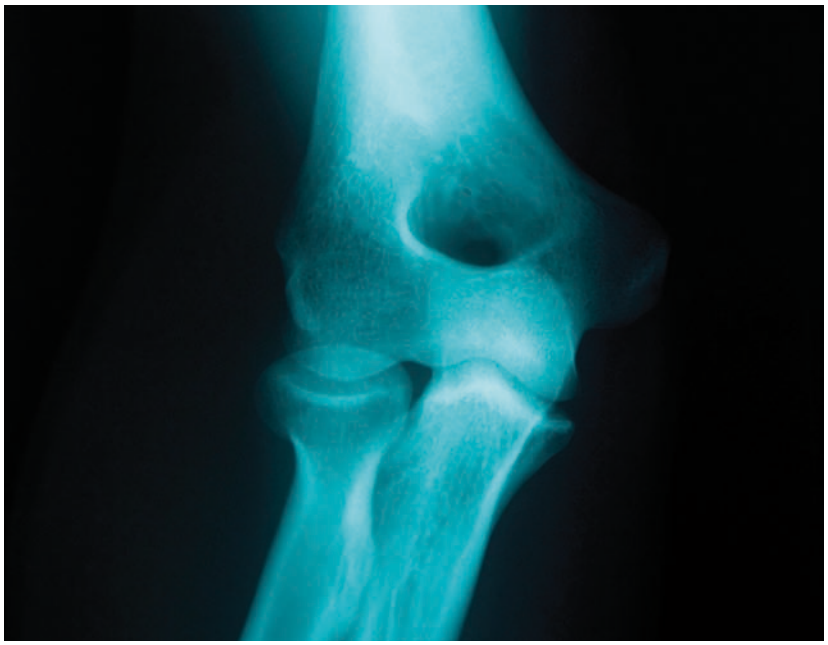
MITSUBISHI ELECTRIC
Changes for the Better

LIFE SCIENCE

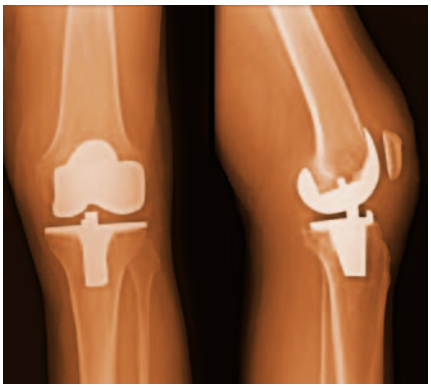
Applications and solutions

Automation for
a complex world



Compliance / Repeatability and stability / **Batch processing** / Increasing throughput / **Traceability** / MES Integration / **Increased up-time** / Energy reduction strategies /

Always under pressure



Mitsubishi Electric's Electro-discharge Machines help to shape and form some of the specialist alloys used in medicine today for replacement body parts as well as instruments – and all within tight tolerances and with final surface finishes.

Secondary packaging handling systems and batching processes require precision, speed and repeatability to ensure everything is processed and tracked in an optimum way – this is what Mitsubishi Electric's automation systems deliver.

From medical procedures, such as surgery support to controlling innovative internal body scanning, Mitsubishi Electric's robotic technology brings a new dimension to Life Science.

The Life science industries are one of the most regulated and controlled of the process and hybrid sectors. Profits need to be maximised and protected wherever possible. However, medical, drug and health supplements are also subject to the critical dynamics of:

Time to market/ Product Velocity

With the massive investments in drugs going through the development pipeline, significant missed opportunities can result if new innovative products cannot capitalise on a strong, leading market position.

Production stability

Ensuring production is repeatable and consistent, in order to increase and maximise yield and maintain product quality.

