



# PHASE

## *Compliance and Validation Services*



PHASE

[www.pha-se.it](http://www.pha-se.it)





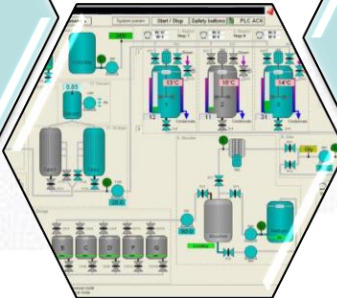
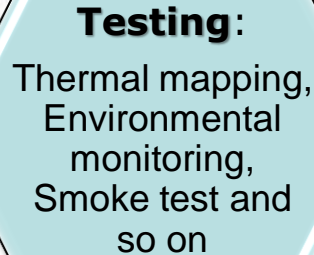
**PHASE** was founded in 2000 as a company that provides validation and compliance services to the pharmaceutical and related industries.

VMP, Cleaning &  
Process  
Validation, Risk  
Analysis,  
IQ/OQ/PQ

Support customer on vendor Audit (FAT,SAT,...)



Manages and performs commissioning activities



Expertise in automation and system completely customized, maintenance

Layout analysis,  
design support,  
developing and  
revamping  
manufacturing area



IT Infrastructure  
Gap Analysis  
Stand Alone  
systems  
from PLC to ERP  
systems  
Qualification



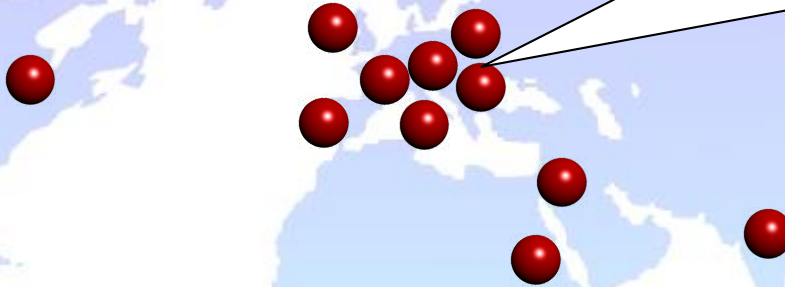


# OUR GLOBAL SERVICE

From our operative office  
based in Milan (IT)



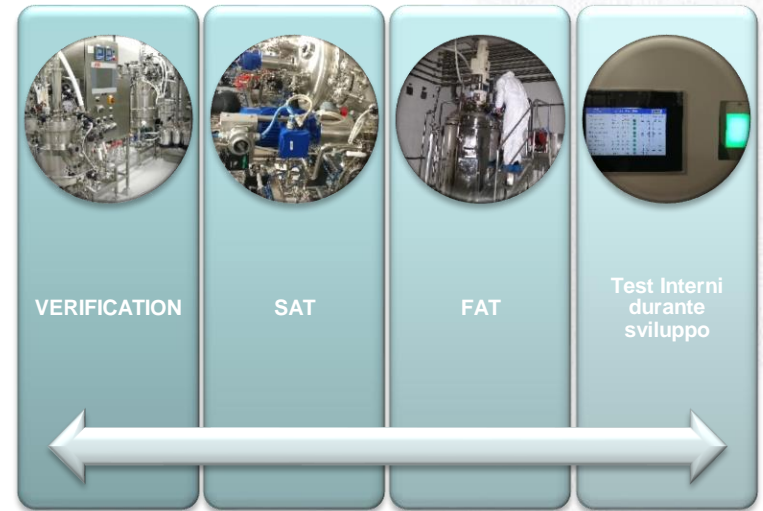
Via Bernina 41- 20158  
(MI)- ITALY





# COMMISSIONING

- ❑ **Commissioning Plan Definition**
- ❑ **Management Commissioning activities**
- ❑ **Process Utilities (PW, WFI & CS) Commissioning**
- ❑ **HVAC systems commissioning & start-up**
- ❑ **Process utilities commissioning & start-up**
- ❑ **Systems FAT & SAT execution**
- ❑ **Equipment and packages FAT & SAT execution**
- ❑ **Commissioning procedures writing & compiling**
- ❑ **Vendor audit**



