SmartPro Vinnova Report WP2

Abstract

This report presents the findings of WP2 with respect to challenges and use-cases relevant to smart production and maintenance systems. WP2 gathers information and determines the challenges the industrial partners (Astra Zeneca and Ericsson) in Sweden and India have. These challenges have been translated into concrete problems and purposes, which finally describes a main project problem and purpose. WP2 also focuses on specific use cases where smart automation and information gathering can help relieve potential bottlenecks. An exhaustive study of technologies and challenges has also been included. It is the view of WP2 that smart production maintenance technologies should be bundled with other solutions to have an increased impact within factory production systems. At the current stage, production maintenance is a secondary aspect in both Astra Zeneca and Ericsson factories.

Contributors

- Aiyshwaryaa Z(Astra Zeneca)
- Mina Patel (Astra Zeneca)
- Divya Sachdeva (Ericsson)
- Ajay Kattepur(Ericsson)
- Anil Nair (Ericsson)
- Arvind Selvan (Uppsala University)
- Basim Al-Najjar (Linnaeus University)
- Mikael Jonsson (E-Maintenance)

Contents

1 Glossary of Abbreviations

AI	Artificial Intelligence
AR/VR	Augmented Reality Virtual Reality
CAPAs	Corrective actions and/or preventative actions
Capex/Opex	Capital/Operational Expenditures
ERP	Enterprise Resource Planning
GMP	Good Manufacturing Practices
IoT	Internet of Things
JIT	Just In Time (Production)
KSA’s	Knowledge, skills, and abilities
MES	Manufacturing Execution Systems
ML	Machine Learning
MSME	Micro, Small and Medium Enterprises
MRP	Materials Requirements Planning
RFID	Radio-frequency identification
ROI	Return on Investment
Smart-Pro	Smart Sustainable Integrated Production and Maintenance
OEE	Overall Equipment Effectiveness
OPT	Optimized Production Technology
PdM 4.0	Predictive Maintenance 4.0
TPM	Total Productive Maintenance
VDT	Voice recorded guidance
5G	5th Generation Cellular Communication Technology

2 Introduction

Failures, stoppages and unplanned maintenance activities have a considerable impact in production scheduling, supply chain continuity and on-time delivery (Krupitzer et al., 2020). It is necessary to thus integrate cutting edge technologies such as the Internet of Things (IoT), Edge/Cloud Computing, Artificial Intelligence and robotic automation techniques to improve production, monitoring and maintenance of such systems.

Smart-Pro aims to improve industry profitability and competitiveness by maintaining production continuity and production system quality, which can be achieved through reliable and condition-based production planning, optimization of production-maintenance economy, reduction of failures and unnecessary stops that usually lead to losses in energy, materials and production.

In our pre-study we will investigate the possibility of necessary technologies needed for integrating maintenance and production in a cost-effective way for automatic data acquisition to providing what-to-do report submitted to the end user. The pre-study aims to prepare the required underlying information needed to develop a reasonable proposal for a project within smart manufacturing in relation to the collaboration between Sweden and India.

2.1 Work Package Objectives

The major goal of the pre-study is to identify and prepare the required information knowledge, tools, modules, technologies across Indians partners for a project within Smart Manufacturing in the spirit of the collaboration between Sweden and India

- We aim to develop a conceptual model describing a smart sustainable integrated production-maintenance (Smart-Pro) system for, e.g. flexible and Just-in-time (JIT) production, for effective production planning, scheduling, follow up and decision making
- For supporting Smart-Pro system, it will also describe a Plug-and-Play solution for automatic detection-localizing of damages, severity estimation, predicting damage development, recommending what, where and when to act cost-effectively to maintain production process quality. A consortium from Swedish academia and industry (with couple of their Indians fabrics) is developed

2.2 Report Structure

Section 3 presents a brief survey of manufacturing processes, evolution of smart manufacturing. Section 4 provides and overview of the industrial partners who are part of this work package along with relationships to other companies. Section 5 provides a detailed overview of the use cases of interest for smart production maintenance. Challenges to be observed in production and maintenance systems are outlined in Section 6. Technologies of interest and integration within smart production and maintenance systems are explored in Section 7. This is followed by conclusions and outlook for WP3. The appendix provides a set of interview questions used in our interactions with stakeholders.

3 Background (State-of-the art)

This section reviews some background literature on manufacturing processes, smart factory evolution, and predictive maintenance techniques.

3.1 Classification of Manufacturing Setups

As we deal with different manufacturing verticals such as pharmaceuticals, telecommunications, semiconductor, consumer goods and large hardware, a systematic technique to classify and contrast various manufacturing setups.

3.1.1 Manufacturing Setup

Here are a few manufacturing setups dependent on the types of products, manufacturing flexibility, worker skillset and scale (Mahmoud, 2015).

Project manufacture: The defining feature of project manufacture is the type of layout employed. There is a very low production rate, that is, not many units produced. The layout is known as a *fixed position layout*. In the fixed position layout, the product remains at the same location(i.e., a fixed position), usually due to the size/weight of the product. The workers and all tools and equipment are then brought to the product to carry out work. It should be noted that component parts, sub-assemblies and assemblies might be manufactured elsewhere and then brought to the product location. The workers are usually highly skilled and material handling is high. It is also common for products manufactured using this layout to be one-of-a-kind, for example, ships, aircraft, space vehicles, bridges, buildings.

Jobbing shop manufacture: The jobbing shop's distinguishing feature is the production of a wide variety of products. Manufacture is very often specific to customer order and specification. This usually means very small lot sizes and very often the production of one of kind. However, some job shops manufacture to fill finished goods inventories. As a wide variety of products are produced, a wide variety of manufacturing processes is required. Typical products of job shops are special purpose machine tools, fabricated sub-assemblies and components for the aerospace industry. Within job shops, production equipment is usually general purpose and generally arranged according to the general type of manufacturing process. For example, the lathes are in one department, milling machines in another and drill presses in still another and so forth. This is known as a *process- focused layout* and allows the job shop to make such a wide variety of products.

Batch manufacture: The main feature of batch manufacture is the production of medium size lots of a product in either single runs or repeated runs at given times. The lot size range is approximately 5–1000 and even possibly more. Again, as the product variety can be high, the number of processes required is high and therefore the equipment is general purpose. Similar to job shop manufacture, the workforce must be skilled and flexible to cope with the high product variety. The process-focused organization of the job shop is also equally applicable for batch production.

Flow/mass manufacture: The main characteristic of flow line manufacture is the high volume of products produced. It is usually referred to as mass manufacture due to the very large quantities of products manufactured. It is also common for mass manufacture systems to have high production rates. Regarding the process equipment, this tends to be of a specialized nature, with processes being dedicated to a particular product. Products flow through a sequence of operations by material-handling devices such as conveyors and other transfer devices. They move through the operations one at a time with the time at each process fixed.

Cellular manufacturing: A cellular manufacturing system is usually composed of a number of linked cells. The cells themselves are usually composed of a number of grouped processes. These are normally grouped according to the sequence and operations needed to make a particular component part, sub-assembly or product. The arrangement within the cell is much like that of a flow system, but it is more flexible. To implement a cellular manufacturing system, the current system must be converted into stages. This will entail taking parts of the current system and converting it into cells. The cells should be designed in such a way as to allow the manufacture of specific groups or families of parts, that is, parts that have similar geometrical features and require the same manufacturing processes to make. Cells are generally linked directly to each other or to assembly points. Finally, the cells can be linked in such a way as to allow synchronous operation with sub-assembly and final assembly lines.

Continuous/process manufacture: Continuous/process manufacture involves the continuous production of a product and often uses chemical as well as physical and/or mechanical means, for example, sugar production, fertilizer production, etc. The main characteristic of continuous manufacture sometimes referred to as process manufacture is that the equipment is in operation 24h a day for weeks or even months without a halt. However, this rarely happens due to equipment breakdown and/or planned maintenance. There is no discrete product manufactured. Instead, the product being made is manufactured in bulk and output is likely to be measured in physical volume or weight. The process equipment will be highly specialized, probably automated, and thus very expensive and will be organized in a product-focused arrangement. However, the workforce is likely to vary in skill level depending on their role, i.e., semi-skilled plant operators and skilled maintenance technicians.

3.1.2 Production Operations Management

In tandem with various types of production systems, there has been considerable work in classifying the production planning, scheduling and operations systems for optimal manufacturing/production deployment. There have been multiple techniques to optimize production systems (S. Aggarwal, 1985):

- **Materials Requirements Planning (MRP)** - MRP allows for an extraordinary degree of advance planning for medium-inventory, mass- production companies but at a cost in flexibility and informality. MRP makes available purchased and company- manufactured components and subassemblies just before they are needed by the next stage of production or for dispatch. This system enables managers to track orders through the entire manufacturing process and helps purchasing and production control departments to move the right number of materials at the right time to production-distribution stages. MRP assumes uneven demand, attempts to achieve zero stockouts, and concentrates on setting priorities. It requires that a precise demand forecast for each product is available and that each and every product or subassembly’s bill of materials is accurate. MRP requires that every employee—whether operator, analyst, quality inspector, salesman, purchasing agent, or planner—be thoroughly and strictly disciplined about feeding updates into the system. Without such adherence, the MRP system memory starts accumulating errors with regard to stock on hand, quantities needed, and when items are needed for specific parts or assemblies. MRP requires tremendous amounts of data inputs and is complex.

- **Enterprise Resource Planning (ERP)**: This is an extension of MRP with the following characteristics:
  - Integrated systems that cover the firm's entire value by transition from an internal view of the firm to business network vision.

  - "Electronic commerce" by developing "HTML" interfaces for the internet/internet and supporting complete commercial transactions.
  - Applications with an object-oriented structure by transition from a highly integrated structure to modules with a higher complementarity and "plug and play" facilities.

- **Just In Time (Kanban)** – Kanban keeps inventory costs down and involves employees but requires well-structured supply lines and cooperative workers. Kanban's core objective is to obtain low-cost, high-quality, on-time production. The system attempts to eliminate stock between the successive processes and minimize any idle equipment, facilities, or workers to achieve this. Kanban assumes that the production rate at the final assembly line is even. Revisions in the monthly master production schedule needed to meet market condition changes must be small. It cannot tolerate load fluctuations of more than ±10%, and it starts breaking down under larger deviations from average conditions. It also requires that the daily schedule for each part or assembly remain nearly the same every day. Each kanban worker has the right to stop the assembly line when he or she is falling behind or discovers a defective part or subassembly. The approach also assumes that employees will help other people when they fall behind and that each person is capable of doing different types of jobs. The kanban move ticket replaces the job orders and routing sheets of the past. It emphasizes small lot sizes. The system requires short lead times, which translate into small inventories at every stage. Because a chain of move tickets connects all stages from suppliers to retailers, companies never need additional paperwork for planning and control.

- **Optimized Production Technology (OPT)** – Optimized production technology focuses on clearing up bottlenecks in the manufacturing process but can adversely affect non bottleneck areas and is a proprietary system. The OPT system calculates the near-optimum schedule and sequence of operations for all a manufacturing company's work centers, taking into account priorities and capacities. Advocates claim it can simultaneously maximize the use of critical resources and the plant output and minimize work-in-process inventories and manufacturing lead times or throughput times. This approach determines priorities for each operation using a weighted function of a number of important criteria, like advantageous product mix, due dates, necessary safety stocks, and use of bottleneck machines. However, OPT requires detailed information about inventory levels, product structures, routings, and setup and operation timings for each and every procedure of each product. The developers claim that only the bottleneck stages need to be planned in detail; the other phases can be planned in very general terms. They also assert that the system takes into account scores of factors that control production efficiency, plant capacity, work in progress, setup times, substitutions, overlapping among process batches, subcontracts, and safety stocks.

