



IV BAG PRODUCTION-INTRODUCTION



Due to the mentioned wide range of infusion applications, a growing world population and the tremendous bag log demand of developing and emerging countries, the IV solution market is forecasted to grow with 13.5 % annually. Facing such a significant market increase an investment in this area has a high potential to become profitable. Especially price efficient low capacity production lines which are suitable for the local supply and local standards denote a high demand.

Setting up an IV production line is therefore an attractive Investment for private investors as well for Governmental and Non Governmental Organizations' which are interested to serve the local market by their own.

Importance

IV is one of the most important and basic medical items

High demand

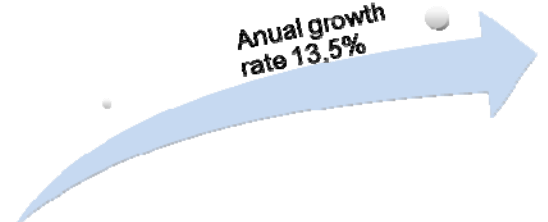
The IV solution market is forecasted to grow with 13.5 % annually

Trend

Price efficient low capacity production lines which are suitable for the local supply and local standards denote a high demand

As one of the most important and basic medical items, I.V. Solution has a lot of demands whole through the world. In general, I.V. solution is set for the care of nurture, before and after surgical operation, improvement of circulation of blood and care for burn etc.

Annual growth rate 13.5%





IV BAG MARKET

Although the U.S. market comprises almost 70% of the total world market for IV solutions, the market for third world and emerging nations is growing much faster and presents a tremendous opportunity for the IVPC Facility™.

World market growth is driven by population increases and constant up-scaling and sophistication of health care delivery. As part of this up-scaling, IV infusion therapy is becoming increasingly important in overall health care treatment regimens as new developments in antibiotics and other medications used in areas such as chemotherapy, burn centers, and renal/peritoneal dialysis centers favor intravenous use and application. For emerging countries it is attractive to produce I.V. products by themselves locally to avoid the relatively expensive import products. The economic advantages of producing IV solutions locally in emerging and medically developing nations via EWMA IVPC Facility™ can result in an extremely short return on initial investment. Profitability can be established at only 50% production capacity. The total annual consumption is about 18 billion 500ml units approx. That means a production expectation for one I.V. production plant at 5.4 million units annually meets approx. 2.5 hours of the annual world consumption.





IV BAG PRODUCTION

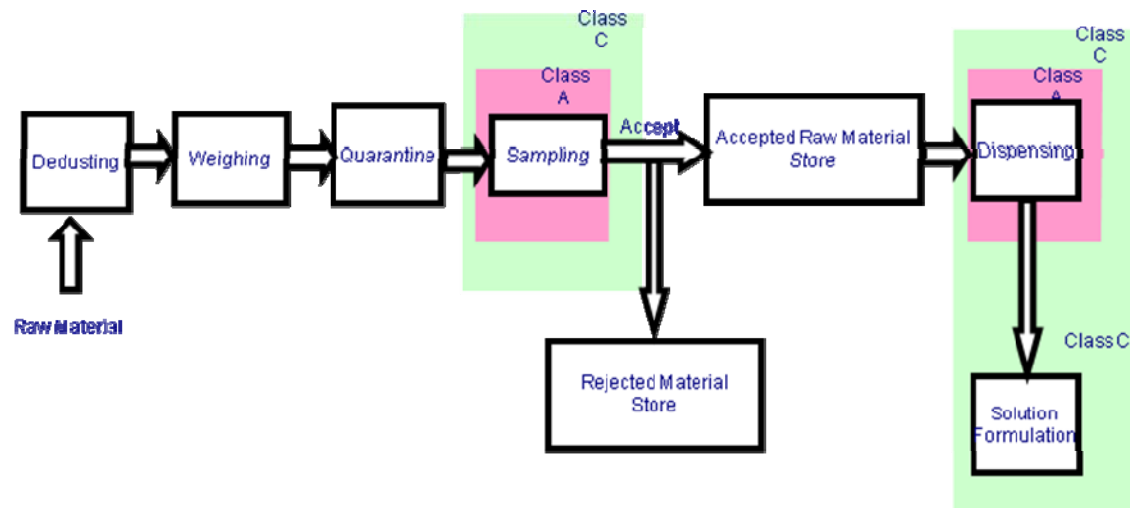
Raw Material Sampling and Dispensing

Especially, I.V. Solution requires extremely high purity because it is directly injected into human blood. For this reason, the production know-how and reliability of production line are essential ones to guarantee the safety of the final product. In this regard general production standards concerning the hygiene, the production process, the storage etc. have to be fulfilled. Besides certain standards our offer is specialized in project management for setting up an I.V. Solution manufacturing plant

I.V. Solution manufacturing plant.

