GMP REGULATORY COMPLIANCE

At the pharmaceutical industry's service.
Achieving compliance with the strictest regulation quick and easy.

comser | GMP QUALIFICATION & VALIDATION

GMP QUALIFICATION AND VALIDATION

COMSER, through the GMP qualification and validation department, helps pharmaceutical laboratories and medical equipment manufacturers to comply with the strict requirements of the current GMP and medical equipment regulations.

COMSER takes care of the management of GMP projects in a way that includes all stages from start to end: before, during and after the production process.

The company is present throughout the journey and manages all the steps to be followed entirely, from the design phase to process validation.

360º PROJECT MANAGEMENT

END TO END MONITORING

QUALIFICATION OF UTILITIES AND FACILITIES	EQUIPMENT QUALIFICATION	PROCESS VALIDATION	• EQUIPMENT REQUALIFICATION • PROCESS REVALIDATION • SUPPLIER AUDITS

PROJECT MANAGEMENT

RISK ANALYSIS AND TRAINING

Size and experience

+40 GMP CONSULTANTS

Constantly undergoing training on GMP regulations and requirements

+10 YEARS collaborating with multinational laboratories

+20 YEARS collaborating with manufacturers of equipment for GMP requirements

+200 PROJECTS working on the qualification of equipment under GMP regulation

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Adding value through our way of being and knowledge

OUR VALUES

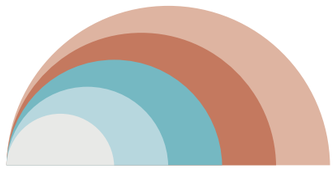
- HUMILITY
- QUALITY
- FLEXIBILITY
- HONESTY
- COMMITMENT

The team of people working at COMSER stands out due to the balanced relationship between their human and professional side. Both focused in committing with each project in a natural way, while offering the best service possible.

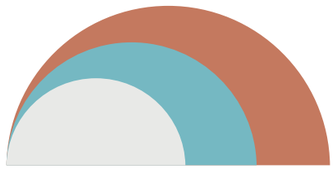
This particularity makes **COMSER** a workplace with high staff loyalty, low rotation levels and professionals who are highly committed with the company. At the same time, these professionals with their competencies and their way of being, obtain high levels of loyalty from clients. This is the key to the company's growth.

OUR COMPETENCIES

TECHNICAL COMPETENCIES (HARD)



PERSONAL COMPETENCIES (SOFT)



TRUSTING RELATIONSHIPS

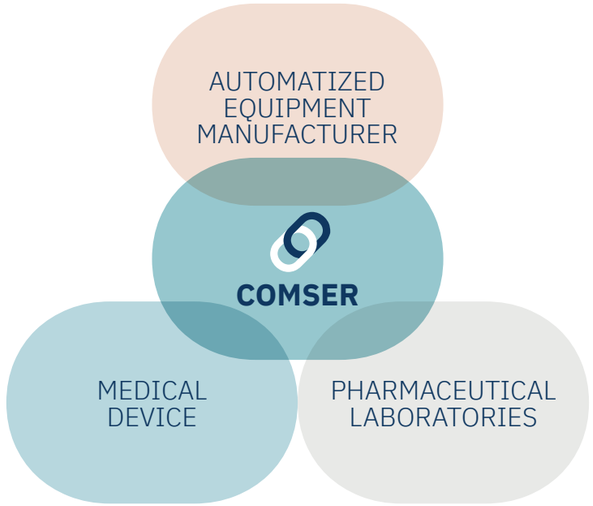
Our growth is based in the creation of stable links with our clients.

MARKETS

Specialists in the specific needs of each market

COMSER has ample experience in the regulated GMP sector as well as in the medical equipment sector.

Both the European regulation (EU GMP) and the American regulation (FDA) require that these markets show the validity of their equipment and processes through qualification and validation. In **COMSER** we help these sectors attest the strictest regulatory compliance.



WE PROVIDE THE EXPERIENCE OF WORKING FOR BOTH THE PHARMACEUTICAL SECTOR AS WELL AS EQUIPMENT MANUFACTURERS.

REGULATION:

- EU GMP
- FDA
- 21 CFR part 210 y 211
- 21 CFR part 11
- ISO 13485
- ISO 11607
- ISO 17665

GUIDES:

- ICH Q8, Q9, Q10 y Q11
- GAMP 5
- Data Integrity
- ISPE Guidelines
- PDA Technical reports
- ASME BPE

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SCENARIOS

Because the added value is in the service

Thanks to its knowledge and experience, COMSER is able to solve the challenges posed in the most diverse scenarios, both in the pharmaceutical sector and while working with medical equipment manufacturers.

