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# Simulation Based Assessment of Lean and Industry 4.0 Measures in Changeable Production Systems

## *Simulationsbasierte Bewertung von Lean und Industrie 4.0 Maßnahmen in wandlungsfähigen Produktionssystemen*

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**Abstract:** Increasing demand for individualized products as well as the need for flexible and variable manufacturing leads to an increase in the complexity of modern production systems (PS). This complexity requires the implementation of digitalised lean as well as Industry 4.0 (I4.0) measures. Even though these measures might enable the handling of this complexity in the operation phase, their planning and implementation is complex. This paper presents a simulation framework that targets the planning and assessment of digitalised lean and I4.0 measures in a systemic context. The framework consists of the main PS components and additional I4.0 elements. These have been modelled using an agent-based simulation approach and is applicable to multiple manufacturing scenarios. An exemplary application to a changeable PS for individualized pharmaceutical products concludes the paper.

## 1 Introduction

Shorter product and process innovation cycles, a high demand for individualized products and the transformation to a sustainable economy create a turbulent market environment. Production planners and operators are challenged to cope with the resulting internal complexity and to meet customer demands with the implementation of changeable PSs. The inherent complexity of changeable PSs can be handled with the implementation of digitalised lean methods or I4.0 measures, so called cyber-physical production systems (CPPS) (Wagner et al., 2017). CPPS contain four elements: i) a physical world, to which the CPPS is referenced, ii) a data acquisition and treatment with technical components such as sensors and data storages, iii) a cyber world applying digital methods on the data allowing an iv) feedback to the physical world. Those systems are considered enablers for I4.0 (Veile et al., 2020; Inkermann et al., 2019). Even though I4.0 measures might enable the operation of complex PS, their planning and implementation further increases the already existing complexity of the PS. Consequently, production planners, especially in small and medium sized enterprises, struggle with the implementation of I4.0 measures. The challenges can be traced back to several hurdles, such as the unknown impacts of single measures on PS level, combined with high investments and uncertain payback periods (Orzes et al., 2020; Veile et al., 2020; Wischmann et al., 2015). Therefore, a particular need for generic approaches that are able to plan and evaluate I4.0 applications in specific use cases exists. In this context, simulation approaches can provide an effective means for a planning support. While respecting process chain inherent dynamics, they can enable the prospective evaluation of I4.0 applications in complex production systems and their investigation in different scenarios (Martin et al., 2020). Against this background, this paper proposes a generic I4.0 simulation framework for planning and assessing digitalised lean and I4.0 measures (further only called I4.0 measures). The framework is applied in the context of individualized pharmaceutical production.

# 2 Digitalised Lean and Generic Simulation

## 2.1 The digitalisation of lean measures

Transparent and structured processes as well as the interrelation with relevant indicators are indispensable to simulate the impacts of the implementation of I4.0 measures. An important prerequisite for the targeted implementation of I4.0 measures is to view production from a lean perspective - as a holistic PS (Bick, 2014; Dombrowski and Richter, 2016). The fundamental principles of holistic PSs, such as standardisation and continuous improvement, still apply even with the introduction of I4.0. Furthermore, the principles can be used to enhance existing methods and tools through the functions of I4.0 (Deuse et al., 2020). In this way, I4.0 can complement existing lean approaches and raise new potentials.

Within the Verein Deutscher Ingenieure (VDI - The Association of German Engineers) guideline 2870, lean methods are already evaluated regarding the target indicators quality, cost and time (VDI-2870). Further and new developed lean methods considering I4.0 were also evaluated with regard to these indicators and described with method sheets ("GaProSys 4.0", 19804 N). Based on this guideline, a structured catalogue of I4.0 and lean measures was developed within the scope of this research work (Figure 1). As an example of a digitalised lean application, this work examines a digital assistant system (DAS), which supports assembly processes as a human-machine interface by providing assisting information for the employee. Through the integrated testing of individual process steps up to quality control, specific process and product characteristics can be depicted. DASs use advanced sensor technologies to allow imaging processes or pick-by-light for example.

