



Doppel

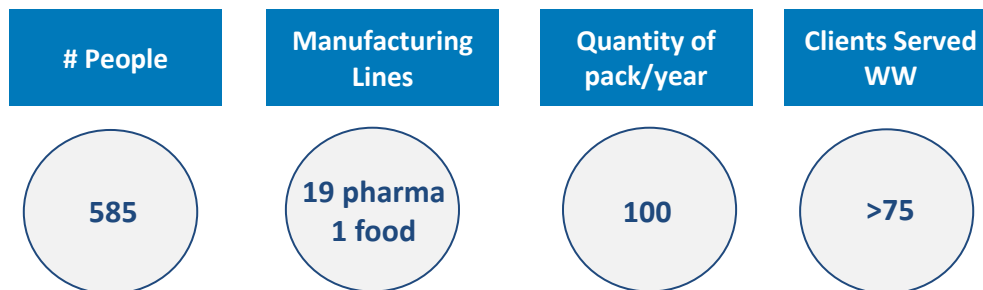
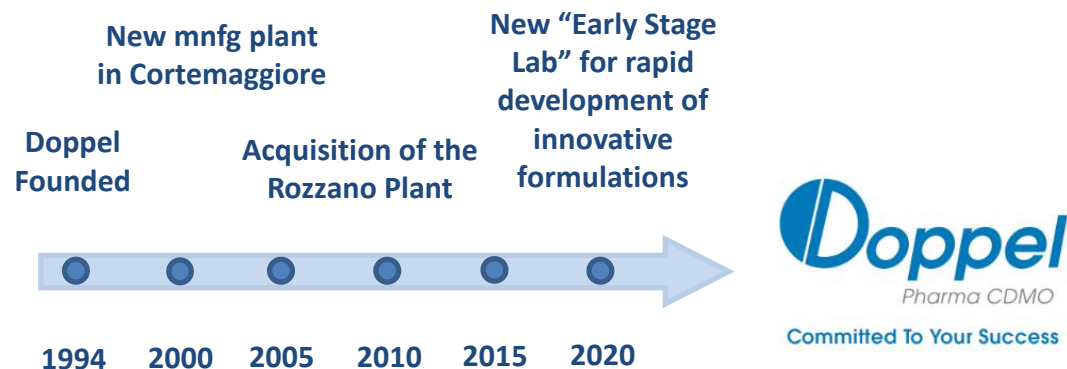
Pharma CDMO

Committed To Your Success

Sept 2023

Doppel at glance

In 2022, Italy consolidated its position as the pivotal Pharma Manufacturing country within EU*. Owned by Trilantic Capital Partner EU, Doppel is the leading independent domestic pharma CDMO.



*Source: https://www.quotidianosanita.it/scienza-e-farmaci/articolo.php?articolo_id=109535

The Management Team



GIORGIO OBERRAUCH
CEO
(Zambon, Recordati)



ROCCO PARACCHINI
CCO
(Indena, Adare)



SABINA GUALAZZINI
COO
(Recipharm, Italfarmaco)



MAURIZIO RUSCONI
CFO
(Clariant, Euticals)

















**SALVATORE AGOSTINO
GIAMMILLARI**
R&D DIRECTOR
(Italfarmaco, Monteresearch)



GIANPIERO POLLASTRO
COMMERCIAL DIRECTOR
(UCB, Takeda)

State of the Art Plants

		Rozzano (MI)	Cortemaggiore (PC)	Pharma GMP				
Facilities							Forms	
		25,000 sqm	44,000 sqm	Capsules	Soft Gel	Coated Tablets		
		280 FTEs	305 FTEs					
	44mn packs/ year	49mn packs/ year	Granules	Powders	Liquids, Creams, suppositories			
Inspections and Certifications	Regular Client Audits							
	AIFA (EU GMP)				AIFA (EU GMP)			
	US FDA		China FDA		US FDA		US FDA food	
	Russia		Kenya		China FDA		Anvisa Brasil	
	Belarus				Russia		Kenya	
					Belarus		Korea FDA	
			ISO 13485		ISO 22000		ISO 13485	
			IFS		ISO 9001		IFS	
							Packaging	
				Blisters	Creams	Single-Dose		
								
				Bottles	Sachets	Injectables		

Blue Chip Clients

Pharmaceutical and Nutraceutical Key Clients



HALEON

SANDOZ

teva



sanofi



More than 100 clients served worldwide

Industry Leading Development Capabilities

R&D Labs



4 R&D Labs in Rozzano and Medolla, including a newly launched “Early stage Lab” in Rozzano, able to serve nutraceutical clients



A team of **26 scientists** dedicated to pharmaceutical and nutraceutical development



Industry leading scale up manufacturing capabilities, with **over 950 sqm of R&D space**

Development Capabilities



Over **700 pharma development projects** completed since 2000 and over **50 supplements development projects** each year



