for a greener tomorrow

MITSUBISHI ELECTRIC
Changes for the Better

FDA: CFR 21 PART 11

Simply applied

- A Brief Introduction
- Electronic records & signatures
- When it goes wrong
- Compliance features
- Smart manufacturing: e-F@ctory

GLOBAL IMPACT OF MITSUBISHI ELECTRIC

Through Mitsubishi Electric's vision, "Changes for the Better" are possible for a brighter future.

Changes for the Better

We bring together the best minds to create the best technologies. At Mitsubishi Electric, we understand that technology is the driving force of change in our lives. By bringing greater comfort to daily life, maximising the efficiency of businesses and keeping things running across society, we integrate technology and innovation to bring changes for the better.

Mitsubishi Electric is involved in many areas including the following

Energy and Electric Systems
A wide range of power and electrical products from generators to large-scale displays.

Electronic Devices
A wide portfolio of cutting-edge semiconductor devices for systems and products.

Home Appliance
Dependable consumer products like air conditioners and home entertainment systems.

Information and Communication Systems
Commercial and consumer-centric equipment, products and systems.

Industrial Automation Systems
Maximising productivity and efficiency with cutting-edge automation technology

OVERVIEW

FDA: A BRIEF INTRODUCTION

FDA is shorthand for Food and Drug Administration which is an agency within the U.S. Department of Health and Human Services.

Caption

FDA IS RESPONSIBLE FOR:

- Protecting the public health by assuring that foods (except for items regulated by U.S. Department of Agriculture) are safe, wholesome, sanitized and properly labeled
- Ensuring that the drugs, vaccines, biological products and medical devices intended for human use are safe and effective
- Protecting the public from radiation derived from electronic products, assuring safety of cosmetics & diet supplements, regulating tobacco products
- Advancing the public health by helping to speed up the product innovations

WHY FDA NEEDS TO BE FOLLOWED?

US government has made regulations which the food and drug manufactures have to follow in for manufacturing or selling their products in US. These regulations are aimed at protecting humans against any harm or loss of life due to consumption of contaminated or adulterated food or drugs.

For example some of the factors which can cause harm or loss of human life are:

- Change in the composition of food & drug due to any change in manufacturing process
- Not following standard procedures about hygiene leading to contamination
- Introducing products into the market without thorough testing & clearances from regulatory bodies
- Consumption of foods which are sold after their expiry date

This list could be endless and not limited to just four cases as mentioned above.

To put it simply, FDA is good for public health.

WHAT IF FDA IS NOT FOLLOWED?

The consequences of not following the regulations may lead to:

- Loss of human life or serious injury
- Cancellation of license for manufacturing in US or exporting to US
- Heavy financial penalties / Legal proceedings
- Closure of manufacturing facilities

These are few consequences just mentioned for reference and is not an exhaustive list.

IS IT THE ONLY REGULATION?

No, there are other regulations also. e.g. European regulation is called EUDRALEX.

Its important to understand that each country has its own food and drug laws, however since FDA is very popular so obviously would be some overlaps. Even though you may be following FDA guidelines still it may not necessarily allow you to conform to local regulations. Please be sure to check the local regulations.

GOOD MANUFACTURING PRACTICES

FDA guidelines are one of the basis for manufacturers to follow GMP (good manufacturing practices).

GMP could be used across buildings and facilities, equipment, production and process controls.

EXPANDING INFLUENCE OF FDA

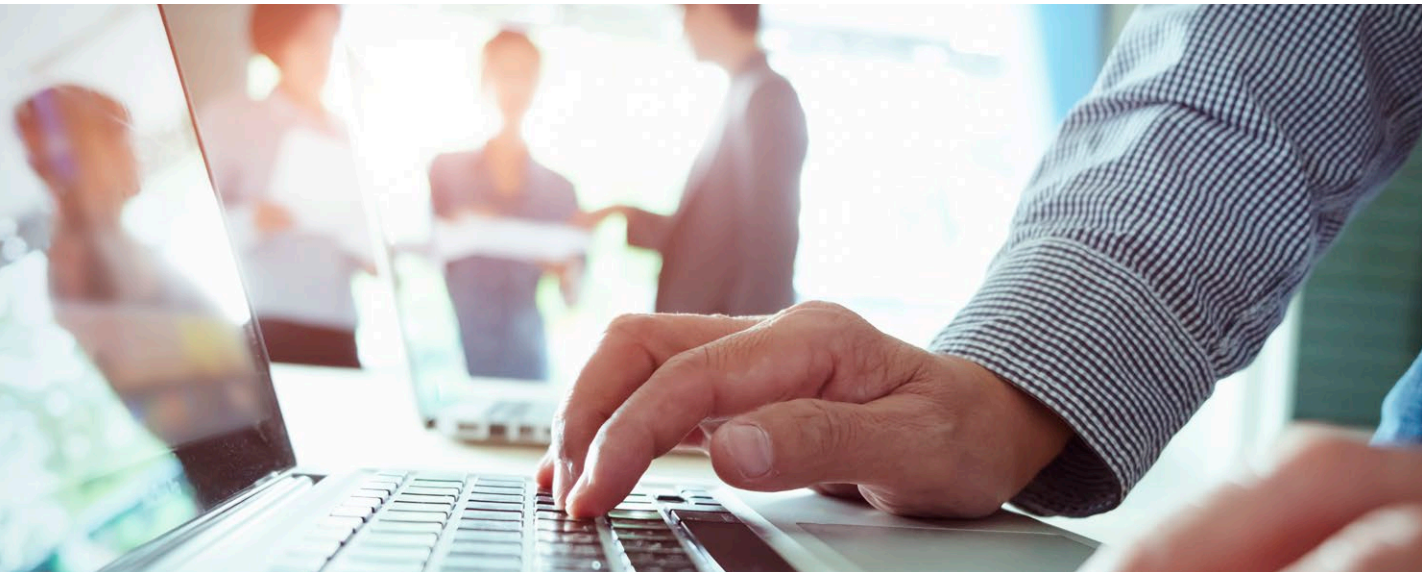
The living set of regulations are continuously reviewed and updated.

While the original development started with Pharmaceutical industry, it gradually moved into F&B industry also.

It should be noted that FDA obligations for Pharmaceutical and F&B are getting closer & closer.

CFR 21 PART 11: ORIGIN

It's a very popular term amongst drug manufacturers & suppliers. However it should be understood that it is just a part of the regulations and not the whole regulation itself. Lets trace each word individually "CFR" "21" "Part 11" and for better understanding.



CaptionNequid exerupta voluptius.

What is... CFR 21 Part 11

"CFR"

The Code of Federal Regulations (CFR) is the codification of the general, permanent rules and regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States.

The CFR is divided into 50 titles that represent many subjects. Tile no. 21 is related to Food and Drugs.

"21"

Title 21 is the portion of the Code of Federal Regulations that governs food and drugs within the United States. It has three chapters. Chapter 1 for the Food and Drug Administration (FDA), Chapter 2 for the Drug Enforcement Administration (DEA), and Chapter 3 for the Office of National Drug Control Policy (ONDCP).

Chapter 1 has 99 parts and Part 11 is one of them.

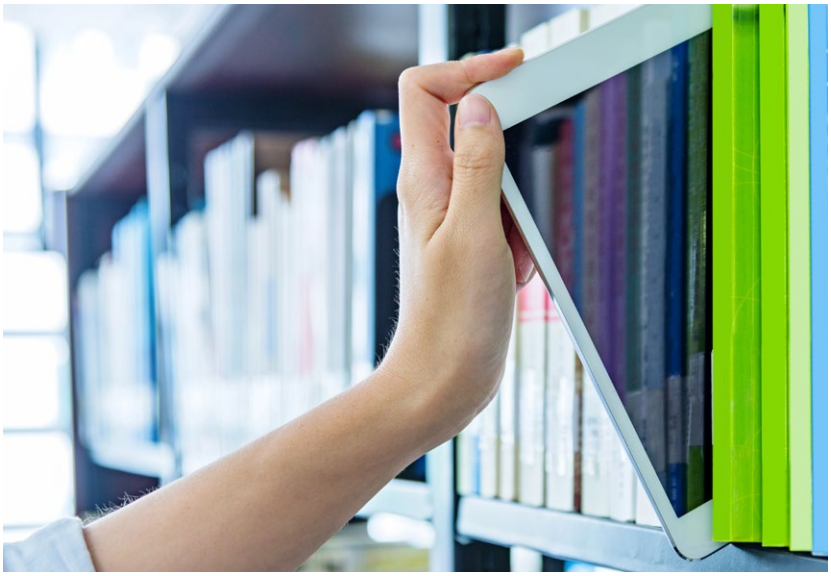
"PART 11"

Part 11 lies in the Chapter 1 for Food and drug Administration.

It deals mainly with electronic records and electronic signatures.

THE “MOVE” TO E-RECORDS

Traditionally in earlier times, all the records used to be on paper and were saved for any kind of regulatory issue or audit etc.