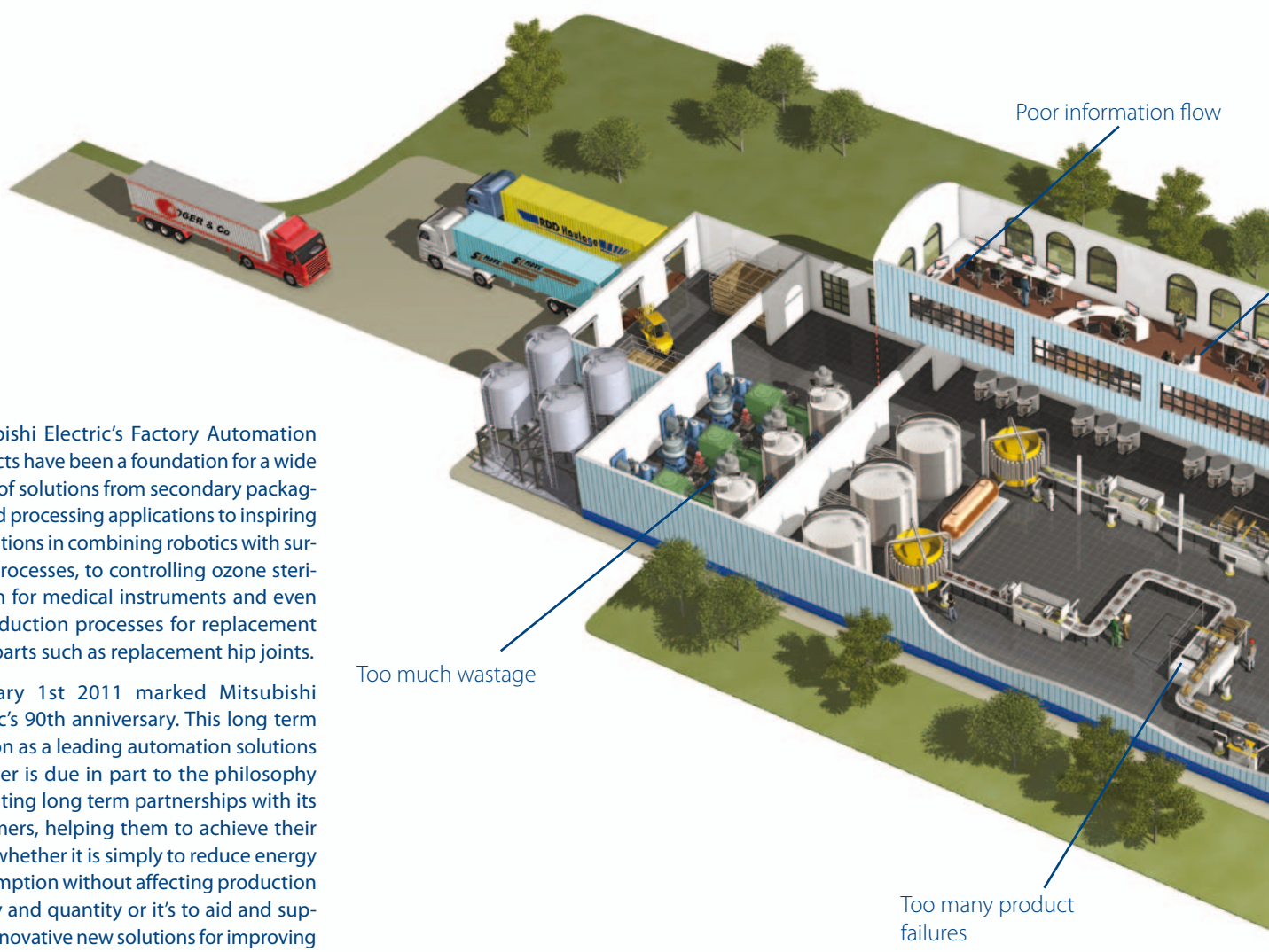
Batch Track and Traceability

Compliance is a keyword for the life science sector – even if excellent product quality is proven time and time again, still the tracking of production batches must go on to meet regulatory requirements, which is never optional.

Production Efficiency

With the increase in the number of generic products in the marketplace and the rise in contract manufacturing, the Life Science industry more and more finds itself affected by similar commercial pressures to other process industries such as Food & Beverage manufacturing, with the constant demand to improve efficiency and reduce cost in order to maintain a competitive advantage.

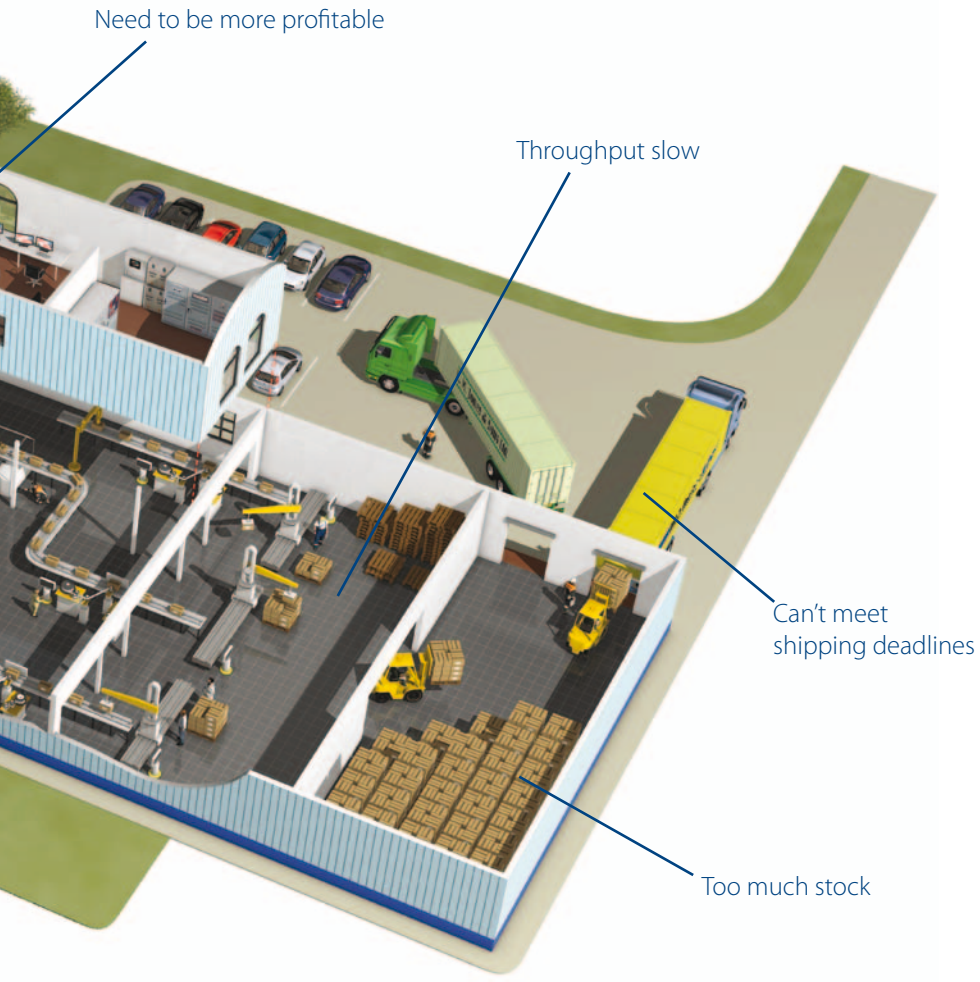
Experience and innovation



Mitsubishi Electric's Factory Automation products have been a foundation for a wide range of solutions from secondary packaging and processing applications to inspiring innovations in combining robotics with surgical processes, to controlling ozone sterilisation for medical instruments and even to production processes for replacement body parts such as replacement hip joints.

