



Digital transformation of medical devices terminal sterilization by means of ethylene oxide

A new perspective of the future manufacturing process

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ABSTRACT

According to the World Economic Forum, “Digital transformation is generating a fierce debate among policymakers, economists and industry leaders about its societal impact. As digitalization disrupts society ever more profoundly, concern is growing about how it is affecting issues such as jobs, wages, inequality, health, resource efficiency and security” (1) The purpose of this article is to provide a perspective of the digital transformation of a manufacturing process, using as an example the terminal sterilization process of medical devices such as the syringes that will likely be used to vaccinate us from COVID-19.

This example reflects how industry 4.0 is integrated in the evolution towards the Society 5.0. This is a concept developed in Japan referring to the digitalization across all levels of the society.

Covid-19, the catalyst of the digital transformation of our society

Covid -19 has accelerated the digital transformation of our society at all levels. Among other examples, it could be highlighted, an article (2) published by Cathly Li and Farah Lalani a few months after the first lockdowns in China stated that more than 1.2 billion children were no longer in the classroom. A rise of e-learning emerged, whereby teaching is undertaken remotely and on digital platforms.

Another one could be the shortage of mask protection in many hospitals, which lead to collaboration between numerous 3D printing manufacturers to share their knowledge and resources to start manufacturing protective masks in a very short space of time. A project supported by LEITAT and HP (among other organizations in the Barcelona Area), resulted in the full manufacture of a new ventilator, LEITAT 1, which was fully functional in just over a week (3).

The agility of companies in Industry 4.0

Among the many definitions of Industry 4.0, I prefer the one that described it as the “current trend of automation and data exchange in manufacturing technologies, including cyber-physical systems, the Internet of things, cloud computing and cognitive computing and creating the smart factory” (4)

The Smart Factory is a concept for expressing the end goal of digitization in manufacturing. These industrial plants are a highly digitized shop floor that continuously collects and shares data through connected machines, devices, and production systems. (5)

The same authors states that agility is a strategic characteristic that is becoming increasingly

important for the success of companies. In this context agility denotes the ability to implement changes in the company in real time including fundamental systematic change to the company’s business model and production process flexibility to specific customer requirements.

Therefore, the significance of Industry 4.0 relies on the key role of information processing by enabling rapid organisational process adaptation.



From vaccine development to vaccination program through the syringe supply chain

Over the last year, many pharmaceutical companies have been using the most novel technologies such as Artificial Intelligence technology to develop drugs to treat various viruses, including COVID-19. Et voilà! Now, many manufacturers are producing their vaccines and struggling with their supply chain to delivery vials containing the valued drug on time. Recently, The Manufacturer and IBM confirmed that the current pandemic has accelerated the adoption of digital technologies in two-thirds of manufacturers. (6)

Nevertheless, according to several studies, digital maturity varies significantly by sector. The pharma industry was proved to be one of the lowest. So, now that many of us will be vaccinated (or

has been already vaccinated). What do we know about the complex manufacturing process behind a syringe? This article will not cover their manufacturing process. Instead, this article will review the terminal sterilization of a medical device process, syringes in this case, as one of the latest steps in the supply chain. Indeed, the process is under a (digital) transformation.

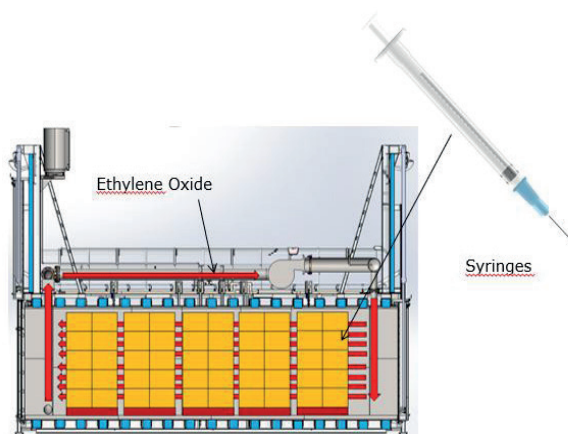
WHO defines as a medical device any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used for specific medical purpose.

