Production logistics improves productivity in the medical device industry

The medical device industry is undergoing a very strong growth period. Spurred by advancements in medical research, an aging population and increased standard of living, the growth potential is enormous. According to Medtech Insight (a medical device industry analyst), the medical device industry is expected to grow 7,5 percent annually between 2005 and 2010.

"In cases where a company produces single separate units, for instance glasses, or braces, we know that Youtilize™ presents completely new possibilities for keeping every product under control. In this way you can dramatically increase the percentage of faultless products within the production flow."
Göran Nystedt, Chief Technical Officer

Challenges

But all this growth comes with a backside. Realizing the potential for growth, new players are entering the market. These new players spend less on R&D and focus on producing products similar to those already in the market, but at a lower cost. Current players need to respond quickly to changes in the marketplace – manufacturing costs must go down, flexibility and quality levels must increase. Furthermore, the product life cycle is constantly getting shorter.

Traditionally, medical devices have been produced by operators organized according to function, a so called functional factory layout.

The operators have a batch of products to work with, and when done, they manually move these to the next station, where the products wait for the next operator to be available. Although flexible, this system causes a very long throughput time and a high WIP (Work In Process).

This makes QA work cumbersome and time consuming, and errors are costly, since many units can be manufactured before defects are found. Long throughput time also raises the risk for overproduction, and increases the response time to customer demands.

More importantly, manual manufacturing lines lack automatic quality control and the possibility of electronic batch records. FDA regulations (cGMP and CFR 21, part 11) now require electronic batch records. Manual records have proven not only difficult and costly to keep, but also error-prone.

Improved production logistics solutions are leading the way in productivity development in the medical device industry.

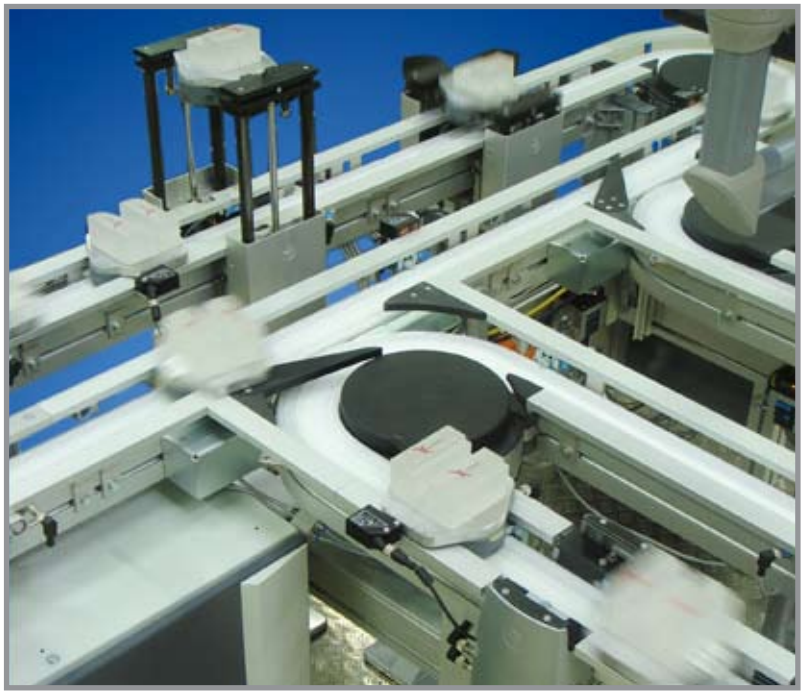
Solutions

When preparing the implementation of a new production logistics solution, a mapping and analysis of the processes involved sets the basis for the choice of solutions and line layout. Parameters to consider are takt time and required flexibility. A good advice is to perform a value stream analysis, mapping the material and information flow covering all logistics from loading dock to shipping dock, to identify bottlenecks, throughput time, productivity and be the base for new implementations. Validation must be a part of this work.

A well-designed and flexible assembly line can achieve major cost reduction results, with reduced throughput time and increased control of products in process.

Three major elements are crucial in a more efficient medical de-

Individual work stations for manual or automatic operations, testing etc. can easily be added to a line.



vice manufacturing line. These are standardization, balancing and single-piece flow.

By standardizing manufacturing procedures, quality can be raised and sustained. It is important that each manufacturing procedure is performed in the exact same way, to achieve consistent results. This is achieved by maintaining Standard Operating Procedures (SOP) and by giving the work instructions at the work stations at the right time. Of course, it is also imperative that the operator is authorized for the manufacturing operation concerned. This could be done through login procedures, making it impossible to perform the operation without the qualification.

It is desirable to achieve a high degree of utilization of resources at manufacturing plants. Reducing idle time and procedures that do not add value to the product dramatically raises manufacturing efficiency. It is not uncommon that the Overall Equipment Efficiency (OEE) is below 50% which means a lot of lost manufacturing capacity. The solution is two folded, stabilizing the processes, and then releasing the bottleneck.