The aforementioned target variables quality, cost and time were supplemented by sustainability to address the growing challenges of sustainable production. These are integrated as dimensions and divided into categories. Thus, the dimension quality is subdivided into the categories product and process quality. According to VDI guideline 2870, product quality is composed of the product characteristics lifetime, safety and functionality. Since these indicators are not directly related to the production logistic processes, they are not considered in this approach.

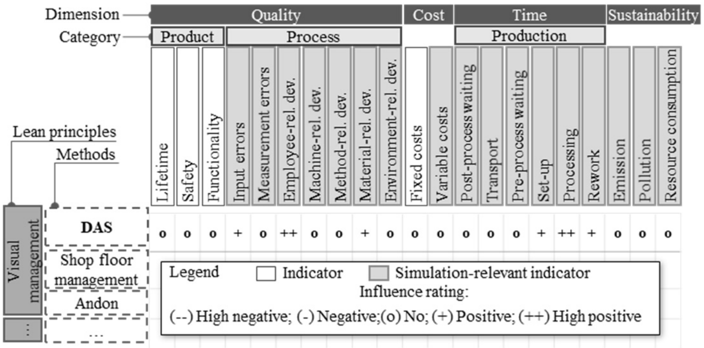


***Figure 1:*** *Extract for a proposed structured catalogue of I4.0 and lean measures*

The decisive influencing variables for process quality result from possible process discrepancies. Discrepancies are caused by input or measurement errors or due to machines, employees, material, environmental influences or methods (VDI-2870). For the dimension time, the throughput element according to Wiendahl was supplemented by the rework time (Wiendahl, 2010). The sustainability indicators for sustainable manufacturing according to Joung are used (Joung et al., 2013). Only indicators relevant to the simulation were considered. To enable decision support, a more granular evaluation of the indicators is required. The target variables summarised generically in VDI guideline 2870 must therefore be converted into simulation-specific key indicators.

## 2.2 Generic simulation approaches for the planning

With respect to the manifold performance indicators and the high planning complexity, Albrecht et al. present an integrated planning and optimisation methodology for designing the changeability of PSs (Albrecht et al., 2014). The approach combines system dynamics (SD) and discrete event simulation (DE) modelling for the evaluation of changeability measures on a prodution system. Aspects of integrating I4.0 measures are however beyond the scope of the approach. The dynamic relationships within changeable manufacturing systems can also be modelled by combining agent-based simulation (AB) and DE. In this way, product-specific flows as well as specific elements of PSs (e.g. storage, workstation) can be modelled. A generic approach allows adaptations of the model elements and enables the focus on specific key performance indicators (KPIs) (Schönemann et al., 2019).

By now, simulation models for changeable PS use sub-models to model the existing elements of this system. Those elements can be connected via material, energy and information flows (Florescu and Barabas, 2020; Filz et al., 2019; Kirchner and März, 2002). The used agent-based approach of Filz et al. allows the flexible rearrangement of the system. Each of the generic agents consist of parameters, a specific behaviour and interconnections to other agents (Filz et al., 2019). The change of parameters within the sub-models allows the investigation of different sub-model types, e.g. a transportation agent can be either a tugger train or an automated guided vehicle (Filz et al., 2019). This enables the investigation of several scenarios.

The planning and assessment of I4.0 measures is difficult due to the case specific complexity of PSs. None of the above models investigates the impact of I4.0 measures in a systemic context and provides decision support prior to implementation based on quantifiable performance indicators. Hence, there is a strong research need for the planning and assessment of I4.0 measures in changeable production systems.