CaptionNequid exerupta voluptius.

OUTLINE

Example of the challenges faced:

- To find record easily when required
- Preserve it against aging
- Safeguarding it against disaster’s

However with the rapidly increasing use of IT systems, the regulation for electronic records and signatures was established in 1997 with the objectives:

- Allow the maximum use of IT
- Reduce the manual efforts & cost
- Prevent any kind of tampering

ELECTRONIC RECORD

An electronic record means any information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.

ELECTRONIC SIGNATURES

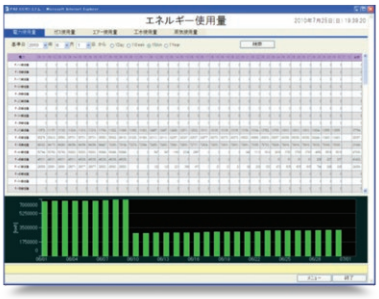
An electronic signature is the electronic authorization by an individual which is seen as a legally binding equivalent of the individual‘s handwritten signature.

PRE-REQUISITES

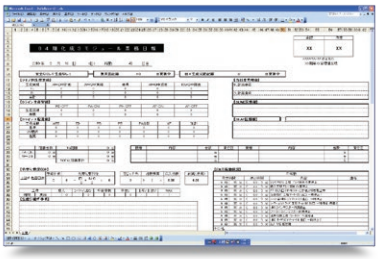
FDA accepts electronic records & signature as same as those of paper records/signature provided the computer system meets some prerequisites.

Example of the prerequisites:

- Validation of computer system
- Ability of electronic records to have proper and valid backups
- Security function of electronic records (no chance of tampering, access management etc.)
- Inspection evidence (in case of any change in records)
- Education plan and execution especially about managing the computer systems



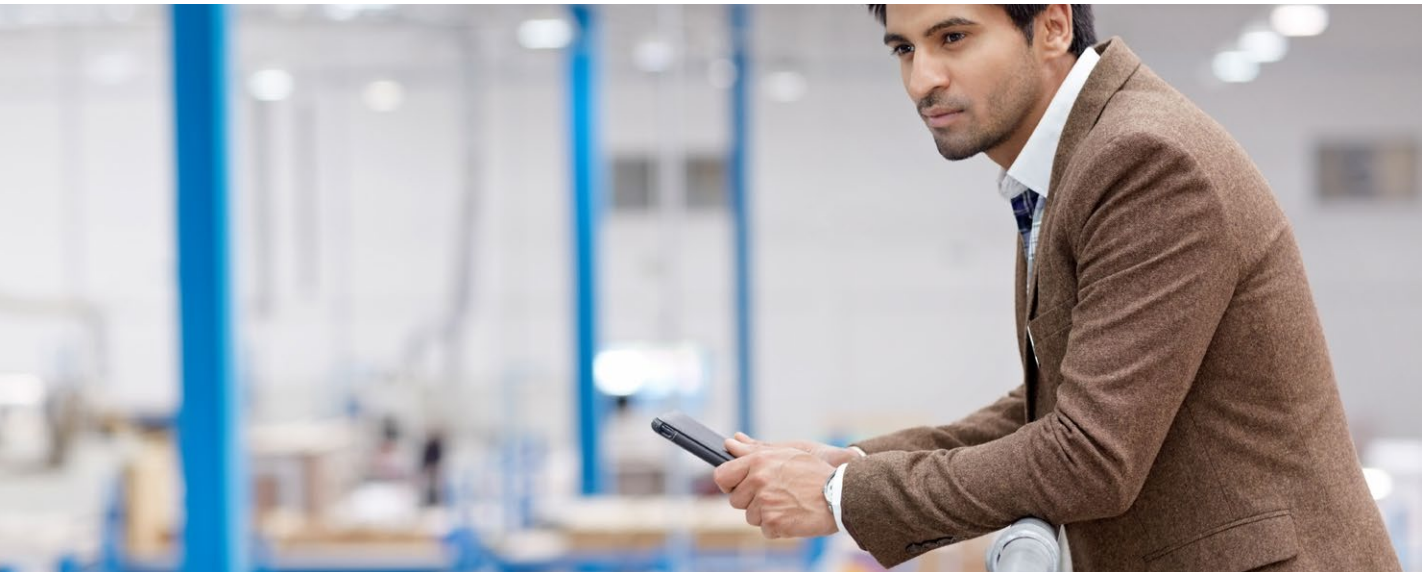
Vast quantities of data are stored in databases for audit purpose as well as for analyses to improve the manufacturing the process



Everything can be retrieved at a single click making your audits faster and easier

CAPTURING "ELECTRONIC DATA"

Automation plays a very crucial role in getting the data from shop floor and moving it to top floor. The role of automation product suppliers is getting more and more important as new technologies are developed continuously. Integration of automation with IT is also expanding at a rapid rate as the demands from end-users about data collection, availability and analysis are continuously increasing.



CaptionNequid exerupta voluptius.

WHICH DATA IS REQUIRED

Any data which is critical and may affect the process would be required. The most important point is that irrespective of the amount of data storage, there should be no chance of tampering with the data.

SHARING RESPONSIBILITY

Everyone has a part to play in data management & compliance. Please note that in addition to technical features & capabilities of products, the system integrator and end user have to ensure that overall system is compliant with CFR 21 Part 11.

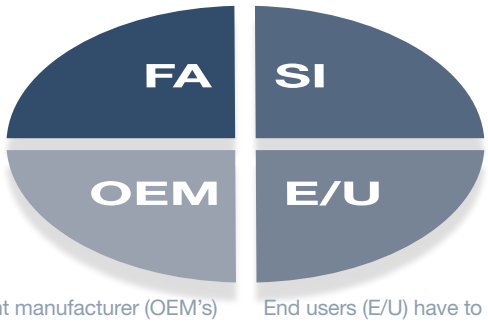
CLAIMS FOR COMPLIANCE

It should be noted that no one can say that its products are directly complaint for CFR 21 Part 11.

FA product suppliers can say that their products can be made complaint if certain rules are followed & GMP are implemented.

FA product suppliers need to explain the technical features and educate the users

System integrators (SI) need to build the entire system for data management & compliance.



Original equipment manufacturer (OEM's) need to utilize the technical features

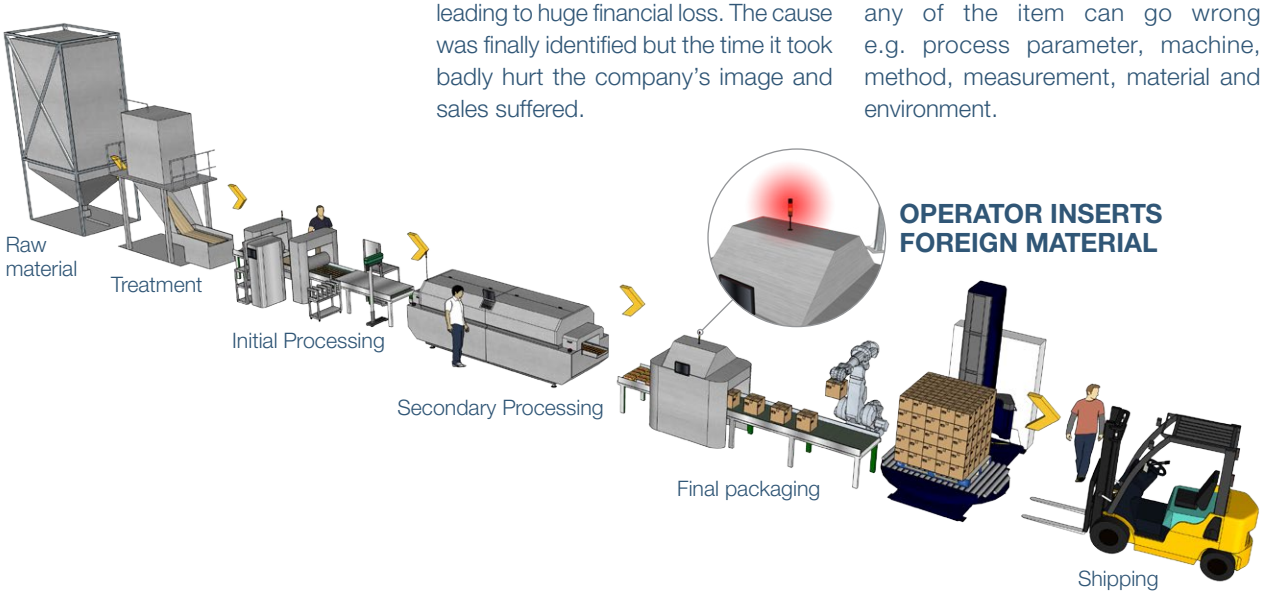
End users (E/U) have to implement administrative, operational procedures

WHEN THINGS GO WRONG

Lets see a real life example when the things took a wrong turn. An operator pricked & inserted foreign material in the food packets during packaging. Once the claim came from the market, the company could not take quick action and had to shut down the complete operations for weeks to analyze the cause.

