

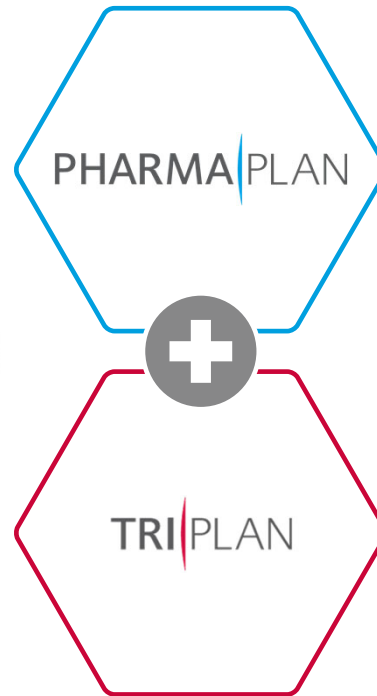
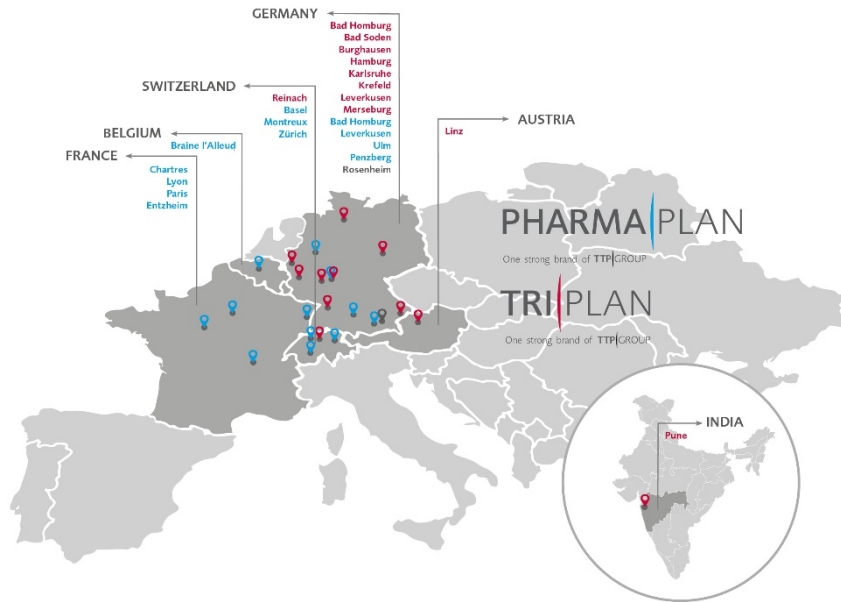


# PHARMA | PLAN

〈 Passion for  
**pharma engineering** 〉

# TTP GROUP: PHARMAPLAN + TRIPLAN

*COVERING THE ENTIRE VALUE CHAIN AND ASSET LIFECYCLE*



**900**

**Pharma/  
 Chemistry**

**1 000**  
 Projects/year



**PHARMA|PLAN**

# PHARMAPLAN IN FRANCE & BELGIUM

*DEDICATED TO PHARMA & BIOTECH*

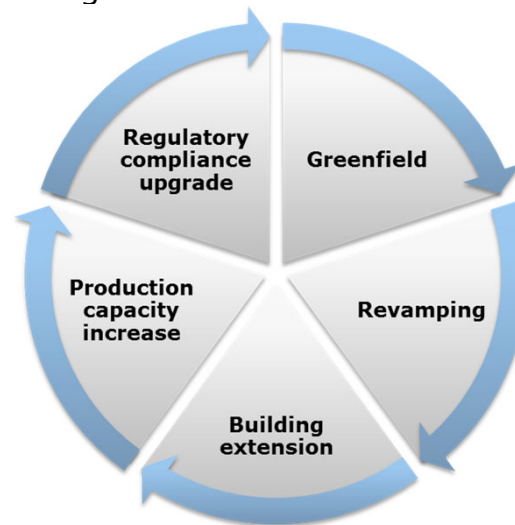
## Our assets

### Facts

- Over 15 years experience
- France : Chartres, Paris, Lyon, Strasbourg
- Belgium : Braine l'Alleud
- 77 employees

### Our disciplines

- Project Management
- Process
- HVAC
- Clean & Black Utilities
- Process & building Automation
- Clean rooms
- Building
- Electricity



