Available online at www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2018; 10(4): 90-94

ISSN- 0975 1556

Research Article

Building Audit Compliant Pharmaceutical Manufacturing Environment by the Aid of the Industrial Internet of Things (Iiot)

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Received: 31st Oct, 17; Revised: 12th Feb, 18; Accepted: 24th Mar, 18; Available Online:25th April, 18

ABSTRACT

The updated version of automation and connectivity through the internet is known as Industrial Internet of Things (IIoT)This has been for many decades in the plant environment as a machine to machine communication without the advancement and connectivity. Pharmaceutical manufacturing has seen many changes in which automation is one, IIoT is nothing but automation of the entire plants situated at different places by the internet as the choice of network. Real-time auditing, by IIoT analyzing and interpreting the large data, can be made easier. IIOT acts as a tool for an industrial organization to improve connectivity, scalability, efficiency. along with these IIoT also saves time and money for organizations. SCADA, HMI, PLCs, RTUs, and network play important role in IIoT. Supervisory control and data acquisition (SCADA) is a system of software and hardware elements that allows industrial organizations to Control industrial processes locally or at remote locations. SCADA acts as a vehicle that communicates with the operator and operation by carrying the information from the field level i.e., valves, motors, sensors and human-machine interface (HMI). It has both software and hardware elements which helps the operator to control the operation from the remote locations. the software is built to log and record the events which are performed through it by this SCADA helps the organization to make smarter decisions, communicate system issues to help mitigate downtime. PLC, RTU. HMI, sensors act as a supporting system. Automation in manufacturing can be divided into field level, automation level, and management level.by incorporation of IBCs with automation, manufacturing could see a different perspective in terms of analyzing the data and make important decisions. It also makes process and system more compliant to audits.

Keywords: Human-machine interface (HMI), Supervisory control and data acquisition (SCADA), Programmable Logic Controllers (PLC), Remote terminal units (RTUs) Intermediate bulk containers(IBC), Industrial internet of things (IIoT).

INTRODUCTION

The use of internet of things (IoT) technologies in manufacturing is the industrial internet of things (IIoT). IIoT is also referenced as the industrial internet. The incorporation of machine-to-machine (M2M) communication, big data management, collecting sensor data and automation technologies is IIoT. These technicalities were part of the industrial environment for decades but in a separate system, IIoT has brought them together which has led to efficiencies and reduction of time and cost for the firms. The key for the development of IIoT is the clever machines which are smarter than humans in consistently communicating and capturing data. IIoT acts a vehicle for firms to pick up inadequacies and resolving glitches preferably by saving money and time. In a manufacturing facility, IIoT supports the quality control and green practice's[1].

The updated version of automation and connectivity through the internet is known as Industrial Internet of Things (IIoT) This has been for many decades in the plant environment as a machine to machine communication without the advancement and connectivity.

IIoT is the step towards innovation, showing the glimpse of what tomorrow's factory would look like for all the automated manufacturing plants IIoT would be its eyes and ears[2].

In the current scenario, pharmaceutical manufacturing has seen many changes in which automation is one, IIoT is nothing but automation of the entire plants situated at different places by the internet as the choice of network. Since the data is more critical and valuable, it is better to have an own networking system.

What can IIOT change in pharmaceutical manufacturing?

IIoT is the key for,

Real-time auditing: Analysing and interpreting the large data, can be made easier.

Real-time tracking in the supply chain.

Real-time tracking of the dispensed material and its progress in manufacturing can be analyzed by (RFID)Radio-frequency identification with the help of IIoT.

Real-time auditing of vendors and contract manufacturing organizations(CMO's.)

How will IIoT change the perspective of manufacturing?

Network of smart devices collects the large data from the ground level i.e.: manufacturing plant level and sends the same data to the cloud system i.e.: the central cloud service here the data are combined and arranged in such a way

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which helps the end user to easily understand the large data IIoT is the application of IoT to the manufacturing. There are companies which have implemented IIoT by leveraging intelligent, connected devices in their factories

Benefits of IIoT

IIoT significantly improves efficiency, connectivity, cost savings, scalability and time savings for pharmaceutical companies. There are companies which are benefitted through economical management due to predictive maintenance, upgraded safety, and other operational efficiencies of IIoT.