- **Flexible manufacturing systems** offer the hope of eliminating many of the weaknesses of the other three approaches but possible at a cost of cutting out many jobs. The systems integrate such functions as loading, unloading, storing parts, changing tools automatically, machining, and the data processing activities of the manufacturing processes into coordinated production centers. Basically, these systems can be viewed as small- or medium-size, totally automated production lines. The FMSs are designed to provide much diversification of parts or assemblies in batches. They are supposed to obtain greater productivity from machines. Production utilization of most general purpose machines is between 6% and 30%; these systems are expected to enhance machinery utilization to an 80% or even a 90% level. Once managers have selected their performance criteria and defined limitations and work rules for their FMS installations, the computerized integrated-control systems take over and can prioritize and schedule individual orders (production batches) in a near-optimum manner. Thus FMS integrated-control systems not only regulate the times when machines operate but also the flow of parts. An FMS, therefore, does not need any of the other operations planning and control systems discussed in this article; it has planning and control built into its machinery controls themselves.

3.2 Smart Manufacturing Evolution

NIST (https://www.nist.gov/smart-manufacturing) defines smart manufacturing systems as "fully-integrated, collaborative manufacturing systems that respond in real time to meet changing demands and conditions in the factory, in the supply network, and customer needs." Current manual processes, lack of connectivity and absence of end-to-end view of the factory floor make it prone to defects, failures and downtimes. There is heavy reliance on manual data crunching, monitoring and provisioning to take care of failures.

Several studies (IBM, 2020) (Capgemini Research Institute, 2019) have proposed the evolution of standard factories to "smart factories":

1. **Standard Factories:** Make use of historical statistics to monitor and Manufacturing Execution Systems (MES), which track and monitor current data about the production lifecycle and operations. Lean manufacturing and end-to-end view of the supply chain are still in infancy. Adaptive production and short lead time manufacturing are difficult.
2. **Automated factory:** Here software and hardware robots make use of real-time analytics to improve end-to-end systems. Here, there are predictive failures and outages monitored. However, the optimization has still been within a small cell or set of robots. Hierarchies of optimization and cobots are still to be integrated.
3. **Smart factory:** Digital twins, edge-cloud computation models, 5g connectivity, AI assisted production are parts of future smart factories. Self-directing, self-learning and self-healing

systems within the factory. Final vision of Industry 4.0. The ability to be modular and flexibly reconfigure is needed and is missing from current factory deployments.

The advantages and components of a smart manufacturing ecosystem are (IBM, 2020)(Capgemini Research Institute, 2019):

- **Smart Production:** Manufacturing systems augmented with cognitive intelligence can take over more and more production jobs. Connected and self-organizing manufacturing systems will tackle new manufacturing tasks with high efficiency and flexibility.
- **Smart Production Network:** Connected cyber-physical production systems will form a global production network that can respond in almost real-time to dynamic changes in local production systems and external supply chain. A production network of adaptive and self-optimizing production systems can enable autonomous configuration and planning of production activities for production jobs at changing scales to achieve sound economic, environmental and social impacts.
- **Mass Personalization:** Production model will move from a push- type mass production model to pull-type mass personalization. Smart factories that are fully responsive to changes and demands from the factory, supply chain, and customer side can achieve batch- size-of-1 production with high efficiency and flexibility.
- **Reconfiguration:** The ubiquitous manufacturing intelligence in distributed factories and production systems can sense, configure and collaborate by themselves based on near real-time production status and demands, which therefore provides the required agility for producing highly personalized products.

In tandem with this evolution is the development of Industry 4.0 (Bocella et al, 2020) (Y, Yin 2018). Industry 4.0 led by 4 disruptors: the astonishing rise in data volumes, computational power and improvements in transferring digital instructions to the physical world, such as advanced robotics and 3-D printing. There is also a need for **decentralized control** and **modular production systems**. The requirements of Industry 4.0 smart factories has been provided with the following principles (Mabkhot, 2018):

1. Modularity: System components are modular, flexible and can be composed using plug and play principles. Modules may be provided by multiple vendors. The basic component of the smart factory is known as a module, which is an autonomous machine tool, workstation or material handling device that can perform a set of tasks. This also provides the ability to scale up/out with demand.
2. Interoperability: This refers to both the ability to share technical information within system components, including products and to the ability to share business information between manufacturing enterprises and customers. Semantic representations, common data formats and flexible controllers needed in this space.

3. Decentralization: Units or cells can work in autonomous modes. Through machine to machine communication and data exchange, self-configuration and learning may be enabled.
4. Virtualization: Virtual representation of the factory floor components that may be interacted via Augmented Reality Virtual Reality AR/VR. This forms the basis of digital twins.
5. Service orientation: Core processes are managed in house with additional services (third-party) composed on the fly.
6. Real-time requirement: Ability of the system to identify and react to defects, mis-configurations or faults in real time.
7. Workforce: As the components of the factory are constantly interacting and learning, the role of the human participants is to monitor the learning rates, rectify inaccurate assumptions and improve automation processes.
8. Closed Loop: The main characteristic of a smart factory is “closed-loop,” data-driven optimization of end-to-end operations. Advanced analytics are first used for decision support, but the ultimate goal is to reach “self-optimizing operations” where the factory constantly adapts to demand, variations in supply and process deviations.

Proposing the integration of many of these technologies into smart production system challenges forms the core of this work packages.

3.3 Predictive Maintenance Framework

Predictive maintenance (Krupitzer, 2020) is based on the idea that certain characteristics of machinery can be monitored and the gathered date be used to derive an estimation about the remaining useful life of the equipment. Hence, this kind of maintenance policy implicates several important improvements in the manufacturing and maintenance process which can severely reduce production costs. First, predictive maintenance can reduce the number of unnecessary maintenance activities as it is not based on periodic maintenance intervals bound to average life-time. Thus, potentially reducing the overall number of maintenance activities over a machine’s life. Second, too early maintenance activities can be avoided and too late activities as equipment might fail before the next periodic maintenance interval since the intervals rely on average lifetime, which likely includes significant positive and negative deviations from the mean.

This approach is based on condition monitoring ideally conducted by sensors, which allows a continuous monitoring process of relevant machine parameters such as vibration and temperature. However, condition monitoring in isolation cannot be considered predictive as it only allows to identify the parameter changes that occur before a failure, but it does not allow to predict a relatively narrow future period of time in which the parameter changes happen and thus the failure might occur. Consequently, a reliable prognostic technique is necessary to transform the acquired data into valuable information for failure prediction.

Typically, there are the following types of maintenance activities followed:

1. **Corrective maintenance** always takes place after a failure occurred. Afterwards, the repairing of the machine can be done immediately or at some later point. A production plant that uses this approach is following a *run-to-failure* management based on the philosophy
2. **Preventive maintenance** policies, also called proactive maintenance, are attempted to be executed before a fatal failure occurs.
    a. preventive maintenance where the maintenance activities are conducted on pre-scheduled intervals based on historic average equipment lifetime
    b. condition-based maintenance monitors the current condition of a machine and schedules maintenance activities based on the observations made
3. **Predictive maintenance strategy** which is carried out in isolation of other relevant processes still has potential for optimization. Hence, the efficiency can be severely improved by connecting multiple machines across manufacturing locations of a production facility and monitoring them remotely with wireless sensors. A web application and cloud-based monitoring infrastructure allows to synchronize the process of maintenance with the overall operation even across production facilities.

Predictive Maintenance 4.0 (PWC, 2017) is about predicting future failures in assets and ultimately prescribing the most effective preventive measure by applying advanced analytic techniques on big data about technical condition, usage, environment, maintenance history, similar equipment elsewhere and in fact anything that may correlate with the performance of an asset.

PdM Maturity Stage

Capability	1. Visual Inspections	2. Instument Inspections	3. Real Time Conditions Monitoring	4. PdM4.0
Processes	- periodic inspection (physical) - checklist - paper recording	- periodic inspection (physical) - instruments - digital recording	- continouos inspection (remote) - sensors - digital recording	- continuous inspection (remote) - sensors and other data - digital recording
Content	- paper based condition data - multiple inspection points	- digital condition data - single inspection points	- digital condition data - multiple inspection points	- digital condition data - multiple inspection points - digital environment data - digital maintenance history
Performance Measurement	- visual norm verification - paper based trend analyses - prediction by expert opinion	- automatic norm verification - digital trend analyses - prediction by expert opinion	- automatic norm verification - digital trend analyses - monitoring by CM software	- automatic norm verification - digital trend analyses - prediction by statistical software - advanced decision support
IT	- MS Excel/MS Access	- embedded instrument software	- condition monitoring software - condition database	- condition monitoring software - big data platform - wifi network - statistical software
Organisation	- experienced craftsmen	- trained inspectors	- reliability engineers	- reliability engineers - data scientists

Figure 1: Predictive Maintenance 4.0 (PWC 2017)

As seen in Figure 1, there are multiple levels of maintenance that are followed in factories:

- Level 1 Visual inspections: periodic physical inspections; conclusions are based solely on inspector’s expertise.
- Level 2 Instrument inspections: periodic inspections; conclusions are based on a combination of inspector’s expertise and instrument read-outs.
- Level 3 Real-time condition monitoring: continuous real-time monitoring of assets, with alerts given based on pre-established rules or critical levels.
- Level 4 PdM 4.0: continuous real-time monitoring of assets, with alerts sent based on predictive techniques, such as regression analysis.

The requirements and objectives of predictive maintenance systems are:

- **Goals**: the predictive maintenance system would reduce the number of spare parts in stock and the overall storage size while still maintaining a proper maintenance process and avoiding production downtime due to unavailable spare parts. Predictive maintenance can in fact prolong the overall life of machines and components. This is because the predictive maintenance system monitors the health condition and predicts the remaining useful life of a machine and thus reduces the risk of a fatal breakdown which might reduce the lifespan of the machine. As a reliable predictive maintenance system leads to an overall more efficient way of the maintenance process this results in an overall reduction of costs.

- **Monitoring:** Since advancements in sensor technology make sensors for various types of parameters more affordable, the majority of studies base their research on sensor-based monitoring. With sensor-based monitoring different types of sensors for instance to observe vibration and temperature are used to collect the relevant data. Online/real monitoring is a condition monitoring technique which allows the collection of data in the running state of a machine (Potentially done with digital twins, to be presented later).
- **Degradation models:** Multiple types of component degradation models may be using such as Exponential Degradation Assumption, Random Failure Assumption or Linear Degradation Assumption. These differing schemes would predict the most likely time of failure.
- **Component types:** Single-component systems are defined by the present survey as either single components, e.g. experimental studies which conduct laboratory tests with merely single bearings, or single machines considered solely in an isolated context. Multi-component system consists of multiple machines or separate components which together form or are part of larger system, e.g. an entire manufacturing line. The implementation of a successful predictive maintenance system is much more complicated for these multi-component systems since more data needs to be processed and dependencies between the system's components become relevant. stochastic dependencies are dependencies in consequence of stochastic relations between components of their deterioration process. Hence, the degradation of one component affects the state of one or multiple other components of the system.
- **Prognostics:** The category of prognostic techniques is clearly one of the most important ones for predictive maintenance. While all the monitoring and data acquisition is indispensable the prognostic technique is what transforms the raw data into valuable information. Note that since a prognostic technique attempts to predict a prospective failure of a machine or component the generated information are just probabilities. Model based or data driven approaches used. Generally, a data-driven prognostic technique is based on a large amount of available historic monitoring data while a model-based technique is applied for new or untested systems which lack this comprehensive measurement data.

