



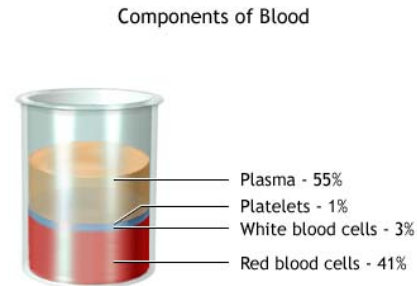
**Project Abstract
for
Production of Blood Bags as a Turnkey Plant**



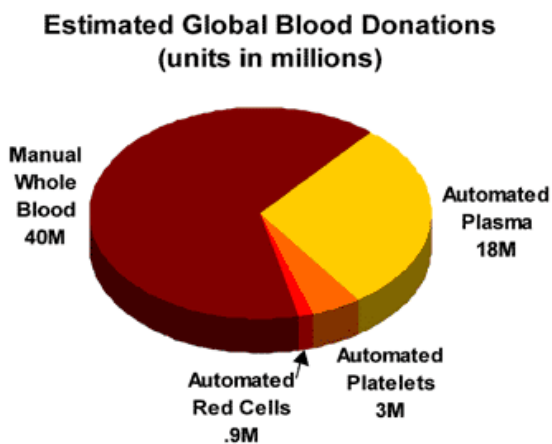
Description:

Blood bag systems are the fundamentals for worldwide blood supply by "classical" blood donation. More than 90 percent of all blood donations are processed in these systems that have up to six different bags with variable functions. A combination of PVC bags with retractable needles, pre-donation sampling pouches and different filtration devices form the basis for highly professional whole blood collection systems.

Blood donation and processing with these systems is supplemented by further devices such as automated scales, automated blood separators, sterile docking systems, sealers and filtration racks.



ADAM



Haemonetics' Donor products are a growing part of the large, global blood collection market. The chart below shows the estimated number of blood collections each year worldwide. On the right are the automated collections, in which Haemonetics markets its products. On the left are non-automated collections in which a pint of whole blood is collected from a donor in order to get a unit of red cells. While Haemonetics' does not sell technology for non-automated collections, its automated red cell collection technology is expected to cannibalize some of the non-automated, whole blood market as blood collectors can obtain more red cell units from

automated donors than from whole blood donations. While Haemonetics' automated blood collection technologies all operate in the same manner, each has a specific application to address the transfusion markets above: plasma, platelets, and red cells.

Technology Description:

The manufacture of blood components:

At the collection, the donor's blood is collected into a plastic bag (the main bag), a part of a set consisting of three plastic bags connected with plastic tubes. The whole set is sterile and has never been used before. The tubes enable the transfer of parts of the blood from one bag to another without breaking the chain of sterility. The main bag contains matter preventing the blood from coagulating.

After the collection, the blood is centrifuged so that it is divided into three layers in the main bag, according to the density of each part. After the centrifugation, the plasma, which is on top, is pressed into an empty plastic bag (the plasma bag) through a plastic tube in the top of the bag. The red blood corpuscles, which are on the bottom, are lead into another plastic bag (the SAG-M bag), containing liquid with nutrients for the red blood corpuscles, through a tube in the bottom of the bag. The layer in between, which remains in the main bag, is called the buffy coat. It contains large amounts of blood platelets and white blood corpuscles, and it is used for producing concentrates of blood platelets. Thus, the collected whole blood is split into three different components in each their plastic bag. In this way, it is possible to store the components separately under optimum conditions, depending on their respective requirements.



All blood components are labeled with a unique and clear collection number that makes it possible to trace where the blood has been collected, where it has been stored, and to which patient it has been administered. All this information is registered in the blood bank's computer system.

Storing the blood components:

Distinct rules have been laid down regarding the storage of the individual blood components. The rules take the storage temperature into special account because the shelf life is particularly dependent on the temperature. The requirement for correct and constant temperature when storing blood is due to the fact that the blood has to stay as fresh as possible. When storing blood, the temperature must be measured all the time and registered continuously so that the storage temperature can be documented.

Process Options:

There are two different options for investment of blood bag production line in general. It could make sense for capturing and checking the market to start with a semi automatic, small investment production line. A worker has to operate within this connection a semi automatic machine by filling purchased empty bags.

The larger investment option is the full automatic production line including the productions process, the manufacturing and the bag filling. All steps are done complete automatically. Investors can increase the profitability of the project throughout including all parts of the blood bag value chain.

The following subsections are describing the processes of the above mentioned options.

Blood bag semi automatic manufacturing process:

The desktop stand-alone unit beside is designed for semi automatic filling and sealing blood bags in one process step in compliance with GMP and FDA standards.

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

An operator has to put each bag manually under the filling nozzle. Evacuating, filling, gassing and sealing are an automatic process. Sealing is done by inserting the needle into the tube. Precondition is a Polycarbonate shaft to be inserted in the tube, which will close safely after sterilization.

The machine is equipped to handle one needle type.



Blood bag full automatic manufacturing process:

The core of the lines is the full automatic bags manufacturing line, provided with computerized shuttles which perform all the assembly processes.

In brief:



1. A special high Frequency welding machine is perimetralling welding the calendared PCVC film (not collapsible) with the pipes.

2. An operator brings the bags to the automatic shuttle

3. Another operator loads the different stations with the necessary components for the bags (needles, pre. brack connectors, etc)

4. In case of KITS (double / triple bags) each operator inserts the bags onto a shuttle, which is taking the bags to the following assembling stations.

