

Life Science: Facts, Trends and Future Prospects

Preparing pharmaceutical and medical technology for the future

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Production environment requirements in the pharmaceutical and medical technology sectors are very high. Not least, the strict cleanroom criteria present a particular challenge. In order to survive in a highly competitive market, companies also need to make sure that they increase their production effectiveness and minimise costs. Current trends include process optimisation for the purpose of increasing overall equipment effectiveness (OEE), effective asset life cycle management and predictive maintenance using enterprise mobility and intelligent solutions (smart apps). Increasing networking along with the use of automation technology in accordance with Industry 4.0 have paved the way for these developments.

Identifying and benefiting from improvement potential

[The Internet of Things has also found its way into production in the form of Industry 4.0:](#) increasingly networked systems with more and more communication-capable components have meant an ever-increasing volume of data. That also applies to the [pharmaceutical and medical technology sectors](#). Thanks to "big data", production is being made more and more intelligent, with the pinnacle of achievement being the smart factory. The key to success lies in determining the right information from the mass of data available, analysing the data and drawing findings from

them. The aim of such Smart Data Management is to optimise the plant in question and prepare it for the future in terms of site operational excellence.

In addition, overall equipment effectiveness has developed into an obvious trend that extends beyond industry boundaries, including within the life science sector. The main factors that have contributed towards this have been optimised plant utilisation and productivity for which manufacturing execution systems (MES) and enterprise resource planning (ERP) are of vital importance. Interfaces such as the MES interface from Mitsubishi Electric enable data to be collected quickly and easily at work level throughout a plant and transferred to higher-level MES or ERP systems at control level for further evaluation and analysis. Overall equipment effectiveness can be specifically optimised based on the results without the need for a gateway PC to transfer the data. Based on the [MELSEC System Q PLC](#) from Mitsubishi Electric, but compatible with controller platforms produced by various manufacturers, the MES interface can be commissioned by a plant engineer in just around 15 minutes.

During the course of plant optimisation by means of OEE, effective asset life cycle management is also required in order to minimise the life cycle costs of investment goods. Those costs include not only the provisioning costs but also the follow-up costs throughout the life cycle of the goods, e.g. for operation, maintenance, predictive maintenance, modification and disposal. The prerequisite for this is complete transparency which can be achieved through extensive data collection and analysis via the comprehensive networking of all components. Cost control strategies also look for a more compact design, shorter production cycles and substantially minimised waste. Automation technologies strongly support these approaches. Above all, robot technology is being used more and more to achieve these aims.

Robots on the advance

Robots bring flexibility and effectiveness to production. As a result, they are increasingly being used to carry out handling tasks within the pharmaceutical and medical technology sectors. For example, Mitsubishi Electric [robots](#) are mainly used to assemble components and for so-called secondary packaging, i.e. for the [packaging](#) of products pre-packed under strict cleanroom conditions, such as filled syringes and pill or tablet blister packs which are then packed in foil or cardboard packaging.

For example, the German medical technology manufacturer Maquet Cardiopulmonary GmbH, part of the Getinge Group, uses SCARA and articulated arm robots from Mitsubishi Electric to assemble oxygenators. The main component of heart-lung machines takes over the gas exchange in the lungs and carries out mechanical breathing. Because they are designed as single-use products, production costs are an important part of the design process. Robot-assisted production enables corresponding cost efficiency to be achieved. Selection criteria included a high level of flexibility, easy handling and the possibility to make program adjustments at short notice for the purpose of optimising work processes. In addition, production is carried out under cleanroom conditions in accordance with ISO class 7 to 8. MELFA robots meet all these requirements.

Robots make work easier for the workforce, enabling them to devote their time to value-adding tasks. For example, Mitsubishi Electric robots take care of the handling of stem cells, a task carried out at a microscope workstation which is both monotonous and physically demanding for employees. They work with great care and precision, are at least as efficient as humans and meet the necessary cleanroom class requirements. They are increasingly being used to carry out quality control tasks too. For example, the integrity of packaging can be checked

via a vision system at the robotic arm.

Robot-assisted handling solutions: compact, flexible and quick

Space is an expensive commodity, especially in cleanrooms. The manufacture and maintenance of these plants where an extremely high level of hygiene is required are extremely costly. Compact components are all the more important as ultimately, the machine needs to be space-saving. Mitsubishi Electric components such as SCARA, double arm SCARA and articulated arm robots or controllers and servo drives are characterised by their particularly space-saving design and are suitable for flexible applications even when space is restricted. Easy handling enables fast integration, commissioning and adjustment.

