The modular route to optimised process control

A dedicated modular manufacturing execution system can provide higher flexibility, lower-risk solutions to the problem of maintaining high production yields while ensuring strict quality control.

There is a growing demand for flexible automation in medical device production. The key factors driving this need are increased production of assembled kits, cost reduction pressures and the requirement for shorter lead times and product life cycles as well as FDA validation.

Keeping product yields high while maintaining consistent quality is crucial to successful medical device production. In addition to common manufacturing execution systems, the assembly process dedicated manufacturing execution system (MES) can help safeguard both product yields and quality by providing: product quality control; tracking and tracing; operator information; line flow control; production statistics; and automatic documentation for FDA validation

The modular approach

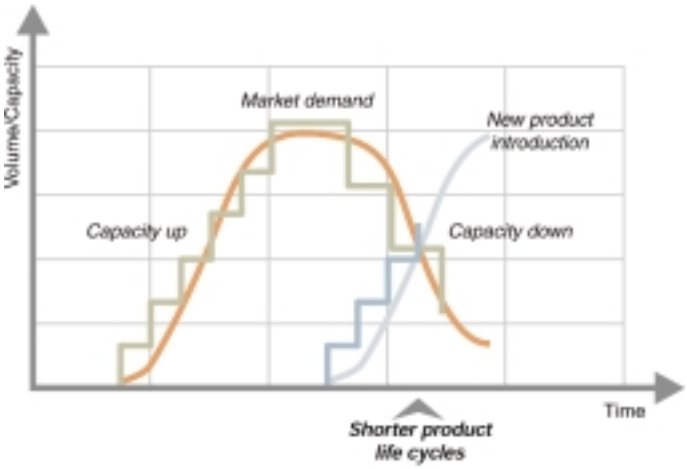
To invest safely in MES, it is important to find software that suits your process and covers all the information and logistics required in a step-by-step automated production, whether it consists of single serial lines or highly sophisticated logistical production systems.

Product and process life cycle management is now possible using a modular, step-by-step plug-and-play system which can adapt layouts, from manual assembly processes to fully automated lines, in line with business needs. Such a step-by-step approach to automation reduces a company's investment risk and allows it to take a flexible approach to the automation process. A modular dedicated MES solution offers the following advantages:

- It can adapt to future production mixes and volumes.
- Its plug-and-play software and hardware modules are highly reusable.
- It allows for flexible production layouts and fast line reconfiguration.
- It is easy to introduce additional operations.
- It is possible to add build-to-order and full traceability functionality to the system.
- It can be developed in well-defined stages, thus reducing the financial and project risks.

Assembly dedicated MES solutions

The main requirements for assembly process MES manufacturing



Life cycle management through step-by-step automation

are: quality control; operator information; tracking and tracing; line flow control; automation cell integration; feeding and buffer control; dynamic enterprise resource planning connection; order execution; and statistics and reporting. The dedicated MES solution safeguards maximum utilisation of modular and reconfigurable assembly automation equipment.

Successful MES implementations have led to dramatic improvements in assembly production. These may include:

- A reduction in work in progress of up to 90 per cent
- A reduction in manual documentation of up to 100 per cent
- An increase in production up-time of 30–50 per cent due to:
  - Zero re-set time
  - No line clearance, through full batch control
  - Dynamic line balancing
- A decrease in order throughput time of 30–90 per cent
- A reduced need for floor space of 30–50 per cent
- An increase in production system reusability of 70–80 per cent

MES solutions should enable automatic data traceability throughout the production process, double redundant operator interface and individual / batch control line clearance. Furthermore, using an audit trail with password / user name handling, MES can support automatic documentation in line with FDA validation requirements. II

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