5. The bags are then filled with anticoagulants (25 – 45 ml each, depending on different formulations).

6. An automatic labeling sticks special labels onto the bags.

7. A vacuum overwrapping machine performs the overwrapping in special alu-foils. Before loading the Overwrapping trays, an operator inspects the quality of the bag.

8. The overwrapped bags are then laid onto the trays of the Autoclave and sterilized with a steam-air automatic process.

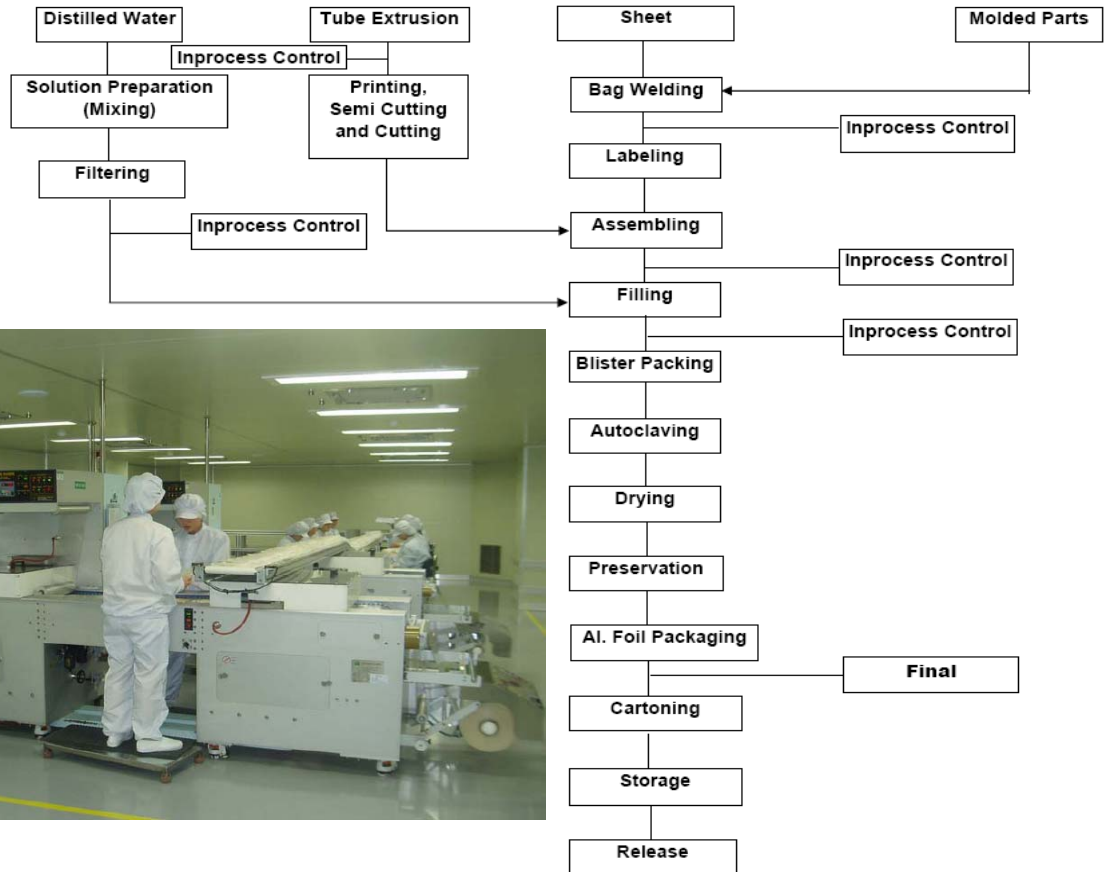
This base process could be then optionally integrated, in future investment steps as follows:

A. The Project shall be optional provided with an Injection Molding Department with several presses and molds, allowing the Project to be independent in the manufacturing of all of the plastic blood bag components.

B. The Optional Division of Leukocyte Filter will produce the shells of the filters, purchase the pre-cut and washed Filtering Tissue from an external Source and automatically assemble the filters, to be installed on line on the blood bags kits.

Layout of a Production Line:

BLOOD BAG PRODUCTION FLOW CHART



Blood bags:

There exist five different scales and specifications for blood bags.

In brief:

Single Blood Bag: Designed for collection, storage and transfusion of whole blood **Double**

Double Blood Bag: Designed to separate whole blood into plasma and red cells. Eliminates the possibility of contamination.

Triple Blood Bag: Designed to separate whole blood into three parts:

1. Red blood cells, platelets & plasma
2. Red blood cells, leucocytes & plasma

Quadruple Blood Bag: Designed to separate whole blood into four parts:

1. Red blood cells, platelets, plasma & cryoprecipitate
2. Red blood cells, leucocytes, platelets & plasma



Transfer Bag: Designed to transfer specific blood components from whole blood

Ensymm service concerning blood bag turnkey plants:

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

Profile:

Ensymm is a consulting company based in Duesseldorf/Germany. Our company offers Technology Transfer, Project Management and Consulting for companies, governmental organization and universities. We have a strong network of more than 30 suppliers in the EU, Iran and India 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.

Benefit of Ensymm Project Management:

- Client design 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 gurantee for used plants
 4. Coordination of the Project from A-Z
 5. Quality control
 6. Advisery related to the project
 7. After sales services
- Project coordination from A-Z
- Support for raw material and technical services
- Support for formoulation and compounding
- Support for certification and validation for approvals



Our Roadmap for this project:

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



Could we intrigue you ?