It could be done, for instance, by balancing the line through flexible routing between the machines and work places. Applying a single piece flow means releasing manufacturing capacity while reducing the number of products in process, reducing throughput time and increasing the control of the process. It also becomes easier to increase the flexibility and in the end, a customer order initiated production, eliminating any risk of overproduction. In a single piece production process, each part is manufactured after another and the pull principle is fully applied. A single-piece flow also facilitates quality assurance, since traceability to the individual unit level is accomplished. When adding routing flexibility, which is managed through an intelligent system, we come close to an ideal situation and what is called an FMS, a Flexible Manufacturing System.

A well-designed and flexible assembly line can achieve major cost reduction results, and at the same time be robust for its job and withstand continuous production with the longest possible MTBF (Mean Time Between Failures). Maintenance should be kept at a minimum, be predictable and easy to perform, even in a sensitive environment.

New developments

For many years, FlexLink has developed and sold production logistics solutions, enabling the medical device industry to meet the rising challenges in the best possible way. In the latest development, a host of aspects of the production line have been improved. From the design of the conveyor system, to the pallet system, to an efficient line control and intelligent software which control the entire production process.

The new X85 conveyor, pallet system, and line control makes a solid platform for high efficient logistic solutions of products up to 10 kg. On top of this, a production logistics software - Youtilize™ - enables the management of all resources available in the production line.

A high performance conveyor

system, robust and flexible is the platform for an efficient logistics system in a manufacturing line. Developing a state of the art conveyor may sound easy but in fact, details make the difference to the user and it is not an easy task. Several patents, registered designs and further patent applications are covering the pallet system and line control.

The X85 conveyor platform offers high flexibility, a rigid installation, smooth running and a low noise level. The MTBF (Mean Time Between Failures) is significantly higher and power consumption lower than comparable systems in the market. The X85 pallet system complies with clean room regulations (class 7 acc to ISO, US class 10.000 FED Std 209).

Efficiency

An efficient pallet system should handle each product, or cluster of products if they are small, individually, thus offering:

- a product identity carrier for tracking and tracing
- a fast throughput time
- protection of the product
- minimal machine and equipment re-setting

Fast throughput is achieved through a single-piece flow, meaning a controlled flow of individual products through the manufacturing process, with a minimum of losses and waiting time. After a completed operation, the pallet goes directly to the next station in a pull-flow according to the Kanban principles. This enables controllability of the manufacturing line process, a short throughput time and minimum of WIP (Work In Process). The logic is managed through Youtilize™, the production logistics software controlling the complete process for each individual product, the machines and the support functions. It communicates with the pallets carrying the products and the handling functions for routing, pallet location etc.

RFID technology offers a dynamic identity method for communication in real time between the product, the process and the production logistics software. The state of the art X85 pallet system is prepared for RFID communication. The pallet is a standardized carrier of the product, thus enabling handling being unchanged irrespective of the product distributed through the line.

The pallet handling functions such as locating modules, tunnel locating modules, merge and divert modules, and elevators all have readers for identifying the pallet and communicate with the line control, which may be linked to the overall manufacturing software.

Keeping track of every single item in real time combined with routing flexibility, allows the line to be balanced with the lowest possible throughput time. Products are kept separate during transport and assembly, minimizing potential damage to the product. Since products are uniquely identifiable, machines can perform different operations on different products without the need to reset the line.

The pallet comes in different configurations depending on the application. There are conductive, ESD-approved versions for the handling of products sensitive to electrostatic shocks. There are variants with low friction and for clean environments.

Preconfigured functions make the line re-build easy and efficient, standardized interfaces and prov-

Tunnel locating modules can in pair serve one robot or machine, enabling continuous operation – highest possible utilization of the equipment.

en functionality make the job effort-free and the ramp-up fast with a minimum of standstill.

Functions for line balancing

A major improvement has been achieved in the modularity of the conveyor, pallet and control system. All necessary pallet handling functions, such as merge and divert modules, locating modules, elevators, and tunnel locating modules come as functional modules, greatly decreasing engineering time and adding flexibility to the line.

The tunnel locating module introduces the possibility to create parallel processes in a sequential layout. Two machines can be placed after the machine calling for the product, combining capacity for different product variants in the same line or to achieve a doubling of the capacity. The first one can be activated elevating the pallet to the machine above, letting the second pallet pass by under and reach the second tunnel module, where it is elevated to another machine. This way, it is very easy to balance capacity of operations with a long cycle time, or to introduce a complimentary machine for product variants.

It is also possible to have two working positions, one per tunnel locating station, for one machine or robot. This way it can work on one position while the pallet is exchanged on the other, allowing the machine or robot to work continuously. This solution drastically increases the utilization of the equipment involved.