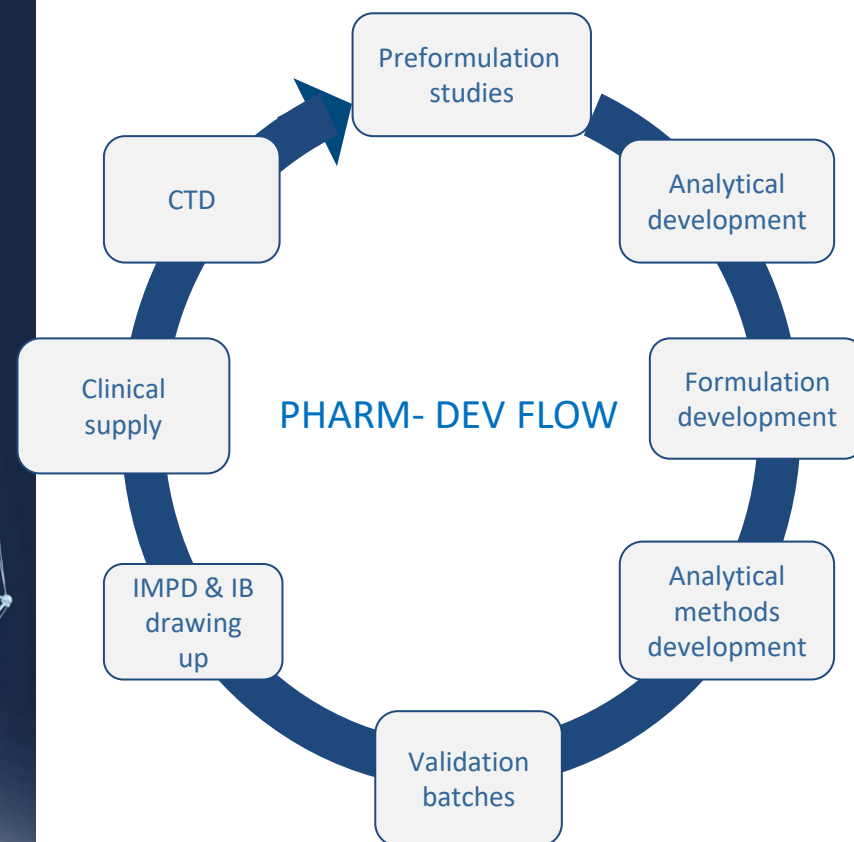
6 regulatory specialists, able to comply with global regulations



124 FTEs in QC and QA assuring the highest quality standards in every site

Doppel R&D

We bring
your molecules
to their
best shape



Doppel R&D: formulation capabilities

Standard

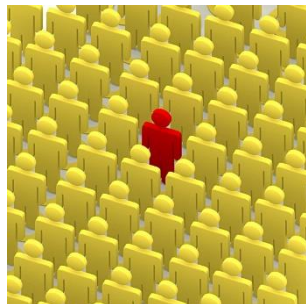
- Sterile ampoules
- Softgels
- Solid oral forms (tabs; sachets; caps)
- Semisolids (creams; suppositories)
- Liquids (drops; drinkable vials; syrups)



Functional

- Minitablets
- Multilayered tabs
- Modified release
- Bioavailability enhancement
- Specific site delivery/Chrono-therap.

Doppel R&D: areas of expertise



- Orphan drug product: end-to-end R&D to commercial

- High potent oral: end-to-end R&D to commercial



- Pediatrics: development (minitabs, semisolid, acceptance studies)



- Clinical kit preparation

- GMP and Non –GMP formulation area

- Regulatory status: EMA and FDA (orphan)*



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

T-Chrono Platform Technology*

- **A Modified Controlled-Release** solid oral pharmaceutical composition comprising one or more active ingredients in a core and an outer coating of said core, characterised in that:
- the **core** consists of:
 - a **complex monolithic matrixes** containing an active ingredient,
or
 - a **complex monolithic matrix** as defined above adjacent to an **immediate-release layer** comprising the same active ingredient as contained in the monolithic matrix;
- the **coating** consists of a layer comprising pH dependent and / or pH independent polymer.

Strong IP position*

- ORAL SOLID PHARMACEUTICAL COMPOSITION WITH COMPLEX MONOLITHIC MATRICES FOR THE Chrono TROPIC ADMINISTRATION OF MEDICATIONS IN THE **GASTROENTERIC TRACT**
December 14 - 2018
- ORAL SOLID PHARMACEUTICAL COMPOSITIONS FOR THE Chrono TROPIC ADMINISTRATION OF **ANTI-INFLAMMATORY DRUGS TO TREAT INTESTINAL BOWEL DISEASES**
December 14 - 2018
- ORAL SOLID PHARMACEUTICAL COMPOSITIONS FOR THE Chrono TROPIC ADMINISTRATION OF **ANTIDIABETICS DRUGS**
December 14 – 2018
- ORAL SOLID PHARMACEUTICAL COMPOSITIONS FOR THE Chrono TROPIC ADMINISTRATION OF **CARDIOVASCULAR DRUGS**
December 14 – 2018
- ORAL SOLID PHARMACEUTICAL COMPOSITIONS FOR THE Chrono TROPIC ADMINISTRATION OF **ANTIBIOTICS DRUGS**
March 18 - 2020

*T-Chrono platform and related IP is propriety of DPL pharma, owned subsidiary of Doppel

Product showcase Doppel*



* **Disclaimer:** the present slide is for illustration purpose only, nothing here represented implies implicitly nor explicitly any ownership of Doppel in any brands exposed



***Thank you for
the attention!***

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