One example of a highly compact handling solution came from Robotronic AG in Switzerland. Its customer, a contract packer for an international pharmaceutical company, was looking for a secondary packaging solution for supplying and packing filled vials of various sizes. The solution was to be integrated in an existing system which meant that the available space was extremely limited. The modular design principle of the modular robot technology (MRT) produced by Robotronic provides excellent design flexibility. As a result, the basic module for the MRT cell has a footprint of just 1.0 x 1.30 metres and is approximately 2.20 metres high, so it also meets the minimal space requirements. The solution for the cleanroom class in accordance with GMP standard level D consists of two MRT cells, each with a compact overhead articulated arm robot from Mitsubishi Electric and a conveyor line with eight positioning screws, driven by Mitsubishi Electric servo motors. Using vacuum grippers, the robots place the vials in the blister packs provided at a processing speed of 300 units per minute.

One advantage of robot-assisted production is the high cycle rate that can be achieved while maintaining a high level of precision, enabling line

efficiency to be increased. Another application example for Robotronic products is described below: the machine manufacturer designed a handling module for supplying pre-filled syringes to the end-of-line packaging station for an international pharmaceutical company based in Germany. The solution enables switching between various syringe carriers and formats to be carried out quite easily. It is also based on a MRT cell with two Mitsubishi Electric overhead articulated arm robots. Competitors' products take up three to four times more space compared to the compact MRT cell. The machine can supply syringes to the discharge track at a rate of 400 per minute. With this solution, a maximum of up to 600 units per minute can be processed, thus meeting cleanroom requirements in accordance with GMP standard level D.

Hygiene in cleanroom systems

The increasing use of automation technologies, especially robots, has led to an increase in the demand for systems which meet high cleanroom requirements within the pharmaceutical and medical technology sectors. It is also just as important to be able to clean a plant before a production changeover without any major costs being incurred. That also means that it must be possible to clean the components in place in the cleanroom without having to remove them, i.e. they must be CIP-compatible (CIP: Cleaning In Place). In the process, appropriate aggressive chemicals will be used, generally hydrogen peroxide (H₂O₂), and then sterilisation will be carried out.

For that reason, Mitsubishi Electric also offers its customers multi-resistant versions of the models from its new F-series generation of MELFA robots which have been approved for regular CIP cleaning using H₂O₂. According to the type in each case, MELFA robots can even meet cleanroom class requirements to ISO 3 or ISO 5 and be dust and splash-proof to IP54 to IP67 if required.

Conclusion

Automation enables plants to be prepared for the future and that includes the life science sector as well. In particular, robot technology enables flexible and efficient production to be achieved while keeping the space required to a minimum and meeting the relevant cleanroom class requirements. The aim of every manufacturer is to optimise overall equipment effectiveness and increasingly networked production offers a wide range of opportunities to do just that. The accompanying increase in efficiency can bring numerous improvements, not least in the return on investment (ROI).

Note:

¹ See how Mitsubishi Electric is able to respond to today's automation demands:

<https://ie3a.mitsubishielectric.com/fa/en/solutions>

<https://youtu.be/fEh5muQhlc>

Image captions:



Picture 1: The modular design principle of the modular robot technology (MRT) produced by Robotronic enables excellent design flexibility and compact dimensions to be achieved. The basic module for the MRT cell has a footprint of 1.0 x 1.30 metres and is approximately 2.20 metres high.

[Source: Robotronic AG]



Picture 2: The solution for supplying and packaging filled vials consists of two MRT cells, each with a compact overhead articulated arm robot from Mitsubishi Electric and a conveyor line with eight positioning screws, driven by Mitsubishi Electric servo motors.

[Source: Robotronic AG]



Picture 3: Michael Suer, Director Life Science, Factory Automation – European Business Group, Mitsubishi Electric Europe B.V. explains "Robots bring flexibility and increase effectiveness in production. They make work easier for the workforce, enabling them to devote their time to value-adding tasks."

[Source: Robotronic AG]



Picture 4: In a handling module for supplying pre-filled syringes to the end-of-line packaging station, Robotronic integrated no less than two Mitsubishi Electric overhead articulated arm robots in one MRT cell.

[Source: Robotronic AG]



Picture 5: The solution can supply syringes to the discharge track at a rate of 400 per minute. Other products on the market take up three to four times more space compared to the compact MRT cell.

[Source: Robotronic AG]



Picture 6: Robots bring flexibility and efficiency to production. In the pharmaceutical and medical technology sectors, they are increasingly taking on handling tasks to reduce human effort, for example by supplying filled syringes to the end-of-line packaging station.

[Source: Robotronic AG]



Picture 7: The German medical technology manufacturer Maquet Cardiopulmonary GmbH uses SCARA and articulated arm robots from Mitsubishi Electric to assemble oxygenators.

[Source: Maquet Cardiopulmonary GmbH]



Picture 8: Michael Suer, Director Life Science, Factory Automation – European Business Group, Mitsubishi Electric Europe B.V.

[Source: Mitsubishi Electric Europe B.V.]



Picture 9: [Source: Thinkstock]

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With around 129.000 employees the company recorded consolidated group sales of 36,0 billion US Dollar* in the fiscal year ended March 31, 2015.

Our sales offices, research & development centres and manufacturing plants are located in over 30 countries.

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