One of the most common sterilization techniques for all these medical devices is the Ethylene oxide sterilization due to its high compatibility with most materials used in the manufacture of medical devices. (7)

The main benefit of this technology is that materials sterilized with ethylene oxide are not exposed to heat, moisture, or radiation. Therefore, a wide range of materials, particularly polymeric components commonly found in medical devices, can be sterilized with ethylene oxide. (8)

In addition, products can be sterilized in their final packaging as the ethylene oxide can permeate the sealed films and boxes used to package the device. This is due to the high diffusion coefficient of the gas.

In the following image the cross section of a sterilization chamber is presented. Inside the pallets can be identified and in red the recirculation of the gas throughout the chamber.



Currently, more than 50% of medical devices are being sterilized using ethylene oxide. Although this technology has been used for almost a century, and proved to be safe, in recent years,

citizens and governmental agencies have showed their concerns about EO emissions from sterilization facilities and the potential health effects on plant workers and nearby population. This preoccupation was shown during the 2020 Virtual Engineering Week, where the conference entitled "Ethylene Oxide Sterilization: An FDA & EPA Update" presented the foundations of future regulations, as well as strategies for reducing dependence on EO. (9)

Exploring into more detail of ethylene oxide sterilization, the main steps of the sterilization process are:

- Non-sterilized product warehouse
- Pre-conditioning
- Sterilization
- Aeration
- Sterilized product warehouse

Even though some installations are starting to introduce automatization systems, most of the industry is being manually operated, including manual loading systems. Another example are Bioindicators (BI) which are manually placed in the pallets to verify sterility of the process. Depending on the installation, during unloading operations, some operators must wear masks to protect themselves from the small concentration of ethylene oxide released by the pallets.

In addition, traceability of the pallets is done manually, and the reports are usually hand signed by the process owners.

The control system of each phase is independent with no connection to the MES system of the plant. Finally, repetitive preventive maintenance plans are pursued regardless of the real state of the installation.

Due to the increasing demand of medical devices around the world, medical device manufacturers and third-party sterilization services companies have been forced to increase their sterilization production capacity.

In addition, the highly competitive market is pushing these companies to modernize their facilities and to start digital transformation of their processes.

The OEE (Overall Equipment Effectiveness) is the metric for measuring manufacturing productivity, which is a key parameter in the current challenging environment. (10)

Overall Equipment Effectiveness	Recommended Six Big Losses	Traditional Six Big Losses
Availability Loss	Unplanned Stops	Equipment Failure
	Planned Stops	Setup and Adjustments
Performance Loss	Small Stops	Idling and Minor Stops
	Slow Cycles	Reduced Speed
Quality Loss	Production Rejects	Process Defects
	Startup Rejects	Reduced Yield
OEE	Fully Productive Time	Valuable Operating Time

OEE considers all losses. An OEE score of 100% means you are manufacturing only Good Parts, as fast as possible, with no Stop Time. (www.oeecom.com)

Digital transformation could be defined, according to ZMaxmedia, as the integration of digital technologies into all areas of a business, fundamentally changing how value is produced and delivered value to customers. Additionally, it is also a cultural change that requires organizations to continually challenge the status quo, experiment, and get comfortable with failure.

Companies such as Telstar, specialized in the design and construction of industrial scale Ethylene Oxide sterilization units gives advice and guidance to its clients in their digital transformation journey, providing best-in-class solutions to optimize the OEE of ethylene oxide sterilization plants.

Furthermore, in line with WhatIs.com, “digitization is the process of converting information into a digital (i.e., computer-readable) format. The result is the representation of an object, image, sound, document, or signal (usually an analog signal) by generating a series of numbers that describe a discrete set of points or samples”.

The other concept refers to something more complex such as transforming a complete process and the integration of the digitalized operations.

For example, the first case could be shifting from manual operations and approvals in the factory to digital signatures and the second one the transformation of the production plant. For this reason, the current trend is the digitization and automatization towards the smart factory.

Know yourself! The ancient Greek phrase is an invitation to think how our business is running. Thus, suppliers and end users in this industry need

to understand which is their level of digitalization and define together part of this transformational journey.

The national Academy of Science and Engineering in Germany published an interesting report about Industry 4.0 Maturity Index - Managing the Digital Transformation of companies. Briefly, the study proposes a six-stage maturity model that analyses the capabilities in the areas of resources, information systems, culture and organisational structure that are required by companies operating in a digitalised industrial environment.

Going back to our example, changes in the configuration of the plants as well as novel technologies are being used.