The entire stock had to be scraped leading to huge financial loss. The cause was finally identified but the time it took badly hurt the company's image and sales suffered.

Similar issues can happen when any of the item can go wrong e.g. process parameter, machine, method, measurement, material and environment.

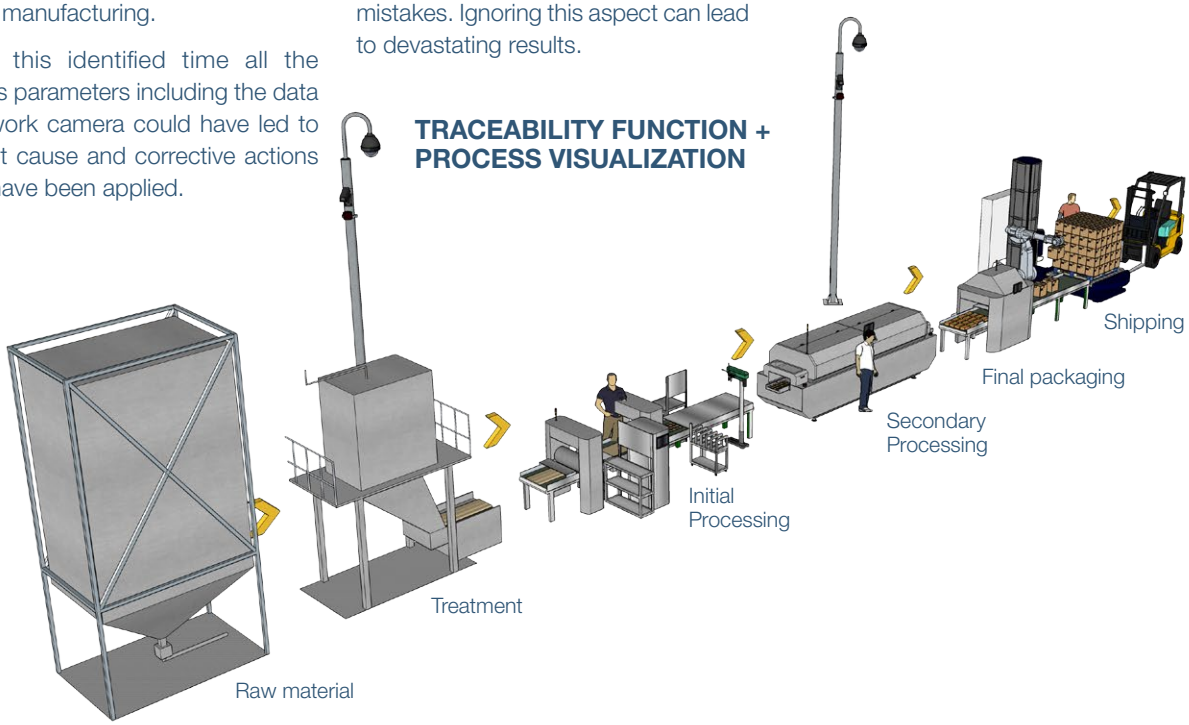


SOLUTION : INTRODUCE TRACEABILITY & STRENGTHEN PROCESS VISUALIZATION

The traceability function from the batch code could have identified the date and time of manufacturing.

During this identified time all the process parameters including the data of network camera could have led to the root cause and corrective actions could have been applied.

Its important to note that not only machines but human also can make mistakes. Ignoring this aspect can lead to devastating results.



WHAT MAKES US DIFFERENT?

Mitsubishi Electric works closely with system integrators (SI) and end users (EU) to educate and provide the necessary information about the product features which can be applied by SI/OEM's for making system complaint with CFR 21 part 11. The picture shows the image about the way data needs to be preserved and maintained right from development to delivery.

CaptionNequid exerupta voluptius.

TECHNOLOGICAL ALLIANCES

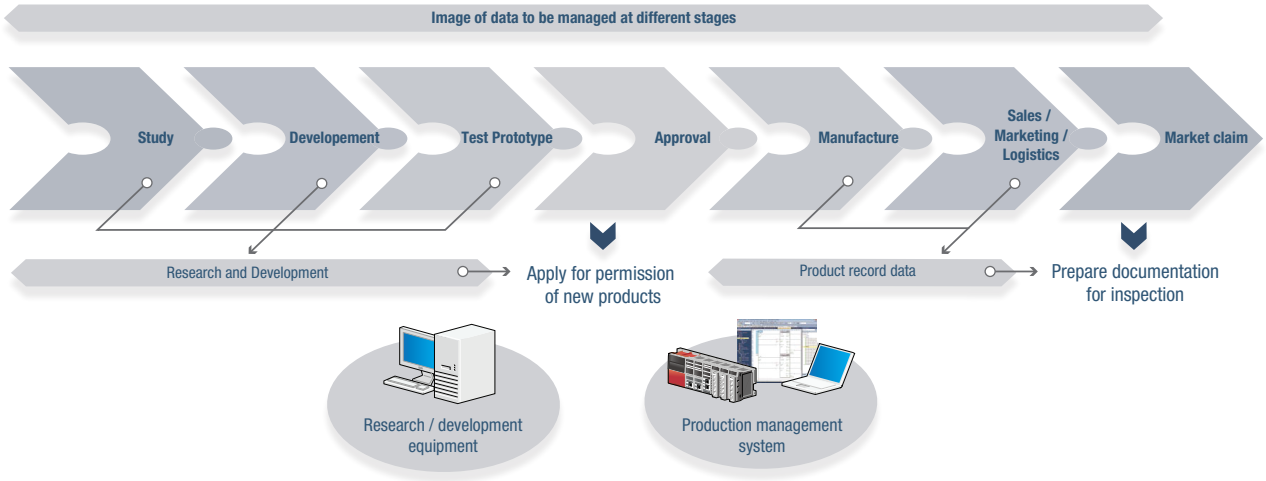
Partnering with specialized product manufacturers, we offer best in class solution approach for end-users, empowering them with the choice of products.

The e-F@ctory alliance has over 300 direct and 3200 indirect partners.

NAMES YOU KNOW AND CAN TRUST

- 3M
- Anywire
- AS-i
- ATOS
- Auvesys
- Balluff
- Canon Systems
- Cisco
- ePLan
- eWon
- Festo
- HMS
- IBM
- iTAC
- MPDV
- NTT
- P&F
- SAP
- Schaeffler FAG
- Secomea
- Sick
- SMS
- Wago

etc...



Covering all the steps: Design to delivery

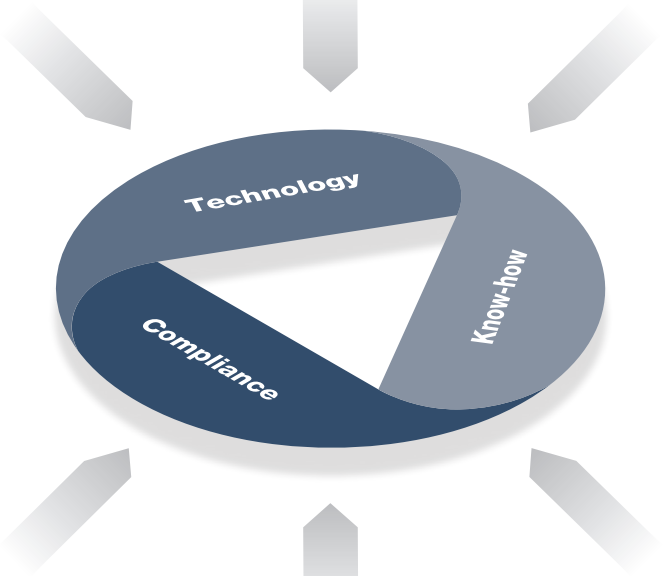
EXAMPLES WHERE WE HELPED

As a manufacturer ourselves, we understand the challenges in the manufacturing environment. We share our latest technologies to help in creating a win-win situation.

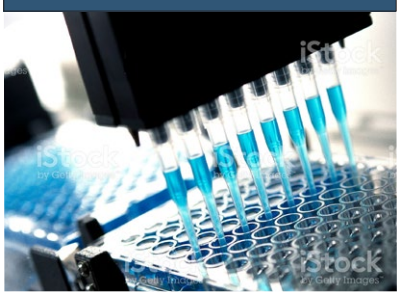
SYRINGE PACKAGING LINE

LIFE SUPPORT SYSTEM*2

MEDICAL SUPPORT ROBOTS*1

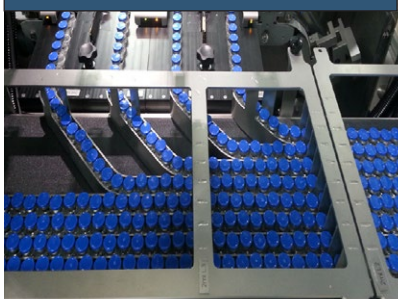


MEDICAL RESEARCH



CLINICAL NUTRITION

VIALS HANDLING*1



*1 System developed by our partner Robotronic. For more details please see http://robotronic.ch/

*2 System developed by R&D Production Engineering MAQUET Cardiopulmonary AG, Sister company of the Getinge Group

THE UNDERLYING TECHNOLOGY

As a preferred automation product supplier, it is our endeavor to continuously develop new technologies and help our end-users to reap the benefits. Mitsubishi Electric offers a wide range of products such as PLC, SCADA, HMI etc. along with developing tools which help in achieving the compliance.