Challenges

As technology writer Margaret R observes, that "A major concern surrounding the Industrial IoT is interoperability between devices and machines that use different protocols and have different architectures."

Security of the data is a major concern for pharmaceutical companies. The proliferation of sensors and other smart network device has resulted in a parallel explosion in security vulnerabilities.

The concern of IIoT is the use of different protocol and different architecture which affects inter-operability between machines and devices. So the non-profit industrial internet consortium was founded in 2014 which focuses on creating standards that promote open interoperability and the development of common architectures.

Solution

Automated factories which exist today are comparatively in an enclosed environment capable of communicating within the plant network, not with the outside world. Majority of the firms feel better when they are in this environment as the outside world internet seems to be prone to hacking and has many security issues. IIoT is seen as a threatening investment as the firm's information gets readily available to the outside hackers in which the information can be hacked or get affected by the viruses. But it can be easily rectified by adapting and building a network of your own which doesn't require the outside internet yet it works same as the IIoT .software like Stuxnet is industrialized and installed with best intentions, for firms to change their perspective of threatening investment to reliable investment as the Stuxnet gives you an internal system of internet and makes your system more compliant to audit.

It's conceivable that you can obtain many of the benefits of IIoT without that outside connection. Upgrading or changing the internal network to Internet Protocol should allow a company to install and use the new devices and sensors in an internal IIoT and that may be perfectly adequate.

Understanding the process and architecture of automation and its level is essential for IIoT, so we need to get familiarize with SCADA, HMI, PLCs, RTUs, and network. SCADA plays an important role in automation of a process.(3)

Supervisory control and data acquisition (SCADA)

Software and hardware foundations contribute to form Supervisory control and data acquisition (SCADA) that permits industries to:

Regulate industrial activities from plant or from anywhere outside the plant

Screen, compile and develop real-time data

Links and helps to connect the ground devices like sensors, valves, motors, PLCs by the help of human-machine interface (HMI) software.it behaves as an interactive platform for between the ground devices and the SCADA.

Records and recalls every activity performed on the ground.

SCADA helps in processing the data in order to take a decision which is more smarter and can bring changes which reduce the downtime by communicating the system issues and maintain the efficiencies. by the implementation of SCADA.

The architecture of SCADA starts with programmable logic controllers (PLCs) or remote terminal units (RTUs). Microcomputers that communicate with an array of objects such as factory machines, HMIs, sensors, and end devices are PLCs and RTUs, These PLCs and RTUs then route the information from those objects to computers with SCADA software as shown in fig:1. The SCADA software helps operators and other employees by processing, distributing and displaying the data, which intern helps them to analyze and make important decisions this makes IIoT more audit compliant.

For example, Operator gets notified about the upcoming error in the system by the help of SCADA and the problem found was. RMG was taking a long time to form granules. Operator can analyse the operation by the SCADA system by which he/she can be determine the cause of the issue by reviewing the data, in the above case operator reviews the data and discovers that RMG was malfunctioning sensors deployed in RMG can give a live image of granules formed but there is no decrease in amperage reading due to the malfunctioning of the current /voltage sensor. Loss of product can be reduced by SCADA system as it notifies the operator the upcoming issues with reason by the application of the knowledge and the data presented by SCADA helps him to make a smart decision[4].

PLC (Programmable Logic Controllers)

Mini industrial computers equipped with both hardware and software and has the ability to perform and control the function is called Programmable Logic Controllers (PLC). PLCs can control machinery and perform functions in the industrial environment They are designed for multiple arrangements of digital and analog inputs and outputs with extended temperature ranges, immunity to electrical noise, and resistance to vibration and impact As shown in fig 2 PLC will consist of two basic sections: the central processing unit (CPU) and the Input/output (I/O) interface system[6]

Human Machine Interface (HMI)

HMI is a medium for information exchange and mutual communication between electromechanical systems and the user.The replacement for the traditional control panels with wiring is HMI and it has an advantage of fast and convenient control of manufacturing automation. It is more user-friendly as it provides touch panel and keys which are more interactive and helps the operator to make recipes and complete the settings by using the touch panel[7].

