

Liquid II

Cell Culture Media
Manufacturing Plant

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Overview

History of BioConcept and Amimed

BioConcept has close to forty years of experience serving the Swiss biological community. Since its foundation in 1978 we have become a leading supplier and service partner for numerous respected pharmaceutical and academic institutions in Switzerland.

In 1993, BioConcept added the Amimed® brand to its portfolio. Bioconcept's expansion into the tissue culture market allowed us to meet the needs of the sophisticated and evolving pharmaceutical and bio-pharmaceutical markets. BioConcept has developed a strong international presence with its Amimed® brand. We have achieved this through building a positive reputation and constantly updating our practices in order to keep up with the ever-advancing field of cell biology.

Amimed

AMIMED® is the brand name of BioConcept's cell and tissue culture product line. Based in Switzerland, we offer a broad range of special (customized) and standard (classical) media in order to give our customers the opportunity to create the ideal cell growth medium and other sterile liquids.

Our services include:

1. Special customer-designed media
2. Individual solutions for your cell culture
3. Complete cell system applications
4. Standard media
5. Liquid and powder media
6. Animal sera
7. Buffers and balanced salt solutions
8. Supplements and auxiliary reagents

Customized products are delivered within four to six weeks after the order has been placed.



“At BioConcept we listen to our customers and adapt our services to meet their needs.”

The New Liquid Media Plant Offers:

1. Automated media handling
2. Class A GMP / ISO 5 Cleanroom
3. Water For Injection production (WFI)
4. 5,000 L/day batch capacity
5. ISO 9001:2008 certified
6. High level of flexibility



Our brand new filling machine, located in the center of the plant, is made almost entirely of stainless steel.

Customized Products

At BioConcept we pride ourselves on our ability to listen to our customers and create services to meet their varying requirements. We offer the flexibility and control that our users need:

1. Modifications: We make simple modifications to standard products.
2. Custom Recipe: We manufacture new products according to customer recipes.
3. Custom Batches: We offer a broad range of batch sizes:
Liquid: - 5 to 5,000 L
Powder: -2 to 800 kg
4. Sterilization: Our sterilization can be performed through sterile filtration of 0.22 μm and/or with vapor sterilization.
5. Choice of Medium: Serum free and Animal Component Free (ACF) media.
6. Choice of Container: Our containers come in a variety of types and sizes, including glass, Sterile Flexboy® bags and PET bottles. We also fulfil specific requirements when requested.

