BIOGLAN | a REIG JOFRE company

HELPING YOU SOLVE YOUR CHALLENGES

Bioglan is a Contract Development & Manufacturing Organisation (CDMO) supporting pharmaceutical and med-tech companies in the development and manufacturing of topical formulations. Bioglan is located in southern Sweden and is a part of Reig Jofré group, a pharmaceutical company founded in 1929 in Barcelona and listed on the Spanish stock exchange market.

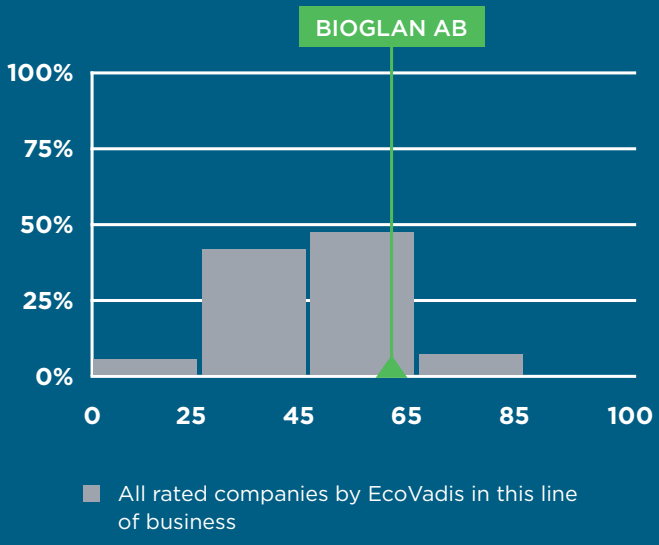
We are EU GMP approved and hold an ISO13485 certificate. Our quality management system is compliant to current legislations and guidelines. With over 40 years of experience & competence within topical formulation and commercial manufacturing, Bioglan can be considered as your preferred single service provider. We offer a one-stop solution from development to commercial manufacturing with short turnaround time for projects.

Our vast experience as a CMO has honed our understanding of the high requirements and expectations from customers as we will play an integral part of our customer's supply chain. We believe in long lasting partnership based on trust and transparency.

Sustainability

Sustainability is very important to Bioglan. Bioglan has a strictly controlled environmental monitoring system where current ISO14001 certification soon will be expanded to cover all parts of the company including the full supply chain. 100% of our electricity comes from renewable energy. In 2023, Bioglan ranked within the 78th percentile in Ecovadis business sustainability rating.

Overall score distribution



Bioglan Services

Development services

Our team of experienced scientists and dedicated project managers will support and guide you through the development process of topical formulations of semi-solids. Most of the products developed and manufactured at Bioglan are creams, gels, ointments or lotions for topical skin application. We have a wide range of on-site manufacturing capabilities, from small lab scale to commercial batch scale. On-site commercial manufacturing is key to our understanding of the importance to develop formulations and processes that easily can be transferred to large scale manufacturing.

Our focus during the development phase is:

- Dosage forms compatible with the target disease
- Excipients that are not sensitizers and have low potential for irritation or other immunological reactions
- Formulation is cosmetically elegant and user-friendly
- Formulation is physically stable
- Drug delivery is optimized
- Active pharmaceutical ingredient is chemically stable in the formulation
- Requirement of stabilising agents and/or preservatives

Clinical and preclinical trial services

Bioglan has experience in the manufacturing of clinical trial materials for all stages of your clinical development. Our special pilot plant allows us to produce small scale clinical trial batches for the initial trials, while our main facility allows us to produce commercial scale batches often needed in the later pivotal trials.

Clinical trial manufacturing and packaging services include:

- Adherence to US, EU, Japanese and other market standards
- Non-sterile manufacturing of phase I, II, III & registration batches
- Full clinical trial material formulation, manufacturing, labelling, packaging, QC and QP release services
- CMC documentation support

Analytical services

Bioglan provides a high-quality analytical service, customised to the specific requirements of your project. We have skilled and experienced staff supporting you in every aspect of your analytical demands. Our well-equipped laboratories and network of partners facilitate every need for the product during its life cycle.

Core activities:

- Development and verification/validation of analytical methods
- Method transfer
- Testing of raw materials, intermediates and finished products
- Forced degradation studies, stress testing
- In-use stability studies
- Stability testing according to ICH guidelines

Bioglan utilises a broad range of analytical techniques and equipment including:

- High and Ultra High Performance Liquid Chromatographs (HPLC/UPLC) with UV, DAD and RI detectors
- Gas Chromatography (GC) with head space and FID detector
- FTIR
- Penetrometer
- Viscometer (rotationary and capillary)
- Rheometer
- Densitometer
- Melting point equipment
- Conductivity
- Kjeldahl
- Titration equipment
- Spectrophotometer (UV and IR)
- Refractometer
- Microscopy

Contract manufacturing –specialised in semi-solids

We are a committed CMO and a full-service provider taking care of your needs.

It's important to Bioglan to grow with our partners. By continuous investments and improvements in our facilities, staff and quality system we ensure that future increasing demands are met. We value feedback and close partnership with our customers. Our close cooperation and monitoring of the supply chain from order to shipment assures a high service level.

Our services include:

- Equipment suitable for batch sizes ranging from 250 kg to 1250 kg. Further expansion with larger batch sizes is planned.
- Packaging capacity of tubes, bottles and jars in various sizes and materials, such as aluminium, plastic or laminated.
- Different packaging sizes of tubes from 5 g to 250 g and jars from 250 g to 700 g.
- ATEX approved bulk manufacturing and filling
- Possibility to serialize products according to European Falsified Medicines Directive
- Supplier quality assurance including audit services
- Artwork support
- Sourcing & stock keeping of raw materials and packaging materials including cold storage
- Modern equipped laboratories
- On-going stability
- QC from starting material to release of finished product
- QP release to market

Tech transfer service

The experienced team of project managers support you in the tech transfer process and have extensive understanding of the commercial manufacturing processes. We use a risk-based approach and well established project practices. Transparency through the project and frequent status reporting will assure you are involved in the project and decision process.

Tech transfer core activities:

- GAP analysis sending vs receiving unit
- Risk assessment
- Analytical method transfer and verification/validation
- Sourcing and supplier qualification including audit services
- Process optimization including technical batches
- Cleaning validation
- Process validation
- Manufacturing of stability batches
- Stability studies (ICH)
- Regulatory support

Life cycle management

The close partnership with our customers also involves support during the entire product life cycle.

- Proactive communication regarding product improvements
- Timely communication of changes to support maintenance of the product dossier
- Using annual PQR as a source of continuous improvement of the product
- Support in risk assessments according to regulations
- Safety data exchange support

Bioglan

Mailing address
Bioglan AB
PO Box 50310
SE-202 13 Malmö
Sweden

Visiting address
Borrgatan 31
Malmö, Sweden

+46 (0)40 28 75 00
info@bioglan.se
bioglan.se

BIOGLAN

a REIG JOFRE company