February 1st 2011 marked Mitsubishi Electric's 90th anniversary. This long term position as a leading automation solutions provider is due in part to the philosophy of creating long term partnerships with its customers, helping them to achieve their goals whether it is simply to reduce energy consumption without affecting production quality and quantity or it's to aid and support innovative new solutions for improving the human condition.

This is at the heart of Mitsubishi Electric and is reflected in the company statement "Changes for the better".

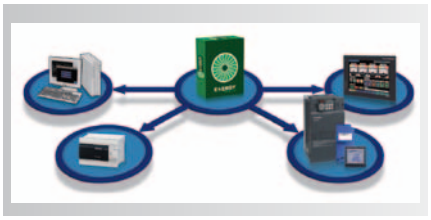


" Typically, a production process covering the areas shown below, with manual interaction points between workflows will benefit from a MES proposition"

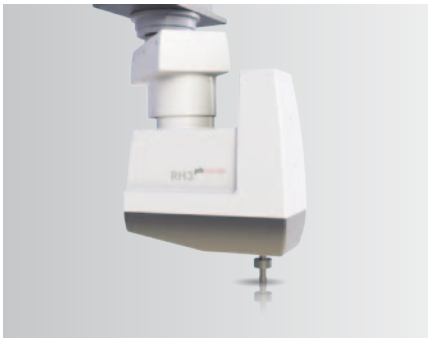
PAC Controller
Mitsubishi Electric offers a C Based programmable controller that utilises non PC based industrial proven hardware.

MES Interfacing
Pulling data from the production environment to the business environment, even directly to your ERP was never easier.

C Batch
Small to medium batch control/processing using the S.88 standard, without relying on a PC with its inherent security/maintenance risks.



Energy Control Pack
Delivering a scalable energy management concept without affecting production quality.



Robotic precision
Repeatable, reliable and steady and accurate – essentials for Life Science applications.

Security

Protecting your assets from all threats

The stuff of legends

Cybercrime was something that Hollywood legends were made of. But the process based industries have realised that cybercrime can not only mean the loss of important product knowledge and Intellectual Property but also a real threat of cyber terrorism means important plant can also be damaged with incredible consequential losses.

That is why many notable bodies such as ISA, Center for Chemical Process Safety and various governmental bodies throughout the developed world have been raising the awareness of this important topic.

When does safe = secure?

Interestingly, in Swedish the word for safety is the same as that for security and in some ways it is not really surprising as the two "worlds" are so closely intertwined.

It would be wrong to suggest that there is a perfect system which guarantees full protection of all concerned. The fact is all systems are vulnerable. It comes down to understanding the nature of a threat, its potential damage footprint, making a risk management process and designing in sensible precautions.

A big bad world

We live in a world of personal computers, in some way they either interact or control every aspect of our lives – this makes them a target for a minority of people with malicious intent. But even in this world some PC technology is targeted more frequently than others – this is simply down to access and availability of the needed education, tools and opportunity to be attacked.

Therefore precautions should be taken at all levels. Where a PC technology is used, often a firewalled system is used, but firewalls themselves also need constant maintenance. Forget it on one occasion and you can be immediately exposed.

Is there another way?

Actually we believe there is. In fact we believe there are several other ways. For example:

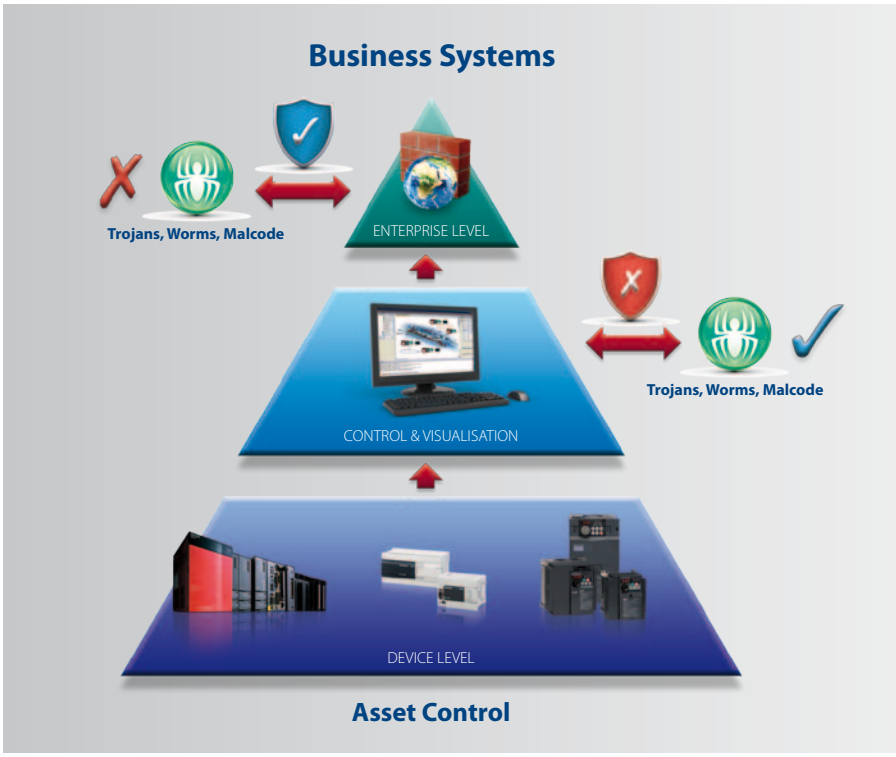
Reducing complexity

Instead of using several layers of system architecture reflecting data from the shop floor PAC and PLCs to line PCs and then ever upwards, why not let the two high reliability, high availability systems interact directly, i.e. the shop floor PLCs and PACs interface directly with management and ERP level systems. The benefits are several fold, system reliability/availability is protected as weaker PC layer technology is no longer the controlling gateway. Engineering costs are reduced as system complexity is simplified. Open vulnerabilities are removed as operating systems and virus checkers do not have to be maintained. Mitsubishi Electric's MES, MES IT and C Connector solutions bring a range of flexible solutions to do just this – offering connectivity directly to almost any higher level system including DB2, Oracle and SAP.

