

COMPLIANCE AND ENGINEERING SERVICES



```
1 <!DOCTYPE html>
2 <html lang="en">
3 <head>
4 <title> My perfect website </title>
5 <meta charset="utf-8">
6 <link rel="stylesheet" href="/63/mystyle.com">
7 <link rel="stylesheet" href="/63/mystyle.com">
```

```
27 mytag.defineSlot("homepageSquareSizeMapping", mytag.sizeMapping(),
28   addSize([245, 250], [200, 200]),
29   addSize([0, 0], [300, 250]),
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mytag.defineSlot("10237A2/homepageDynamicSquare", [[300, 250], [200, 200]], "reserved-div-1").
```

Your business integrator



Our mission is to provide **engineering and compliance services** to meet and exceed customer expectations

Our core values and team culture is **our day-to-day co-responsible approach** offering a high quality, friendly, knowledgeable and professional service

PHASE is a company that provides Engineering, Compliance & Validation Services for life science and aerospace sectors, proudly

specialized in supporting its clients with a dynamic and flexible approach with high expertise and consolidated experience.



Our **vision**

Our vision is enhance the world around us, taking part in it with passion and creativity.

Our team **values**

We work hard everyday to be the company that best understands and satisfies all customers compliance needs.

PHASE has professional figures and financial capability to deal with major projects and investments and to ensure compliance with the agreed timeline and the quality of execution.

Significant presence of its specialist consultants as committee members of life science associations (international standards committees responsible for the elaboration of standards and guidelines in the field of contamination control and compliance, for example GAMP, ISPE, AFI, ASCCA, AiCARR).



Quality service & performance

We believe that customer satisfaction is central to quality and performance. We are committed to delivery a professional and proactive service.

Our people are experts in their field and are encouraged to continually update their skills to ensure we are always improving our support service and meeting the needs of our customers.

We contribute to client's success through the provision of timely, high quality and professional support adding value as their business integrator.



Phase can be the ideal synergic support, able to integrate perfectly into projects and production logics, to improve your projects evolution



In the Life Science industries, Compliance must be an opportunity to ensure growth and modernization. We strive to guarantee a constant quality improvement for all the critical processes during manufacturing and control activities, contributing to achieve companies' future goals and business competitiveness. Our high competence and

knowledge are focused to meet the quality compliances in the industries operating in:
PHARMA and BIOTECH
ISOLATION TECHNOLOGY
BIOLOGICAL CONTAINMENT
MEDICAL DEVICES
ADVANCED THERAPIES
NUTRACEUTICAL
COSMETIC
AEROSPACE



The ability to design and identify **innovative solutions** in all engineering disciplines focusing on the process, control of contamination and HVAC advanced concepts

A **top-level compliance services** to ensure quality of your processes and products. A multi disciplinary team dedicated to obtain and maintain compliance according to the current directives



Engineering services

PHASE has the capabilities to design and manage systems of advanced facilities. This enabled a continuous exchange with the management of life science companies, therefore the solutions that PHASE may propose are improvement over the state of the art.

Conceptual study

Develop of Conceptual Study as first step of a project approach. This phase helps the user or the investor to understand the technical feasibility of the project and to have a first economic impact defining a budget price. Conceptual Study consist of:

- Project approach description
- Material & personnel flow
- General & equipment layout
- HVAC System Definition
- Automation specification
- Cost estimation class 3/4 (according to AACE)
- Compliance requirement

Basic design

Basic design development that includes all deliverables involved in the projects. The documentation consist of detailed deliverables as per project approach description, URS definition, GMP approach, detailed drawings, material

specification, material take off, P&Id, electrical block scheme, architectural SCADA definition, applicable for all sectors of the project as per:

- General aspects
- Architectural and civil finishing
- HVAC Plants
- Process & Mechanical Plants
- Electrical Plants & Instrumentation systems

Project management services

Services for project management as per:

- Main management
- Planning-cost control-purchase assistance
- Commissioning agent
- Construction supervision
- HVAC supervision
- Electrical & automation supervision
- Technical and process utilities supervision

Compliance services

Auditing

We support our clients on Vendor Audit: verification considering design, construction, organization, documentation and testing properly in compliance with standard, internationally recognized methodologies as well as and cGMP regulation, European and US Pharmacopoeia. Supplier audit and regulatory inspections.

Validation

Manage entire validation roadmap of equipment and systems.

Commissioning

We manages and performs commissioning activities for systems, equipments, facilities, HVAC, process gases and utilities.

Testing

High experience in equipment testing, environment monitoring and thermal mapping.

CSV

In accordance with GAMP, PIC/S guidance, FDA 21 CFR Part 11 and data integrity guidelines.

Metrology

Expertise in on-site calibration including configuration, adjustment and MGMT customer's database.

Hazop

Our qualified team ensure the effectiveness of the HAZard and OPerability study.





phase

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