## Our core expertise

### Pharma regulations

- GMP, FDA, Japan, Brazil, ...
- GAMP5
- BSL & OEB products containment

### Pharma Process

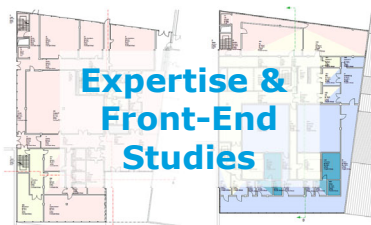
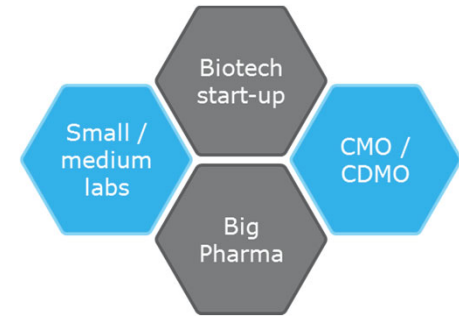
- Biotech
- Injectables
- OSD
- Chemical API
- Medical devices

### Production steps

- Development
- Formulation
- Fill & Finish
- Assembly & Packaging
- Laboratories (R&D, QC)

# ORGANIZATIONAL SET-UP

## OUR BUSINESS AREAS



- Site Master Plan
- Feasibility study / Conceptual Design
- Design and validation of computerized & automated systems
- Expertise: GMP, Quality, Process, Cleanroom, Automation and Digitalization

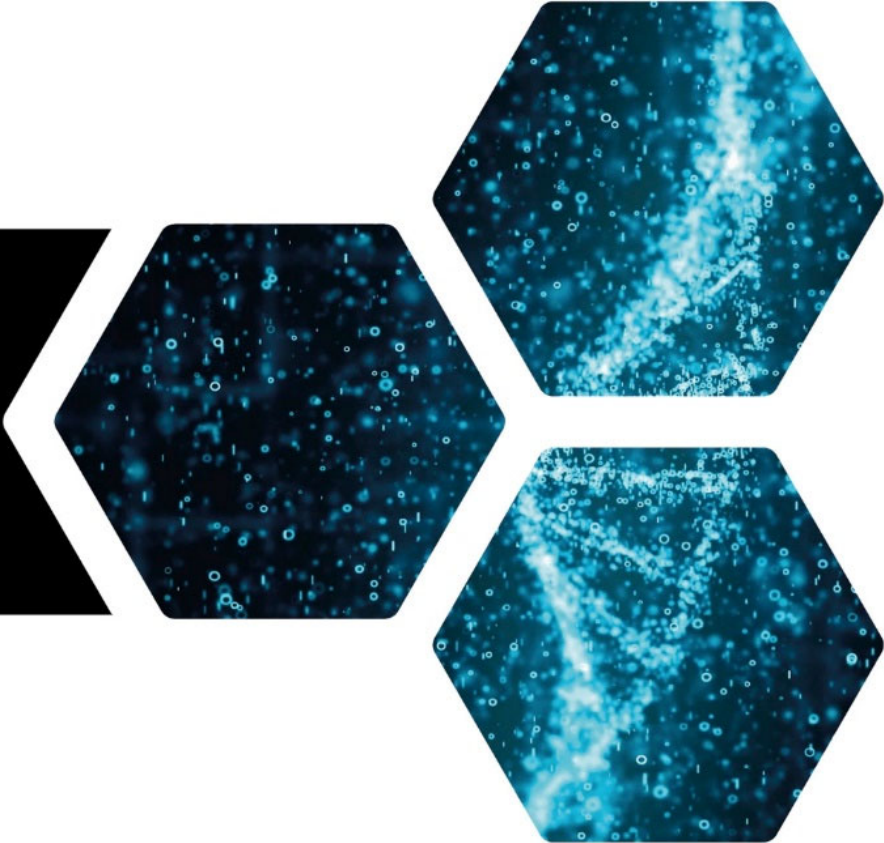


- Basic & Detailed Design (APS, APD, PRO)
- Procurement support (DCE, ACT)
- Design review of suppliers' execution studies & space management (VISA, SYN)
- Construction Management (DET, OPC)
- Commissioning, Qualification and Validation
- Handover operations (AOR)