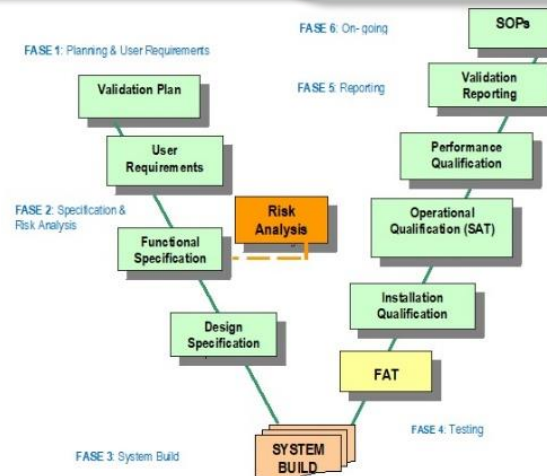
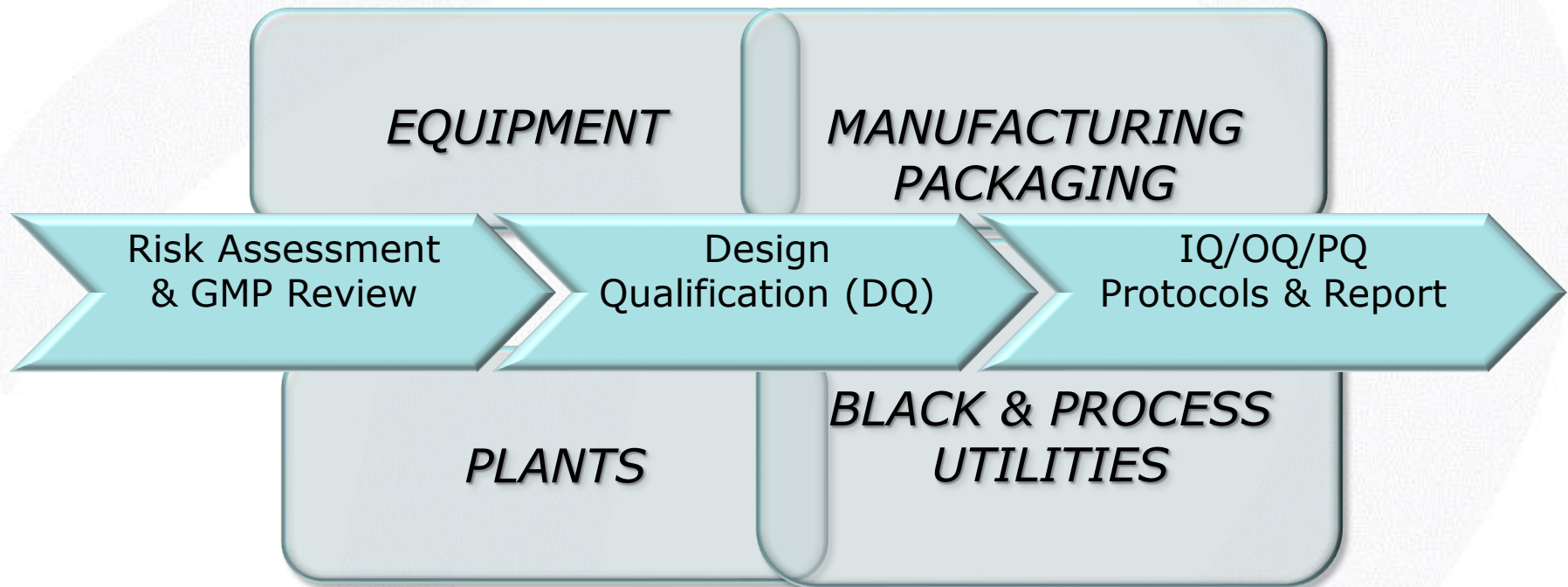