Handling systems (Robot): FDA* compliant for food & medicine

Operator terminal (GOT) HMI: Open frame model, Easy installation, washdown

PC based visualization (SCADA): Security configurator & server, Alarm viewer, History logger

Controller (iQR, iQF): Structured or open programming environment

Compliance: Within your reach

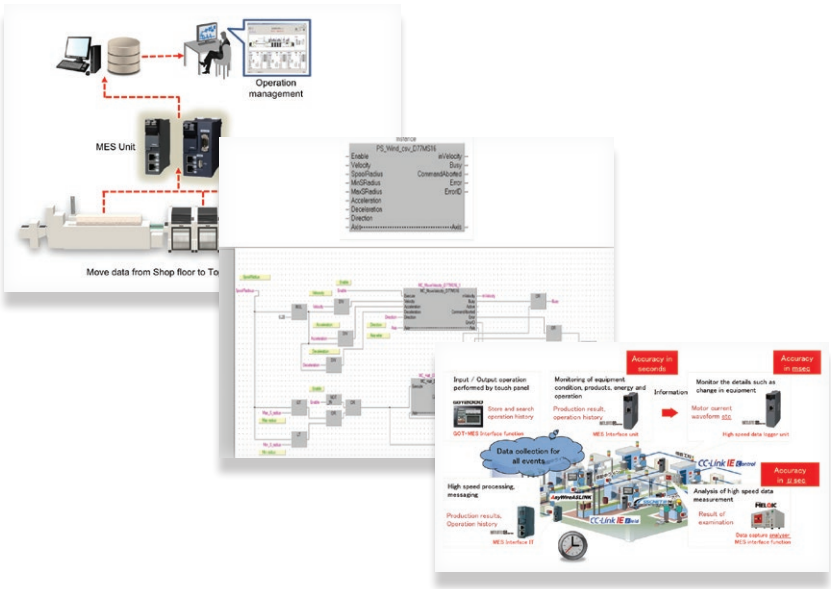
*NSF H1-certified grease applied to joint oil seals, Tool flange made of stainless steel, special hexagon flange bolts made of stainless steel, chemical resistant coating, fluorine resin used for bellows.

SEAMLESS INTEGRATION

Compliance is made easier when your systems seamlessly integrate and can be optimized for best performance.

We support in developing special function blocks for your ease.

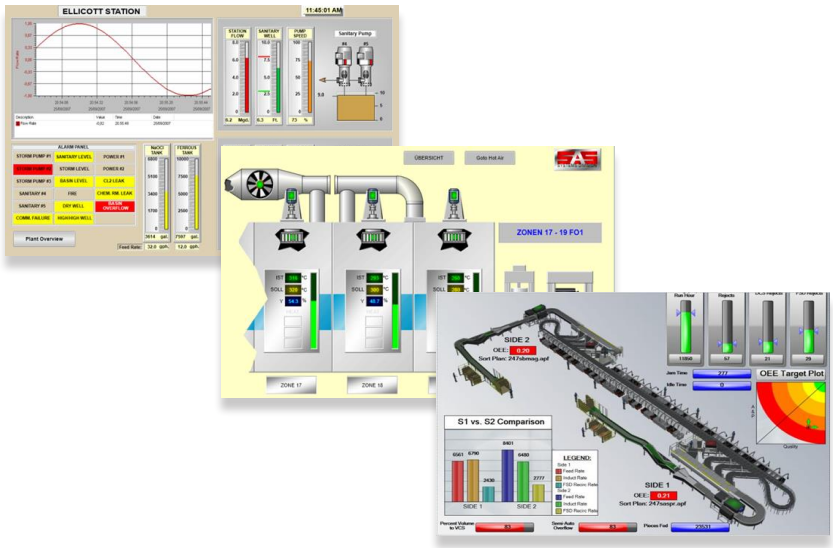
Depending upon the criticality of process and your requirement, you can record any kind of data or operation even upto microsecond level.



UNMATCHED VISUALIZATION

You can create two and three dimensional graphics with the features of enlargement, reduction, rotation and parallel movement.

To put it simply you are able to dig deep as you may like according to your needs and process requirements.



COMPLIANCE AT A GLANCE

As a part of compliance under subpart B for electronic records & under subpart C for electronic signatures, we offer the following features.

ELECTRONIC RECORDS

Item	Detail	Operator terminal GOT 2000 (HMI) features	SCADA (MC Works64) features	Comments
§ 11.10 Controls for closed systems.	a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	-	-	End user's discretion
	(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	✓	✓	
	(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	-	-	End user's discretion
	(d) Limiting system access to authorized individuals.	✓*	✓*	
	(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	✓	✓	
	(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	✓	✓	
	(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	✓	✓	
	(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	✓	✓	
	(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	-	-	End user's discretion
	(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	-	-	End user's discretion
	(k) Use of appropriate controls over systems documentation including: (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. (2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	-	-	End user's discretion
§ 11.30 Controls for open systems.	Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.	-	-	End user's discretion

* Please note that in addition to the features provided on the products, end user needs to secure the database itself

Item	Detail	Operator terminal GOT 2000 (HMI) features	SCADA (MC Works64) features	Comments
§ 11.50 Signature manifestations.	(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: (1) The printed name of the signer; (2) The date and time when the signature was executed; and (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.	✓	✓	
	(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	✓	✓	
§ 11.70 Signature/ record linking.	Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	-	-	End user's discretion

