Abstract IV Production Line

Ensymm abstract for IV production Line

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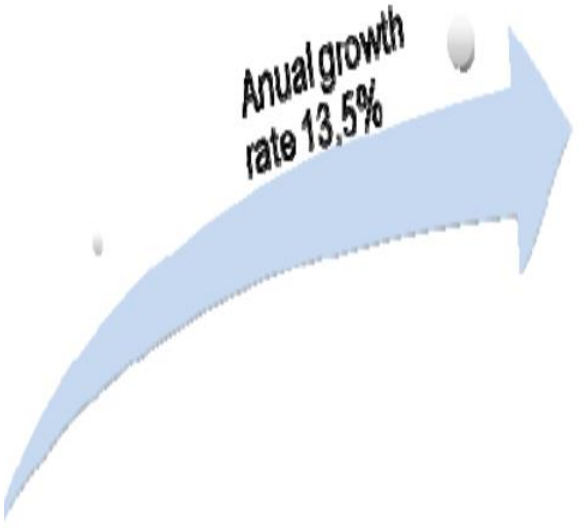
INTRODUCTION

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.



Mixed 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. As one of the most important and basic medical items, IV solution has a lot of demands whole through the world. In general, IV solutions are set for the care of nurture, before and after surgical operation, improvement of circulation of blood and care for severe burnings etc.

IV BAG MARKET

Although the U.S. market comprises almost 70% of the total world market for IV solutions, the market for third world countries 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 therapies are 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 IV products by themselves locally to avoid 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. That means a production expectation for one IV production plant at 5.4 million units annually meets approx. 2.5 hours of the annual world consumption.

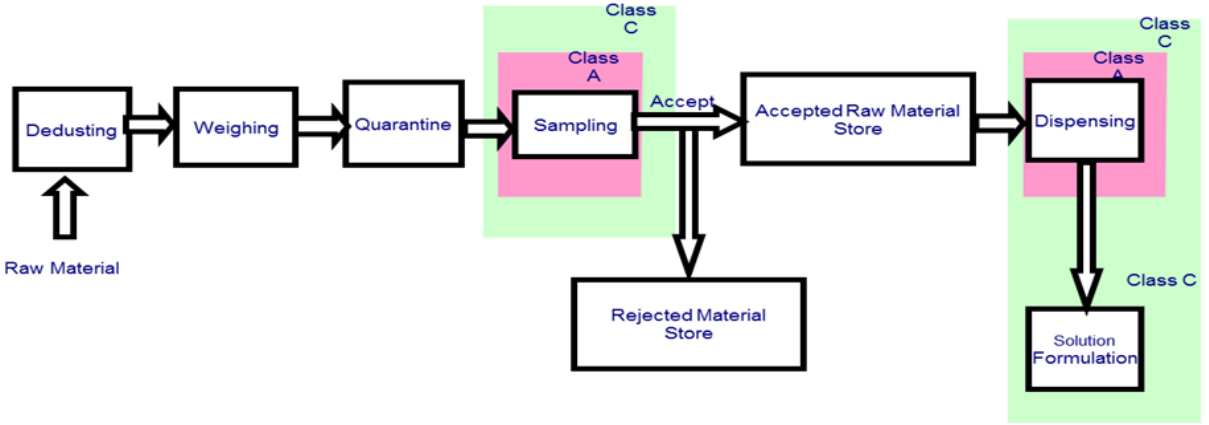
IV BAG PRODUCTION

Raw Material Sampling and Dispensing

Especially IV solutions require extremely high purity because it is directly injected into human blood. For this reason, the production know-how and reliability of production lines are essential 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 IV solution manufacturing plant.

The production of IV Solution production line consists of five main phases:

1. Water purification
2. Distillation
3. Solution filling
4. Sterilization
5. Packing



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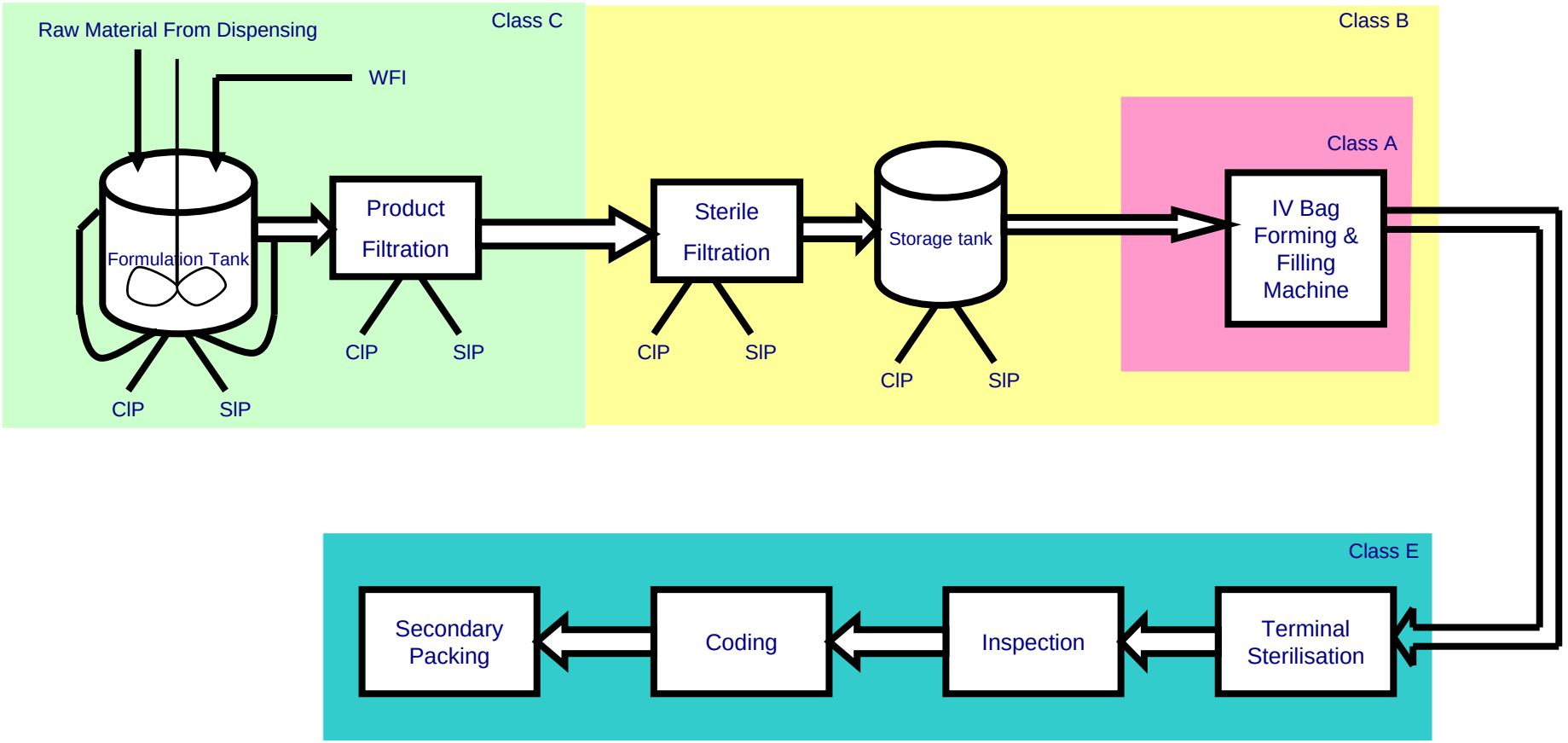
IV BAG PRODUCTION

IV Production and Packing



IV BAG PRODUCTION

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

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.

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.

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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. Furthermore, 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 premade empty bags with infusion liquid. The more investment intensive option is, the more the production line runs automatically. The production process includes the manufacturing and filling of the bags. All steps are done full automatically. By including all parts of the IV bag value chain in the process, investors can increase the profitability of the project.

IV bag semi automatic manufacturing process

The desktop stand-alone unit beside is designed for semi automatic filling and sealing of IV 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 in accordance to customers application.

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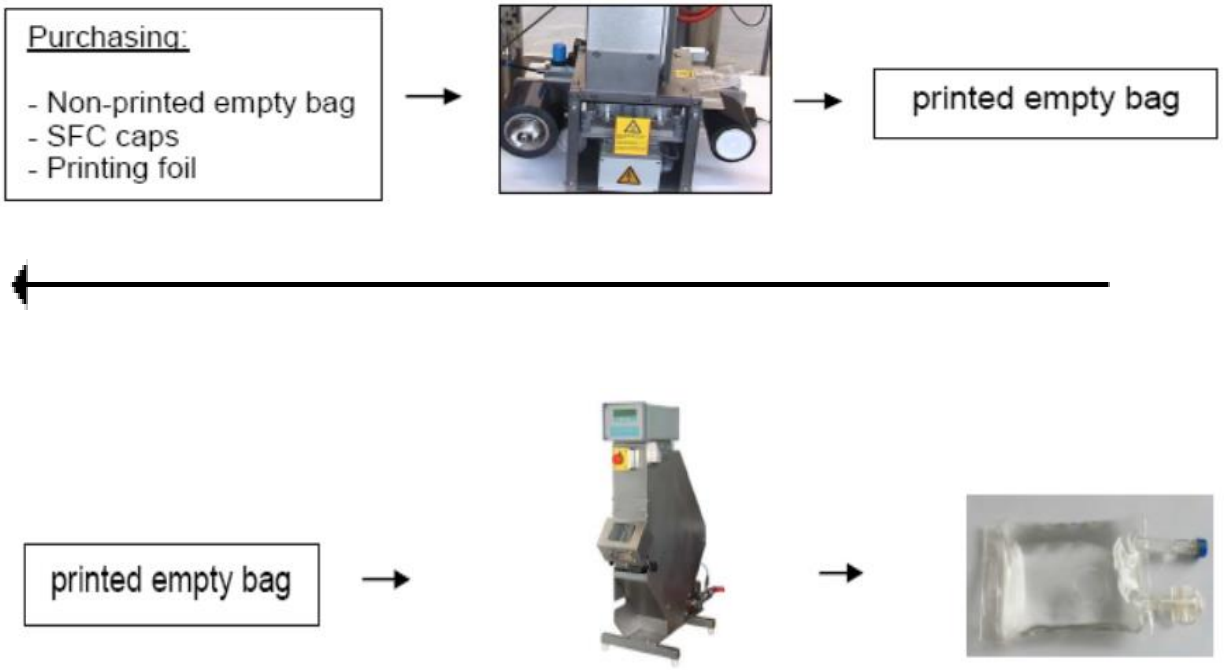
IV BAG PRODUCTION

Labelling

As the bags get filled only 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 IV bags for different clients which intend to sell the bags under their own brand name.

As you can see on the scheme above, 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.



IV 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 can be produced in each station per cycle.

IV BAG PRODUCTION

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

Bag volumes:
- mainly 500ml, 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

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For further inquiries and quotes, please contact:

ensymm UG & Co.KG
Life Science Center Dusseldorf
Merowingerplatz 1
40225 Dusseldorf
Germany

Tel: 0049 2113367527
Project_assistant@ensymm.com
www.ensymm.com