As easy as ABC

To increase system flexibility and resilience to some of the shop floor vulnerabilities Mitsubishi Electric has developed a platform control concept.

The systems is flexible enough that it can combine PAC based technologies with traditional PLC technologies, robotics, NC control and even an open C based control philosophy. The latter has also been used by Mitsubishi Electric along with its innovative e-F@ctory partners such as INEA, Ubigrate and Felten to develop a wide range of industry solutions including secure solutions for Batch control, Integration with business systems such as SAP and provision of manufacturing intelligence.



Hackers and malicious users have traditionally focused on attacking the higher level business PCs, however now there are some signs they are increasing the scope of their focus to include shop floor systems.

Secure your IT

Of course it goes without saying that IT security is paramount. But this usually starts and stops with the server or PC itself. Mitsubishi Electric realised this and has been working with its e-F@ctory partner Green Hills Software and their subsidiary company, Integrity Global Solutions, to bring a new dimension and definition to a secure manufacturing PC environment. The Green Hills "integrity" operating system allows solutions to be built on a secure hypervisor based operating systems that puts "hard" protection between the different systems running on the client device.

Want to know more?

Ask for our security white paper or contact us for details about our secure solutions.

Energy – quietly eroding your profitability

Energy management and control is a vital ingredient to reduce waste

Energy management is key

Sustainable manufacturing is a topic that has received a lot of focus, especially in the discrete and hybrid sectors. It has mainly centred around material resources or commodities such as in-organic compounds or flavours and fragrances for example.

However there is one other very important resource that is silently eroding the manufacturer's bottom line: Energy.

Manage it, reduce it or pay for it!

Sadly many manufacturers often end up paying the penalty of extra energy usage as they simply do not know what can be done to reduce and manage their current energy consumption.

Of course the use of inverter technology is well known but even the inverters of today are far far more efficient than those of even just 10 years ago.

Peak performance

However, by taking a holistic approach to reviewing the energy usage and consumption even greater savings can be made.

For example, regardless of the country, peak energy costs will affect the tariff levels used. Of course the method of calculation will differ but any efforts to reduce the peak energy consumption will then reduce the tariff rate and any possible penalty payments.

In this case knowing what the peak level was and when it occurred can be used to make a predictive model allowing loads to be managed and shed before the peak is reached.

Recycle

Of course everyone knows that plastics and other waste materials can be recycled, but not many people know that energy can also be recovered.

In a simple hoist application using an inverter is good, but using a regenerative inverter can make your hoist turn in to a generator when carried loads are lowered.

Imagine all the waste heat and finally energy disappearing in to the environment from a hot forming or exothermic process. However, with the use of heat pump technologies the "waste" hot air can be easily turned in to useful hot water for use as process water or even showers for the line workers. Use an air to air system and during the winter warehouses and office blocks could be heated from the waste production heat.

As much or as little as you want

Mitsubishi Electric is in an enviable position to be able to offer its customers energy efficient solutions from air conditioning, heat pumps and high speed hand dryers to drives and control solutions as well as direct reporting and interfacing with existing ERP systems.

Even the roof of the production site could be turned in to a power generator with Mitsubishi Electric's photovoltaic panels!

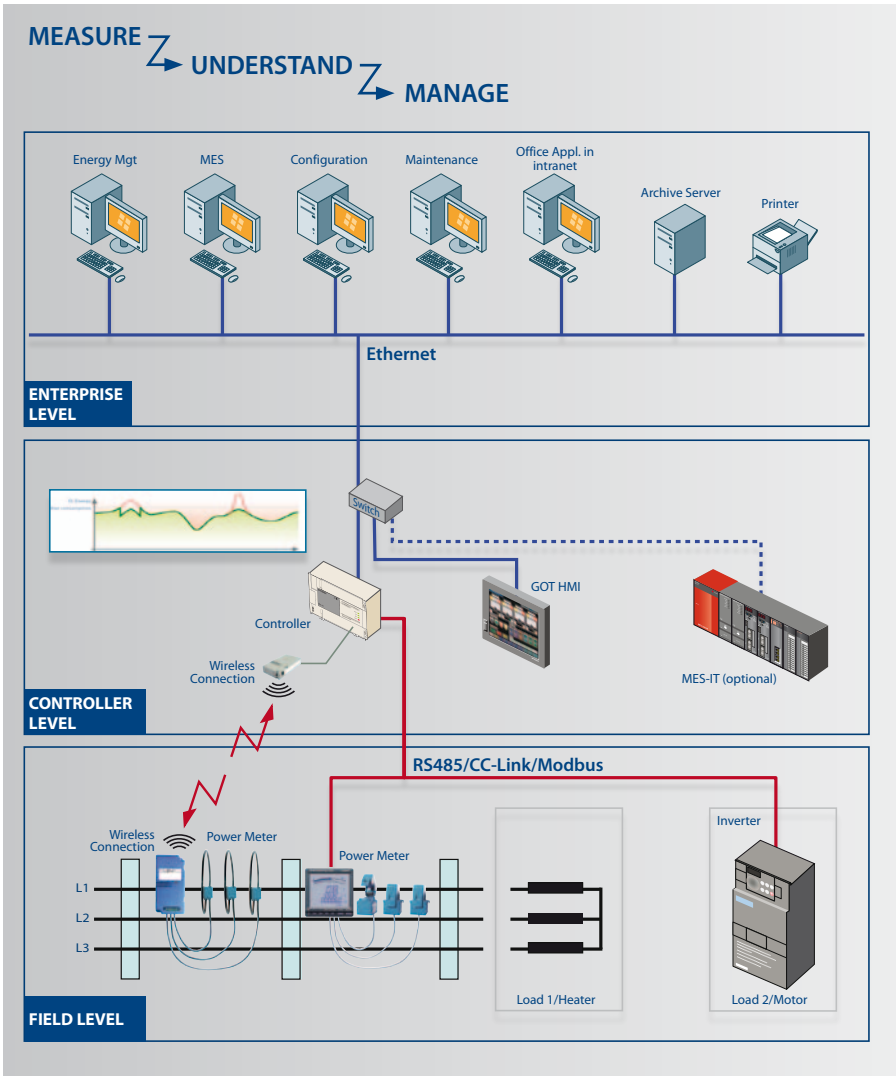
Furthermore Mitsubishi Electric's innovative total energy management system brings together all the parts needed to create a modular energy management solution.