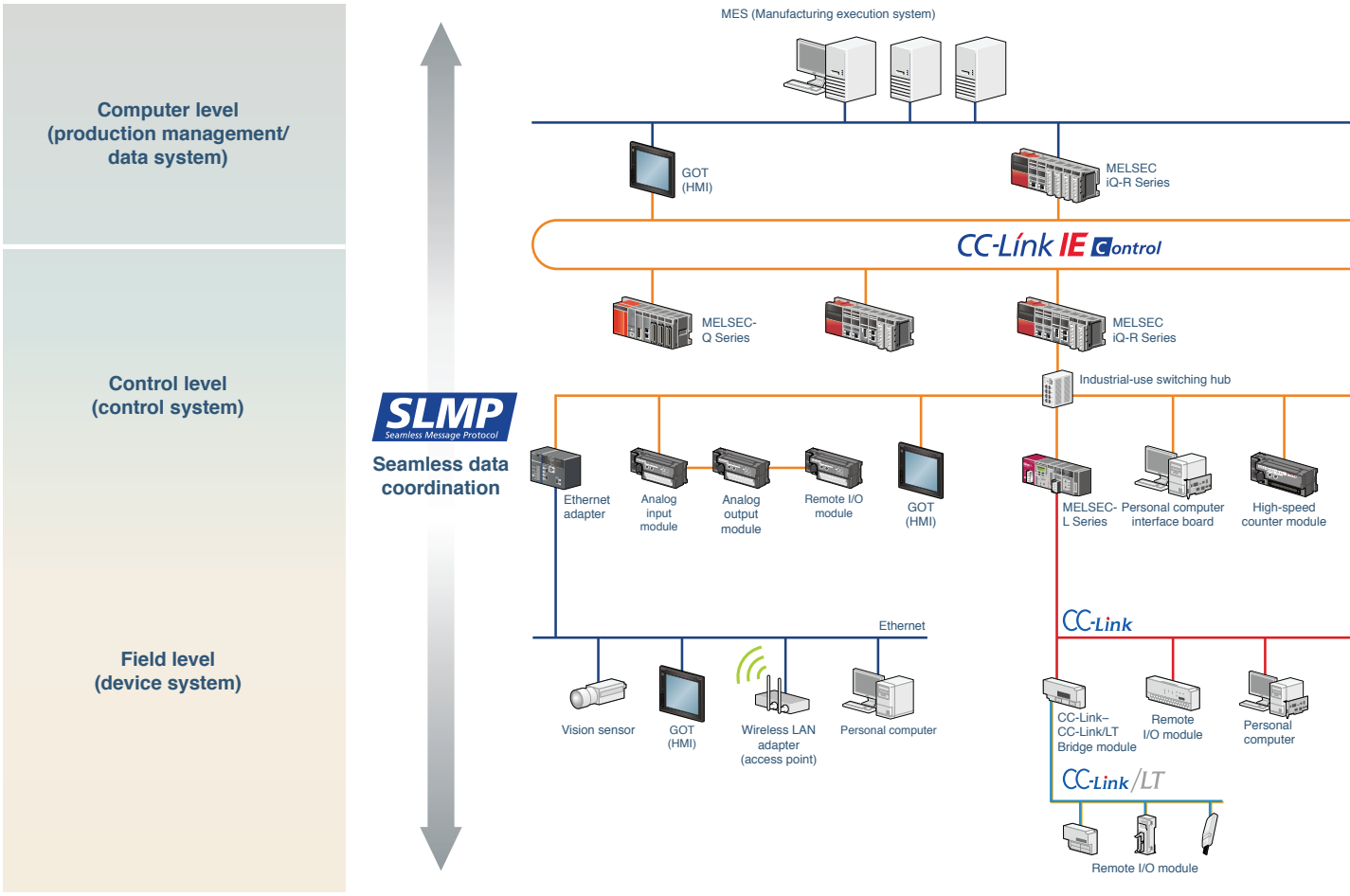
ELECTRONIC SIGNATURES

Item	Detail	Operator terminal GOT 2000 (HMI) features	SCADA (MC Works64) features	Comments
§ 11.100 General requirements.	(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	✓*	✓*	End user's discretion
	(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	✓*	✓*	End user's discretion
	(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures. (1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations HFC–100), 5600 Fishers Lane, Rockville, MD 20857. (2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.	-	-	End user's discretion
§ 11.200 Electronic signature components and controls.	(a) Electronic signatures that are not based upon biometrics shall: (1) Employ at least two distinct identification components such as an identification code and password. (i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual. (ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components. (2) Be used only by their genuine owners; and (3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	✓ ✓* ✓*	✓ ✓* ✓*	End user's discretion End user's discretion
	(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	-	✓	End user's discretion
§ 11.300 Controls for identification codes / passwords.	(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	✓*	✓*	
	(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g. to cover such events as password aging).	✓	✓	
	(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	-	-	End user's discretion
	(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	✓	✓	
	(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	-	-	End user's discretion

* Please note that in addition to the features provided on products, end user has to establish policy and ensure the adherence

FLEXIBLE CONFIGURATIONS

A wide range of configurations is possible which supports in building up the compliance ranging from complete plant operations to individual operations.



SCALABLE SOLUTIONS

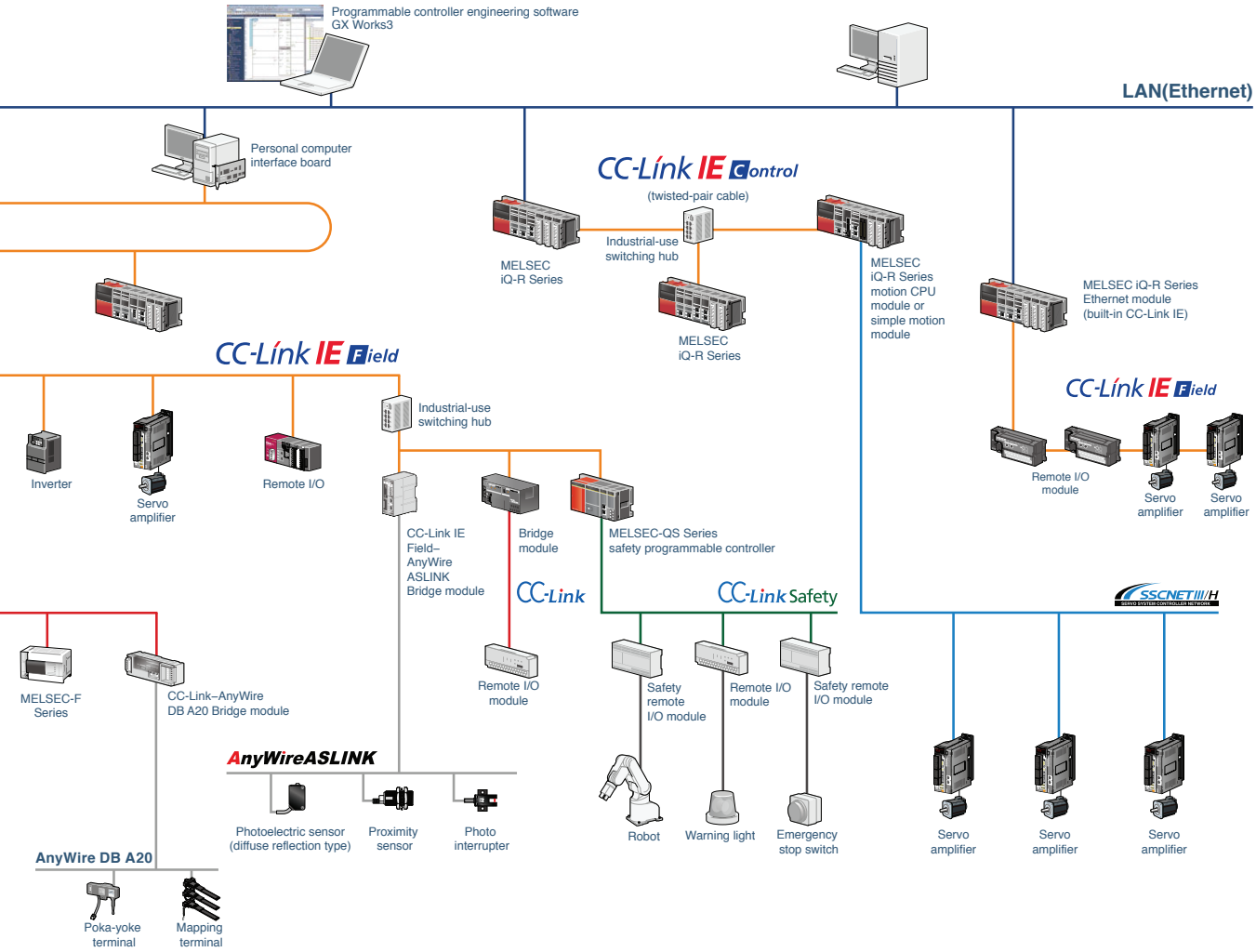
Our concept utilizes a modular structure so it is flexible to be adapted in small, medium or large deployments.

This means that you can easily select the parts you need and still benefit from the network connectivity, fitting your budget and existing site's methodology.

This configuration utilizes Process CPU, Redundant CPU, local I/O's and remote I/O's which come as standard product.

Using our topologies like star, ring etc. you can be assured that if there is any breakage in the cables you still have the required control and most importantly the data.

Compatibility with diverse platforms and databases ensures direct connections between the shop floor and information systems making everything truly visible.


Programmable controller engineering software
GX Works3
LAN(Ethernet)
Personal computer
interface board
CC-Link IE Control
(twisted-pair cable)
MELSEC
iQ-R Series
Industrial-use
switching hub
MELSEC
iQ-R Series
MELSEC
iQ-R Series
motion CPU
module or
simple motion
module
MELSEC iQ-R Series
Ethernet module
(built-in CC-Link IE)
CC-Link IE Field
CC-Link IE Field
Inverter
Servo
amplifier
Remote I/O
Industrial-use
switching hub
Remote I/O
module
Servo
amplifier
Servo
amplifier
CC-Link IE
Field–
AnyWire
ASLINK
Bridge
module
Bridge
module
MELSEC-QS Series
safety programmable controller
CC-Link
CC-Link Safety
SSCNETIII/H
MELSEC-F
Series
CC-Link–AnyWire
DB A20 Bridge module
Remote I/O
module
Safety
remote
I/O module
Remote I/O
module
Safety remote
I/O module
AnyWireASLINK
Photoelectric sensor
(diffuse reflection type)
Proximity
sensor
Photo
interrupter
Robot
Warning light
Emergency
stop switch
Servo
amplifier
Servo
amplifier
Servo
amplifier
AnyWire DB A20
Poka-yoke
terminal
Mapping
terminal

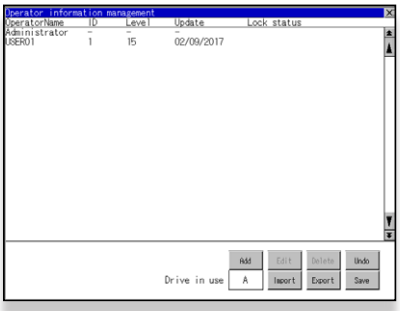
OPERATOR TERMINAL FEATURES

Mitsubishi Electric's GOT 2000 series (Human Machine Interface) provides a open frame model which complements machine design. It helps in easy data collection, enhanced security and operation management thereby reducing total cost of production. The features come as standard ones. How convenient is that?? All things readily available

MANAGING USER ACCESS

Operator authentication function allows to manage the access of users for logging in.

The users must have individual identification and each user id should be unique.

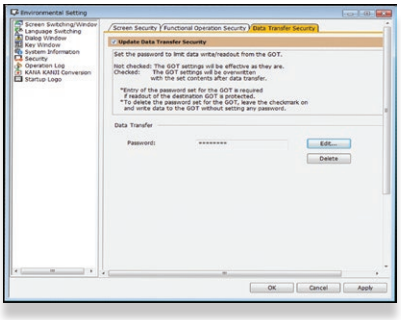


Operator management

DATA SECURITY

To prevent any unauthorized access, password facility can be setup for reading and writing the data.