# Compliance & Validation





# Compliance & Validation





# Testing

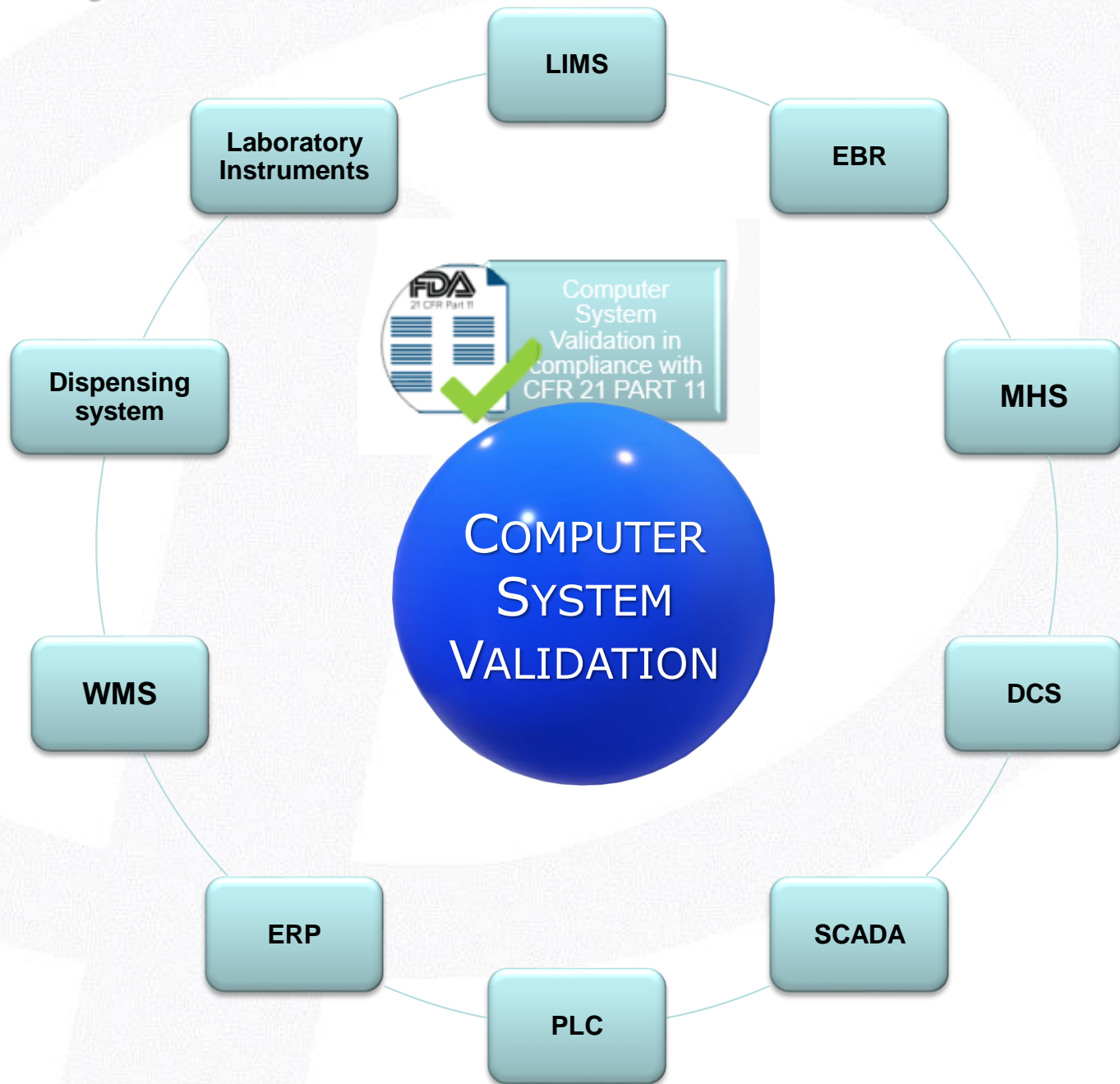
Laboratory Area



- ✓ **Environmental monitoring**
- ✓ **Temperature & %RH**
- Verification (Dataloggers)**
- ✓ **Thermal mapping test**
- ✓ **Chemical, Physical and Microbial test on gas (N<sub>2</sub>, CA, etc.)**
- ✓ **Particle Counts**
- ✓ **Flow Pattern Test**
- ✓ **HVAC seasonal monitoring**
- ✓ **Air flows and laminarity**
- ✓ **Smoke test and differential pressure measurements**
- ✓ **Leak test for HEPA filters (PAO)**
- ✓ **Recovery Time definition**
- ✓ **Cleaning validation**