## 3 Generic I4.0 simulation framework

Core of the framework is an agent-based production system model that is supplemented with a generic module for I4.0 measures (Figure 2). The module contains a structured catalogue of I4.0 measures and characterizes them according to quality, cost, time and sustainability dimensions (see also Figure 1). Within the production system model, the I4.0 measures are evaluated in a systemic context. Therefore, potential cross-impacts between measures and inside the process chain (e.g. shifting of bottlenecks) are evaluated with regard to relevant KPIs. A generic model library contains PS elements covering a wide variety of real-life scenarios. These are used to flexibly set up production systems on a case specific basis. The input and output module provide an interface for parametrizing the models and investigating the assessment results. In the following, the production system model and the generic model library will be described with a special focus on the integration of I4.0 measures.

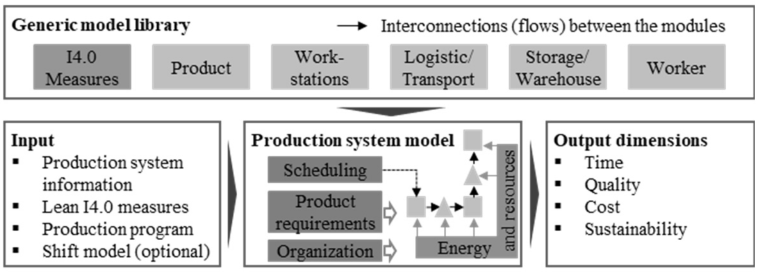


***Figure 2:*** *Overview of generic I4.0 simulation framework*

### 3.1 Production system model

This module coordinates the material flow inside the production system and provides functionality to calculate KPIs, e.g. lead times or utilization. The module is a generic process chain modelling environment. Therefore, it can be used to model any process chain in discrete manufacturing according to the user's input. The underlying logic applies agent-based modelling to allow for a multidirectional interaction between the generic production system elements from the model library. Consequently, the system performance evolves in a bottom-up manner. For example, product agents store their individual processing sequence based on the incoming orders. During simulation, material supply agents and workstations respond to the specific processing sequence and execute the transformation process.

### 3.2 Generic model library

The model library consists of generic agent types, which represent fundamental elements of a PS. As modelling of generic elements of a PS has already been discussed in literature, a reference should be made to models that served as inspiration for the model library: logistic/ transport (Filz et al., 2019), product (Schönemann et al., 2019), workstations (manual and automatic) (Langer et al., 2021) and human worker (Halubeck and Herrmann, 2011; Schönemann et al., 2019). The agents have interfaces to interconnect different flows. Material flows determine the processing route of the (individualised) products through a PS. Energy flows allow the forecast of energy demands and are mainly modelled as inputs into the system boundaries. The data flows are mainly used for the interconnection between the agents. This is especially useful for the implementation of I4.0 measures. From a generic point of view, there are two different groups of I4.0 measures – process and process chain related measures. Both are depicted in Figure 3 within an exemplary process chain of two workstations and two warehouses connected via transport agents. The process related I4.0 measure is shown with its system boundary influencing only a single process step (here, the first workstation). The process chain related I4.0 measures either influence and/or receive data from several agents in the process chain.

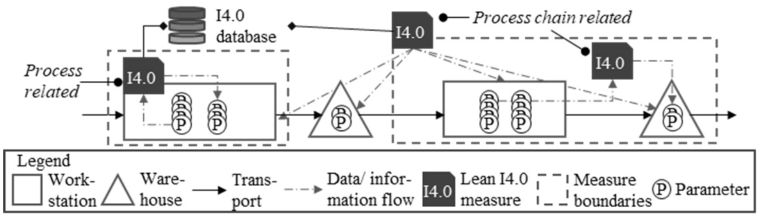


***Figure 3:*** *Schematic I4.0 measures implementation into the production system model*

The behaviour of the agents is determined by the agents' parameters as well as state charts. For a better description of how I4.0 measures interact with the generic elements, the agent storage supplemented with a I4.0 measure, the aforementioned digital assistant system (DAS), is illustrated in Figure 4.