The production of I.V. Solution production line consists of 5 main phases:

1. water purifying
2. distillation
3. solution filling
4. sterilization
5. packing

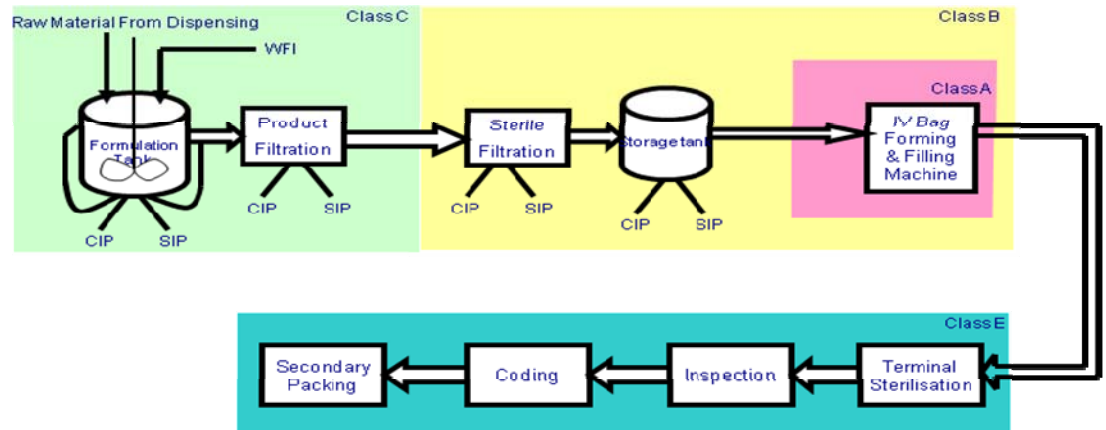


The process chart above clarifies the complexity and sensitivity of I.V. Production. As you can see the majority of the process steps have to be executed under clean room conditions (clean room classes A-E).



IV BAG PRODUCTION

IV Production and Packing



As the I.V solution consists mainly of water, the water purification and distilling is a very important step to guarantee the purity of the water. (Beside: Water purification)



The FFS machine (forming filling sealing) can be seen as the heart of the Production line. PP-foils get formed to bags, filled with the I.V solution and sealed. Further a stopper will be adjusted to avoid any I.V solution lost.



To ensure a contamination free product which is priority number one in this business, the filled bags have to be sterilized after the filling.



During the secondary packaging the filled I.V. bags get overwrapped with a plastic bag to ensure contamination free storage. The single bags get packed into cartons manually or with another machine.



Different production options

In general there exist two different production options:

- Full automatic production
- Semi automatic production

Semi automatic production

Less investment intensive flexible production line for small capacities

IV BAG PRODUCTION

IV bag production options

There exist generally two different options for IV bag production line investments. For capturing and checking the market it could make sense to start with a semi automatic, less investment intensive production line. Further such a small capacity Production line could be used to serve the local market.

During the process a worker has to operate the semi automatic machine by filling the pre made empty bags with infusion liquid.

The more investment intensive option is the full automatic production line. The production process includes the manufacturing and filling of the bags. All steps are done full automatically. By including all parts of the I.V. bag value chain in the process, investors can increase the profitability of the project.

The following subchapters describe roughly the processes of the mentioned options.

I.V. bag semi automatic manufacturing process:

The desktop stand-alone unit beside is designed for semi automatic filling and sealing of I.V. bags in one process step, in compliance with WHO GMP or European GMP/FDA standards.

The module is including a vacuum, filling system and one needle insertion device.

An operator has to put each empty bag (which has to be procured or produced with a separate machine) manually under the filling nozzle. Filling, sealing and drop out are an automatic process. Sealing is done by inserting the needle into the tube. This device is equipped with a gripper system. The gripper is especially designed for used stopper type. This enables an exchange of the gripper and makes the device flexible regarding other stoppers to be used for different bag designs. Each gripper has to be designed according to customers application.





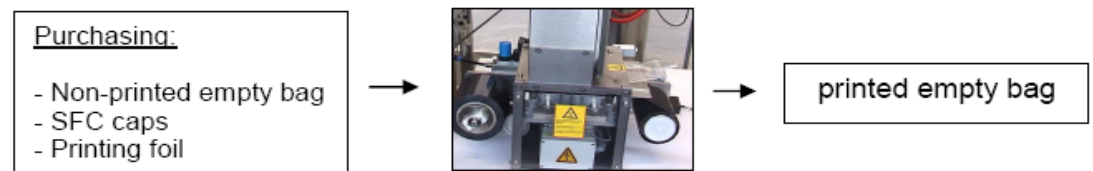
IV BAG PRODUCTION

Labeling

As the bags get only filled by the semi automatic filling machine, an additional production step has to be considered. By using a semi automatic labeling machine you are able to attach your own self designed label. Further, in case you intend to enter the contract manufacturing business, you are also able to fill and label I.V. bags for different clients which intend to sell the bags under their own brand name.

Semi automatic labeling

A necessary step to label the empty bags with your own- or the costumers label.



As you can see on the above scheme it is possible to add a printing machine to your production. Here the producer has the possibility to print the purchased empty bags flexible by himself.



