

Products

Solid Oral Dosage form

Tablets

Capsules

Sachets

Liquid Oral Dosage form

Injectables and Lyophilisates

Large Volume Parenterals

Eye Drops

Monodose strips

Multiple vials with normal dropper

Multiple vials without conservants and absolutel filter caps

Vials with absolute filter cap or normal dropper

Oncological

Injectables

Solids



Case Studies

VIETNAM

Project

Oncological facilities for injectables, liquids and lyophilizates and in second step in solid dosage forms.

What we did

Turn key project with supply of dossiers, technology transfer, GMP and personnel training support. Revamping two pharmaceutical production sites for β -lactamics into GMP standards.

IRAN

Project

Two solid dosage form sites: Injectable & Lyophilizate facility

What we did

Supply of dossiers, technology transfer, GMP and personnel training support.

TUNISIA

Project

Solid dosage form site: Biotech injectable site for insulin and eritropoyetine.

What we did

Supply of Dossiers, technology transfer, GMP and personnel training support.

DUBAI

Project

Solid dosage form site: Injectable & Lyophilizate facility

What we did

Supply of dossiers, technology transfer, GMP and personnel training support.

ALGERIA

Project

Solid dosage form site: Injectable & Lyophilizate facility

What we did

Supply of dossiers, technology transfer, GMP and personnel training support.

Biorè Consulting

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Company Profile

What we do

Biorè is the one stop shop for the Pharmaceutical Industry.

We provide our clients with a fully customizable package that include the drafting of the required registration dossiers, the documentation for obtaining the Good Manufacturing Practices (GMP) certificate, the training of highly-specialized personnel, the design and use of technical facilities.

BIORÈ WAS FOUNDED IN 2000

But our history is much longer. Our Technical Director Luis Adell has more than 40 years of experience in the pharmaceutical industry. Our President, Mirco Pellacani, has been managing Teco for 20 years, building an impressive portfolio of clients.



01

Registration Dossiers

We draft and prepare the necessary Registration dossiers to comply with international standards. In particular, we focus on providing our customers with the documentation necessary to obtain the GMP certificate. We help with drafting the Marketing Authorization Application for registration in the European Union and with the necessary documentation for obtaining the Certificate of Pharmaceutical Products within the European Union.

Pilot and Validation Batches - Stability Studies

We ensure full technical support for production of Pilot/Validation Batches and performance of stability studies, by providing:

- Drafting of the necessary Documentation;
- Personnel support with physical presence during the production phase.

GMP documentation

We are able to provide our customers with:

- Batch Records
- Standard Operating Procedures (SOPs) s for relevant processes:
- Validation procedures including media fills;
- Qualification procedures of machinery and main services: WFI, PW, HVAC, autoclaves, tunnels and filling machines;
- Cleaning Validation procedures.

02

Startup

We are able to provide our customers with a whole "startup" package that includes:

- Qualification & Validation;
- Technology transfer;
- Drafting of the documentation for obtaining the GMP certification;
- Personnel training and support on the premises;
- Use of technical facilities;
- Engineering and building support.

03

Online Support & Maintenance

During the routine production phase, we are able to provide all necessary online support and maintenance, in particular:

- Any necessary follow up of the lyophilization process;
- On line maintenance service in order to resolve the majority of the routine incidents.