4 Industrial partners

4.1 Astra Zeneca and associated factories

AstraZeneca is a British-Swedish multinational pharmaceutical and biotechnology company with headquarters in Cambridge, England.

AstraZeneca India was established in 1979 and is headquartered at Bengaluru, Karnataka. AstraZeneca Pharma India Limited (AZPIL) is the operating company and covers manufacturing, sales and marketing activities of the company in India. The company has an innovative portfolio in crucial areas of healthcare including cardiovascular, renal & metabolic diseases, oncology and respiratory.

AstraZeneca's Indian manufacturing facility has a sophisticated production facility designed to meet the most stringent international standards, conforming to WHO cGMP (current Good Manufacturing Practices) norms. The facility is an ISO 14001 certified company and has a full-fledged environment management system in place.

For the purposes of this study, the manufacturing facilities at Sweden and India were considered. Manufacturing and IT Systems/process owners were interviewed during this study. The manufacturing sites in Sweden and India were considered.

4.2 Ericsson's internal and external factories

Ericsson is a Swedish multinational networking and telecommunications company headquartered in Stockholm. The company offers services, software and infrastructure in information and communications technology for telecommunications operators, traditional telecommunications and networking equipment, mobile and fixed broadband, operations and business support services, cable television, video systems, and an extensive services operation.

Ericsson India Private Ltd. operates as a manufacturer of telecommunication equipment. The Company provides wire telephone, cell telephone, and telegraph equipment. Ericsson India also offers digital, networks, managed services, and IT solutions. Ericsson India serves customers worldwide.

Ericsson Supply Hub Pune is part of the Global supply hubs of Ericsson. Ericsson Supply Centre is a Customer Specific Solution and it is implemented to further improve assembly of hardware and software based on customer needs. In addition, this study considered smart factories of thirty party providers for which Ericsson is a communication infrastructure partner. Interviews were conducted with factory supply chain owners and automation specialists.

4.3 Identification of additional Indian partners

We attended a workshop on introducing digitization within Micro, Small and Medium Enterprises (MSME) by the Government of India (https://msme.gov.in/information-technology-leading-path-indian-msmes-march-champions). The definitions are given in Figure 2.

What's MSME

Revised Classification applicable w.e.f 1st July 2020			
Composite Criteria: Investment in Plant & Machinery/equipment and Annual Turnover			
Classification	Micro	Small	Medium
Manufacturing Enterprises and Enterprises rendering Services	Investment in Plant and Machinery or Equipment: Not more than Rs.1 crore and Annual Turnover ; not more than Rs. 5 crore	Investment in Plant and Machinery or Equipment: Not more than Rs.10 crore and Annual Turnover ; not more than Rs. 50 crore	Investment in Plant and Machinery or Equipment: Not more than Rs.50 crore and Annual Turnover ; not more than Rs. 250 crore

Figure 2: Micro, Small, Medium Enterprises

In the forum, multiple challenges for introducing of digital and smart technologies within MSME's were identified:

- Local industries must support MSME. Difficulties in investing in futuristic digital technologies.
- Larger companies should partner / help smaller companies to implement technologies
- Lean manufacturing and digitisation yet to proliferate within MSME
- Need better interactions / government led platforms to educate and cooperate changes in MSME plants.
- Better resource efficiency and reduction of failures needed within MSME
- Better skill development to understand standards, digital products and forecasting techniques.
- Better digital thread to link all MSMEs and increase visibility
- Where manpower is available, robots are not needed !
- MSMEs prone to takeover by larger ecosystem players

In addition, multiple small start-ups presented some cutting edge work that are of relevance to smart manufacturing. While these are not direct partners of either AZ or Ericsson, capabilities demonstrated by these startups can be expected in other technology partners of SmartPro.

- **Greenie (smart energy management)** - IoT based power management. Using single hardware, identify “electrical fingerprint” to determine when a particular device is working. Plug and play with web/mobile connectivity. Load, tariffs and optimisation may be done on each sub-system. Monthly and seasonal consumption patterns. Can help budget for power.
- **NU Verse (worker’s health and safety)** - Covid contactless sanitiser, temperature monitors for employees. Android based health monitor using android application.
- **Syook** - Digital Twin/Map of the facility with IoT. Monitors assets, employees, contractors, vendors and workers. Can trigger real time changes on a map. Constraints on the map can be provided. Machine maintenance, regulatory forms and safety protocols can be generated. Optimising throughput, processes and turnaround time.
- **Melzo** - AR/VR platform. Easy integration of AR/VR view within web. Can be used for training as there is realistic use. People can use the view for end-to-end view of the factory floor and products.
- **Saven** - Energy efficiency in Capex/Opex. Ai and IoT solutions.

Good startups within India providing cutting-edge solutions to global players. However, MSMEs have not adapted these solutions / are not open to spending onto future digital technologies.

In addition we interview multiple small factories and vendors of Astra Zeneca and Ericsson to identify challenges from an Indian context.

5 Production and Maintenance Use Cases

5.1 Identification and brief description of the production and maintenance systems that are considered

In this section, we provide specific use cases where increased digitization and smart production systems can improve processes. The section is divided into use cases identified by AZ and Ericsson. Further emphasis is provided on Sweden/India specific problems and challenges in case of human activity in the factories/warehouses.

5.1.1 Astra Zeneca

Identify challenges on "**Packing lines**" – TPM, Lean methodology. This section describes challenges in Astra Zeneca's packing assembly line and the improvements that may be provided by smart production, process and maintenance integration.

Total Productive Maintenance (TPM) is a holistic approach to equipment maintenance that strives to achieve perfect production: No Breakdowns. Figure 3 provides a high level overview of the problems faced in packing lines. This is translated int specific challenges/requirements needed by the SmartPro system. The enablers considered in Figure 3 are workforce, technology and process improvements.

- People: Challenges and improvements to be made in the manpower
- Process: Changes in the supply chain processes envisioned
- Technology: Integration and impact of cutting edge technologies
- Regulatory: Requirements for specific industries emitting from geographies

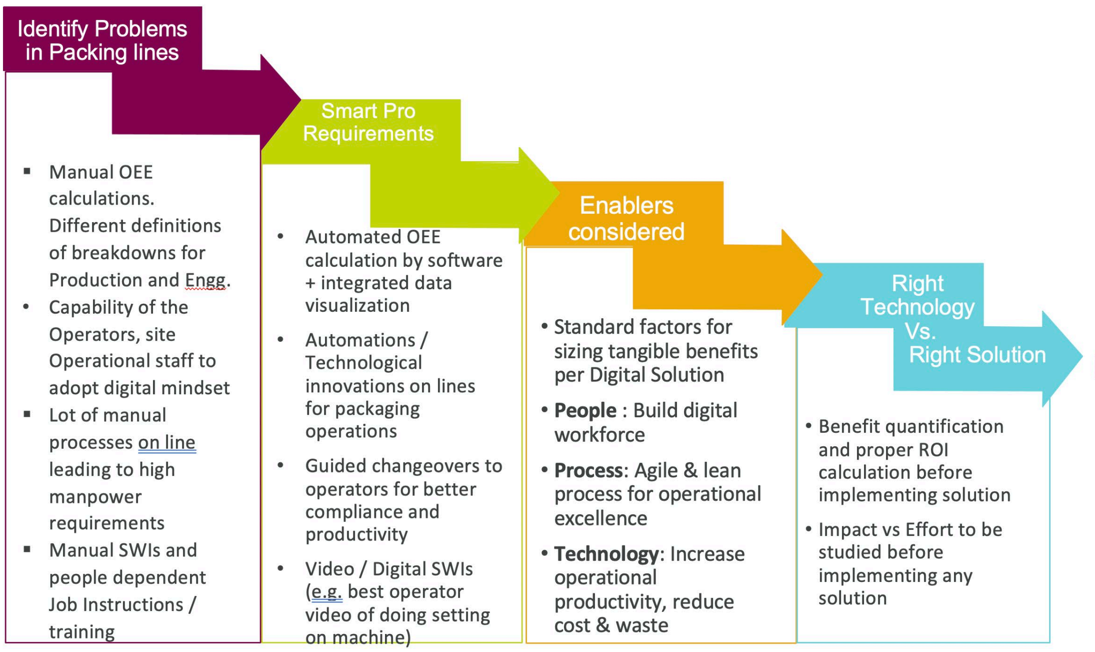

Figure 3: Challenges in Astra Zeneca Packing Lines

This system is a Batch Manufacturing Operation that makes use of Enterprise Resource Planning for Manufacturing Optimization.

Deep dive "Packing Line" Process Uplift - AZ(India)

This is an indepth view of the solutions for process line uplift which will ensure "zero defect" production. Figure 4 presents the potential changes needed in people, process, technology and compliance to ensure zero defect packing line operations. Multiple challenges and technologies are to be addressed within this process.

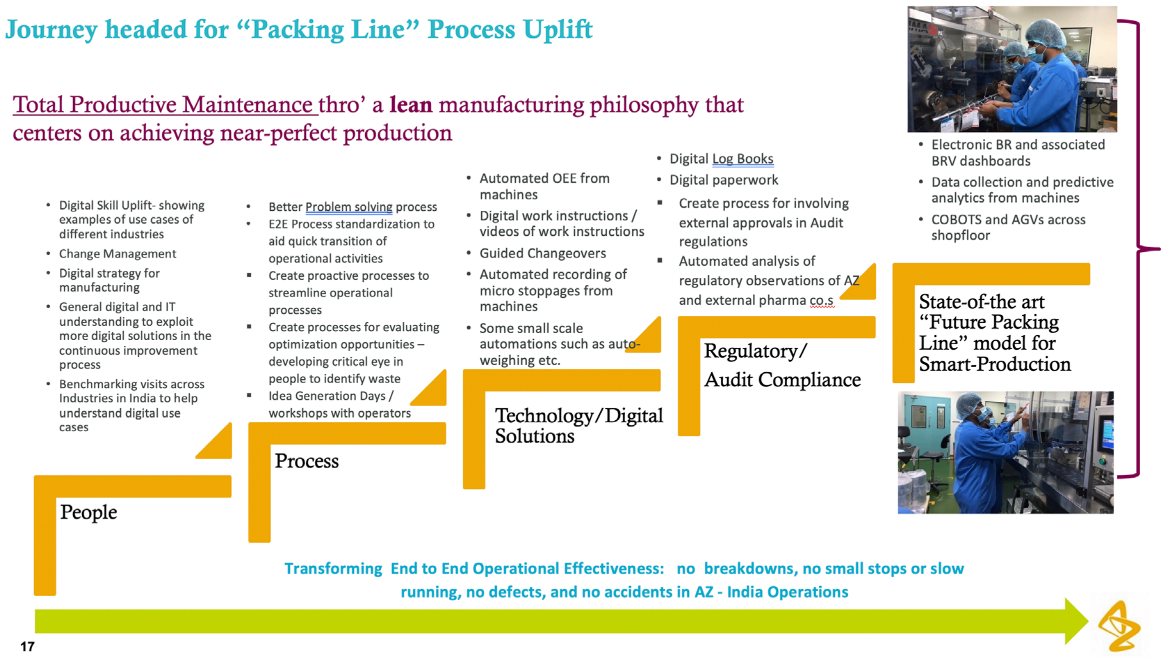

Figure 4: Packing Line Process Uplift

A Look at Reducing Human Error on the AstraZeneca Manufacturing Floor

Figure 5: Human Participants in a Factory

As technology advances, human error in manufacturing becomes more and more visible every day. Human error is responsible for more than 80 percent of process deviations in the pharmaceutical and related manufacturing environments this is taken very seriously. In AstraZeneca, we follow Good Manufacturing Practices (GMP), where we address human error deviations not only because they are an inconvenience, but also do it because we have the highest Compliance & Regulatory standards (Figure 5).