I.V. bag full automatic manufacturing process:

This production line is a fully automatic linear single lane system suitable for the sterile bag making, filling and sealing of e.g. IV bags under pharmaceutical requirements. The machine is constructed in compliance with WHO GMP or European GMP/FDA regulations.

The production line processes Double wound PP- Multilayer material for bag making. The film is caught by several grippers and passed through the machine. Separate Modules fulfill the steps: Printing, bag making, filling and sealing. At the end of the process the filled and sealed bags are carried out on a conveyor belt. Two bags are produced in each station per cycle.



Full automatic Production

Sterile bag making, filling and sealing of e.g. IV bags under pharmaceutical requirements



IV BAG PRODUCTION



Machine output: e.g. 2500bph / 500ml bags

Bag volumes: mainly 500, 1000ml (others on request)

Sealing method: any port system

Processed film: Polyolefin film, double wound PP-multilayer flat film

Sterilization temp.: 121°C

Printing: machine is equipped with hot foil printing device

Operation: One operator permanently, second temporary

Bag format

Exchange: approx. one hour, by the operator

Flexibility: Highest flexibility regarding

- Various bag volumes
- Bag designs
- Machine output
- Time of operation
- Exchange tools for bag layout
- Processing of various pharmaceutical fluids

Options: - welding devices as exchange parts to go for different bag volumes



Experience

Besides our own experience you can benefit from our network which offers different competences and different standards according to your requirements

Multiple competences

Based on the different core competences of our employees and partners we are able to serve you beyond the project execution –for example with the distribution of your products.

IV BAG PRODUCTION-ENSYMM SERVICE

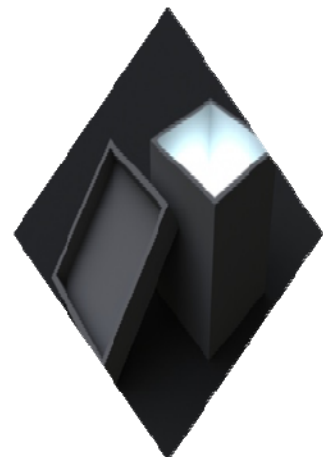
Ensymm can help you to plan and realize your I.V. bag production line project. Referring to this look at the ensymm profile, ensymm benefits and ensymm project roadmap as follows.

Profile:

Ensymm is a consulting company based in Dueseldorf/Germany. Our company offers Technology Transfer, Project Management and Consulting for private investors, companies, governmental organization and universities. We have a strong network of more than 35 suppliers in the EU, Middle East, South America and Asia and 15 cooperation offices worldwide. Beside our expertise for managing your project puzzle, we are specialist for Turnkey Plants (Transfer of Technology and Equipment) and Outsourcing. The transfer of technology contains the areas:

- Biotech processing
- Pharmaceutical processing
- Chemical processing
- Food processing

So we have the pleasure to provide you with new and fresh ideas for preparing your company for future challenges and developing its marketing and sales strategy for the global competition.





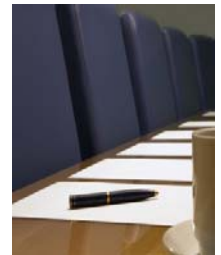
Several Benefits

By providing a bunch of benefits you are able to enhance the chances of a successful project execution and a higher profitability

IV BAG PRODUCTION-ENSYMM SERVICE

Benefit of Ensymm Project Management:

- Client designed offer
- Local support
- State of art Technology
- Feasible production capacity
- Offers designed for the budget of investors
- Competence team for:



1. Business and scientific issues
 2. Supervising for engineering, installation and production
 3. Inspection and guarantee for used plants
 4. Coordination of the Project from A-Z
 5. Quality control
 6. Advisory related to the project
 7. After sales services
- Project coordination from A-Z
 - Support for raw material and technical services



IV BAG PRODUCTION-ENSYMM SERVICE

IV related Ensymm project management:

Ensymm provides you an I.V. specified service to realize your project on turnkey or part key base. We have 5 engineering companies and more than 10 manufacturers from Europe/China/India (Worldwide reference projects are available for your visit) within our network. Therefore we can select the perfect team for every kind of capacity and quality standard (EU/FDA/WHO GMP) as required by the target market.

As an additional option (recommended by ensymm) a technical engineering team from Finland can be involved. It will check all equipments/processes preliminary and during the project execution to give the client the highest security.

Meetings with our manufacturers and also a site visit at an IV bag/bottle production plant will be arranged by ensymm.

Beyond the project execution the client can also profit of our after sales services. Beside the line we are also able to provide complete components for the production of infusion bag systems throughout our network of suppliers. Further ensymm would be glad to support you regarding the marketing and distributing your I.V. products.





IV BAG PRODUCTION- ENSYMMSERVICE

Roadmap till project execution

1. Our email with a short introduction along with an abstract and general budget plan
2. Signing a MOU
3. Delivery of a detailed proposal with list of equipment, machinery, raw material, general feasibility calculation and references.
4. Meeting between client and our supplying/technology team
5. Further decisions for signing a project contract
6. Signing the supplier contracts



Structured approach

As you can see beside, ensymm follows a structured approach to the client and the project itself