- Operational support
- Optimization
- GMP and 'Business Continuity' audits

**Project  
references**





# Packaging and logistics center CARBOGEN AMCIS, Switzerland cGMP chemical API Greenfield



## THE PROJECT

- New API facility consisting of four new buildings:
- Production building
  - Warehouse
  - Lab building
  - Utilities Building

- The scope of the warehouse includes the following:
- 4 Deep cold rooms (-20°C)
  - High bay warehouse (ambient)
  - API sampling isolators
  - For up to and including OEL category 3 (1.0 µg/m³)
  - Compliant with cGMP and ATEX

## SUCCESS CRITERIA

- > Qualification, compliance and therefore quality requirements fulfilled
- > No business continuity risks for the production and other relevant facilities

## SIZE & TIC

Size: 4'333 m<sup>2</sup> from overall 16'836 m<sup>2</sup>  
TIC: 150 Mio. CHF (overall)

## DURATION

11/2020 – ongoing

SERVICES	CD	BD	DD	CM	CQV	OS
Project Management			Partner	Planned / in scope	Planned / in scope	Planned / in scope
Warehouse			Partner	Planned / in scope	Planned / in scope	Planned / in scope
Technical Services			Partner	Planned / in scope	Planned / in scope	Planned / in scope
Architecture + Civil			Partner	Planned / in scope	Planned / in scope	Planned / in scope
Qualification			Partner	Planned / in scope	Planned / in scope	Planned / in scope

- not in scope
- planned / in scope
- work in progress
- completed
- partner



# Greenfield injectables facility

## CARBOGEN AMCIS, France, Riom RIOM2



### THE PROJECT

CARBOGEN AMCIS, pharmaceutical company dedicated to clinical development including API and drug product manufacturing, is building a new 9 500 square meters facility dedicated to injectables. These new premises will enable CARBOGEN AMCIS to enlarge their services portfolio notably with complex formulation using various chemical and biological agents.

### SUCCESS CRITERIA

Pharmaplan designed an evolutive facility and conducted a Containment Risk Assessment aiming to define the right strategy to handle High Potent products. We developed a flexible design for process, to deal with clinical and commercial batches: development, formulation, and filling of freeze-dried and liquid products. The building will also include Research & Development and Quality Control laboratories, as well as administrative functions.

SERVICES	CB	APS	APD	PRO	ACT	DET	AOR
Project Management	Completed	Completed	Completed	Completed	Work in progress	In scope	In scope
Process	Not in scope	Not in scope	Completed	Completed	Work in progress	In scope	In scope
Technical Services	Completed	Completed	Completed	Completed	Work in progress	In scope	In scope
Architecture + Civil	Completed	Completed	Partner	Partner	Partner	Partner	Partner
Qualification	Not in scope	Completed	Completed	Completed	Work in progress	In scope	In scope

- not in scope
- in scope
- work in progress
- completed
- partner

### DURATION

2017 - ongoing

### SIZE & TIC

Size: 9 500 m<sup>2</sup>  
TIC: 45 M€



# Veterinary vaccines greenfield

## Boehringer Ingelheim Animal Health, France, Lyon

F<sup>2</sup>ve



### THE PROJECT

Boehringer Ingelheim Animal Health needed a new large-scale facility for formulation and filling of inactivated virus vaccines for farm animals. The new facility is three levels and a total of 6 000 square meters. It includes a formulation area, high complexity transfer and CIP/SIP systems, an aseptic filling line, areas for storage, support functions, and an administrative area.

### SUCCESS CRITERIA

Pharmaplan brought together both local and global experts to provide the customer with a strong team from the very beginning of the project.

Our team was fully integrated with the customer on site to enable close cooperation and used the scrum methodology to address all delays and other key challenges. Adopting this methodology was key in enabling the team to deliver the detailed design of the formulation tender package in one month's time - two weeks faster than the customer's goal of 1.5 months.

