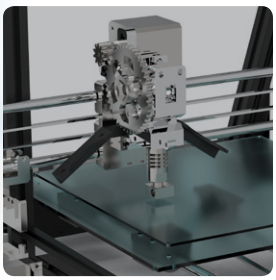
Making changes to medical devices

How do you automate your processes to help ensure product quality and meet changing market demand?



LISTEN.
THINK.
SOLVE.®

Allen-Bradley • Rockwell Software

Rockwell Automation

Introduction

Medical devices sales have increased at 9 percent annually for the past decade, and the market is expected to grow at 4.5 percent per year to 2018, reaching global sales of $455 billion.

At the same time, the industry is experiencing increasing pressures in terms of pricing, organisational structures and legislation. Companies need to produce more products in more varieties and packaging options to meet changing consumer health, taste and cost preferences.

Success comes in using automation to work collaboratively, both internally and externally, to make the changes in production that maximise output and flexibility while upholding product quality.

Regulation

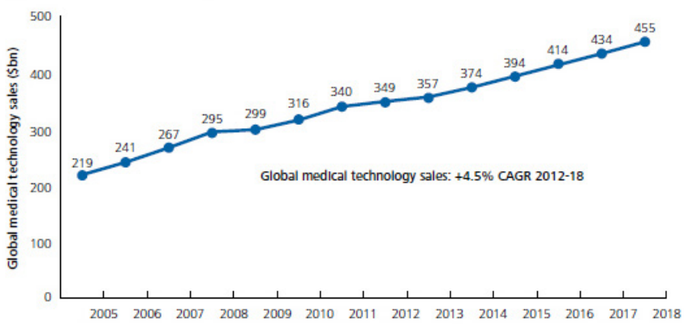
Regulations for medical device approvals are becoming more stringent across markets. Set to take effect in 2015, proposed changes to the Comparative Effectiveness (CE) marking process in the EU could require device makers to meet ever-higher standards to sell their products.

In the US, FDA overall requirements have been getting tougher, and the agency is considering bringing laboratory-developed tests, currently sold without requiring direct regulatory oversight, under its control. This is alongside the implications of the medical devices, much talked-about and still in existence.

Product quality

Quality issues have to be at the forefront of every medical device company's strategy for advancement. Media attention will always be a threat – in the past decade, an average of one company per year has seen a 10 percent drop in share price after a major quality event like a product recall.

Figure 3: Global medical technology sales, 2005-2018



Source: DTTL Global Life Sciences and Health Care Industry Group analysis of EvaluateMedTech World Preview 2013 Outlook to 2018

1 Source: Business Monitor International
2 Source: IBISWorld Industry Report, July 2014

As demand and device complexity rises, so does the potential for a quality issue. So quality control becomes central at every touchpoint in the supply chain, from raw materials through production to packaged goods.

Top performers are using best practices that reduce risk and the costs of maintaining quality, driving product development by way of defined quality measures, and embedding a culture of quality into their organisations.

...it may pay to explore how other industries such as automotive have evolved their systems and processes, and progress on that basis.

Supply chain

Historically for many medical device companies, high margins and acceptance of the status quo have resulted in a siloed, disconnected and inefficient supply chain. There are significant financial incentives to aligning and integrating every aspect of the manufacturing process.

Manufacturing is often carried out in multiple plants in relatively expensive countries, with purchasing, logistics and warehousing also managed regionally. Best practice looks towards a reduction of plants and production in countries with lower labour costs, without compromising product quality.

With the supply chain a new area of focus for the medical device industry, it may pay to explore how other industries such as automotive have evolved their systems and processes, and progress on that basis.

Interoperability

The appearance of new technologies capable of integrating medical devices into a connected platform enhances functionality, reduces labour costs and minimises errors. Cost containment initiatives are encouraging technical innovations that offer multiple diagnostic and therapeutic advantages and reduce costs.

The solution

More than ever before, automated assembly works harder and more efficiently than manual labour even at small-scale, low-volume production levels, bringing consistency, visibility and accountability the production line.

Automated systems are by definition more complex than manual systems. It follows that they take longer to validate. However, increased functionality and adaptability for global standards, improved design and development, and the benefits of full integration make automation the logical and most practical way forward.

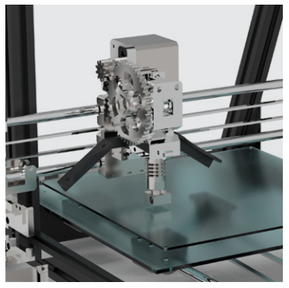
Modular assembly cells give customers a way to introduce automation to a new line with the flexibility to make additions at a later date. Modular cells can also be adapted to fit changing floor layouts and are not restricted by the initial assembly line layout.

Automation is essential in making manufacturers competitive with offshore locations. Companies wanting to compete in a value-driven market will be aiming to take full advantage of automation technologies that enable jobs to be completed faster, with fewer mistakes and improved efficiency.

Making the most of the technologies

As with every sector of manufacturing, big data and the internet of things is impacting the way companies set about developing and producing medical devices.

These technologies open up new vistas in terms of device functionality and efficacy. And the manufacturing process, too, is changing fundamentally is being reinvented by the internet of things, where services allow interaction with "smart objects" over the Internet and where physical objects can become active participants in business processes, taking into account security and privacy issues.



Three ways technology is changing medical devices

Nanotechnology

Nano-manufacturing will incorporate new materials into the manufacture of existing products, stimulate the introduction of new products based upon new material properties, and herald new breeds of nano-machines.