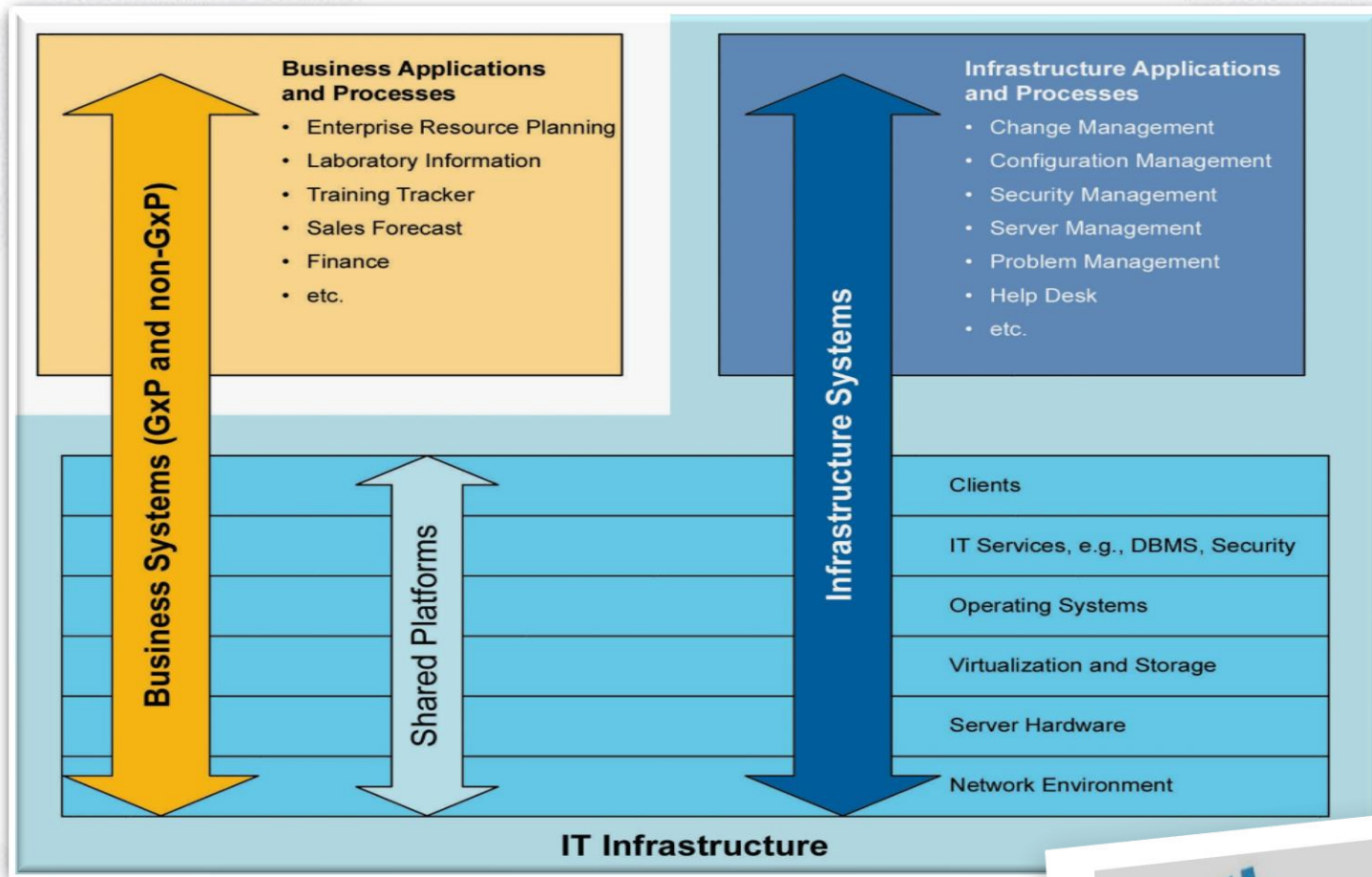


# Computer System Validation





# IT INFRASTRUCTURE QUALIFICATION





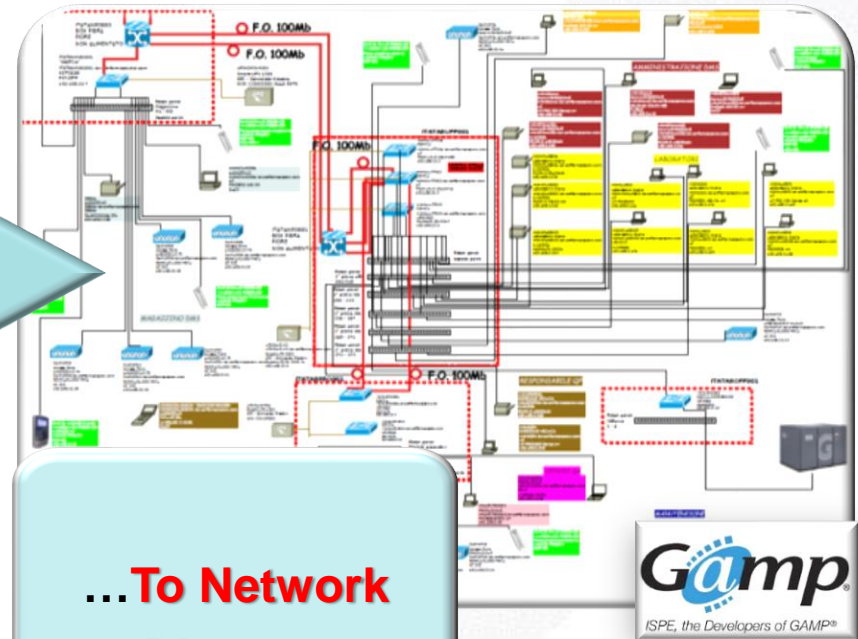
# IT INFRASTRUCTURE QUALIFICATION

ITATANNAS01	Server Room	ITATANNAS01.lan.sit.farmaceutici.com	active	IT	IT	NETGEAR	n.a.	n.a.	n.a.	2012	Storage
ITATANNAS02	Server Room	ITATANNAS02.lan.sit.farmaceutici.com	active	IT	IT	NETGEAR	n.a.	n.a.	n.a.	2014	Storage
ITATASVIRT01	Server Room	ITATASVIRT01.lan.sit.farmaceutici.com	active	IT	IT	HP	n.a.	Host Server	n.a.	Feb 18	Host Server(Virtual)
ITATASVIRT02	Server Room	ITATASVIRT02.lan.sit.farmaceutici.com	active	IT	IT	HP	n.a.	Host Server	n.a.	Feb 18	Host Server(Virtual)
ITATASVIRT03	Server Room	ITATASVIRT03.lan.sit.farmaceutici.com	active	IT	IT	HP	n.a.	Host Server	n.a.	Feb 18	999999
ITATASDC01	Server Room	ITATASDC01.lan.sit.farmaceutici.com	active	IT	ALL	n.a.	n.a.	Domain Controller	n.a.	2017	Server Virtual
ITATASPL01	Server Room	ITATASPL01.lan.sit.farmaceutici.com	active	IT	ALL	n.a.	n.a.	File Server	n.a.	2017	Server Virtual
ITATASPL02	Server Room	ITATASPL02.lan.sit.farmaceutici.com	active	IT	ALL	n.a.	n.a.	File Gateway	n.a.	2018	Server Virtual
ITATASPL03	Server Room	ITATASPL03.lan.sit.farmaceutici.com	active	IT	ALL	n.a.	n.a.	File Gateway	n.a.	2018	Server Virtual

IP Address	Model	Operating System	O.S. Platform	Processor	RAM	network card	firmware	SLM
192.168.2.40	M5A2040	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
192.168.2.41	M5A2040	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
192.168.2.30	ReadyNAS 1100	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
192.168.2.21	ReadyNAS 2120 v2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