We have payed significant attention to this subject & have undergone many "**Batch Doc Simplifications"** to reduce human errors. As part of our **Quality control unit** that shall have the **responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labelling, and drug products, and the authority to review production records** to assure that **no errors have occurred or, if errors have occurred, that they have been fully investigated**."

Now, let's look specifically at this section of the sentence: "…if errors have occurred, that they have been thoroughly investigated." It's important to note human error is NOT a root cause because it may be the reason for the error, but it doesn't fully explain why the error occurred.

As per the Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, we follow a Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensures that: **An appropriate level of root cause analysis is applied** during the investigation of deviations, suspected product defects, and other problems. Then it continues "Where **human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked, if present.** Appropriate corrective actions and/or preventative actions (CAPAs) are identified and taken in response to investigations. The effectiveness of such actions are monitored and assessed, in line with Quality Risk Management principles.

When we investigate quality events, the focus is on explaining what happened in the process and how the product was affected. A human error usually explains the reason for the occurrence of the deviation; nevertheless, the reason for that error remains unexplained, and consequently, the CAPAs fail to address the underlying conditions for that failure. This, in turn, translates into ineffective action plans that result in non-value-added activities, wasting resources and eventually resulting in recurrences and repeated events.

Human error is about explaining human behavior. Chemical engineers explain product behaviour, mechanical engineers explain equipment behavior, industrial engineers explain process behavior, but who explains human behavior?

Human behavior is complex, and just like equipment, product, and process, it needs to be analysed in depth. We would never end an investigation with only “equipment failure.” We would explain exactly what the equipment failure was so it could be fixed.

To assure effective CAPA’s, human error events need to be fully investigated. Regulations require that errors be fully investigated, meaning that you identify the reasons why they occurred. In order to comply with this expectation, we need to understand how human behavior is affected by external variables as well as internal variables.

First, we understand what a human error is. Human error is defined in many ways. One definition that I like is “any action, performed by a person, which exceeds a system’s tolerance.” Human error is an error and not an intentional act for harm. Sabotage is not considered a human error unless the result of the actual intentions is different than was expected. So stating that a human error has occurred does not necessarily mean that it is the “human’s” fault.

We, as humans, do not operate in a vacuum. Behaviours are influenced by external as well as internal variables. In manufacturing environments, these variables can be divided into six major categories: **procedures, human factors, training, supervision, communication, and the individual itself.**

Individuals are undoubtedly responsible for their actions. But before we determine that internal factors like attitude or attention are accountable for the mistake, we as organizations are responsible for eliminating the possibilities of external factors influencing human behavior. Individual performance in manufacturing is proven to be responsible for less than 5%of deviations. For example, if an employee overlooks defects because of a lack of appropriate vision, shouldn’t the organization make sure visual exams are performed regularly? Even in this example, we can see that a “fit for duty” system is weak.

On the other hand, training is usually used as a corrective action. Although training has proven to be effective for transferring knowledge, skills, and abilities (KSA’s), it will only work for new employees, new processes, or to instruct on changes to existing processes if the employees who perform the task lack the new KSA's.

The most effective way to control human error is to implement adequate systems. Systems take care of human factors (any aspect of the workplace or job implementation that makes it more likely for the worker to make an error) and external factors. We can start by:

1. Providing clear, accurate procedures, instructions, and other job aids.
2. Implementing good human factors engineering for control systems, processes, equipment, and work environments.
3. Provide relevant training and practice.
4. Provide appropriate supervision.
5. Assure good communications.
6. Make sure the personnel have all the capabilities needed to succeed in the assigned task.

The Process

Understand the difference between explaining an event and explaining a human error. Once the human error has been identified as a cause for the deviation, consider the human error itself as a new event that needs to be explained to assure conditions are identified and fixed.

Past behavior predicts future behavior if changes are not made. We need to perform an assessment of past events and assure the reasons for the error, besides the reasons for the event, are identified. Then we need to categorize these causes (conditions for error) in a systematic/uniform way. This allows you to analyze significant contributors and, based on priorities, create an action plan that addresses these conditions. For example, if most of your human error events were related to incomplete procedures, then revising them and adding the missing instructions would be an action to consider.

Human error will not be eradicated unless we are able to really identify what is causing humans to err. If eliminating or "fixing" the actual individual eliminates or potentially reduces the probabilities of making that mistake again, then addressing the employee would be effective. If we challenge ourselves, we can't categorically assure that this will correct the problem; intervening with the individual will only create a liability to the organization, and we will end up in the same place we were at the beginning, trying to correct another individual's same mistake.

What do follow?

- A structured human error investigation process.

- Consistent terminology (root causes).
- Tracking/trending/monitoring system.
- Effectiveness based on root cause recurrence.

CAPA's will be effective when we can eliminate conditions (causes) that make people deviate from the expected outcome. Therefore, CAPA effectiveness is measured by root cause recurrence and event recurrence. Most events, although different in nature, share the same causes. Real CAPA effectiveness will be achieved when the number of deviations decreases. Not when particular events fail to reoccur.

This way, we are more productive and fairer ensuring we stay compliant & meet our Quality standards at all times.

5.1.2 Ericsson

The first use case considered is from Ericsson's assembly hub, wherein multiple components manufactured from various vendors are procured, stored, assembled, packed and shipped.

These specific problems were identified after interviewing multiple key factory stakeholders from India and Sweden. The discussions involved multiple types of questions revolving around current production systems, technologies, manpower, business directions and ecosystems. A complete set of questions is provided in **Appendix 1.**

Process- Warehouse Assembly Line Operations

The current problem in the Ericsson supply hub involves variation in demand and increased manual operations that can lead to failures / errors in the process. We provide an outlook from the people, process, technology and regulatory perspective. There needs to be better training and integration of autonomous robotic machinery from. Similarly, process improvements can involve automating certain processes, end-to-end view of the system and integration of superior scheduling systems. This involves the use of multiple technologies such as robotics, IoT, AI, 5G communication and digital twins. An example of such a factory is shown in Figure 6.

This is a job shop manufacturing system that makes use of Kanban Management systems.

Compared to the Indian hub, the Sweden hub also has similar automation challenges with increased automation with lower number of workforce.

Monitoring human workforce: Currently, human workers interacting with warehouse management and robotic automation systems are provided with portable devices such as ipads to push jobs and record completion rates. There has been effort to integrate wearable health monitors. However, privacy concerns are surrounding these systems. In future, the sensors on board the ipads should reduce manual data entry and automatically record work completion times, order processing and potential failures.

Figure 6: Automated Factory Operation.

We present the following overview of challenges / improvements in Table 1:

- People: Challenges and improvements to be made in the manpower
- Process: Changes in the supply chain processes envisioned
- Technology: Integration and impact of cutting edge technologies
- Regulatory: Requirements for specific industries emitting from geographies

Table 1 specifies the current challenges in manual operations in warehouse operations that can cause delays or errors in operations. Strategies towards improved processes, technologies and possible business use cases are provided in Table 1.

Table 1: Warehouse Assembly Line Use Case Requirements.

Problems	People	Process	Technology	Business Specific
• Manual operations in picking and moving of equipment in warehouse • Prone to manual errors and variations in demand/supply of drivers operating forklifts • Loose coupling of warehouse management systems with supply chain • No real-time visibility of the shop floor • Manual entries	• Use of manual operations can induce faults in processes. Require better automation features. • Require training to interact with technologies such as automated guided vehicles, advanced warehouse tracking systems and data analytics.	• The use of hybrid manual + automation in multiple parts of the warehouse picking and stowing process automated. • Better scheduling of transport and picking processes with dynamic changes in requirements considered. • End-to-end view of shopfloor operations through data collection and analytics. • The maintenance of automation components handled by vendors.	• IoT and data analytics to correlate and predict deviations in estimations • Robotics (AGVs) and drones for inventory handling and management • Real-time monitoring of people and tools through phones, sensors. • Initial version of a digital twin of all shopfloor operations. • The network could provide intelligence to connect various device types for easier registration, coordination and interoperability.	• Capital expenditure vs operational improvements are to be considered • Lack of plug and play technologies. Involves solution integration and extended configuration. • Evolution of the technologies is difficult to envision. • Lack of common integration and interfaces to connect multiple types of devices.

Process – End to End Operations and Equipment Visibility

Another challenge identified within Ericsson’s partner factories was connectivity, data and production of production failures. This is an issue over current WiFi networks and requires more reliable connectivity. For hard to reach places such as internal ball bearings of indoor cranes (Figure 7), it is important to install accurate sensors to identify deterioration of components. There are multiple challenges in these real time monitoring and predictive analytics, which have been identified.

Figure 7: Hard to Reach Indoor Crane Maintenance

Table 2: End-to-end equipment visibility and maintenance challenges

Problems	People	Process	Technology	Business Specific
• Getting an end-to-end view of the factory production system is not an easy task • Factories are connected with WiFi sensors that have limited range • IoT data for predictive maintenance and analytics of machinery requires customised installation (IoT sensors for hard to reach ball bearings) • No real-time visibility of shop floors • Maintenance is typically done by exports on a periodic basis. It is a reactive process. • Lack of an ecosystem that shows micro and macro visibility	• Visual inspection of equipment and manual entry of data on factory and manufacturing floors. • Lack of familiarity with telecommunication standards and exposure interfaces. Need for an intelligent network. • Require training to interact with technologies such as IoT, AI predictive models, visual sensors, tracking systems and data analytics.	• End-to-end view of shopfloor operations through data collection and analytics. • The maintenance of automation components handled by predictive and prescriptive processes • Current focus on historical statistics; very little implementation of predictive / proscribing models	• IoT and data analytics to correlate and predict deviations in estimations • Real-time monitoring of people and tools through phones, sensors. • Digital twin technologies with accurate models of deterioration. • 5G connectivity to ascertain macro and micro level performance. • Specialized sensors needed for prediction other than those used for traditional data collection. • More involved AI models for predictive maintenance and analysis.	• Capital expenditure vs operational improvements are to be considered • Lack of plug and play models • Lack of maturity in making use of advanced analytics solutions. • Black-box AI solution lack explainable features.

This is typically deployed on a Cellular Manufacturing Factory which makes use of Flexible Manufacturing Systems for optimization.

Table 2 identifies the challenges within this use case and provides improvements in process, workforce and technology that should be incorporated. This would ensure end-to-end visibility, data collection and preventive fault identification.