From feasibility study to proposal, predefined solutions leaving the last 20 % for customisation are available to speed up the system implementation and, of course, lower costs.

Our experience

With our partners we have installed total energy systems in Europe saving many megawatts of power annually and reducing power peaks by an average of 11.7 %.

Naturally the value of these saving varies country by country and in fact increases over time as the tariff rates increase.



Energy management concept

Want to know more?

Ask for details about our Energy Control Pack

Manufacturing Intelligence & Data Management

A wide variety of distributed assets can all be integrated into a single system

Mitsubishi Electric can help you improve your manufacturing and production efficiency by utilising our innovative non PC based data logging and data collection solutions to seamlessly link assets to business information systems.

Holistic approach

Taking a holistic approach to data means it can be either targeted to the business application where it is needed or shared with a master production system creating a cost effective solution for tracking and reporting asset level production data. This makes it easier to create Key Performance Indicators (KPIs) that are meaningful to your business, for example Overall Equipment Effectiveness (OEE) may be something that is critical to your scheduling and planning processes as well as an early alarm for maintenance engineers.

Concise and easy to use real time and historic reports for all personnel from the plant level to the boardroom will help all involved become more in touch with the actual daily business. This approach is essential for implementing Six Sigma projects, TPM/TQM processes and Lean Manufacturing techniques which are targeted to deliver immediate significant efficiency improvements where you are typically looking for payback times of less than a year.

10 minutes to success

Depending upon the style and type of data integration, Mitsubishi Electric have solutions to suit almost all situations and in some cases direct data connection from your shop floor controller to your management system (database/MES or ERP) can take less than 10 minutes. It is also important to remember that, with a large number of communications options, the use of our data management solutions can be implemented independent of the underlying control platform on an asset or assets.

That means you have more time to concentrate on the main tasks to improve your business and manufacturing performance.

TIMWOOD (The Seven Wastes)

Toyota Production Systems have long been famed for their attention to manufacturing detail and implementation of a lean culture. In fact Taiichi Ohno came up with the concept of the seven wastes (Transportation, Inventory, Motion, Waiting, Over processing, Over production and Defect control). The idea being to control these wastes will result in productivity increases and reduction in non-traceable costs.

These concepts are in fact common between Japanese companies – hence Mitsubishi Electric's own motto of "Changes for the better".

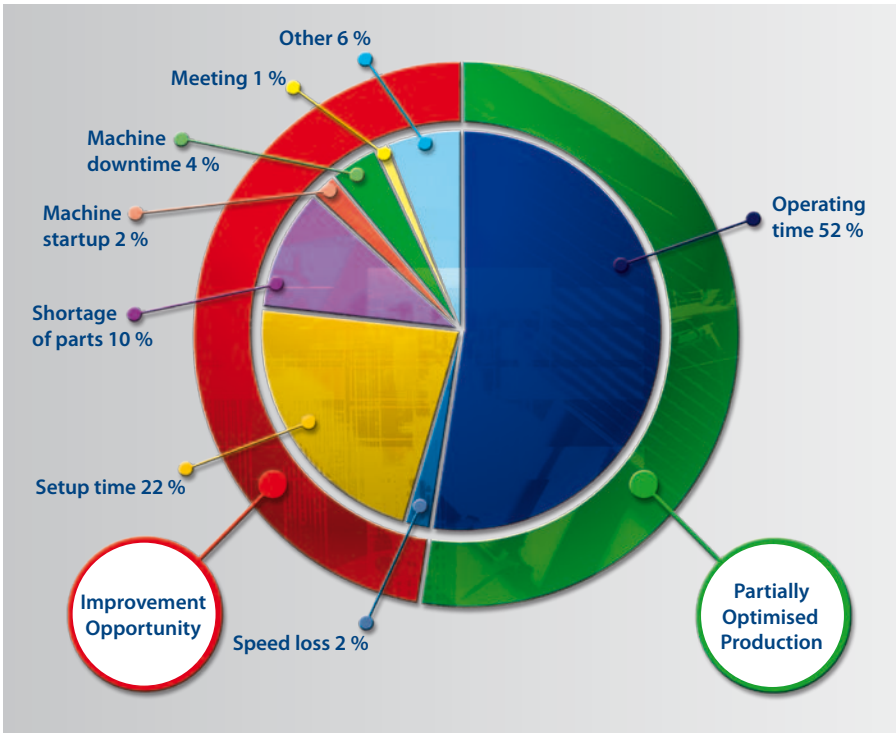
Changes for the better

Mitsubishi Electric's work on the concept of the e-F@ctory has led to an understanding that while many companies have automated and mechanised parts of the production process there are still a lot of opportunities through associated activities to improve the productivity ratio.