How we make

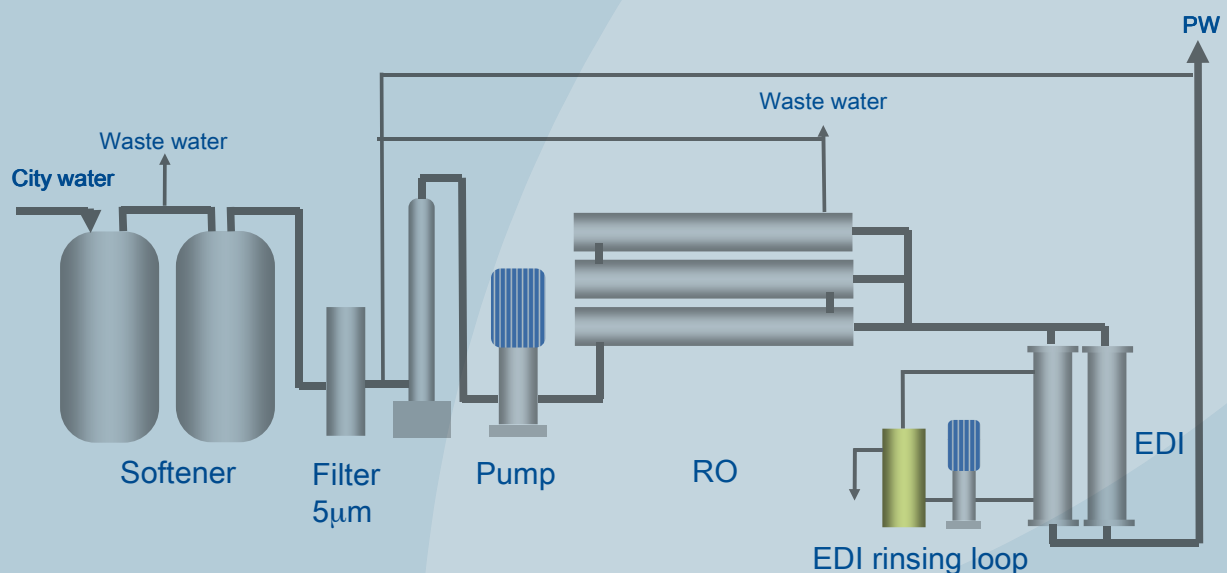
Water For Injection

Water Preparation

Water is a key component in manufacturing liquid biopharmaceutical medium. Because of this we have invested heavily into our new water purification facilities. Our new water purification system sets a new standard for BioConcept and enhances our competitive edge in the market. The water preparation facilities were carefully engineered for optimum quality assurance, efficiency, and sustainability and are able to quickly and effectively generate the highest standard water for injection (WFI) available. Furthermore, quality has not been sacrificed to improve the quantity; at BioConcept we now produce up to 5000 L/day with our new liquid media plant, which allows us to meet the rising demands from our customers.

Reverse Osmosis

The process to achieve high quality water starts with reverse osmosis. The pure water created by this process is then integrated into the cleaning system. This saves electricity and therefore contributes to the plant being more ecological and financially sustainable.



Our water purification system has been designed to produce purified water.

Pure Steam

We use a powerful electric steam generator instead of the commonly used petrol-powered alternative. This reduces our carbon emissions as a company.

The steam has multiple purposes within the manufacturing process. It is connected to the Clean-in-Place / Sterilize-in-Place (CIP/ SIP) systems, the sterilizer and it is also used to produce WFI.



Our brand new electric steam generator reduces our carbon footprint.

WFI

The steam is condensed to make WFI. During this process the heat is extracted and recycled into the air conditioning system. It is then used to control the humidity and temperature of the rooms. We are able to produce 5,000 L of WFI a day in a sustainable and efficient manner with these new facilities.

The WFI must be kept at a stable temperature above 80 °C in order to avoid microbiological contamination. To maintain a sustainable and constant temperature, the energy from the heat exchangers is recycled around the water circuits. This is monitored constantly using sensors.

Monitoring

We monitor and certify our water quality. This is done using various methods such as recording pH as well as determining osmolality measurements, conductivity, and endotoxin and bioburden levels.



Our engineers regularly monitor the water quality.

Sterile Environment

Cleanroom Air Processing

Air processing is a very important factor in the process of manufacturing pharmaceutical substances. The plant was designed to create an environment that upholds a high degree of sterility, ensuring a sterile final product. We use a state of the art air processing system that supplies us with the optimal conditions we need for sterile liquid production.

We constantly monitor and control the pressure, temperature, humidity and particle count in the air and regularly disinfect our facilities using H_2O_2 . The cleanroom filtration standards are according to ISO 5 and GMP class A guidelines.



The cleanroom was designed to enable a smooth workflow of both product and personnel.

“We use a complex and effective air processing facility to achieve a high level of cleanliness.”

Steam Sterilization

The sterilizer has been produced in Switzerland using high quality materials and components by the renowned Belimed Company. The machine is designed to disinfect both solid and porous products such as filters, rubber stoppers, and system components. The sterile filters are regularly disinfected in order to avoid cross-contamination. An automated integrity test monitors each of the filters to make sure they are operating correctly. It is a reliable GMP-compliant design.



Our new Belimed steam sterilizer.

H₂O₂ Disinfection

Our equipment uses modern spinning disk technology to produce a fine fog of uniform and controlled droplets (size range between 5 µm and 10 µm). The machine disinfects effectively without using any nozzle or compressed air and the machine also stores information about each treatment and the data is transmitted to a PC through a USB to guarantee traceability.