For fast operations there are locating modules with fast loaders where a cycle time of less than one second is required. For small and repetitive operations on one product or for multiple small products on one pallet, there are locating modules with indexing allowing two to three positions per pallet, dependent on the pallet size.

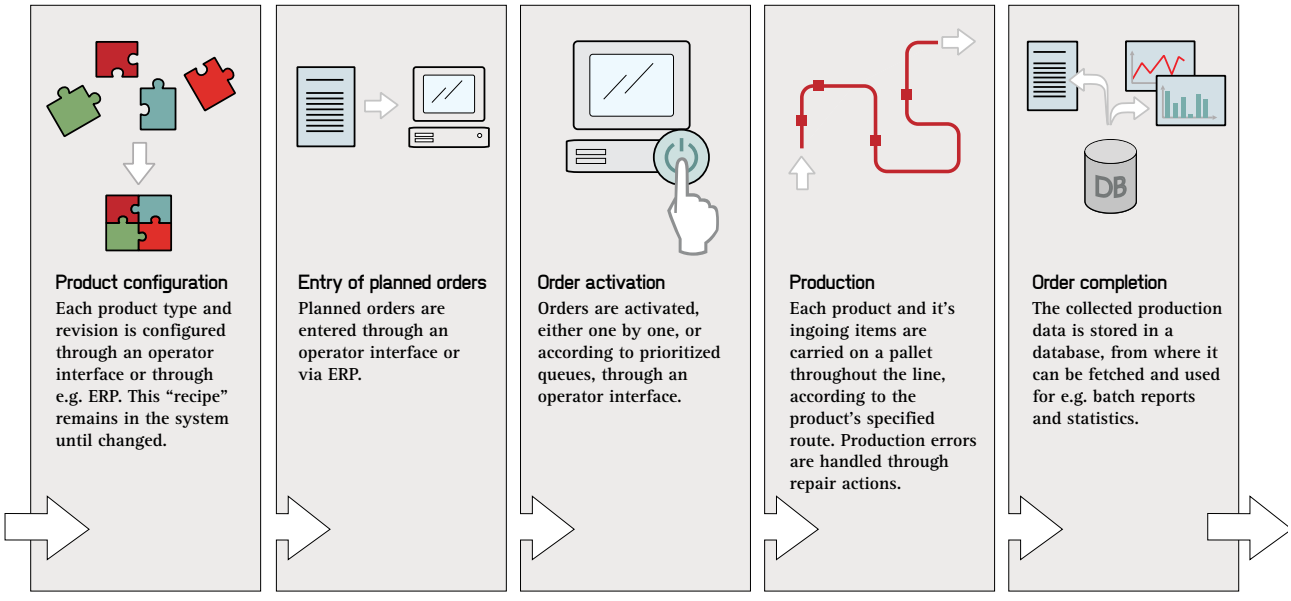
Software for QA and electronic batch records

Youtilize™, the production logistics software, enables manufacturing of multiple products types and batch sizes down to one, yet simplifying the quality assurance and increasing the quality level in production.

It is possible to manage all available resources in a manufacturing line, may it be machinery or equipment, and support operators with instructions and access rights.

Youtilize™ handles the planning, the processes, the routing, and the order execution, including communication between the product and the manufacturing control system. It comprises automatic QA (Quality Assurance) and closes the order after completion. At each workstation, the operator gets his or her interface with work instructions (SOPs) for the respective product and real time statistics. This enables easy standardization of operations and creates a basis for the improvement activities.

Super users can plan and edit the product configurations, orders, routings and workstation content. Through communication with the ERP system, product configurations and production can be easily managed. All this improves reliability and consistency, the automatic QA and reporting features and in-



Youtilize™ is a MES (Manufacturing Execution Software) for the management of the entire manufacturing process. From the establishment of the manufacturing sequence, the execution of the production, to the closing of the manufacturing order.

tegration with existing ERP system makes validation much easier.

Manual paper based documentation is normally complicated and time consuming. These problems are easily solved with the paperless EBR (Electronic Batch Record) functionality, which is an option within Youtilize™.

Smaller batches are easier to manage with less paper work and at same time, the risk of batch mix-ups is eliminated. Most importantly, Youtilize™ handles electronic batch records to comply with FDA regulation 21, CFR part 11.

All manual documentation is avoided, and with it all errors and extra paperwork. The production data is stored in real time which is a platform for continuous improvements and provides full traceability of products manufactured.

To reinforce the line “pulse”, production monitoring displays can be added. Today Youtilize™ is used to manage the production lines for e.g. catheters, braces and instruments.

Efficient production logistics elements, like the X85 conveyor, pallet system, line control and Youtilize™, are crucial for medical device manufacturers to keep up with customer and regulatory demands – today and tomorrow.