The data saved in an SD memory card or USB memory is encrypted binary data.

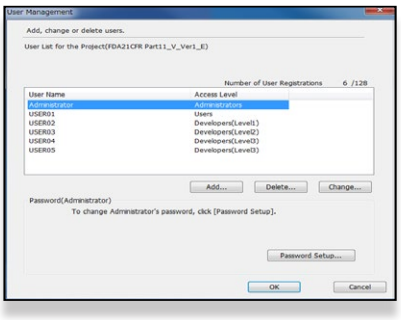


Data transfer security #2

In addition using “Store Forward”, electronic records can be pushed to 3rd party database such as Microsoft SQL server.

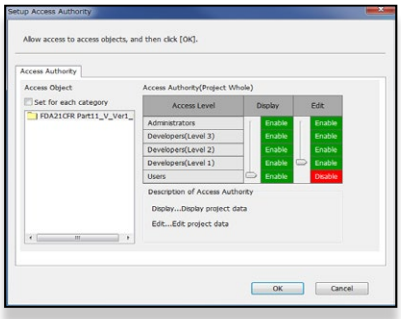
ACCESS TO PROJECT DATA

By using the “user management” function you can setup the users & their authority to display and edit the project.



User management

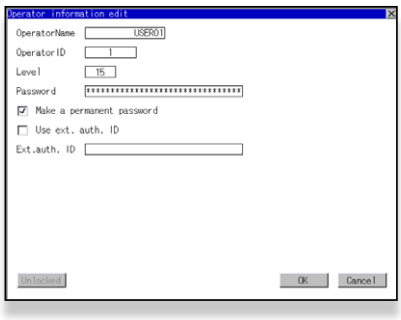
“Setup Access Authority” allows you to restrict the access levels for reading or editing the project data.



Set-up access authority #2

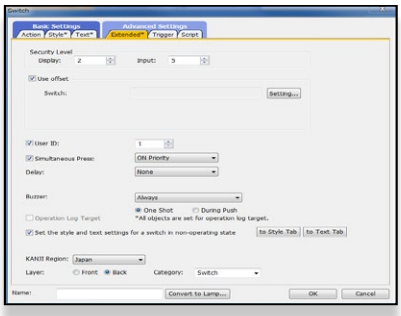
SECURITY FUNCTIONS

The security level can be set for each user. You can even control the availability of certain functions that can be executed by user.



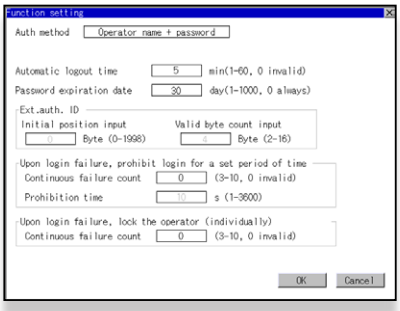
Operator edit #1

Screens / objects displayed can be set according to the security level. The security level can also be set for each object. Doing so, limits the range of operations that each user can perform according to their authorities.



Security level setting #2

Functions like password expiration, automatic log out, time lock activation can be easily set. Users will be locked in case of login failure.

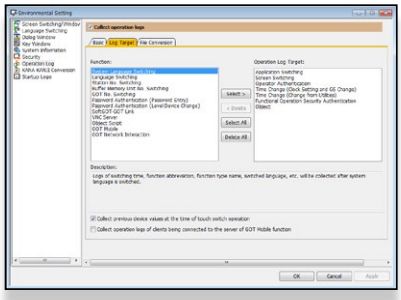


Password logout & expiry #1

AUDIT TRAIL

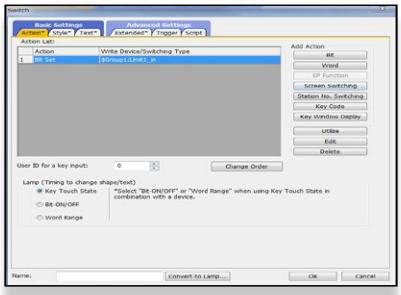
Checking the history is easier for any kind of survey as the audit trail can be recorded by setting the operation logs.

Time stamp and the user name who logged in can be recorded.



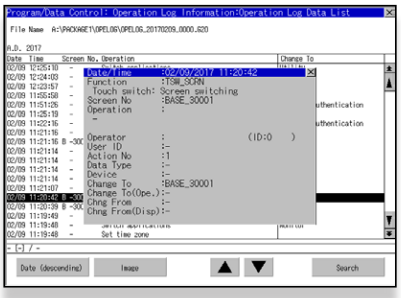
Operation log target

The names can be given to objects which can be utilized for recording the operation performed



Object name

Description and details of operation done by user e.g. changing result of data etc. can be recorded and displayed.



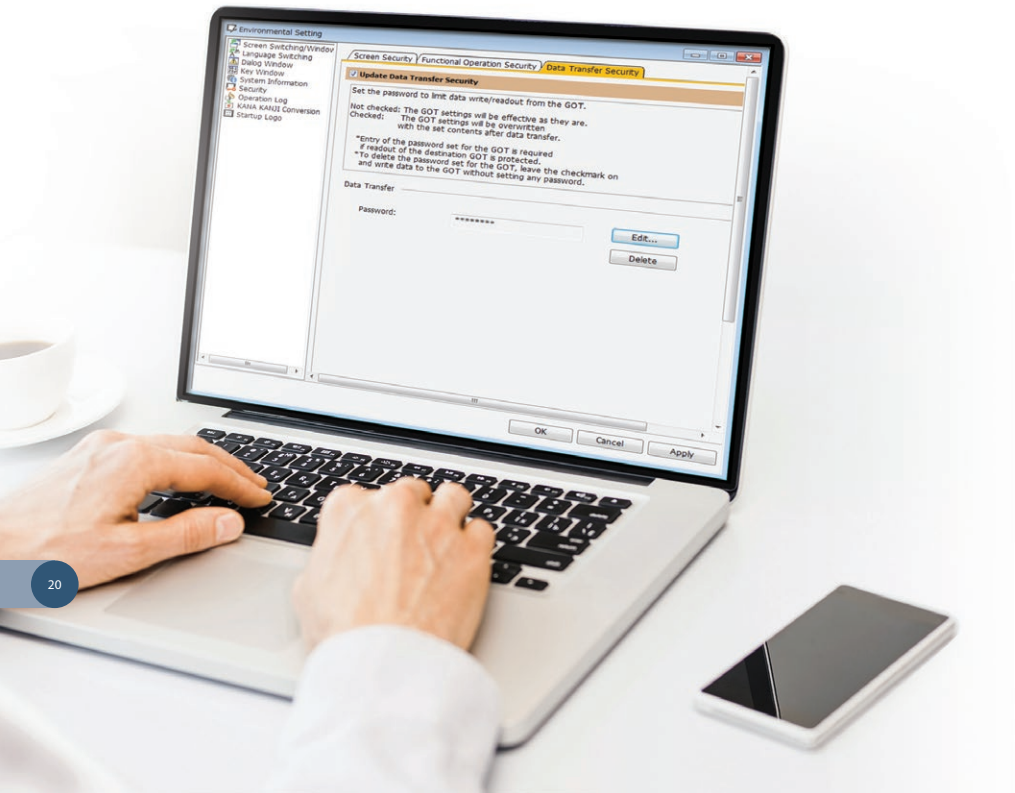
User log information

ELECTRONIC SIGNATURES

Data is stored within the GOT 2000 on CF card. Human readable reports can be prepared by conversion into formats with a security function to prevent the tampering of data.

Electronic signatures can be obtained form the PC which contains the data of GOT 2000.

End user needs to ensure the authenticity and legal binding of electronic signature along with managing the security of database.



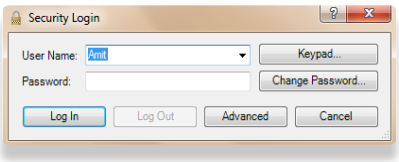
SCADA FEATURES

Mitsubishi Electric's SCADA MC Works64 provides a highly functional monitoring & control system. It enhances the visibility, operability & reliability while reducing engineering costs.

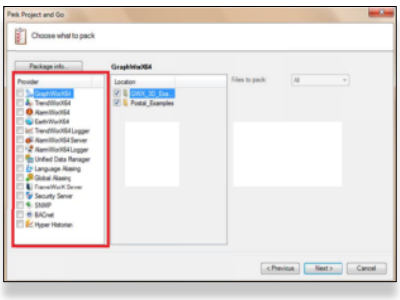
CaptionNequid exerupta voluptius.

MANAGING USER ACCESS & REVISION CONTROL

Users are prompted for a User Name and Password, when they need to log in. Users must have individual identification & each user id should be unique.



MC Works incorporates the latest Project tracking technology to create detailed reports of any engineering or configuration change.