However, this is often portrayed as a simple task. It is not. Understanding your production flow is a critical element as many manufacturing processes and plants grow organically over the years and hence the immediate impact is a sub-optimal process.

The second focus has to be to looking to measure and monitor every step of every process. This is in part a difference in culture between Asian based society and a more western society – this is often caricatured as Asia = produce it right first time, while Western practices are produce as much as you can as fast as you can.

In Life Science industries, whether the long process of cutting specialist alloys by erosion or the chemical processes employed in Pharmaceutical applications, getting the wrong process results in a lot of wasted time or a lot of expensive wasted product. The concept of a lean culture and Improvement in the 7 wastes, as described above has become of far greater importance in the Life Science Industry over recent years and Mitsubishi Electric have the solutions to help.



e-F@ctory Alliance means partners working together to make best in class solutions

Improving productivity with e-F@ctory

e-F@ctory is the Mitsubishi Electric solution for improving the performance of any manufacturing enterprise, providing key benefits: Reduced total cost of ownership, maximised productivity, and seamless integration.

It was born out of the expertise Mitsubishi Electric has developed as a global manufacturing enterprise. We are now sharing this expertise with our customers.

This enables solutions to be created based on "best in class" technology and integration to meet the diverse and individual needs each user has. In short, improving productivity is the goal of each of the partners of the e-F@ctory Alliance. For full details visit our special e-F@ctory alliance website: www.e-factory-alliance.com

Here's an example of what some of the solutions can do for the Life science industry.

A picture is worth 1000 words

Machine vision systems hold the key to reliable, consistent, automated inspection in the most demanding manufacturing tasks, even on the highest speed production lines. And when tightly integrated with higher level enterprise controllers, machine vision systems provide the means to capture and record the complex production information that is essential for effective traceability.

Machine vision adds a new layer of intelligence to production systems that helps companies to improve their manufacturing performance. Modern cameras integrated with automation systems can quickly eliminate product defects, verify assembly, and track and capture information at every stage of the process. This information can be passed in turn on to the higher level manufacturing and ERP control systems where it is available to all areas of the business process.

The result is fewer production errors, lower costs, and increased customer satisfaction, with the assurance of full traceability should a problem arise anywhere in the supply chain.

Want to know more?

Ask for our e-F@ctory brochure which also contains examples from our own manufacturing experience, or take a look at the e-F@ctory website: www.e-factory-alliance.com

Manufacturing solutions

Manufacturing should be an integrated process; Mitsubishi Electric helps to achieve that goal

Looking After Your Data

One offering in our portfolio of data management solutions is our MES IT product, which has three major advantages to offer shop floor data collection and archival in the Life Science Arena:

1.) Validation to **GAMP** 5 Procedures. The process of collecting and archiving records to a repository such as SQL Server or **SAP** requires a reduced validation effort using MES IT. This is a process that would typically be scripted and thus classified as Category 5 software. Using MES IT the process becomes parameterised/ configured (Category 2/4 classification) and thus represents a saving in costs and time associated with the validation effort.

2.) **21 CFR 11**. The use of MES IT can assist with compliance to **21 CFR 11** as it meets the requirements of the policy with respect to access security, archival and retrieval of data and provision of concise audit trail information.

3.) Electronic Record Integrity. MES IT utilises "store & forward" technology to mitigate against the loss of electronic records in the advent of connectivity failure with the record repository such as **SAP**, Oracle or SQL Server.

Understanding Your Process

Mitsubishi Electric can provide control, data management and visualisation solutions to help realise **PAT** (Process Analytical Technology) based solutions in Life Science manufacturing. We contribute with our solutions by helping to increase the OEE (Overall Equipment Effectiveness) of a process, through providing meaningful plant data for analysis and problem solving, and then offering solutions providing accurate control using high availability products. Finally everything you do relies on manufacturing. As a player in the Life Science industry you are a creator of chemical, bio-medical or medical solutions for your customers. And in order to remain as a leader in your industry you need to be able to react faster with new developments, increase the volume of saleable product, reduce unnecessary costs while continuously observing compliance issues.

Sharpen your edge

It doesn't matter if you need bottle filling, labelling, bagging, horizontal or vertical pillow processes, case packing or palletising Mitsubishi Electric has solutions and experience to help you achieve your goals with as little fuss as possible.

Mitsubishi Electric is able to bring together support for open standards such as PackML and Weihenstephan protocol with sequential control, process control and high speed motion control on to a single platform which makes engineering faster and reduces costs.

Handling problems

Materials handling needs care, speed and precision to manage the task at hand without damaging the product or creating production bottle necks. Finally this means you need experience.

Mitsubishi Electric's experience in materials handling covers the complete range of applications from in-line sorting through to high level racking and storage to AGV's and robotic solutions.

A deep integration between servo and robotic and control systems, with the ability to receive and pass data directly back to ERP packages such as SAP, means most users applications can be handled – with no problems.

Life-cycle engineering

Mitsubishi Electric and e-F@ctory partner Adroit Technologies have addressed the short-comings of traditional PLC-SCADA integration tools with the Mitsubishi Electric Adroit Process Suite (MAPS).

