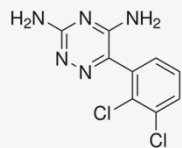
We undertake contract development and contract manufacturing of small molecules from mg to ton scale.



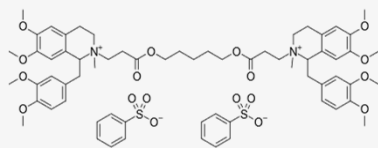
# Process Patents & Know-hows

## Process Patents:

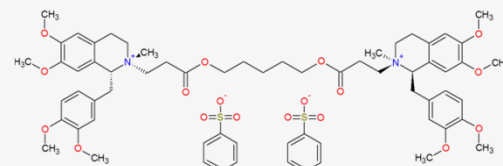
LAMOTRIGINE I.	LAMOTRIGINE II.	BICALUTAMIDE I.	BICALUTAMIDE II.	ROPINIROLE	TOPIRAMATE	LERCANIDIPINE	PRAMIPEXOLE
WO 03008393	HU 0103073	WO 03097590	WO 0134563	EP1568689	EP1627881	EP1860102	EP1878721I
EP1311492		EP1506170	P1669347	US 2005/0191338	US 2006/0040874		
US6683182		US 2005/0033082					



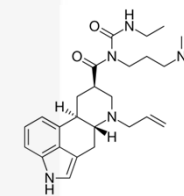
## Know-hows:



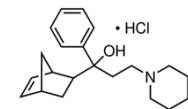
Atracurium besylate



Cisatracurium besylate



Cabergoline



Biperiden HCl and base



## Chemistry capabilities

- Lab Scale: 0.5 – 500 grams
- Pilot Scale: 0.5 – 5 kgs
- Plant Scale: 50-800 kgs
- Temperature range: (-)20°C upto 150 °C
- Pressure range: (-)0.95 Bar upto 5 Bar



- ☆ API ROS developed: 25
- ☆ Intermediate synthesis for 23 years
- ☆ API synthesis for 19 years