192.168.2.39	Proliant DL380p Gen8	VMware ESXi, 6.5.0, 9298722	see O.S.	Intel(R) Xeon(R) CPU E5-2680 v4 @ 2.40GHz	16GB	Intel(R) Ethernet Controller G3300	9298722	n.a.
192.168.2.33	Proliant DL380p Gen8	VMware ESXi, 6.5.0, 9298722	see O.S.	Intel(R) Xeon(R) CPU E5-2680 v4 @ 2.40GHz	16GB	Intel(R) Ethernet Controller G3300	9298722	n.a.
192.168.2.34	Proliant DL380p Gen8	VMware ESXi, 6.5.0, 9298722	see O.S.	Intel(R) Xeon(R) CPU E5-2680 v4 @ 2.40GHz	16GB	Intel(R) Ethernet Controller G3300	9298722	n.a.

**From System  
Inventory....**

**...To Network  
Diagram**





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are  
ering



Software Development

[illegible]

 **Data Integrity Compliance  
Assessment**

analysis

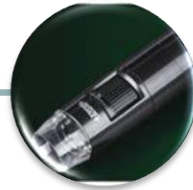


al Process System





# Metrology



Calibration



Maintenance



Configuration

- *Maintenance & Calibration Planning*
- *Follow up*
- *Calibration Procedures*

***Using Our Master Instrumentation with NIST certification***



# Engineering

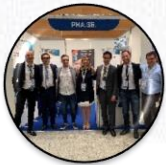
## Basic Design

- ✓ Facility Layout
- ✓ Process Equipment Lay-out
- ✓ Process Utilities Generation and Distribution Lay-Out
- ✓ Design Criteria HVAC
- ✓ P&ID HVAC
- ✓ Process and technical fluids P&ID
- ✓ Process P&ID
- ✓ Piping Lay-Out
- ✓ Duct Lay-out
- ✓ Technical Specifications for Process Equipment, Control Systems, Pharma Finishing and Instrumentation.

## Conceptual Design

- ✓ General & Equipment Layout
- ✓ Material and personell flow
- ✓ Equipment List
- ✓ System List
- ✓ Automation specifications
- ✓ Compliance Requirements
- ✓ Cost Estimation





Passion



Know- How



Commitment



Flexibility