Reliability

The pressure and temperature of the facilities are managed and monitored via independent measuring and control loops, which increases process reliability and traceability. The saturation steam ratio (pressure/temperature) is also constantly monitored in order to further improve the consistency of the procedures. Through installing measures that frequently record process we are able to rapidly and effectively detect and fix any deviations that may arise.

Media Handling

Capacity

In our new facility we use state of the art machinery such as an automatic filling system as well as three new media filling stations that are designed to fill large containers. The modern sensors and equipment are used to ensure a high level of accuracy and flexibility when measuring product parameters. Its capacity ranges from 100 L/day to 5,000 L/day and has the possibility to handle various bottle and container types from 100 ml to 500 L.



The motors and moving parts of the automatic filling machine are oil free.



The robotic arm plays a crucial role in our new automatic filling machine.

Automatic Bottle Filling

The automatic filling line can fill up to 2,000 500 ml bottles of media in one hour. For the preparation of the bottles we use a machine to decrease the chance of contamination and ensure the high standard of the final product. All further steps such as sealing and labeling are also performed automatically.

Container

The three new media filling stations can handle up to three 500 L containers simultaneously. This allows us to complete even big batch sizes within one day. The media pipes are made out of pharmaceutical standard stainless steel and are linked to the CIP/SIP system.



Three brand new media filling points. The large windows between rooms allows staff to communicate with ease.



Our 5,000 L media tank is electro polished to meet pharmaceutical standards.

“Our capacity to produce and ship large orders in a reliable and sustainable manner has substantially increased.”

Cleanroom Interior

Inside the Plant

The cleanroom has been constructed to be as large as needed but as small as possible in order to increase its sustainability and efficiency. Wide windows have been installed to give the plant a sense of space and increase the staff's ability to communicate throughout the facilities.



The main entrance to the liquid media plant.

Rooms

The layout of the rooms create a circular workflow around the plant for the staff and material; this supports the production process. On a smaller scale, the same mechanisms have been applied to individual rooms to allow our staff and the production to run smoothly.

Material

The materials used to build the interior and furniture are sleek, waterproof and are in accordance to GMP standards. We have used stainless steel, HPL, glass and synthetic resin to create such conditions. The materials have the advantage of being easy to clean, thereby minimalizing contamination, and providing an appealing working environment for the staff.



The interior is made out of materials such as glass, synthetic resin and stainless steel.

“The cleanroom is a pleasant and interactive environment to work in.”

Transparency

A large proportion of the interior is made from large windows. The glass has been used in a way that makes the plant more open and transparent. The layout is arranged so it is possible to inspect one side of the plant while standing on the other. This allows the staff to easily supervise the whole production process.



To increase a sense of openness around the plant much of the interior is made out of glass.

Interfaces

The production process is monitored by state of the art sensors and is displayed on several user interfaces. These were tailor-made to suit our needs and are well integrated into the plant's infrastructure. Through the interfaces, our staff can easily observe and control the plants conditions and specific parts of the manufacturing process.



The production process is displayed and controlled through a number of monitors around the plant.

In Conclusion

With our brand new state-of-the-art liquid media production plant, BioConcept Ltd has reached the next stage of our expansion. The plant has been designed to maximize efficiency, sustainability, and productivity through utilizing modern technology and focusing on the fine detail of the plant's design.

We offer you:

1. State-of-the-art facilities:
 - Automated media handling
 - The plant is sustainable and eco-friendly
 - Fully automated and efficient
2. Customer service and customized product:
 - Highly flexible
 - The staff are educated and experienced
 - 5,000 L/day batch capacity
3. Transparency:
 - Customer audits are welcome
 - The documentations of the production steps are clear, traceable, and comprehensive
4. Quality control:
 - Class A GMP / ISO 5 Cleanroom
 - ISO 9001:2008 certified
 - Our processes are scrutinized and validated to ensure excellence
5. A unique product of utmost quality
 - Water For Injection production



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