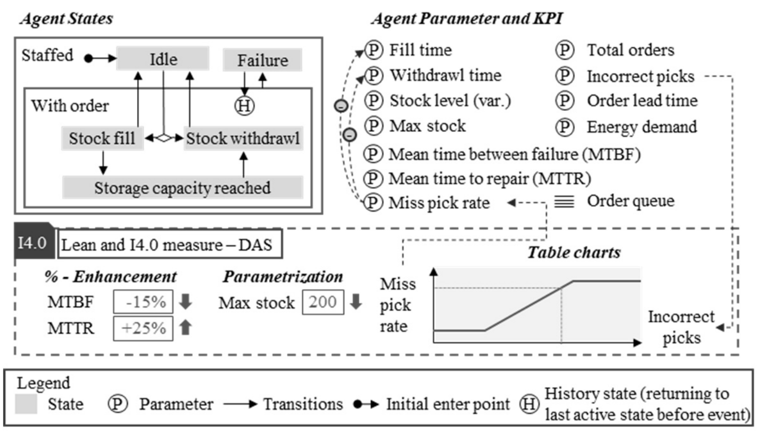


***Figure 4:*** *Exemplary illustration of storage agent with integrated I4.0 measure*

This agent is able to fill and withdraw stock. The orders, which are interconnected with the product agents, reaching the storage agent are inserted into an order queue and consequently worked off. If the stock level reaches maximum stock, then the stock has to be withdrawn first before it can be filled again. The parameters on the right trace the process quality being able to calculate KPIs as the order lead time or picking accuracy. In order to allow for the investigation of process KPIs, the parameters total orders, incorrect picks and order lead time are raised continuously. These parameters are aggregated and can be extended, depending on the KPIs to be assessed (compare section 2).

As an I4.0 measure exists of the elements of a CPPS (compare section 1), the data acquisition of the physical world can be simulated by utilising the agent's parameters. The cyber world and the feedback element of a CPPS can be simulated by modelling the change of an agent's parameter according to the influence of the I4.0 measure. As illustrated in Figure 4, the influence of an I4.0 measure on the agent is modelled using table charts, a percentage enhancement or parametrisation.

The choice of modelling depends on the available data and relevance of the process step. The values can be taken from a database or individually parametrised on a theoretical or empirical basis. Since the specific impact of I4.0 measures is only available for a few applications on usually specific production systems, reference cases for similar I4.0 measures can also be used to allow a first assessment. When more I4.0 measures are implemented on an agent, the beneficial and disadvantageous impacts between the measures need to be addressed. For this, a cross-impact analysis is suggested (Martin et al., 2020). In the exemplary case in Figure 4 the integration of a pick-by-vision DAS is shown, but also further measures could be added. Since the integrated DAS requires further maintenance and will cause failures, the MTBF is decreased by 15 %, while the mean time to repair is increased by 25 %. Furthermore, the integration of the DAS will reduce the maximal stock capacity to 200 products. Additionally, depending on the already existing incorrect picks, the missed pick rate will be adjusted according to a given table function. The fill and withdrawal times are bounded to the missed pick rate and will be reduced according to their calculation within the simulation.

## 4 Framework application

The framework was applied on a changeable PS for the individualised primary and secondary packaging of pharmaceutical solid dosage forms, such as tablets or capsules. Figure 5 illustrates a changeable PS with one of the possible material flow routes in the system. Within the primary packaging, a foil is deep drawn into a blister, then filled with solid dosage forms and in the next step sealed. After printing individual information on each sealed blisters' cavity, the separation process perforates the blister and concludes the fully automated primary packaging process chain. In the secondary packaging step, the blister cavities as well as a pharmaceutical supplement are manually packed into a secondary package.