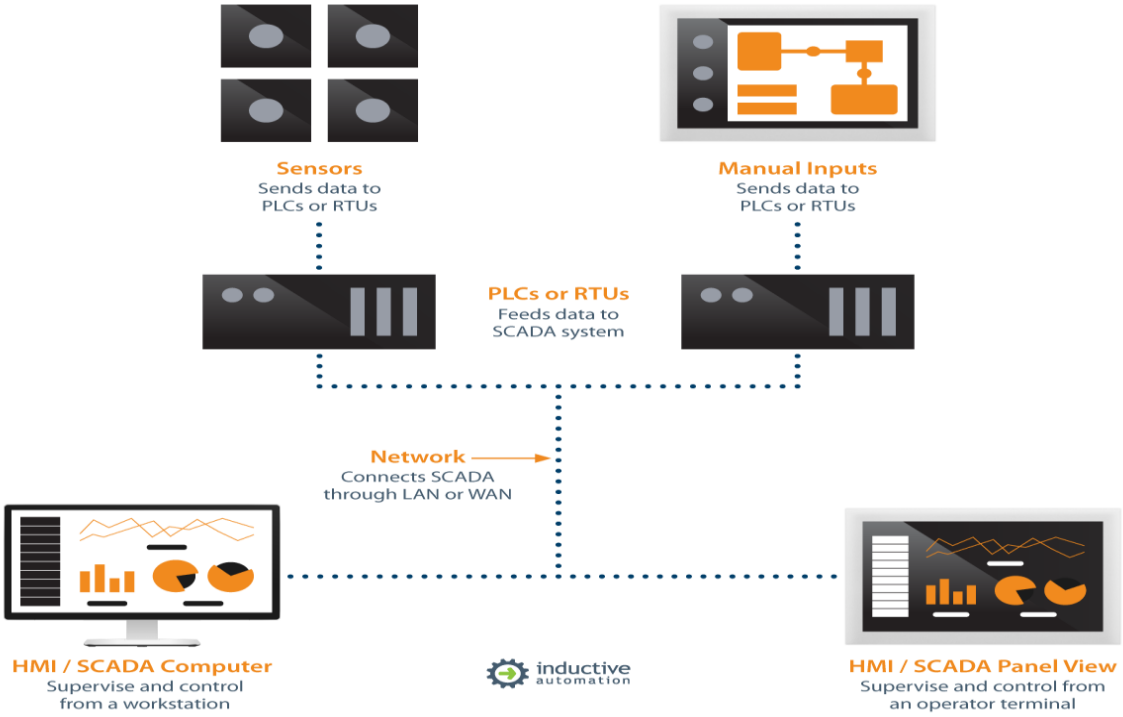

Figure 1: Basic architecture of SCADA [5]