SERVICES	CD	BD	DD	CM	CQV	OS
Project Management						
Process						
Technical Services						
Architecture + Civil						
Qualification						

- not in scope
- in scope
- work in progress
- completed
- partner

### DURATION

2017 - 2021

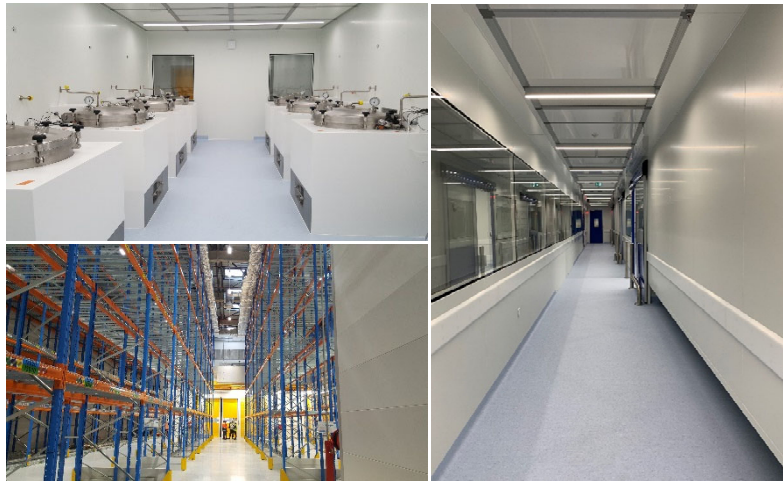
### SIZE & TIC

Size: 6 000 m<sup>2</sup>  
TIC: 62 M€

# Medical device capacity increase - EPCM

## Allergan, France, Pringy

### Pegasus III



SERVICES	CD	BD	DD	CM	CQV	OS
Project Management						
Process						
Technical Services						
Architecture + Civil						
Qualification						

- not in scope
- in scope
- work in progress
- completed
- partner

#### THE PROJECT

In order to increase capacity (25% growth/year – target 14 million packs), Allergan planned to revamp and extend its existing medical device manufacturing plant in France.

The overall project is approximately 4000m<sup>2</sup>.

For this purpose, Allergan developed a Conceptual Design and then looked after the services of an engineering and project management organization able to plan, consult, design and produce all documentation and coordinate the implementation of the project.

#### SUCCESS CRITERIA

PHARMAPLAN supported the project realization by first carrying out a Basic Design (APS) phase in order to develop all the concepts defined during the preliminary studies. This allowed Allergan to validate the technical and pharmaceutical execution of the project with a more precise idea of the costs and schedule.

We then moved into the Detailed Design (APD) phase, expanding the building shell to accommodate new receiving warehouse space and expanding the existing packaging area with one new line in one hand and revamping the bulk area in the other hand. In addition, we defined the upgrade of all associated house and clean utilities and technical areas.

#### SIZE & TIC

SIZE: 4 000 m<sup>2</sup>  
TIC: EUR 17 Mio

#### DURATION

2017 – 2019

**OSD**  
**Boehringer Ingelheim, Germany**  
 REMPA – Ramp Up Empa EPCMV



**THE PROJECT**

**New Ultra Fast Track Facility**  
 Production plant for OSD (blockbuster)

**INVEST**

EUR 30 Million

**SIZE**

1.600 m<sup>2</sup> footprint (3 levels)  
 4.800 m<sup>2</sup> GFA  
 19.000 m<sup>3</sup> GBV

**SUCCESS CRITERIA**

**Ultra Fast Track** project (“start of design” to “validation batches” 15 months; commercial production after 17 months)

**Flexibility** life cycle of OSD blockbuster production ends after 24 months, facility will be remodelled afterwards

**Modular design** to a) serve as blue print for future facilities and b) to enable fast tracking

**DURATION**

**02-2016** Feasibility Study  
**03-2016** Technical Planning  
**06-2016** Construction  
**01-2017** CQV  
**06-2017** Validation batches  
**08-2017** **Commercial production**

SERVICES	CD	BD	DD	CM	CQV	OS
Project Management	Completed	Completed	Completed	Completed	Completed	Completed
Process	Completed	Completed	Completed	Completed	Completed	Completed
Technical Services	Completed	Completed	Completed	Completed	Completed	Completed
Architecture + Civil	Completed	Completed	Completed	Completed	Completed	Completed
Qualification	Completed	Completed	Completed	Completed	Completed	Completed

- not in scope
- in scope
- work in progress
- completed
- partner

# Greenfield multipurpose facility for injectables Aguettant, France, Lyon



## THE PROJECT

Uninspired by a proposed Conceptual Design for its new production facility in Lyon, Aguettant sought experts who could challenge the design with the aim to ensure production capacity while remaining compliant amid high pharmaceutical standards, all of this in a cost-effective manner.