In most cases Wi-Fi has been installed to support mobile applications and handheld devices. Other short-range low-bandwidth wireless connectivity (e.g. Bluetooth and Radio-frequency identification (RFID)) has also been adopted**. Wi-Fi is the current standard for most wireless connectivity on-site. However, there are issues with the high capital costs for sufficient access point deployments required to provide contiguous and reliable coverage.** With the emergence of more reliable connectivity platforms such as 5G, the industry would be more suited to move towards cellular connectivity. This does not have the unreliability of WiFi and can support large data rates. Mobility or components in and out of the factory/warehouse can also be easily done via end-to-end tracking.

6 Challenges in Production and Maintenance Systems

Identification and description of the challenges within production and maintenance of Swedish and Indian factories, i.e. Ericsson and Astra Zeneca.

6.1.1 Astra Zeneca

AZ(Sweden Survey) - Smart Pro Implementation Challenges

The challenges are presented in the following tables with the following columns:

- People: Challenges and improvements to be made in the manpower
- Process: Changes in the supply chain processes envisioned
- Technology: Integration and impact of cutting edge technologies
- Regulatory: Requirements for specific industries emitting from geographies

Table 3: Sweden Smart-Pro Challenges from AZ

Topic	People	Process	Technology	Regulatory
Identify and describe challenges (especially those within production and maintenance) in Swedish industry, classify and prioritize challenges • **Analyze different types of challenges we encounter in the Manufacturing facilities** • **Identify issues relevant and current to Sweden & India factories** • **Classify challenges/issues into categories** • **Prioritize significant areas that need urgent focus**	• General digital and IT understanding to exploit more digital solutions in the continuous improvement process • Lacking IT Architectural, IT security and procurement resources to quickly deliver what we want to do • Better story-telling and business analytics to describe the impact of digital on the business to get buy-in • Clarify roles and responsibilities in high-level strategic programs to remove site confusion on who is doing. • Ensuring GMP capability and partnership and inclusion of regulatory organizations in the digital journey.	▪ More process standardization to aid quick scaling between sites and within big sites ▪ Acceptance to lack of process standardization to aid innovation, engagement and learnings. Finding the right level	• Availability of new technology for sites to explore • Clarifying transformational or non-transformational technology • Clarifying what transformational technology needs to be coordinated globally and what needs to be coordinated locally for the benefit of AstraZeneca • Automation vs. Data applications • Holistic picture of smart factories and connections to digital foundations and the roadmap • Shorter payback period on changing technology landscape and associated costs of change management	• Data sharing agreements between organization across Supply Chain to eliminate inefficiencies will need to be governed, managed & regulated by authorities

Table 3 and 4 describes some of the challenges in smart production and maintenance systems identified in Astra Zeneca's Sweden site.

Table 4: Sweden Smart-Pro Challenges from AZ

Topic	People	Process	Technology	Regulatory
Identify relevant production/manufacturing systems to be considered in Smart-Pro for Swedish and Indian Industries improving our operational efficiency & process - **Smart, predictable manufacturing** - **Real-time process analytics and optimization** - **Structured data gathering & sharing** - **Connected Technology**	▪ Create a culture of continuous smart factory innovation ▪ Change Management effectiveness	▪ Develop processes for integrating data ▪ Use insight analysis and data interpretation to streamline operational processes ▪ Create processes for evaluating optimization opportunities ▪ Sustainability has been a hot topic amongst EU manufacturers; something worth considering as now data and AI can help optimize our energy consumption https://ec.europa.eu/info/news/industry-50-towards-more-sustainable-resilient-and-human-centric-industry-2021-jan-07_en	▪ Adoption of Digital solutions such as Assisted Reality Training, Optimization Analytics, Digital paperwork, Factory Dashboard, Cognitive Computing etc ▪ Implement simulation systems to test, prototype, and optimize the digital factory	▪ Create process for involving external partners in development of digital automation processes that are audit & regulatory friendly

AZ(India Survey) - Smart Pro Implementation Challenges

These are specific challenges and opportunities in the Indian context:

Table 5 and 6 describes some of the challenges in smart production and maintenance systems identified in Astra Zeneca's India site.

Table 5: SmartPro Challenges Indian Context from AZ

Topic	People	Process	Technology	Regulatory
Identify and describe challenges (especially those within production and maintenance) in Swedish industry, classify and prioritize challenges • Analyze different types of challenges we encounter in the Manufacturing facilities • Identify issues relevant and current to Sweden & India factories • Classify challenges/issues into categories • Prioritize significant areas that need urgent focus	▪ Lack of common understanding and vision among employees ▪ Lack of understanding of smart factory potential limiting benefits ▪ Lack of cross-factory collaboration between implementation teams making it hard for innovation ▪ Capability of the Operators, site Operational staff to adopt digital mindset	▪ Difficulties in adapting from traditional routines and work processes to digital transformation ▪ Change Management & governance ▪ Data over flow hindering critical decision making ▪ Agile processes in highly regulated environments pose a risk to Operations ▪ Audit requirements ▪ Regulatory impacts due to Digitization	▪ Pharma Regulatory Requirements makes it hard for implementing latest technology ▪ Struggle to keep up in the face of rapid technology development ▪ Technological complexity creating uncertainty in the business case ▪ Difficulties in long-term planning due to high technology dependence ▪ Global standard solutions are way expensive and not conducive across the organization from a strategic ROI point of view	• Audit & Regulatory process is paper based, time consuming & labour intensive • High risk of human error

Table 6: SmartPro Challenges Indian Context from AZ

Topic	People	Process	Technology	Regulatory
Identify relevant production/manufacturing systems to be considered in Smart-Pro for Swedish and Indian Industries improving our operational efficiency & process - **Smart, predictable manufacturing** - **Real-time process analytics and optimization** - **Structured data gathering & sharing** - **Connected Technology**	▪ - Create a culture of continuous smart factory innovation ▪ Create specialized roles & responsibilities geared toward predictable production ▪ Organize sense-making sessions with suppliers, users, and other stakeholders ▪ Recruit data analysts and data scientists to optimize production ▪ Educate people to Develop the ability to exploit connected data systems ▪ Revise production staff roles to proactively coordinate digital insights & knowledge sharing ▪ Create an inclusive culture for Chg. Mgmt. ▪ Implementation by involving workforce in vision development ▪ Recruit people with digitalization competencies	▪ Develop processes for integrating data visualization into decision making ▪ Create proactive processes for forecasting and planning future production ▪ Use insight analysis and data interpretation to streamline operational processes ▪ Create processes for evaluating optimization opportunities ▪ Create specialized insight-mining processes to support information gathering across departments ▪ Build cross-functional digitalization networks to facilitate knowledge sharing ▪ Formalize hybrid smart factory implementation processes.	▪ Adoption of Digital solutions such as Assisted Reality Training, Optimization Analytics, Digital paperwork, Factory Dashboard, Cognitive Computing etc ▪ Implement systems for real-time performance analysis ▪ Increase accuracy of data collection from technology ▪ Create automated processes for ▪ data mining and sharing across functions	▪ Create process for involving external partners in development of digital automation processes that are audit & regulatory friendly

6.1.2 Ericsson (Sweden / India) Challenges

Table 7: SmartPro Challenges Indi/Sweden from Ericsson

Topic	People	Process	Technology	Industry specific requirements
Identify relevant production/manufacturing systems to be considered in Smart-Pro for Swedish and Indian Industries improving our operational efficiency & process **- Smart, predictable manufacturing** **- Real-time process analytics and optimization** **- Structured data gathering & sharing** **- Connected Technology**	▪ Appropriate training needed to ramp up use of newer technologies ▪ [India] Manual quality control and check of products still used ▪ [India] Defect checking is mainly a manual process	▪ Increased need for automation to take care of fluctuating demands. ▪ Planning based on predictions and forecasts provided on demand over a period. ▪ Business and capital expenditure key factors before changing processes. ▪ The machines and equipment are leased – maintenance is handled based on a service contract. ▪ Require robust and secure processes to collect data and store them for analytics.	▪ IoT and data analytics to correlate and predict deviations in estimations ▪ Robotics (AGVs) and drones for inventory handling and management ▪ Real-time monitoring of people and tools through phones, sensors. ▪ Using image/video processing to guarantee defect detection. The system has to complement human expert ▪ Lack of plug-and-play systems for problems; requires heavy system integration ▪ Digital twins and real-time insights to provide prediction on wear and tear of systems. Better designed factories.	▪ [India] Compact Ericsson warehouses do not have issues on distance delay and failure of components. However, manual processes can cause errors ▪ [Auto manufacturers] Any defects can lead to heavy expenditure on vehicle recall

As presented in Table 7, there are specific challenges in the India and Sweden context:

India: Multiple operations within the factory floor are manual including inspection and maintenance. This can lead to errors and manual faults. There is also inability to quality scale up operations when demands change due to these manual processes. India's specific challenge: manpower being cheaper than the technology and cost of maintaining technology

Sweden: Implementing smart solutions involve business justifications. In many cases, the maintenance of equipment is outsourced to an external vendor following global practices. Lack of turn-key plug and play approaches poses challenges.

6.2 Classification and prioritization of the challenges

This section provides generic common challenges that may be studied as part of the Smart Pro WP3. However, these are common challenges with the next few sections providing specific challenges identified in AZ and Ericsson factories.

Common identified challenges in smart manufacturing:

1. Lack of vision on integrating smart technologies
2. Need for multiple futuristic technologies (5G, AI, digital twins) that are yet to be commercialized. Need for agile deployments that may be prone to failures.
3. New tools and platforms are needed to integrate data at production and enterprise level. It will remove the information silos and bring integrated solutions.
4. Vast amount of data collected required adequate cyber security protection. Manufacturers typically want private data stored in house on private clouds. A holistic security approach is needed to develop a trusted environment for data exchange between partners.
5. Network vulnerabilities (outage, security) is also a cause of concern. Lot of wired connections with redundancies currently used.
6. Re-skilling employees to work with AI, blockchain, robotics, data analytics is a sharp learning curve. Might need partners to outsource some of these aspects.
7. Manufacturers are confronted with short product lifecycles and variable demands.
8. Need for customization of products at scale brings in flexible production challenges
9. Higher investments needed for new technologies – lack of insights into cost tradeoffs between capex and opex.
10. Virtually simulating production systems before physical commissioning (efficiency by design) still not adopted.
11. Data driven decision making for closed loops operations needed across industries
12. Lack of industry ready plug and use solutions for smart manufacturing. Many require vendor customization, field trials, pilots – add to cost.
13. Need to link up legacy systems with IoT, robotics and other intelligent machines. Interoperability and transition processes are of a concern.
14. The ability to scale up solutions with cost advantages has also to be suitably demonstrated.
15. Communication latency and reliability in the case of digital twins and real-time monitoring/operations of equipment.
16. Modeling and estimating wear and tear of industrial components.

17. During this transition, it is important that routine processes of factory should continue as before. Planned downtime is less risky, and costs less as compared to unplanned downtime.

We believe that a step-wise approach is needed, 1st to unravel current challenges and to boost current situation. By doing so, it allows production setting to realize fast edges and create production prepared for future scenarios. This modular or tiered approach can come from the service-oriented area depending on the nature of the problem; Example: For the data exchange problem, introduce a service bus for data exchange or use wrapper patterns for departments to provide the required services.

Existing production lines are more vulnerable to create a loss to the company i.e. if a single system stops it affects whole manufacturing/production line. In order to overcome problems like this, digitalization adaption would be a good technique to fill the gap between the shop-level (production line) and application level.