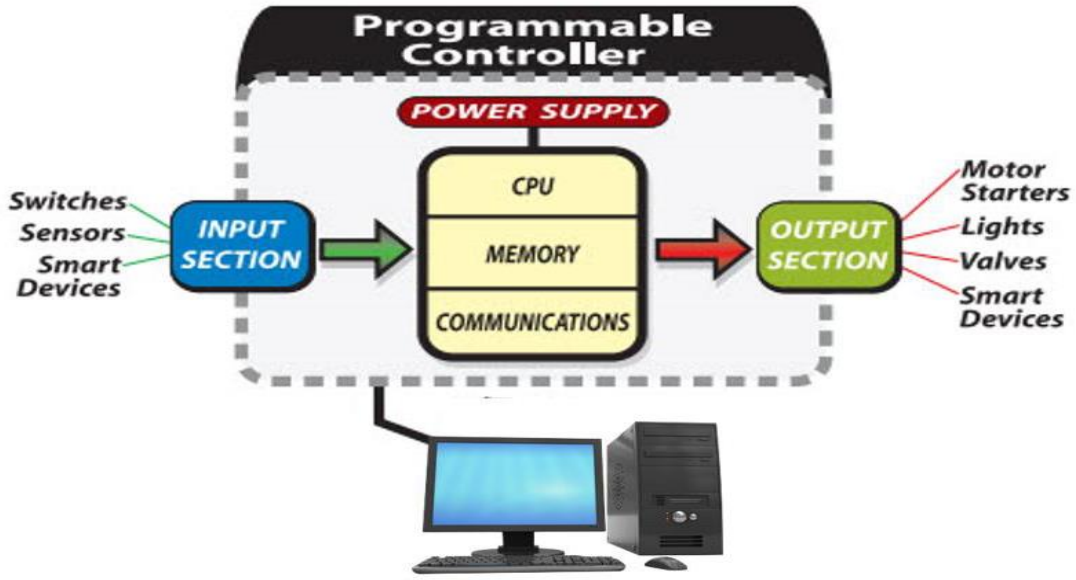

Figure 2: PLC Input/Output (I/O) interface system

Sensors

Advanced devices which can detect and respond to the optical and electrical signals are sensors.. these Sensors help convert the physical parameter (for example temperature, blood pressure, humidity, speed, etc.) into a signal which can be measured electrically.

Types of Sensors

Temperature Sensors

- Thermocouple
- Resistance Temperature Detectors (RTD)
- Thermistors

Thermistors
Airflow sensors
Current
Force
Humidity sensors
Motion and position sensors
Optical sensors
Pressure sensors
Speed sensors[8,9,10]

Fig:3 explains the level of connectivity in IIoT in which field level is the shop floor with manufacturing

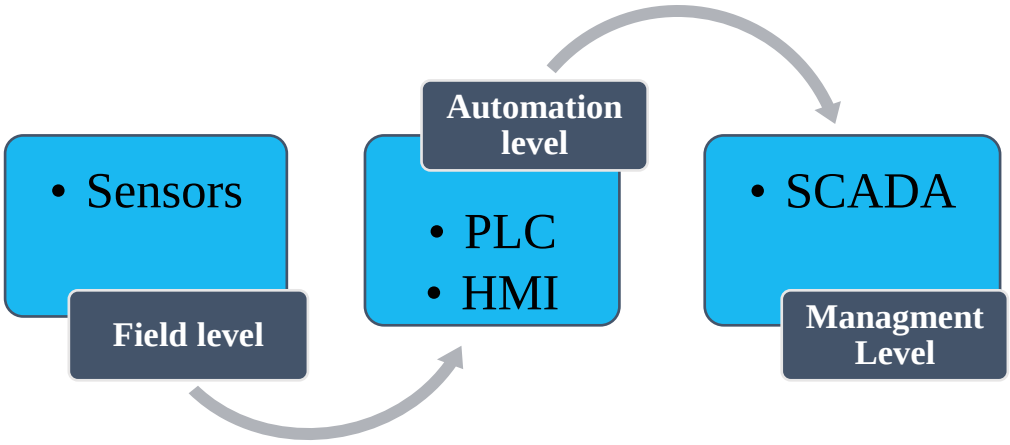

Figure 3: levels of connectivity in IIoT.