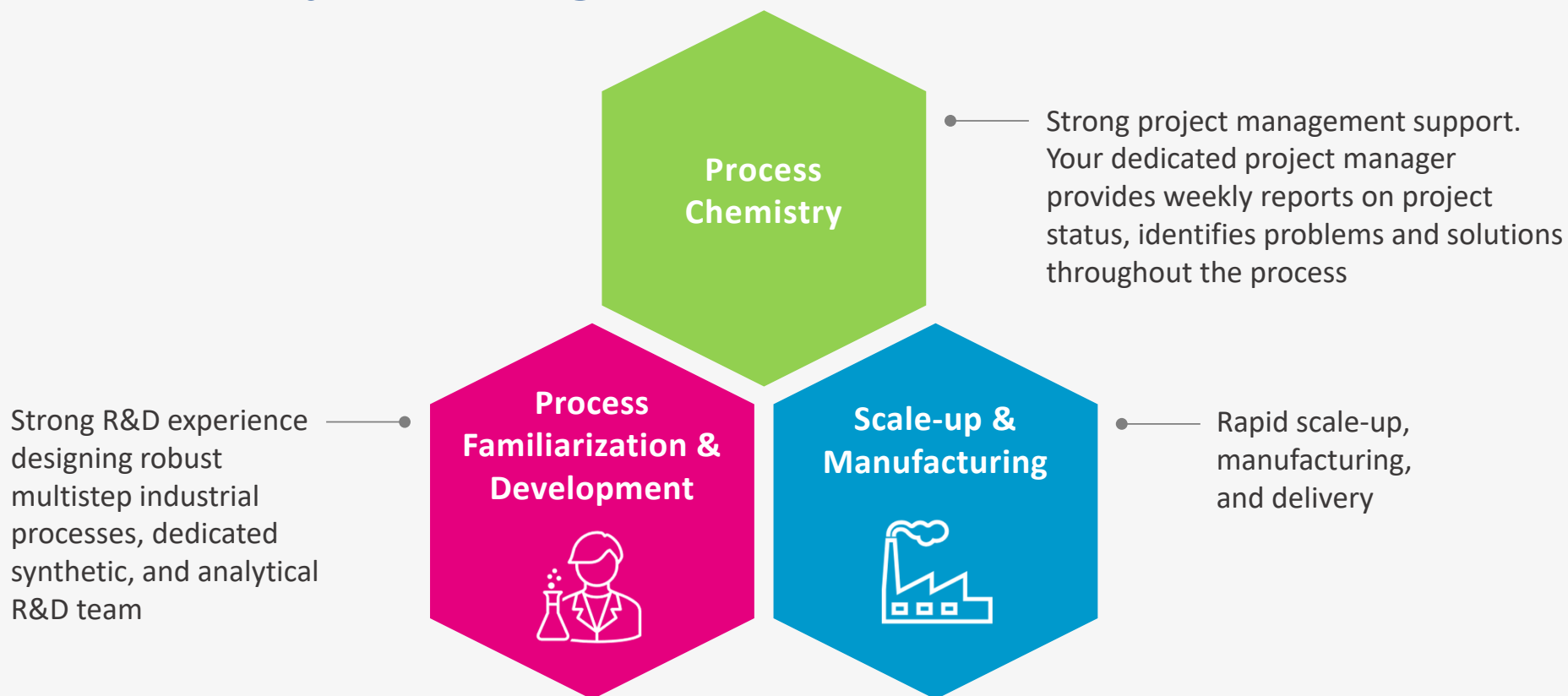


## Representative reaction types and batch sizes

REACTION TYPE	REAGENTS	KG/BATCH
von Braun reaction	Bromocyan	3
Reduction	Pd/C, Hydrogen	125
Chlorination	Chlorine gas	150
Cyclization	anhydr. FeCl <sub>3</sub>	150
Friedel-Crafts Reaction	AlCl <sub>3</sub> / NaCl	155
Monomerization	Dicyclopentadiene	200
Hantzsch reaction	Amino-crotonic acid methyl ester	200
Cyanation	Sodium cyanide	200
Reduction	Pd/C Formic acid, Ammonium salt	220
Pinner Reaction	HCl/EtOH, NH <sub>3</sub>	230
Chlorosulphonation	Clorosulfonic acid	250
Grignard Reaction	Phenyl-Mg-Chloride, Methyl-Mg-Chloride	2-400
Sulfon formation	4-fluoro- benzosulfonylchloride	400
Reduction	Na-Borohydride	400
Sulfamoylation	Chlorosulfonyl isocyanate	500
Nitration	Nitric Acid	800
Hydroxymethylation	Formaldehyde/sulfuric acid-sulfurtrioxide	800
Bromination	Bromine	1000



## Portfolio & Project management



# THE INFRASTRUCTURE



## Main production equipment – pilot scale

COMMERCIAL SCALE	TYPE	NUMBER	VOLUME RANGE	TYPE
Reactor	Glass lined	8	30 – 2000 L Total: 3780 L	Lampart
Centrifuge	Stainless steel	1	600 mm	BVG
Dryer	Stainless steel	1	150 L	Kiskun-Meridian



## Main production equipment – commercial scale

COMMERCIAL SCALE	TYPE	NUMBER	VOLUME RANGE	TYPE
Reactor	Glass lined	33	100 – 16000 L Total: 94 000 L	De Dietrich, Pfaudler, Lampart
	Stainless steel	7	250 – 10000 L Total: 31 000 L	Custom made
Centrifuge	Stainless steel	8	600 – 1250 mm	OMNR, BVGC
Dryer	Stainless steel	1	3000 L	Hosokawa
Filters	Stainless steel	8	5 – 100 L	Sparkler, Pall



## Clean area

COMMERCIAL SCALE	TYPE	NUMBER	VOLUME RANGE	TYPE
Crystallizer	Glas lined	1	1250 L	Pfaudler
Centrifuge	Stainless steel	1	800 mm	Krauss Maffei
Dryer	Stainless steel	3	150 – 1000 L	Pink, Kiskun-Meridian
Hammer mill	Stainless steel	1	5 – 15 kg/h	Micropure



## Main analytical instruments

	NUMBER	TYPE
HPLC	6	Agilent 1260 Infinity II (4) Shimadzu Nexera LC-40 XR (2)
GC, HSGC	3	Agilent 7890 (equipped with liquid and headspace sampler) Agilent 8890 (equipped with liquid sampler) Agilent 8860 (equipped with liquid and headspace sampler)
LC-MS	1	Shimadzu LCMS-8045 Triple quad, Shimadzu Nexera 40 UHPLC, ESI, APCI probe
HS-GC-MS	1	Shimadzu GCMS-QP2020 NX, equipped with liquid and headspace injector
Polarimeter	1	Jasco P-2000 polarimeter
IR	1	Shimadzu IRAffinity 1S FT-IR spectrophotometer
UV	1	Perkin Elmer Lambda 365 UV/VIS spectrophotometer
Particle size determination	1	Malvern Mastersizer 3000 PSD
Automated titrator	3	Metrohm, Mettler Toledo



## Stability chambers

	NUMBER	TYPE
Stability chamber	5	Binder

30±2 °C, 65±5 RH%

40±2 °C, 75±5 RH%

30±2 °C, 75±5 RH%

25±2 °C, 60±5 RH%

5±3 °C





## ESG Approach

Our company is in a very exciting period, as the generation of top management is changing, the governance of the management is changing, the work culture is changing too. As we want to be a true partner of the “best in class”, we have switched our focus to a holistic approach both in business and EHS.