The following are the most common scenarios, the challenges they pose and what are the services **COMSER** provides to successfully address them.

SCENARIO 1

ACQUISITION OF NEW EQUIPMENT

You work in a regulated sector and due to process requirements, you need to incorporate new automatized equipment.

WHAT **CHALLENGES** DOES WORKING UNDER **GMPs** ENTAIL?

What are the **key requirements** of the new equipment?

What **regulations** or internationally recognized guides must **it comply** with?

What **equipment / supplier** suits **your needs** better?

Is the **design documentation** provided by the **supplier suitable**?

The **equipment qualification** must be carried out by the supplier or by an independent company?

Does the **equipment generate** electronic **records**?

Does it **comply** with 21CFR part 11 and Data Integrity?

How do I **apply** the **GAMP 5** guide to this equipment?

In which **category** would it fit?

HOW IS **COMSER HELPING** YOU IN THIS SITUATION?

- **End-to-end** project **management**.
- **GMP** requirements **training**.
- **Review** of design documentation.
- **Drafting** of user requirements.
- Risk **analysis**.
- **Qualification protocols** drafting (DQ/IQ/OQ/PQ).
- Software **validation** following GAMP 5.
- **Implementation** of qualification protocols.
- **Assistance** in FAT and SAT.

SCENARIO 2

MODIFICATION OR CREATION OF A NEW MANUFACTURING AREA

You work in a regulated sector and due to process requirements, you need to set up or modify a new manufacturing area.

WHAT **CHALLENGES** DOES WORKING UNDER **GMPs** ENTAIL?

What are the **key requirements**?

What **regulations** or recognised guides must the new area **comply with**?

Does the preliminary design comply with the **process and regulatory requirements**?

Are the planned services adequate for the **process needs**?

Are the people that will work in the new **area trained in the cGMPs**?

Have you identified the **quality risks** associated?

Have you designed a **validation master plan**?

Does the environmental conditions monitoring system generate **electronic records**?

Do they maintain **data integrity**?

HOW IS **COMSER HELPING** YOU IN THIS SITUATION?

› **Definition** of the validation master plan.

› Global risk **analysis**.

› Design **qualification** of the new area.

› **Drafting** of the qualification protocols (IQ/OQ/PQ).

› **Implementation** of the qualification protocols (IQ/OQ/PQ).

› Software **validation** following GAMP 5.

SCENARIO 3

NEW PRODUCT TO INDUSTRIALIZE

You need to industrialize a new product in your manufacturing facilities.

WHAT **CHALLENGES** DOES WORKING UNDER **GMPs** ENTAIL?

What are the **risks of the process** which have an impact in the quality attributes of the product?

What existing **processes** must be **re-evaluated** due to the introduction of this product?

What tests must be included in the **validation of the manufacturing process** of the new product?

How should I write the **validation report** of the product?

HOW IS **COMSER HELPING** YOU IN THIS SITUATION?

› **Risk** analysis.

› Process validation protocol **drafting**.

› **Evaluation** of the validation results.

› Validation report **writing**.

› Process **revalidation**.

SCENARIO 4

OVERLOAD OF QUALIFICATIONS AND/OR VALIDATIONS

You need the support of experienced people that can integrate quickly into the work dynamic of your engineering/quality/production department.

WHAT **CHALLENGES** DOES WORKING UNDER **GMPs** ENTAIL?

How can **I strengthen** my qualifications and/or validations **department** quickly and efficiently?

HOW IS **COMSER HELPING** YOU IN THIS SITUATION?

› **We fit in your** qualifications **department** quickly.

› We have **extensive experience** collaborating with top level multinational companies.

› We bring all our experience to help you face challenges **integrating** ourselves **in your organisation**.

› We **adapt** to your needs.

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- HIGH VALUE SERVICES -

| FREEZE-DRY SOLUTIONS | HIGH VALUE TRAINING | **GMP QUALIFICATION & VALIDATION** | GMP AUDITS

Doctor Torras i Bages, 100 · 08223 Terrassa (BCN)
T (+34) 93 707 10 97 · info@comserpharma.com
WWW.COMSERPHARMA.COM