

Production

GMP-compliant manufacturing

Meeting global demand for injectable sodium selenite and immunocyanin

In 2009, biosyn Arzneimittel GmbH was the first company worldwide to start producing sodium selenite pentahydrate, the active ingredient in its global blockbuster selenase®, in GMP-compliant quality according to international standards – just one of the many purification and crystallization process technologies especially developed and patented by biosyn for the pathogen-free production of trace element compounds.



Cleanroom production equipment at biosyn

Through its innovative engineering, biosyn is satisfying the demanding quality requirements for the production of injectables: it currently manufactures pharmaceutical-grade oral and parenteral sodium selenite pentahydrate and sodium selenite anhydrous under cleanroom conditions.

€ 1.5 million for GMP-compliant production

The ultramodern production facilities in Fellbach, Germany turn out 120 kilograms annually, supplying medium-sized drugmakers and big pharma with trace element compounds for research and clinical use.

Prior to biosyn's process-engineering innovation, manufacturers were unable to comply with Good Manufacturing Practices, forcing international regulatory authorities to approve the marketing of sodium selenite at sub-pharmaceutical-grade levels.



World's first GMP-compliant manufacturing facility for immunocyanin

The world's First GMP Manufacturing Process for Immunocyanin

biosyn enjoys a unique position on the immunocyanin market. The credit for this goes to its visionary researchers. The first stage of the process – extraction of the hemolymph from the California keyhole limpet, *Megathura crenulata* – takes place at the GMP-compliant manufacturing facility of its American subsidiary, biosyn Corporation in Carlsbad, California.

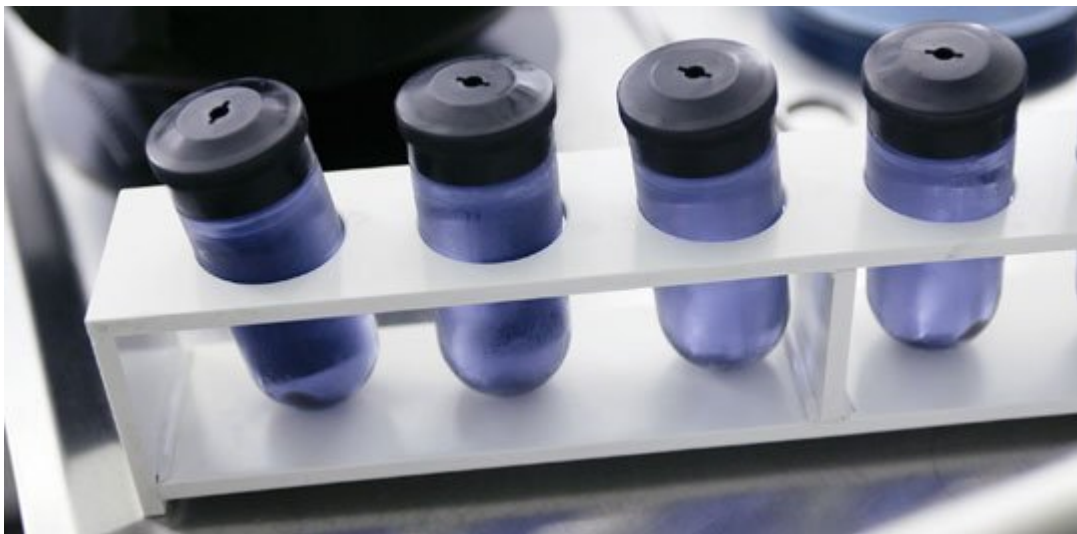
Immunocyanin is the active ingredient marketed under the brand names IMMUCOTHEL® for the treatment of bladder cancer and VACMUNE® a carrier molecule for therapeutic vaccines. This

stable mixture of two types of protein subunits from native Keyhole Limpet Hemocyanin is also gaining importance in immunology. The raw immunocyanin from California is then processed to pharmaceutical-grade quality at the Fellbach facilities, also certified to GMP-compliant standards by the regulatory authorities.

Over 2 decades, biosyn has invested up to € 1.5 million in this transatlantic project.

Environmentally friendly, proprietary and cutting-edge: Blue serum from *Megathura crenulata*

Keyhole limpets can be up to 15 years old when our specially-trained divers borrow them from the permanently cool Californian coastal waters. Harvesting these sea creatures and extracting their serum by non-lethal puncture takes place in compliance with all legal and environmental standards.



Blue test tubes containing hemolymph extracted by non-lethal puncture

Living proof

Around 500 keyhole limpets are required per 2-week production cycle. The marine snails spend this time as guests at biosyn in Carlsbad, housed in specially designed pools and kept on a purifying diet.

Under cold anesthesia, serum is drawn painlessly from their locomotor foot and fluid loss is replenished by a proprietary method. After their job is done, the limpets are returned to their ocean habitat unharmed.