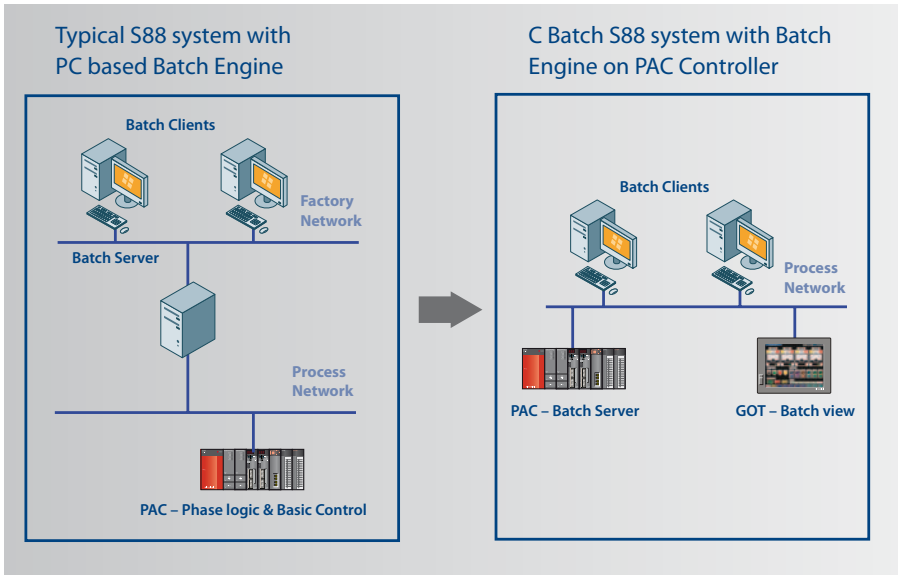
MAPS is a life-cycle software tool that offers value at all stages of a project from the design and engineering phases to the integration, installation and commissioning phases and finally into the running and maintenance phase. This should help the Life Science manufacturer with validation costs.

It also extends the integrity of the 'as delivered' solution as it offers full system documentation from actual wiring through to the installed code. This helps users maintain consistency and integrity within an automation system, improving quality, reducing downtime and associated costs.

An advanced PAC

Process Automation Controllers (PACs) have been around for many years, however, Mitsubishi Electric has really taken this to a new level of automated control offering users the chance to integrate their choice of four control concepts from PAC, Process controller, PLC, Motion Controller, Robot Controller and even NC control in to a single harmonious system. It can also be augmented with an open C based control environment and an embedded PC depending on the needs. Everything in one place, everything interoperating: save time, save costs simplify systems.

Typical production line architecture with intelligent automation

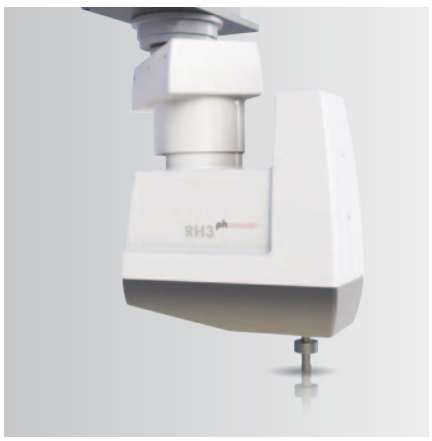


Typical production line architecture with intelligent automation

Advanced robotics

When people think of robots in automation they often have an image of the big car plants and welding activities. In fact robots can be used in many business areas and Life science is no exception.

Robots of course make great optimisers for pick and place processes, especially associated with packaging activities. However, this is only the beginning of their contribution as they can be found in secondary packaging, quality control and test environments for pharma and chemical processes but also have been deployed in secondary supportive roles in medical procedures such as surgery and body scanning.



Typical production line architecture with intelligent automation

C Batch – Innovative thinking

Batch control has always been dominated by expensive PC based solutions feeding data down to local control and implementation stations. These layers of architecture make complex systems. C Batch simplifies this and provides an S.88 based batch engine and configuration tool that reduces the engineering process within the PAC environment, removing the need for PC's and utilising Industrial proven hardware to increase availability and reduce susceptibility to some forms of cyber attack.

Want to know more?

For specific information about our packaging and materials handling solutions please take a look at our dedicated brochures.

For more insight in to our advanced solutions please contact us.

Meeting the requirements of FDA 21 CFR Part 11

Built-in security

This regulation establishes the criteria under which electronic records and signatures will be considered equivalent to paper records and handwritten signatures in manufacturing processes regulated by the FDA.

Part 11 applies to all GxP (i.e. GMP, GLP and GCP) IT systems that create, modify, maintain, archive or retrieve electronic records. If the organisation is a pharmaceutical, biological or medical device manufacture whose products are made for sale within the USA then Part 11 applies.

The regulation covers four key areas:

Data Retention

Electronic records must be retained and be retrievable for as long as the requirement for the equivalent paper record.

Security

Access to electronic records must be restricted to authorised personnel only.

Audit Trail

All operator entries that create, modify or delete an electronic record must be recorded in a secure, computer generated audit trail identifying operator ID, authorisation ID and time stamp.

Signature Form

Maintenance of, typically, ID and password details, including access/authority hierarchy, password aging and access details.

Most of these requirements can be met within the control system through the use of Mitsubishi Electric GOT series HMIs and other data management products. GOT HMIs allow different levels of security-controlled access to be established, from system operators to system administrators. Time stamped audit trails are maintained to record the date and time of operator entries and actions that create, modify or delete electronic records.