The below mentioned are common challenges irrespective of nature of their business. Once again, these are from the literature review on challenges in Smart Manufacturing systems.

1. Integration of Data
2. Flexibility
3. Security

Integration of Data

- In production line machines data are received and controlled by in built sensors used for process, product, plant information, logistics which sum to a huge data to maintain.
- This brings up a need for new technologies to overcome the challenge involved in storing these huge amounts of data.
- Hiring data engineers to build a correlation between the generated data and visualize it using newly coded algorithms to get insights from data which were not thought in previous technology.
- No standard approach is still now maintained for data management, until now data is being transferred through emails and printouts between various departments in the company. So here a redundant data is being stored in each sector of the company which creates an inconsistency in the process and deviation of data interpretation.

- A common operator or engineer relying on these data for making decision in real time production will unknowingly use these inconsistent data leading to incorrect decision.
- In the existing competitive market costs involved in software licenses, timely updates and also hiring more professionals are exponentially increasing day by day.
- In order to overcome these all the above-mentioned different systems or sectors should be integrated to one platform which helps the operator to use the real time data to make decisions which won't lead to any incorrect decision.

Flexibility

- Each product to be Individualized and customized in a cost-effective manner requires a minimum amount of flexibility in the manufacturing level. In order to achieve that flexibility, the manufacturing level should be more flexible towards process level in the unit. E.g. change of process data, programs, production sequence.
- Change management and change structure are equally important in order to execute and take forward a change from one department to another which is totally missing in existing manufacturing technology.
- Currently these changes are handed over in printout or emails individually to each department which leads to higher costs for managing these activities.
- So, we should build a standardized process for synchronization between the departments in order to improve more flexibility in an effective manner.

Security

- In order to keep the products, people and production details in a company securing those data should be the ultimate goal.
- Upgrading our machines with IOT sensors for monitoring possess some tedious task to be handled like keeping track of updates in order to avoid unnecessary threats.
- Strict measures should be taken in order to avoid malfunctioning of these installed devices.

More advanced/futuristic challenges

Integration of Enterprises within and across boundaries

- Activities involved from design until production, customer feedback and services come under one term called product life cycle.
- This is for companies having more than one manufacturing units in same location or in different parts of the world.
- Cross plant manufacturing will help to maintain a clean record on real time data of production load happening in each unit which would help distributing resources to unavailable plants maintaining a zero downtime of the manufacturing unit.
- This idea of cross plant manufacturing will help us to identify more performance factors such as employee efficiency, production capacity, downtime of each plant, which plant gives out better finished products.

Real time data on one hand connectivity at shop floor level

- Accessing the real time data for the operators at shop floor is not available in traditional production methods.
- There is a gap between ERP and the people on shop floor, so an integration between these two would help in achieving a better result and reduce the downtime of the plant.
- As discussed earlier the data are first analyzed filtered and then given in printed formats in mean time there could a problem in the production line, so real time data could produce customized work plans to reduce the possibility of errors during production.
- With this technology applied, machine faults can be directly reported to ERP and initiate an immediate maintenance saving more time for production.

6.3 Analysis of the challenges experience by AZ and Ericsson

The analysis is conduct based on the information provided by AZ and Ericsson covering their plants in India and Sweden as it is introduced in Tables 3-7. The analysis is done with special focus on the introduced challenges that are closely related to the project theme, i.e. the challenges related to production, maintenance, organisation and personnel:

- One of the very interesting and important challenges is how to convert manually assessed and followed up production and maintenance activities and performance using OEE

(Overall Equipment Effectiveness) to an automatic process reflecting real time situation of these processes.

To automate calculation of OEE, there is a necessity of digitalising its constituting variables, i.e. availability, quality rate and performance efficiency. In turn, it means that all stoppages, failures, and downtimes for other reasons, as well as high quality products and total production in addition to the productivity, i.e. number of products done per unit time, should be automatically registered.

- Automated system for calculating OEE demands are well established, flexible, and digitalised/automated data acquisition system, which can be easily accommodated for different processes in the production hall. This system usually consists of, for example: sensors (to pick up signals and measurements from well-defined information parameters); measuring policy to determine where, when and how often these measurements should be done; analysis and diagnosis software programs.
- In order to maintain the technical specifications of the production assets, there is a big need for monitoring the assets' performances using different relevant monitoring parameters. It is important to provide the information needed to act before it is too late, to act before failures.

  Therefore, it is necessary to identify, clarify/describe and understand the deterioration processes that the machine is exposed to in order to be able to identify the most relevant information parameters needed to detect changes in the status of the machine and its significant component at an early stage and enables end user to follow up damage development.
- Digitalising and automating these activities eliminating a lot of the unnecessary manual work and human error, and providing the information needed on time and at need. Besides, it helps to detect changes in the performances of production and maintenance processes before it is too late, i.e. before losing big amount of time and efforts.
- Using IIoT, IIoS, cyber physical systems, AI, and ML for developing suitable smart and automated system for data acquisition, calculation, analysis, and recommendation reduces appreciably the need for usual time and efforts for training of the personnel.
- Production and maintenance staff will acquire better understanding of how the system works and create faith in it based on the results achieved during the implementation, but it is always better to start work on that with the staff in parallel to the time of development and implementation of the smart system.
- To achieve all that the enabling factors have been mentioned clearly in Tables 3-7.

The challenges can be categorised into the following categories:

- **Technological;** concerning the need for advance technologies to meeting the challenges influencing production and maintenance performances. Also, the accuracy of the information and recommendations delivered is very important as well as on-time delivery of the information to the right person is considered crucial.

Of the technologies that are considered relevant and necessary for meeting the challenges in the production and maintenance processes are, for example:

- data acquisition system which operates automatically to avoid human error and manual work.
- Automatic analysis, diagnosis and recommendation in a transparent way to avoid black-box information.
- Secured flow of data, communication between different modules and data storing.
- A reasonable interface for introducing the data/information needed by the end user and at different level of responsibility
- A suitable architect for data presentation to ease communication and interaction between end user and the system

In order to develop, implement and improve the technologies and systems mentioned above, it among other elements, demands:

- Wireless sensors, IIoT, IIoS, Cyber physical systems,
- Digital twins
- Plug-and-play Smart Predictive Maintenance (Smart PdM) and other analytics systems for detecting and localising damages, assessing damage severity, predict future damage development, recommend what, where, why, how and when latest to conduct a necessary action.

  It should also provide economic information for the follow up of production and maintenance performances, which necessary to realise the performance of maintenance and its technical and economic impact on production process and company business.
- Cloud and REST API for establishing and securing data flow and communications.
- Tools, such as hard- and software modules for integrating data from relevant activities, such as production, maintenance, organisation, and economy.
- A flexible platform for integrating maintenance-production-and- economy enables adding of removing any of the modules at need.

- **Organisational;** the organisational challenges cover a wide range of organisation working areas, such as those challenges related to:

  - work culture which should be addressed to prepare the underlaying knowledge and infrastructure for moving to a new epoch where digitalisation and automation of production and maintenance processes are dominating the factory of future.
  - Data is usually gathered based on a specific plan and objectives that should be utilised properly and in a clear way, otherwise it is meaningless investing capital in gathering and analysing data.
  - For each production/maintenance methodology there are always new issues, experience, and knowledge to learn. Therefore, training and re-skilling employees are always an essential step to secure that the planned work will be conducted in the right way and cost-effectively.
  - The recommendation and warnings that will be provided by the production-maintenance system should present reliable and obvious instructions for easing the job needed to be conducted, otherwise it may lead to additional unnecessary losing in time and efforts.
  - Lack of understanding of what it means by a smart factory, and lack of the capability of the personnel and operation/maintenance staff to adopting mindset, which influences operating of any new technology in production and maintenance processes.
  - Production and maintenance processes suffer of manual work. Converting manual to automatic work supports the concept of digitalising and automating production and maintenance activities.
- **Data security:** digitalising and automating of, for example production and maintenance processes, conducting automatic data gathering, analysis and diagnosis expose the whole system to the risk of external disturbances and intervening.

  Therefore, it is necessary to implement advanced technologies for securing data communication, storing and meeting the increased threat of external disturbance and intervening.

For more information, see Table 3-7. All these categories are very important to be addressed in the Smart Pro in order to develop, test and demonstrate suitable solutions.

6.4 Technology Identification/usage across AZ Manufacturing Sites:

These are the technologies that have been implemented within Astra Zeneca's Sweden factories:

- Electronic Batch record implemented in Sweden manufacturing sites to ensure we meet our license to operate
- VDT - Voice recorded guidance (VDT) in use. This, frees a worker's hands and eyes, voice directed systems typically improve efficiency, accuracy, and safety

- Use of Robots in packing lines
- Warehouse Control/Management Systems
- RF Scanners
- Virtuosi to provide real time staff training in lines with safety, health & environment
- Aspentech or OSI PI tools being considered. This helps to streamline engineering and maintenance processes, leading to reduce downtime and increase operational efficiency. No concrete solution in place yet
- SAP Work Manager for Realtime data entry & integration
- **No plug & play solution in place yet. Still infancy state due to lack of Master data**
- No concrete solution in place yet as this is not a priority for AZ up until 2022
- Implementation of BRV – Realtime dashboard that provides an end to end view of the batch timeline view, an operator can click on a batch ID to drill down on the current batch and where it will go through to the next units. Everything on the unit and batch timeline views are all system displayed providing visibility throughout the batch life cycle through to the next units. Everything on the unit and batch timeline views are all system displayed providing visibility throughout the batch life cycle
- RPA(Robotic Process Automation) to automate repetitive time consuming tasks
- SAP Work Manager
- Automated labelling machines are in place to eliminate manual transcription & time consumed
- iPad’s have been introduced in factories where operators can look up instructions and perform actions with speed and accuracy
- Introduction of QR code scanners whereby the latest version of the document is referenced for the relevant line of operations

6.5 Predictive Maintenance Requirements and Cost-Benefit Analysis

Addressing machine maintenance is as important when compared to others (Mauer et al, 2018). This is done by integrating many inbuilt sensors performing the monitoring actions of the machine by checking its temperatures, speed, vibrations and recording it for each production line and it is compared to the historical data of the machine which prevents the unplanned maintenance of the machine and also carrying out planned maintenance without disturbing the production line.

Need for predictive maintenance:

Failure of mechanical and mechatronic devices due to wear and tear will impact the company with significant loses.

Currently, machine maintenance is a time-based approach i.e. maintenance activities are carried out in periodic cycles over a year. This method is not proven to be efficient for the production machines highly facilitated with information technology.

This method fails to predict the time of failure, compensating for this maintenance approach unnecessary maintenance are conducted and it lacks in predicting the oncoming failure in advance. This breaks the entire production process.

Contradictory to time-based maintenance, a well-known technology, predictive maintenance to prevent failure and unnecessary maintenance through continuous monitoring of the system behavior.

Current automated predictive maintenance techniques:

- Pattern recognition
- Empirical & Physical modelling
- Neural networks & fuzzy logic

Challenges involved for adapting Predictive maintenance technology

- Predictive maintenance technology involves many sensors for monitoring various performance factors such as vibration and pressure to maintain the system's stability from critical failures.
- Solutions for some important tasks require deep integration techniques to be monitored in the system, leading to large installation efforts.
- Processing the large amount of data generated by the sensors takes place through a single central unit, this lessens the chances of transferring this data to factory networks due to unexpected blockages and breakdowns.
- The initial costs involved are too high in cases such as data transfer between the production machines requiring specialized and expensive hardware systems combined with high-level technical integration.
- Apart from all these there are quite important legal constraints in implementing predictive maintenance to the existing production lines they are:
- The warranty and leasing conditions of the production machines may get affected by invasion of predictive maintenance approach.