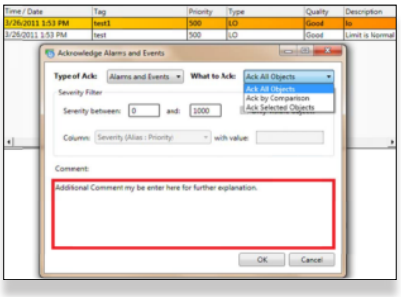
BIOMETRICS

Windows authentication & biometric devices like 'Retina scan' & 'Fingerprint reader' can be integrated to provide higher level of support for identity assurance management.

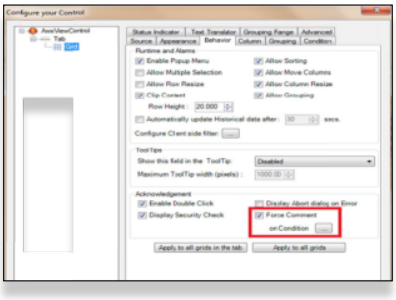
ALARM & EVENTS RECORDS

AlarmWorX64 Viewer offers type in additional comments for Alarm Acknowledgment event.

Operator comments are then propagated along with the Ack Event throughout the alarm system. This permits them to be viewed on other alarm stations in a networked environment, and they can be stored to a database by the alarm logger.



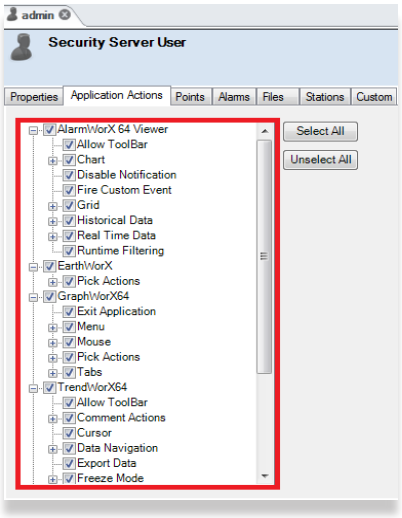
As per the requirement, operators can be forced to enter the comment for each and every alarm by using feature of “force comment”.



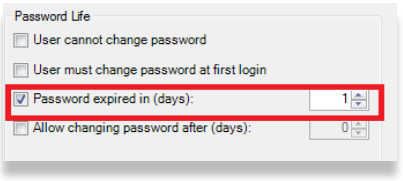
SECURITY FUNCTIONS

Actions and access are restricted based on configuration. Individual and/ or group access to components, sub-components and actions are defined in the security configurator.

The image shows a portion of this utility whereby the system administrator can assign various actions.

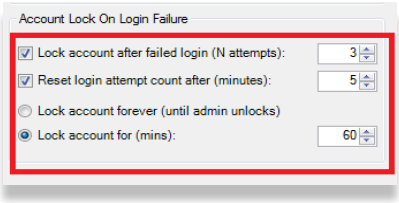


“Maximum Password Age” has been implemented in security server.

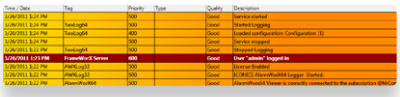


Auto Log-out feature can be enabled on a per-individual basis.

“Account Lockout” feature detects the attempt to hack into the system. The security level can be set for each user. You can even control the availability of certain functions that can be executed by user.



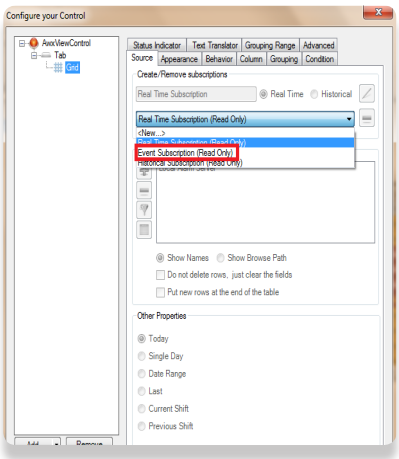
Attempted breach in security is captured and posted in the events. This message can be logged to disk as well as shown on a security or administrator station.



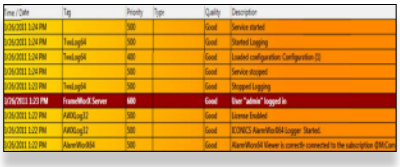
AUDIT TRAILS

GenEvent server can post events (e.g. log in and log out information, operator set point changes)to the alarm system. Date & time stamp is captured along with the name of the person performing the action, as well as the value entered and the tag name being affected.

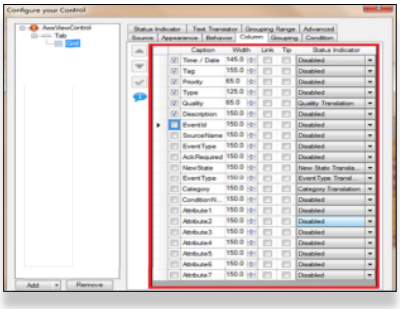
GenEvent Server also captures the node name if it occurs on a networked set of systems, thus recording information pertaining to whom, what, when and where.



Records can be posted to AlarmWorx64 Viewer which must add a subscription to GenEvent Server.



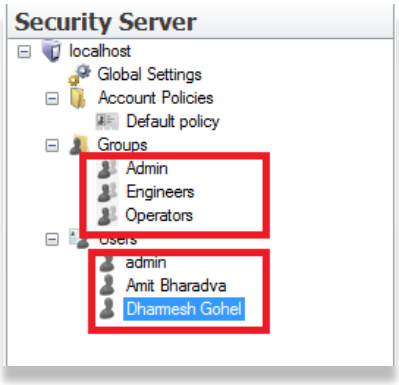
In addition to viewing these events live, the Alarm Logger can be used to log the tracking information to a secure database.



ELECTRONIC SIGNATURES

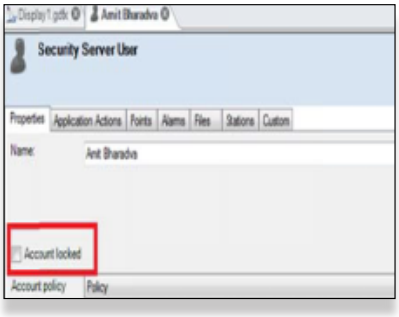
Security Configurator allows you to define full names of persons when you are setting up the user names.

It enforces unique user names thereby ensuring a unique combination of user name and password which FDA counts as Electronic Signature.



FDA regulation also requires that names are not re-used or re-assigned to anyone else. “Account Locked” feature comes in handy.

Electronic signatures can be obtained form the PC which contains the data. End user needs to ensure the authenticity and legal binding of electronic signature.



COMPLIANCE IN PRACTICE

CASE STUDY

Pharma tank monitoring & control

CaptionNequid exerupta voluptius.

This system supports the requirement of FDA 21 CFR Part11 & GMP wherein which various items like records of access & operation, digital signature, audit trails are requested in pharma.

It also supports the documents and data required for validation step's ike DQ, IQ, OQ, PQ which is one of important requirement for quality control in pharmaceutical production.

Enables unified control of huge data like change history, electronic signature of history to integrated database, availability of records of access & operation, digital signature and audit reports.

CaptionNequid exerupta voluptius.

CaptionNequid exerupta voluptius.

CASE STUDY

HVAC system monitoring & control

CaptionNequid exerupta voluptius.

CaptionNequid exerupta voluptius.

MC Works 64 was implemented as the software solution for a variety of control systems applications including the automation of pharmaceutical HVAC, industrial chiller plants in pharmaceutical manufacturing environment.

Trend, Alarm and Historian function were developed. It is easy to expand the control system since it is based on OPC. All data has been made available readily for analysis and decision making.

CaptionNequid exerupta voluptius.

CASE STUDY

Chemical Batch processing

CaptionNequid exerupta voluptius.

For this application related to chemicals the customer was able to realize the solution by using standard products GOT 2000 and QPLC.

All the process parameters are displayed on the screen which provides complete visualization of the actual status of each equipment thereby giving user a total control over the system.

Abore nem fuga. Itaquiam veraten isquame plantio. Ci doloreriam rehenisqui cusaperem. Itatur.

CaptionNequid exerupta voluptius.

CaptionNequid exerupta voluptius.

CASE STUDY

Brewery production

CaptionNequid exerupta voluptius.

CaptionNequid exerupta voluptius.