Secure data storage and Store Forward Capability

GOT HMIs also allow data to be stored securely, complete with validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. In addition, the HMIs provide the ability to generate accurate and complete copies of records in both printed and electronic form.

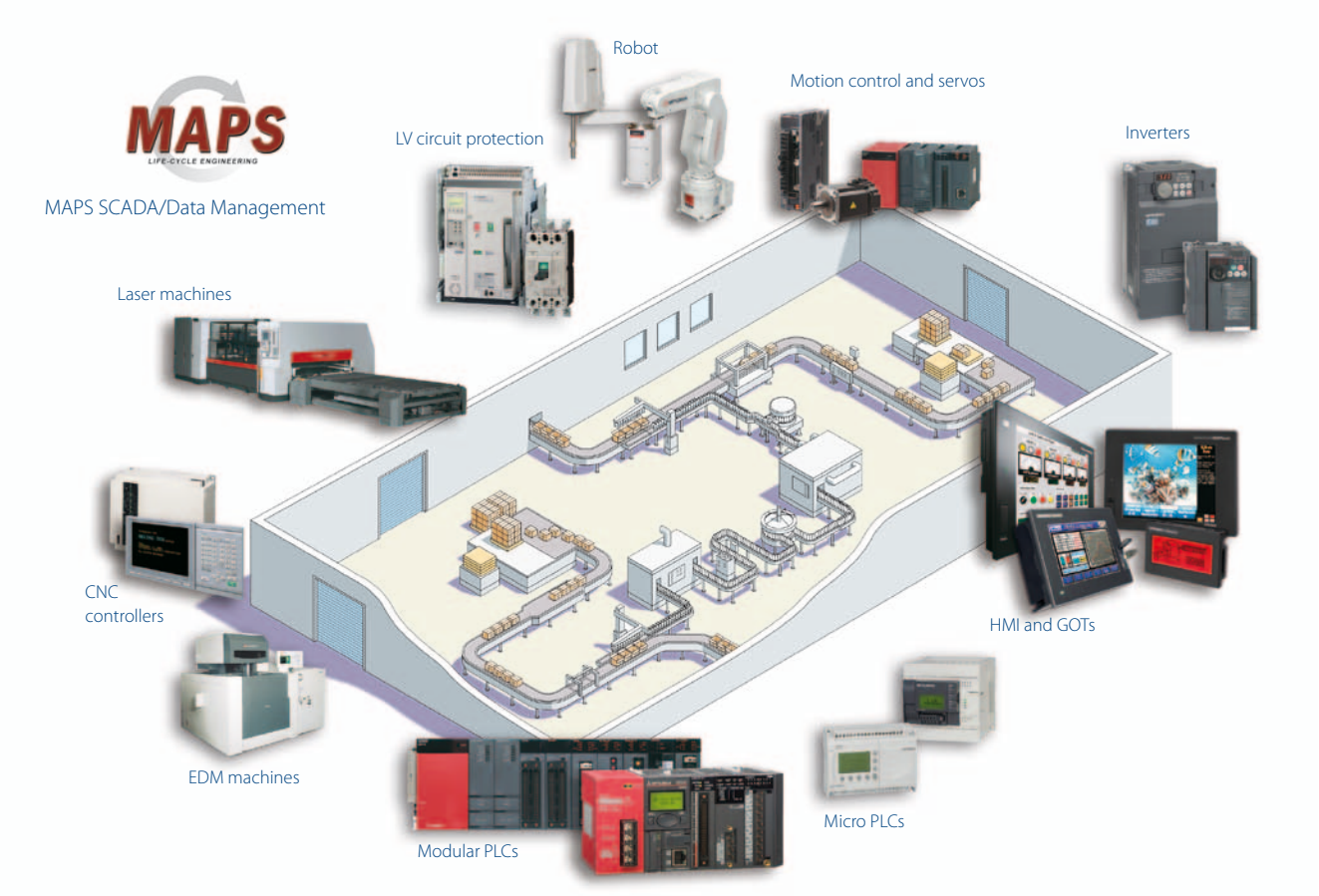
Data is stored within the GOT HMI on CF cards, and cannot be overwritten or deleted. Instead, new records are added when authorised changes are made. In addition using "Store Forward", electronic records can be pushed (on an event or time basis) to a 3rd party secure database such as Microsoft SQL Server thus providing a resilience to data loss as part of 21 CFR 11.

GOT series HMIs can be readily configured to ensure users follow a permitted sequence of steps when operating the system, as defined under the FDA 21 CFR Part 11 requirements, with the graphical user interface covering all possible operational modes.

Mitsubishi Electric GOTs allow different levels of security

For full details of implementing Mitsubishi Electric GOTs to meet the requirements of FDA 21 CFR Part 11, visit www.mitsubishi-automation.com

A world of automation solutions



A name to trust

Since its beginnings in 1870, some 45 companies use the Mitsubishi Electric name, covering a spectrum of finance, commerce and industry.

The Mitsubishi Electric brand name is recognised around the world as a symbol of premium quality.

Mitsubishi Electric Corporation is active in space development, transportation, semiconductors, energy systems, communications and information processing, audio visual equipment, home electronics, building and energy management and automation systems, and has 237 factories and laboratories worldwide in over 121 countries.

This is why you can rely on a Mitsubishi Electric automation solution – because we know first-hand about the need for reliable, efficient, easy-to-use automation and control in our own factories.

As one of the world's leading companies with a global turnover of 4 trillion Yen (over $40 billion), employing over 100,000 people, Mitsubishi Electric has the resource and the commitment to deliver the ultimate in service and support as well as the best products.

Global partner. Local friend.

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