For us, ESG is the right navigation tool for this holistic approach, acting as a link or even as a bridge between the core pillars of our operations.

We have understood, that any of our decision has a direct or indirect effect on the society and on the environment. We produce ethical pharmaceutical products for our customers and the patients, but also feel responsibility to preserve the health of our employees and living environment.

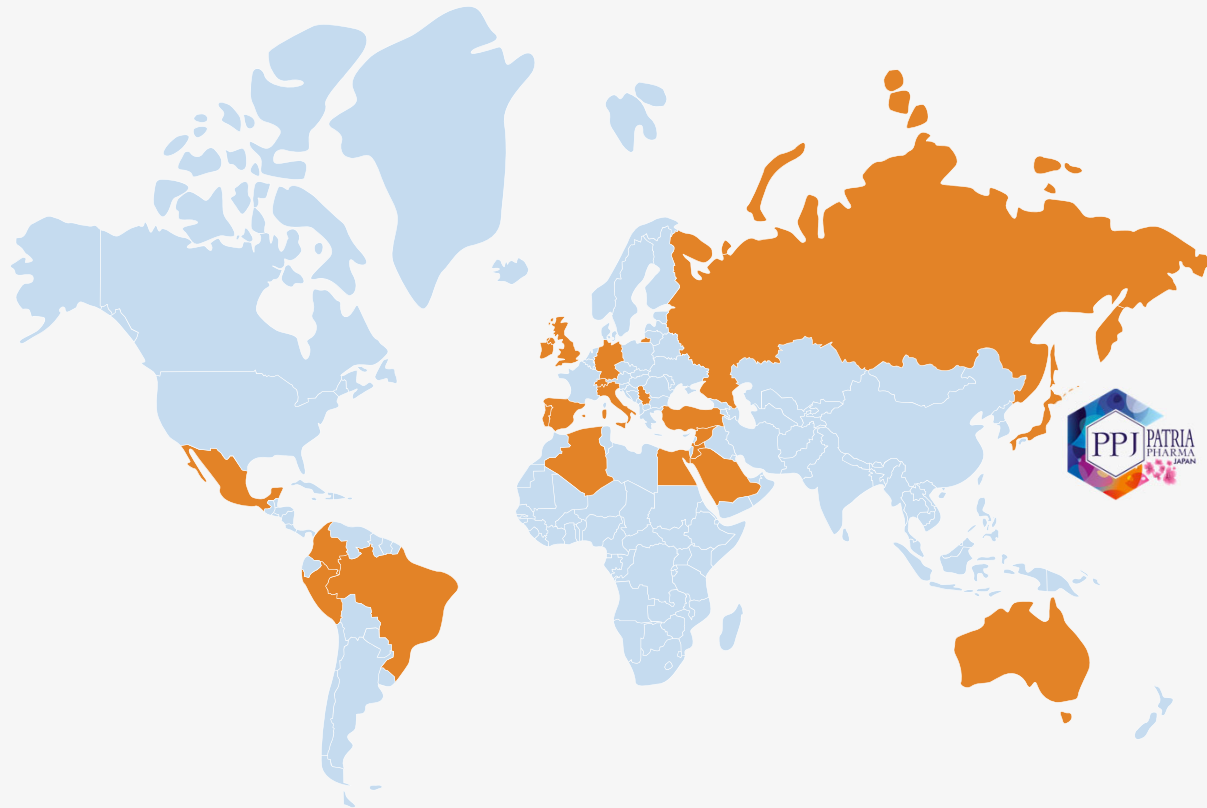
This road map identifies our main ESG targets and KPIs. The first detailed report on the listed issues or topic will be prepared by Q1 2023, and certified in Q2 2023.



## The Partner & Regulatory Experience

Worldwide more than  
**30** countries

and **150** partners  
with offices in  
Budapest, Hungary, Europe,  
and Tokyo, Japan



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