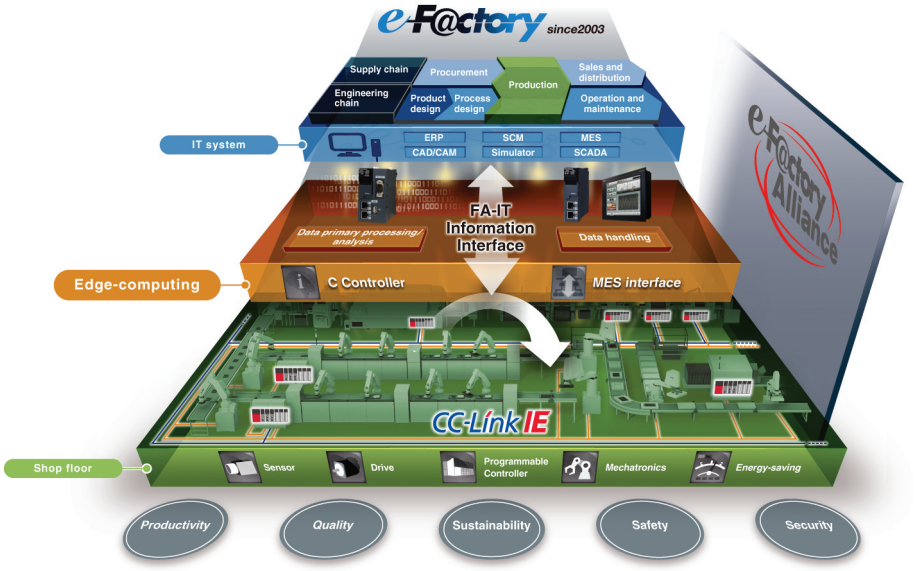
MC Works64 was utilized for the monitoring and control of production processes in beverage plant covering all the aspects like process control, packaging control etc. along with monitoring and control of utilities too.

Along with server & client configuration it involves a redundant server where the load distribution is enabled on a highly reliable network.

Further you can use a MELSECNET/H remote I/O network to distribute and connect I/O's, thus realizing the configuration of a hierarchical network system.

CaptionNequid exerupta voluptius.

FUTURE MANUFACTURING



The Future of Manufacturing as envisioned by Mitsubishi Electric, e-F@ctory: “Manufacturing” that evolves in response to environmental changes in an IoT enabled world.

Established In 2003, e-F@ctory created a Kaizen[#1] automation methodology to help optimize and manage the increasingly complex business of “manufacturing”. Continuously evolving itself, it also utilizes the expanded reach of IT, which has brought “cyber world” benefits of analysis, simulation and virtual engineering, and yet has also placed greater demands on the “physical” world for increased data sensing, collection and communication.
The continued success of e-F@ctory comes from understanding that each manufacturer has individual needs and investment plans but must still deliver; "Reduced management costs” (TCO); production flexibility to make a multitude of product in varying quantities; continuously enhanced quality. In short e-F@ctory’s goal is to deliver operational performance that is "a step ahead of the times", while enabling manufacturing to evolve in response to its environment. To do this it is supported by three key elements:

• The e-F@ctory Alliance Partners; who bring a wide range of software, devices, and system integration skills that enable the creation of the optimal e-F@ctory architecture.

• Advanced communication; utilizing open network technology like CC-Link IE, and communication middleware such as OPC, to open the door to device data, including legacy systems, while supporting high speed extraction.

• Platform thinking; to reduce the number of complex interfaces making it easier to bring together Robotics, Motion, Open programming languages (C language), PACs etc. strengthening the field of control, yet operating on industrial strength hardware.

Kaizen[#1] = continuous improvement
TCO = Total Cost of Ownership

REFERENCES

FDA ORGANIZATION WEBSITE:

FDA guidelines have been taken from website from Code of Federal Regulations Title 21 (Food and Drugs). For complete details about FDA please refer to the website **www.fda.gov.in**

TECHNICAL TERMINOLOGY:

Technical terminology like PLC, e-F@ctory etc. is taken from the website of Mitsubishi Electric Corporation **www.mitsubishielectric.com**

SCADA (MC WORKS 64) TECHNICAL MANUAL:

For more technical details please refer to the Technical Bulletin: [Issue No.] FA-A-0203,

[Title] Guidelines to meet the requirements of FDA 21 CFR Part 11 by MC Works64

GOT 2000 (HMI) TECHNICAL MANUAL:

For more technical details please refer to the Technical Bulletin:

[Issue No.] GOT-A-0077-A,

[Title] Guidelines on Compliance with FDA 21 CFR Part 11 for the GOT 2000 & GOT 1000 Series

SOLUTIONS FOR INDUSTRY

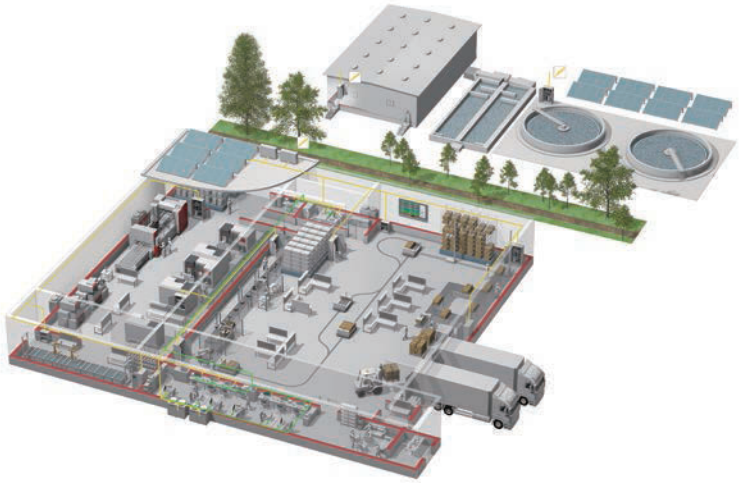
For case studies on Pharmaceutical and F&B please refer the catalogue Solutions for Industry.

PACKML

For all your packaging needs please refer to PackML Solution.

MEMO

YOUR SOLUTION PARTNER



Mitsubishi Electric offers a wide range of automation equipment from PLCs and HMIs to CNC and EDM machines.

A NAME TO TRUST

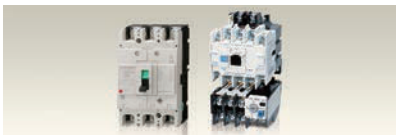
Since its beginnings in 1870, some 45 companies use the Mitsubishi name, covering a spectrum of finance, commerce and industry.

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

Mitsubishi Electric Corporation is active in space development, transportation, semi-conductors, energy systems, communications and information processing, audio visual equipment and 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 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 over 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.



Low voltage: MCCB, MCB, ACB

Medium voltage: VCB, VCC

Power monitoring, energy management

Compact and Modular Controllers

Inverters, Servos and Motors

Visualisation: HMIs, Software, MES connectivity

Numerical Control (NC)

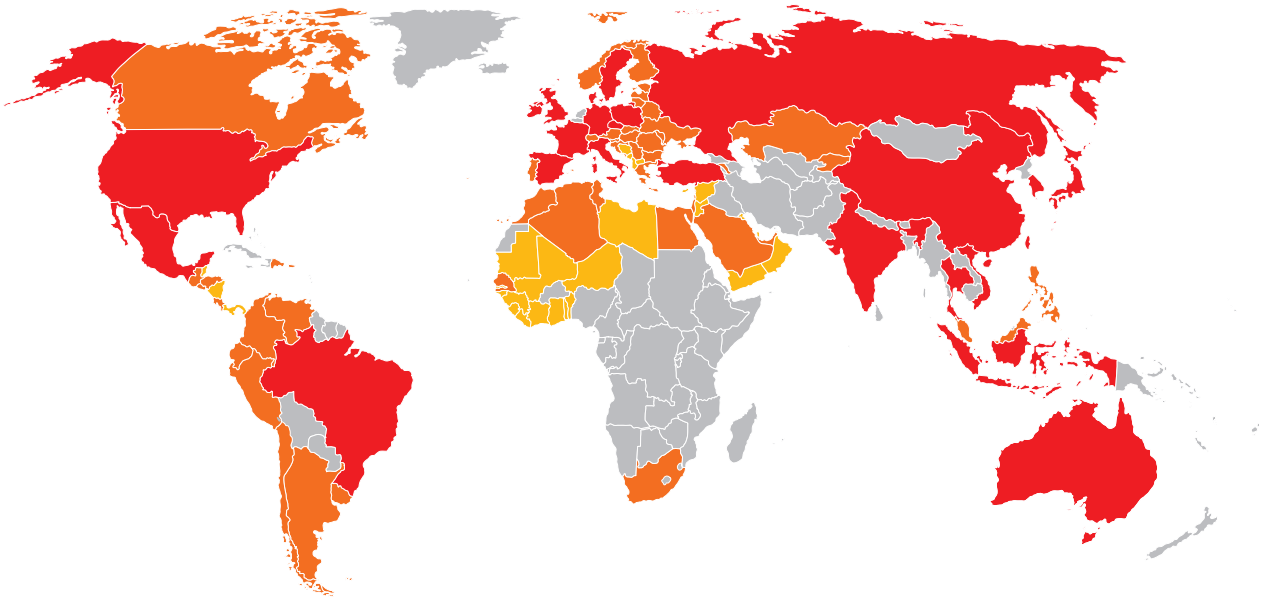
Robots: SCARA, Articulated arm

Processing machines: EDM, Lasers, IDS

Transformers, Air conditioning, Photovoltaic systems

* All products are not available in all countries.

Global Partner. Local Friend.



- Country with a direct Mitsubishi Electric FA office
- Country covered by distributors with "in-country" offices
- Country covered by a sales network

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http://Global.MitsubishiElectric.com

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