

## OUR SERVICES

### PRODUCT DEVELOPMENT

The majority of the products developed and manufactured at Bioglan are creams, gels, ointments and lotions for topical application.

### ANALYTICAL

Bioglan has skilled and experienced staff and well-equipped laboratories ready to solve your analytical problems, and provide routine support testing, from raw material to finished product.

### MANUFACTURING

The Bioglan facility allows us to provide non-sterile clinical trial batches (phase I, II, and III) as well as commercial scale batches for world-wide sales.

### QUALITY

The quality system fulfils the EU and FDA GMP (Good Manufacturing Practices) requirements as well as the ISO 13485 standard for Medical Devices. The facilities are regularly inspected for GMP compliance by MPA.

# Clinical trial material



Clinical trial manufacturing and packaging services include:

- Adherence to U.S., EU, Japanese and other market standards
- Manufacturing of phase I, II, III & registration batches
- Full CTM formulation, manufacturing, labelling, packaging and release testing
- CMC (chemistry, manufacturing and quality control) support documentation
- IND (Investigational New Drug Application)
- IMPD (Investigational Medicinal Product Dossier)
- Full quality support for all clinical materials

Bioglan has experience in the production 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. We can also assist you in labelling, packaging, QP release and distribution of the clinical trial material.

## Its is time to reach the market

The registration support services that can be undertaken are:

- Regulatory guidance from development to commercialization
- Manufacturing, packaging and release testing of registration batches
- Stability study design and monitoring according to ICH (International Conference on Harmonization) guidelines
- Documentation to the CMC part of the registration file



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