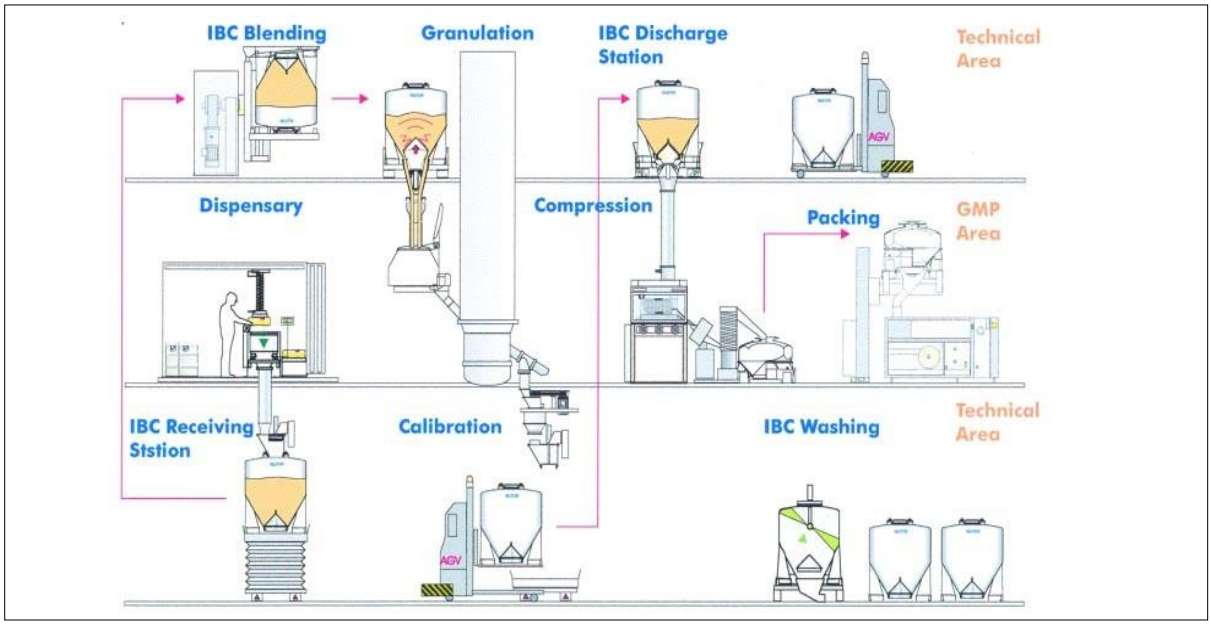

Figure 4: IBCs used in the process chain.

equipment's which are capable of performing the necessary functions and are equipped with the sensors, in order to control the variables and process parameters in the unit operation.

Automation level is the attachment of hardware-software unit for the equipment like PLC and HMI to make an equipment more efficient in terms of communication and decision making.

Management level has SCADA this gives a virtual representation of the manufacturing unit by the help of a software controlling and managing a process can be made easier by SCADA one can control each unit operation and set the limit for the critical process parameter .it also helps to analyze the trend data.

Network this is an important aspect of the automation, which connects the PLCs HMI and SCADA choosing the network is critical and depends on the level of automation. IIoT is nothing but the automation by the use of Ethernet as a choice of network other than the internet local area network (LAN),wide area network (WAN) Profibus ((Process Field Bus) Modbus are the choices which can be opted in the current changing environment having an own integrated network would be a wise choice.

Fig;4 shows the manufacturing of tablets by the use of IBC. IBC can be taken to different manufacturing operation wherein it reduced the material handling. The IBC (intermediate bulk containers) system is preferably right to automation, This reduces the need for operator involvement in handling potent materials and decreases the exposure to potent materials. IBCs is a multipurpose equipment which has an added advantage of reducing operator exposure levels(OLEs) and it protects the product integrity. Filling discharging and movement is made easy and better by IBCs By the help of cone valve clamping devices, IBCs can be transported between pharmaceutical facilities[11].

CONCLUSION

In the challenging environment of the pharmaceutical, change is the only constant. IIoT is new to a pharma sector it

leads to the endless possibilities to make a process robust and audit compliant as it makes the process more transparent for the auditor and it has the ability to completely eliminate the concerns of data integrity if rightly implemented. since the data of the pharmaceutical manufacturing is more valuable it would be precise to take steps to avoid the company details and making it available in the world of internet wherein the data could be hacked or destructed by malware and viruses. So in order to protect the company data its important to have a closed environment, wherein the communication happens within the plant network and not with the outside world. Here the closed environment is nothing but to have a own cloud network which is dedicated to the company/organization which is more safe when compared to the shared servers and the open internet as such which is available IIoT can not only make the system robust but also makes the system more intelligent .it helps to manage the changes and the data provided by the automated system is so enormous analyzing the trend and taking the necessary steps to improve will be easier. Investment in the IIoT is huge but the returns are more of long-term and it reduces the cost in many ways in short IIoT is the solution for many existing problems. IIoT makes the manufacturing environment and process audit compliant.

ACKNOWLEDGEMENT

We sincerely thank Jagadguru Sri Shivarathreeshwara University and Dr.T.M.Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru for providing necessary infrastructure and moral support.

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