The independent phases of the sterilization process are replaced by complete sterilization lines going from preconditioning trough sterilization and finalizing to aeration cells.

As a result of this transformation, batches are moved from each phase by means of automatic loading systems and operators (which are no longer exposed to ethylene oxide. The manual sterilization verification using BI is replaced by novel parametric release programs, reducing required operation time, and boosting process efficiency. The pallets can be transferred by AGV from warehouse to sterilization plants enabling an end to end automatize process. The Scada System, which is connected to the MES system, provides a complete integration of the process into the rest of the plant.

Advanced companies in this sector, as in the case of Telstar have the capacity to support their client and guide them through the path of digitalization and to become a more efficient facility. To accomplish this mission, leading companies are using the most leading edge and novel tools including PLM/ALM software as the foundational technology for digitalization.

A digital thread increases flexibility and agility within an organization by equipping employees across the value chain with the right information at the right time. Digital threads can leverage a variety of technologies and connect data sets from CAD, product lifecycle management, industrial IOT (IIOT), ERP, CRM, MES, BOM and much more. (12)

A digital twin is a digital model that virtually

represents its physical counterparts. Notice that digital twins are not restricted to products but also for operation tasks. Digital twins are used to carry out simulation, allowing to improve performance, reducing mistakes, reducing plan shutdowns time and to avoid risks of dangerous physical operations.

In this context, equipment production companies shall include digitalization techniques all along their processes and machines, enabling digital transformation of their customers, who will get a better and deeper knowledge of their process and improve their behaviour. As an example of the commitment with this digitalization process, Telstar has developed a predictive maintenance program to improve performance, which will greatly benefit the company.

So, what is next? From Industry 4.0 to Society 5.0

As previously introduced, Society 5.0 is a concept developed in Japan that aims to tackle several challenges by going beyond just the digitalization of the economy and pursuing this process also at all levels of the Japanese society, enabling the digital transformation of society, which will be able to get all the benefits of this new era.

Nowadays, companies are becoming more and more committed with the smart society and strive to utilize innovative technologies such as the Internet of Things (IoT), Robotics, Artificial Intelligence (AI), and Big Data across all industries to achieve economic development and solve social & environmental problems. (13)

Digital transformation is not only about technology, but also about people implementing this technology. For that reason, these companies prioritize customer intimacy to define the most appropriate solutions.



Sterilization equipment at Telstar's facility in Terrassa

References

- 1.-Source: Digital Transformation - Reports - World Economic Forum (weforum.org)
- 2.- Source: The rise of online learning during the COVID-19 pandemic | World Economic Forum (weforum.org)
- 3.- Source: LEITAT 1 reaches ICU patients as an accredited field ventilator - Covid Leitlat (covid-leitlat.org)
- 4.- Source: Industry 4.0: fourth industrial revolution guide to Industrie 4.0 (i-scoop.eu)
- 5.-Source: What is a Smart Factory? (And what it means for you) | Tulip
- 6.-Source: Two in three manufacturers say COVID-19 has accelerated their digital transformation - The Manufacturer
- 7.- Source: Why use ethylene oxide (EO) for sterilizing medical devices? | Medical Design and Outsourcing
- 8.- Source: Ethylene Oxide (EtO) Sterilization Process & Services | STERIS AST (steris-ast.com)
- 9.- Source: Medical Device Makers See Progress in EO Sterilization (packagingdigest.com)
- 10.- Source: What Is OEE (Overall Equipment Effectiveness)? | OEE
- 12.- Source: PLM software as the foundational technology for digitalization - English (pro-file.com)
- 13.- Source: Smart Society White Paper | Azbil Corporation (former Yamatake Corporation)

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He has been working at Telstar for more than 8 years in sales and technical positions related to the pharmaceutical market.

About Telstar

Telstar, part of the azbil Group, is a company specialized in the development of engineering & construction projects, integrated process equipment and GMP consultancy solutions, including turnkey projects and critical installations, for companies associated with Life & Health Sciences (pharmaceutical & biotechnology, healthcare, cosmetic, veterinary and food & beverage industries, hospitals, laboratories & research centers). Acknowledged as one of the 10 major suppliers for the pharmaceutical industry, Telstar is one of the few international manufacturers able to offer integrated process solutions for the biopharmaceutical industry with in-house sterilization, freeze drying, containment, process water & waste treatment, clean air and cold storage technologies.