- In machines where sensors are already integrated for monitoring solutions need a simple predictive maintenance approach but machines which are under lease agreement will be a hurdle in accessing the data from the sensor without proper third-party approval.

Figure 8 provides the potential improvements provided by predictive maintenance. The principal improvements are in uptimes and cost reduction.

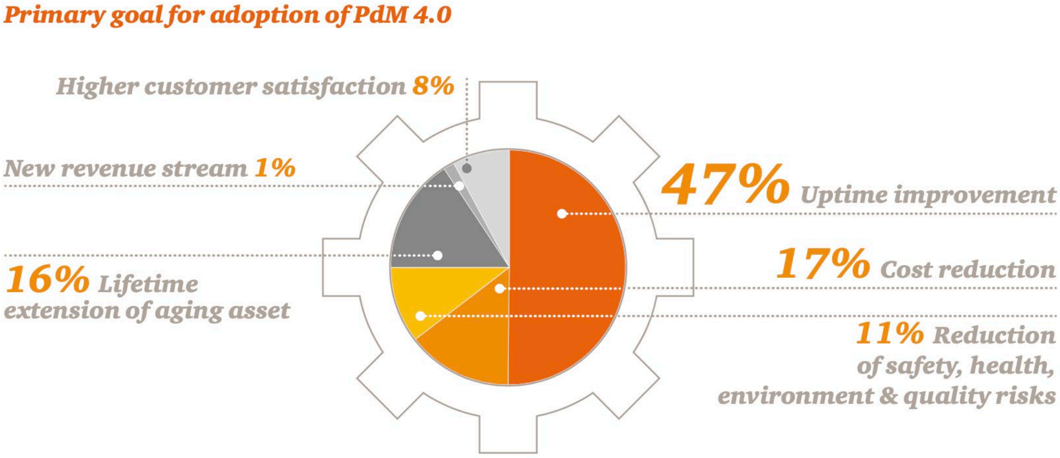

Figure 8: Improvements as a result of Predictive Maintenance (PWC, 2017)

7 Technologies and Vision for Smart-Pro

We present some of the technologies that are relevant to Smart-Pro. Many of these were mentioned during our stakeholder interviews (Appendix 1). The initial set of technologies are applicable to both Sweden and Indian factories. Most of the smart production and maintenance systems are moving towards integration of one or more of these technologies within their production systems. While many of these involve system integration efforts, it is envisioned that more plug-and -play techniques are needed. In addition, the return of investment on investing in these technologies must be traded off with operational efficiencies and manpower reductions.

7.1 Interactions between new technologies, e.g. Smart-Pro, and company organisation.

There are multiple technologies that can have an effect on smart production and maintenance systems:

1. IoT and Cyber-Physical Systems: Millions of sensors providing data the must be collected. RFID devices, robotic sensors, machine data sensors, human monitors.
2. Edge and Cloud processing: Making use of computational power on the factory floor. Hybrid multi-clouds for industries. Cloud manufacturing systems provide a unified view of the factory floor with customer requirements captured. Ability to guarantee SLAs due to end-to-end view.
3. 5G connectivity: High speed, low latency connectivity needed without reliance on inflexible wired communication. This allows seamless mobility and handover of information.
4. Digital twins: Digital replicas of the physical world that receive data from the sensors. Sandbox environments where what-of analysis may be done by stakeholders. The twin should be responsive to product lifecycle management and evolve with manufacturing needs and changes.
5. AI and data analytics: Transform data to predictive actionable insights. Real-time insights needed. Cognitive processes that can think and learn about faults. Needed for predictive analytics, demand estimation and customizing products. Predictive analytics can come from event based or simulation based approaches. **Popular applications of AI/ML in this space are in defect prediction, demand forecasting, optimization (energy, utilization), risk mitigation and scheduling.**

The architectural components of a smart factory where these technologies may be applied:

- Plant Control Tower: Data received from IoT analyzed over the Edge/Cloud to provide insights. Used to optimized end-to-end operations.
- Automated Execution: Robots, Cobots and Data-driven MES to ensure accurate completion of repetitive tasks.
- Real-time monitoring: IoT and AR/VR devices interact with digital twin to provide real-tie insights. Can be used for early intervention.
- Quality assurance and maintenance: Iot data and predictive AI models used for zero defect production and minimal downtimes
- Energy Management: Optimal use of power on factory floor to minimize costs (sensors indicating sleep modes)
- Augmented Worker: Worker with AR/VR and health-monitoring sensor to better interact with smart machines

- Flow Simulation: Digital twin simulations to estimate demand variations and reduce possibility of failures

7.1.1 Role of AI

AI has been applied and has further opportunities to be incorporated within the following problems (Capgemini Research, 2020):

- Demand planning- manufacturers can better estimate demand patterns and the timelines needed for effective scheduling. It also prevents excessive production and spoilage of items. Historical sales, weather patterns, user demography may be supplied to estimate demand projections.
- Production improvements- Bottlenecks in the production process may be identified and alleviated.
- Safer operations on the shop floor
- Research and product development – Automated search and testing enable convergence into superior products with shorter timelines.
- Product quality control and defect estimation. This can be via vision based systems to IoT driven analytics and actuation.
- Maintenance and prediction of component failures
- Optimization and energy management

7.1.2 Role of Digital Twins

Digital Twin (Lu et al., 2019) has evolved into a broader concept that refers to a virtual representation of manufacturing elements such as personnel, products, assets and process definitions, a living model that continuously updates and changes as the physical counterpart changes to represent status, working conditions, product geometries and resource states in a synchronous manner.

Digital Twin can influence future manufacturing from the following aspects.

• **Digital Twin for manufacturing assets**: A manufacturing asset can be connected and abstracted to the cyberspace via its Digital Twin. Manufacturers can gain a clearer picture of real-world performance and operating conditions of a manufacturing asset via near real-time data captured from the asset and make proactive optimal operation decisions.

• **Digital Twin for people**: Digital Twins can also connect workers at the shop floor. The representation of a person, including personal data like weight, health data, activity data, and emotional status can help to establish models to understand personal wellbeing and working conditions of humans in a factory. Workers can also upskill themselves via ultra-realistic training programs which blend physical factory setups with virtual what-if scenarios.

• **Digital Twin for factories**: Digital Twins can also work for factories, making a replica of a live factory environment. Digital Twin and data-driven production operations can allow the establishment of a self-organizing factory environment with complete operational visibility and flexibility. Connectivity and data tracking throughout the complete manufacturing process enable factory operations to be transformed into data-driven evidence-based practices, offering the capabilities of tracing product fault sources, analyzing production efficient bottlenecks and predicting future resource requirements.

•**Digital Twin for production networks**: By connecting manufacturing assets, people and service via Digital Twin, every aspect of business can be virtually represented. Connecting distributed Digital Twins between companies will allow companies to build virtually connected production networks.

7.1.3 Role of Improved Connectivity

Today, this connectivity is predominantly delivered using fixed cabling, which is: (i) Often expensive to install (ii) Constrained to stationary assets only (iii) Difficult to scale to connect the large number of devices envisioned for future smart manufacturing plants.

Ultra-reliable low latency communication is vital for real-time communications between machines. Greater bandwidth and support for higher device density enables use-cases that generate more data traffic and host a greater number of devices / sensors.

Figure 9 provides an overview of multiple cases where 5G can benefit industrial production and supply chains.

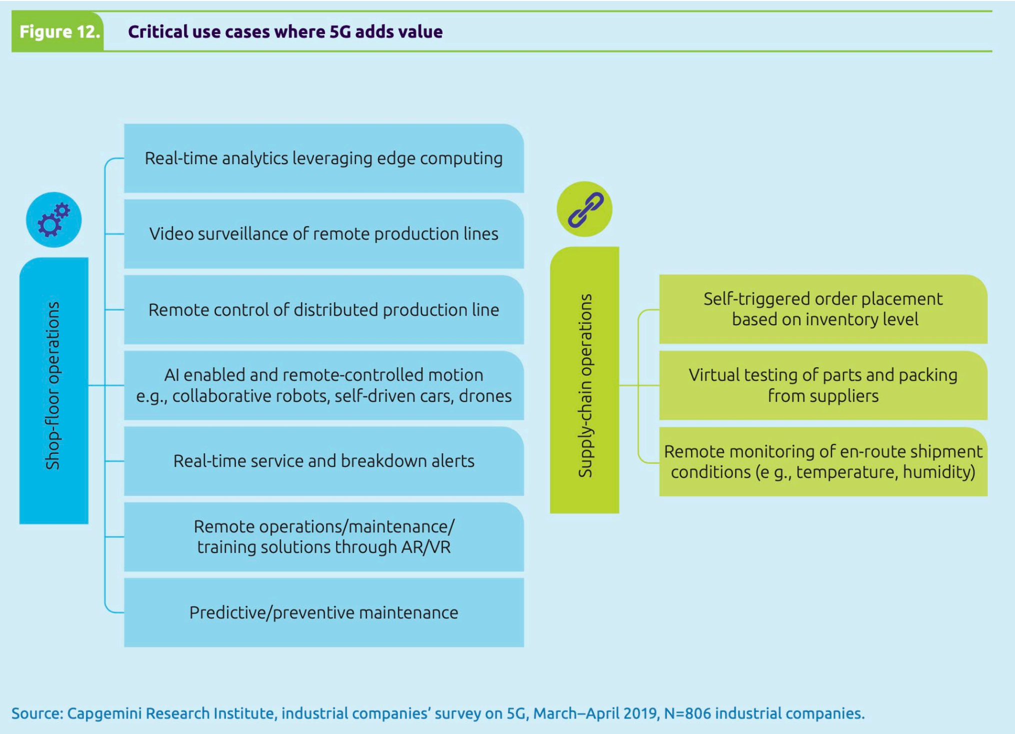

Figure 9: 5G for Industry 4.0

5G can offer the following advantages over multiple aspects of smart manufacturing (PA Consulting, 2020) (Deliotte, 2020)

- Tracking and traceability: RFID tags are prone to errors; 5G could provide higher levels of tracking with smaller error margins.
- Decentralize expertise – Using 5G handheld devices or devices, factory floor employees can easily consult with off site experts.
- Factory floor productivity should be increased with Greater granularity in identifying faults, down to individual components and constant benchmarking of output against either past or product sheet performance.
- Flexible production systems with increased scale up/down of robotic resources.
- End-to-end supply chain connectivity and monitoring.

A combination of cellular connectivity and WiFi access will be useful to update IoT, predictive maintenance and video feed data from the factory floor.

7.2 Identification of cases necessary for sustainable processes covered by Smart-Pro.

To further emphasize the specific challenges identified in the partner factories, we provide some identified use cases within the various parts of the operations.

Table 8 provides a detailed overview of the problems and challenges in AZ and Ericsson factories during various parts of the production cycle. The technologies of interest and those implemented in Sweden and India are described in detail as well.