## SUCCESS CRITERIA

Pharmaplan presented an innovative GMP-compliant Conceptual Design for the greenfield laboratory and packaging facility, and secured production capacity with a new aseptic filling line. We transferred existing lines and coordinated thoroughly with a construction company for building and architecture while focusing on cost-effective manufacturing.

## DURATION

2011 - 2015

“There was strong collaboration within the Pharmaplan teams”, says Christophe Deycard, Industrial Director of Aguettant. “We felt commitment from Pharmaplan from all hierarchical levels.”

In 2016, Aguettant asked Pharmaplan to review Aguettant’s own engineering service to ensure GMP compliance in all processes and piping and instrumentation diagrams for another production site. Ten years after this first project together, Aguettant and Pharmaplan continue fortifying their strong relationship and joint effort to design and build high tech laboratories and facilities.

SERVICES	CD	BD	DD	CM	CQV	OS
Project Management	Completed	Completed	Completed	Completed	Completed	Completed
Process	Completed	Completed	Completed	Completed	Completed	Completed
Technical Services	Completed	Completed	Completed	Completed	Completed	Completed
Architecture + Civil	Completed	Completed	Completed	Completed	Completed	Completed
Qualification	Completed	Completed	Completed	Completed	Completed	Completed

- not in scope
- in scope
- work in progress
- completed
- partner

# API - Production unit revamping and extension

## Confidential Customer, France



### THE PROJECT

Uninspired by a proposed Conceptual Design for its new production facility in Lyon, Aguettant sought experts who could challenge the design with the aim to ensure production capacity while remaining compliant amid high pharmaceutical standards, all of this in a cost-effective manner.

### SUCCESS CRITERIA

Pharmaplan presented an innovative GMP-compliant Conceptual Design for the greenfield laboratory and packaging facility, and secured production capacity with a new aseptic filling line. We transferred existing lines and coordinated thoroughly with a construction company for building and architecture while focusing on cost-effective manufacturing.

### DURATION

2011 - 2015

“There was strong collaboration within the Pharmaplan teams”, says Christophe Deycard, Industrial Director of Aguettant. “We felt commitment from Pharmaplan from all hierarchical levels.”

In 2016, Aguettant asked Pharmaplan to review Aguettant’s own engineering service to ensure GMP compliance in all processes and piping and instrumentation diagrams for another production site. Ten years after this first project together, Aguettant and Pharmaplan continue fortifying their strong relationship and joint effort to design and build high tech laboratories and facilities.

SERVICES	CD	BD	DD	CM	CQV	OS
Project Management						
Process						
Technical Services						
Architecture + Civil						
Qualification						

- not in scope
- in scope
- work in progress
- completed
- partner



# API - Production unit revamping and extension

## Confidential Customer, France



### THE PROJECT

PHARMAPLAN delivered the EPCMQ for both revamping and extension with a focus on GMP compliance and high requirements from HSE aspects. The revamp and extension project focused on the following key areas:

- Freeze-dryer retrofit
- Lyophilisation retrofit
- Isolators
- Biosafety cabinet
- HSE containment solutions (for high potent products)

The project was characterised by tight time constraints with six production shutdowns between summer 2011 and winter 2013. The company needed support to ensure the effective execution of these shutdowns, including change management, cost management and intermixed phasing.

### SUCCESS CRITERIA

PHARMAPLAN delivered the EPCMQ for both revamping and extension with a focus on GMP compliance and high requirements from HSE aspects. We also looked at equipment obsolescence and operations reorganisation.

Working closely with the customer, PHARMAPLAN designed suitable containment solutions for high potent product handling for every process steps.

High attention was given to shutdown preparation to ensure smooth restarts.

SERVICES	CD	BD	DD	CM	CQV	OS
Project Management						
Process						
Technical Services						
Architecture + Civil						
Qualification						

- not in scope
- in scope
- work in progress
- completed
- partner

### DURATION

2009 - 2014

### SIZE & TIC

Size: 2 000 m<sup>2</sup>  
TIC: 26.8 M€