Connectivity

Technologies such as long- and short-range wireless communications, cloud computing, big data analytics, and information security are being employed by an ever increasing number of medical devices such as patient monitors capable of communicating data to remote locations. The amount of health care data being captured due to recent IT infrastructure upgrades is expected to greatly enhance smart functionality for diagnostic and treatment devices.

3-D Printing

Additive manufacturing or 3-D printing is set to be a $3.7 billion sector by 2015. Even now, the majority of hearing aids sold today are made using 3-D printing.

The technology can be used to produce everything from tissue scaffolds to custom prosthetics to microneedles for drug-delivery.

Nanotechnology offers unprecedented benefits in terms of biocompatibility and functionality, supporting the treatment of diseases happening at a cellular level.

Achieving quality and agility through operational efficiencies

When reviewing opportunities for improved operational efficiencies, it's important to consider the entire production-cycle, from raw material receipt to finished goods. At each point during production, there are four key areas to evaluate that can help to increase product quality, efficiency and asset utilisation:

- Machinery: effectively using machines to produce a product right the first time for improved first-pass quality
- Materials: using the correct and required amount of material to minimise waste
- Methods: using the correct tools and most efficient manufacturing processes
- Manpower: ensuring operators have the right skills and are focused on the task at hand while eliminating time spent on unnecessary activities

These four categories are all intertwined, making the need to enhance efficiencies even more complex. Increasing efficiency in one area can impact the other three areas, just as waste in one category can cascade down the rest of the manufacturing process.

Agility is crucial to meeting customer demand today. New product introductions can require several plants across a country to quickly produce them in a greater variety of packaging, such as different sizes or with region- or season-specific packaging variations.

To accomplish this, companies must build flexibility into their machines and manufacturing processes, which starts with an understanding of the impact of every point along the production process. This is critical to making the right product, using the right materials and employing the right processes across the entire production line, while also allowing scope for a seamless transition from one product to the next.

A more granular view

As in other industries, many medical device manufacturers continue to rely on an antiquated paper-based flow of information in operations. Manufacturing execution systems that are designed specifically for sectors such as medical devices, on the other hand, make it easier to capture and compile manufacturing data at a more granular level, giving visibility of each production point and its associated costs, and then identifying differences in performance and costs between different products.

With quality and efficiency improvement goals continuing to be set higher as part of continuous improvement processes, the pencil-and-paper method will only make it harder to reach these goals. MES provides the detailed and holistic view into operations needed to achieve efficiencies and mitigate the risks.

Process Analytical Technology

Process Analytical Technology enables analysis and control of manufacturing processes based on timely measurements of critical parameters and performance attributes to assure end product quality. It delivers more flexible production processes, improved quality and significant cost reductions through better capacity utilisation and increased outputs.

This comes about from a deeper understanding of the manufacturing process, identification of root causes for product quality and process variance.
The benefits for regulated industry include:

- Reduction of cycle times
- Less batch failure
- Faster batch release times by introduction of real time release and electronic batch recording
- Better management of change control
- Reduced compliance and validation effort, time and cost
- Improved project schedule and speed of deployment
- Reduced start-up time

By adopting the PAT framework and building-in quality from the start, medical device manufacturers can help to maximise their production assets and will be better positioned to adapt quickly to market changes. And since PAT initiatives have the support of regulatory agencies, a successful implementation can lead to regulatory incentives.

PAT involves an integrated systems approach, where the development, manufacturing, quality assurance and information technology teams work collaboratively, and where information and knowledge are shared and communicated. This enables rapid product development cycles and simplifies the transfer to manufacturing, while maximizing both manufacturing efficiency and product quality.

By adopting the PAT framework and building-in quality from the start, medical device manufacturers can help to maximise their production assets and will be better positioned to adapt quickly to market changes.

The R&D team, for instance, can develop new manufacturing processes and products more quickly by taking advantage of the wealth of data collected during production runs of existing products, and enhanced with feedback from the manufacturing engineers and quality assurance teams.

In the same way, manufacturing and quality assurance engineers will be able to develop more effective test strategies when they have access to development data related to the formation of defects in critical processes such as welds, crimps or seals. The corporation as a whole will see an increase in revenue and profits as time to market is reduced, production costs are lowered and product quality is improved.

Summary

To address the challenges and take advantages of the opportunities in medical device manufacturing today, it's more important than ever to understand the entire manufacturing spectrum. Manual processes and paper-based records are outdated in terms of process efficiency and control, real-time information provision, and product quality, consistency and repeatability.

Rockwell Automation works closely with individual medical device companies to identify the way forward that's best for them. As one of the world's leading providers of industrial automation, information and control technologies, we're well-placed to deliver validation and value statements before investments are made, which outlines the potential for improvement and the estimated return on those investments.

As demand for medical devices increases and operations become more advanced, the key to success is in finding efficiencies that drive success across the production process and ultimately improve the bottom line.

www.rockwellautomation.com

Power, Control and Information Solutions Headquarters

Americas: Rockwell Automation, 1201 South Second Street, Milwaukee, WI 53204-2496 USA, Tel: (1) 414.382.2000, Fax: (1) 414.382.4444
Europe/Middle East/Africa: Rockwell Automation NV, Pegasus Park, De Kleetlaan 12a, 1831 Diegem, Belgium, Tel: (32) 2 663 0600, Fax: (32) 2 663 0640
Asia Pacific: Rockwell Automation, Level 14, Core F, Cyberport 3, 100 Cyberport Road, Hong Kong, Tel: (852) 2887 4788, Fax: (852) 2508 1846

Publication LS-WP005A-EN-P