Table 8: Identified Challenges for Smart-Pro from Sweden / India

#	Common Challenges Sweden/India	Technology Identification - Sweden	Technology Identification - India
1	▪ Manufacturing process documentation ▪ Document errors ▪ Quality Standards ▪ License to Operate – SHE ▪ Right first time	▪ Electronic Batch record implemented in Sweden manufacturing sites to ensure we meet our license to operate	▪ EBR not implemented in India manufacturing site owing to the high cost involved in procuring this solution
2	▪ Production Operators read instructions and scan barcodes or key-enter information to confirm their manual tasks ▪ Production line cleaning & clearance ▪ Quality Compliance	▪ VDT - Voice recorded guidance (VDT)in use. This, frees a worker's hands and eyes, voice directed systems typically improve efficiency, accuracy, and safety	▪ This is a solution coupled with EBR and since this solution is not in place, VDT is not in scope for India Ops SiteX
3	Performing Non value add work in packing lines	▪ Use of Robots in packing lines ▪ Warehouse Control/Management Systems	▪ Not available due to the high cost solution

		▪ RF Scanners	
4	▪ Sterile Drug Products Produced by Aseptic Processing where the training offered to site staff is not Realtime ▪ Lack of proper understanding of critical regulatory and environmental parameters to comply	▪ We've got Virtuosi to provide real time staff training in lines with safety, health & environment	▪ Not available in India
5	▪ Production Maintenance ▪ Scheduling, planning, executing ▪ Equipment maintenance ▪ Predict damage	▪ Aspentech or OSI PI tools being considered. This helps to streamline engineering and maintenance processes, leading to reduce downtime and increase operational efficiency. **No concrete solution in place yet** ▪ SAP Work Manager for Realtime data entry & integration	▪ Not available in India site
6	▪ Non-GMP functions – Preventative Maintenance	**No plug & play solution in place yet.** Still infancy state due to lack of Master data	▪ Not available in India site
7	▪ PdM – equipment wear & tear tracking, Hardware replacement, alarm devices on shop floor	**No concrete solution in place yet as this is not a priority for AZ up until 2022**	▪ Not available in India site
8	▪ Batch release manufacturing process inefficiencies ▪ Multiple stops and starts related to manual	▪ **Implementation of BRV – Realtime dashboard that provides an end to end view of the batch timeline view, an**	▪ Implementation of BRV – Realtime dashboard that provide an end to end view of the batch timeline view, an operator can click on a batch ID to drill down

	interventions, and there is no visibility into the next task in the sequence or an explanation for a delay.	**operator can click on a batch ID to drill down on the current batch and where it will go through to the next units. Everything on the unit and batch timeline views are all system displayed providing visibility throughout the batch life cyclethrough to the next units. Everything on the unit and batch timeline views are all system displayed providing visibility throughout the batch life cycle**	on the current batch and where it will go through to the next units. Everything on the unit and batch timeline views are all system displayed providing visibility throughout the batch life cyclethrough to the next units. Everything on the unit and batch timeline views are all system displayed providing visibility throughout the batch life cycle
9	▪ Non value add actions in packing lines ▪ Manual transactions in SAP	▪ **RPA(Robotic Process Automation) to automate repetitive time consuming tasks** ▪ **SAP Work Manager**	▪ RPA(Robotic Process Automation) to automate repetitive time consuming tasks ▪ SAP Work Manager available in India
10	▪ Manual labelling of samples/products	▪ **Automated labelling machines are in place to eliminate manual transcription & time consumed**	▪ Automated labelling machines are in place to eliminate manual transcription & time consumed
11	▪ Bulky operator manual needs to be printed out to perform production line operations	▪ **iPad's have been introduced in factories where operators can look up instructions and perform actions with speed and accuracy**	▪ iPad's have been introduced in factories where operators can look up instructions and perform actions with speed and accuracy
12	▪ Packing line operator training is a cumbersome process due to the dependency to download the latest version of the document every time	▪ **Introduction of QR code scanners whereby the latest version of the document is referenced for the**	▪ Introduction of QR code scanners whereby the latest version of the document is referenced for the relevant line of operations

		relevant line of operations	

8 Conclusions

Identification of Common Challenges between AZ & Ericsson on Digital Priorities

- Both companies have a perceived view of delivering against the core attributes of their digital business priorities which is unique & specific to Ericsson & AZ
- Cheap labor vs. expensive digital solutions across Indian industries
- Workforce transformation strategy - Onboarding Digital literacy levels across workforce around adoption, usage & proficiency
- Existing IT strategy focus is not on Production/Predictive/Preventative Maintenance
- Proposed investments around Production/PdM don’t guarantee the ROI (return on investment) for specific production maintenance related digital technology solution across Ericsson & AZ
- There are other key focus areas such as quality, safety and automation.

Current digital focus from AZ perspective

- Proposed digital technology transformation is around Quality, Safety & Compliance
- Deliver digital foundations & build digital capability uplift
- AZ would focus on factory self service visualization , factory dashboards, virtual sterile inspections/audits, virtual aseptic training etc. as shared in the tech. solution slide
- Widescale Automation across manufacturing sites

Current Focus Areas for Ericsson

- Increased automation of factory floor operations to meet variable demands using robotics, smart data processing and artificial intelligence
- Increased connectivity and 5G dedicated networks to meet the requirements of smart manufacturing operations
- Integration of futuristic technologies such as digital twins and process models to ensure zero failures and downtimes

- Many of the predictive maintenance solutions are outsourced to equipment manufacturers.

8.1 Outlook for WP3

In this report, we have highlighted multiple technology challenges, use cases and directions that are to be considered. This has been done with both Astra Zeneca and Ericsson's factories in mind, with geographies of India/Sweden considered. While these are increased emphasis on automation, digital technologies, increased connectivity within the factory floors, predictive maintenance technologies have been secondary. It would be advantageous to combine predictive maintenance with other solutions to provide a more strategic impact to near-term factory floor operations. Smart-Pro solutions should also be plug-and play to enable easy integration within multiple factory floor deployments.

9 References

[1] IBM, "Smart Manufacturing", IBM Expert Insights, May 2020.

[2] Mabkhot et al., "Requirements of the Smart Factory System: A Survey and Perspective", MDPI Machines, vol 6, no. 23, 2018.

[3] Capgemini Research Institute, "Smart Factories @ Scale", 2019.

[4] PA Consulting, "5G for Smart Manufacturing", 2020.

[5] Deliotte, "AI Enablement on the way to Smart Manufacturing", 2020.

[6] Capgemini Research Institute, "Scaling AI in Manufacturing Operations", 2020.

[7] Bocella et al., "Evaluating Centralized and Heterarchical Control of Smart Manufacturing Systems in the Era of Industry 4.0", MDPI, 2020.

[8] Lu et al., "Digital Twin-driven smart manufacturing: Connotation, reference model, applications and research issues", Robotics and Computer Integrated Manufacturing, 2019.

[9] S. Aggarwal, "MRP, JIT, OPT, FMS?", Operations Management, Harvard Business Review, 1985.

[10] C. Krupitzer et al., "A Survey on Predictive Maintenance for Industry 4.0", 2020.

[11] PWC, "Predictive Maintenance 4.0". 2017.

[12] Y. Yin, K. E. Stecke, and D. Li. 2018. "The Evolution of Production Systems from Industry 2.0 through Industry 4.0." International Journal of Production Research 56(1–2):848–861.

[13] Oesterreich, T. D., and F. Teuteberg. 2016. "Understanding the Implications of Digitization and Automation in the Context of Industry 4.0: A Triangulation Approach and Elements of a Research Agenda for the Construction Industry." Computers in Industry 83: 121–139.

[14] Der Mauer, M. A., Behrens, T., Derakhshanmanesh, M., Hansen, C., & Muderack, S. (2018). Applying Sound-Based Analysis at Porsche Production: Towards Predictive Maintenance of Production Machines Using Deep Learning and Internet-of-Things Technology. Digitalization Cases, 79–97

[15] Zangiacomi, A., Pessot, E., Fornasiero, R., Bertetti, M., & Sacco, M. (2019). Moving towards digitalization: a multiple case study in manufacturing. Production Planning & Control, 1–15.

[16] M. Mahmoud, "Classification of Production Systems", Industrial Engineering, 2015.

10 Appendix 1 – Questionnaire Templates

Specifics of Interviewee factory

1. What is the size (employees, area) of your factory ?
2. Location of factory and age ?
3. Which industry verticals do you target ?
4. What are the machines, types that are being used ?
5. What are the critical machines / difficulties in maintenance ?

Current Journey

1. What stage of factory evolution are you in standard → lean manufacturing → IoT enabled → robotic integration → flexible production → digital twin (AI, 5G) ?
2. How are your partners (suppliers / sister-factory concerns) placed in the evolution journey ?
3. What is the competitive landscape with respect to smart manufacturing ?
4. Are there industry specific challenges ?
5. Does the location or size/age of the factory affect transformation decisions ?
6. What are the 3 major challenges in this vertical (quality, operational efficiency, worker safety) ? Any other priority areas ?

Operational Concerns

1. How do you see the process of integrating different teams enabled via information systems, processes and data sharing ?
2. Do your systems make use of data analysis and learning across departments ?
3. How would you see improvements to be made to better align systems to different departments ? to suppliers? To end customers ?
4. How can we improve overall process flows and reliability?
5. What are the impediments against moving towards digitalization (cost, security) ?

Cost Implications

1. How difficult or expensive would it be to transform your IT or operations setup towards smart manufacturing ?
2. How much do you invest in futuristic technologies / R&D and processes ?
3. What are the typical plans to phase out obsolete assets and systems ?
4. What additional value proposition (new products, superior capabilities) do you see traded off vs. smart production costs ?
5. What are the timelines over which operations will recoup costs ? Assumptions ?
6. How much do you spend on software licensing and upgrades ? How often do you upgrade your systems ?

Technologies

1. What are the current digital capabilities that are being employed ?
2. What is the technology level that are currently employed in your vertical ?
3. Do you employ cloud based systems ? Through which vendors ?
4. What is the wired/wireless connectivity infrastructure ? When was it last upgraded ?
5. What are the data driven decision making, analytics and AI prediction (demand, maintenance) technologies used ?
6. Any other technologies – blockchain, AR/VR, novel health monitors ?
7. How do you manage cybersecurity threats ?
8. Simulation design/operations and the use of digital twins ?
9. How do you view your end-to-end supply chain on a dashboard ?
10. How heavily do you rely on IoT to monitor assets ?
11. What is your team structure to aid in understanding and integrating the above technologies ? Do you rely on external vendors ?
12. Do you prefer plug-and-play or customized service deployments ?

Manpower

1. How dependent is your factory/vertical on suitable manpower to operate plants ? What are the training times ?
2. Does your manpower prefer small scale implementation of novel technologies within projects ?
3. What training do you employ to train your manpower with novel ways of working and new digital technologies ?
4. Would reduction in workforce as a result of smart manufacturing be a crucial aspect to consider ?
5. Worker health and safety tracking via digital assets ?

Forward looking directions

1. How will smart manufacturing help serve customers better ?
2. What are the pilot projects envisioned to integrate new technologies ?
3. What new monetization areas will be opened up via smart manufacturing ?
4. Would adopting technologies such as AI/5G help in disrupting competitors (against being disrupted) ?
5. How will integration of smart manufacturing affect vendors and other partners within the supply chain ? Do you transfer technology insights ?
6. Is there enough clarity of the impact that futuristic technologies can take ?

11 List of Figures and Tables