The technical system of the changeable PS consists of a software component, master and service modules. Those modules are connected by material, energy and information flows. The master modules use robots for the systems material flow, are used as small buffer and support the service modules within their process if necessary. The service modules offer a specific manufacturing service and are connected to the master modules via multi-functional, fast-switch plugs allowing all necessary flows. Hence, the service modules can therefore be changed quickly, allowing to change the PS. The centralised software component is used as a broker between products and service modules and as an interface to the user of the system.

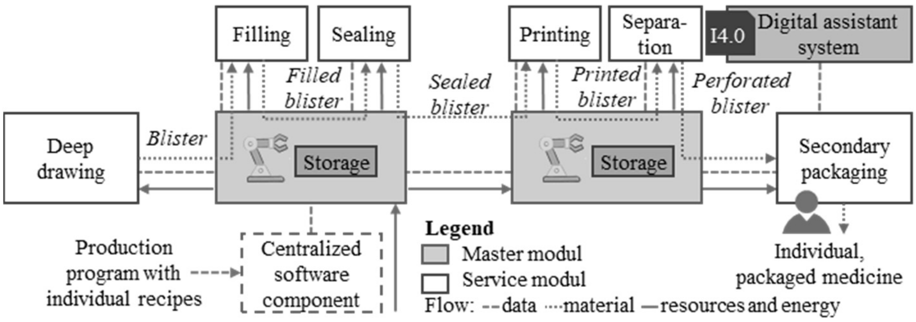


***Figure 5:*** *Overview of changeable production system with I4.0 implementation*

The production program consists of highly individualised pharmaceutical products. Each order can have varying dosage forms, formats and secondary packaging as well as an individualised print on the blisters to name only a few. In this use case, the limiting factor for the overall performance of the system is the quality at the manual process step of secondary packaging. This has been previously assessed with an extended value stream methodology based on (Martin et al., 2020).The core question therefore is how to increase the quality rate by implementing an I4.0 measure and which other performance indicators are affected as well. The above described DAS shall be simulated within this changeable PS, forecasting quality KPIs.

Since rearrangements of flows are necessary, a flexible modelling approach is needed to adapt I4.0 measures. Model libraries of common simulation software are mostly not able to model the impact of I4.0 measures. The required elements for this framework are therefore modelled within the simulation software AnyLogic® from the AnyLogic Company. Allowing a decision support, two scenarios are simulated using the generic I4.0 simulation framework. The first scenario simulates the system without and the second scenario with the described DAS for the secondary packaging step. Within the secondary packaging process step, the DAS guides the user to correctly chose the packaged drugs within the perforated blisters. In addition to the correct selection of the blisters, the quality of the perforated blisters is controlled when reaching the service module. In case of detected quality problems at the secondary packaging, the products are newly produced. For the simulation, the different processes are modelled with a special focus on quality parameters. Since there is no data of the DAS for this specific use case available, empirical data was acquired and transferred from another assembly station from a learning factory with similar basic features and implemented DAS. The parameter changes for the scenario with implemented DAS are shown in Table 1. It can be seen that the (pre-/post-) processing times are significantly decreasing with the implementation of the DAS. The quality rate can be set from 90 % to 100 % and the DAS has a failure detection rate of 95 % instead of 80 % when only the worker checks the incoming quality.

***Table 1:*** *Parameter changes of the DAS for the workstation secondary packaging*

| Pre-processing time | Processing time | Post-processing time | Quality rate | Failure detection rate |
|---|---|---|---|---|
| - 80 % | - 25 % | - 100 % | 100 % | 95 % |

In this use case, the simulation results regarding the quality and lead time of the products are of relevance for the planner's decision. Therefore, Monte Carlo simulation (n=10) has been applied. The resulting quality indicators as well as the lead time is illustrated in Figure 6. In comparison to the reference scenario without the implementation of the DAS,

- the Not-right-first-time (NRFT) indicator has increased on average by 1400 ppm products (+15 %),
- the overall process quality has increased on average by 11 % points reaching 100% compared to 89 % for the reference scenario,
- and the orders' average lead time is reduced by 53 sec (-2,5%).

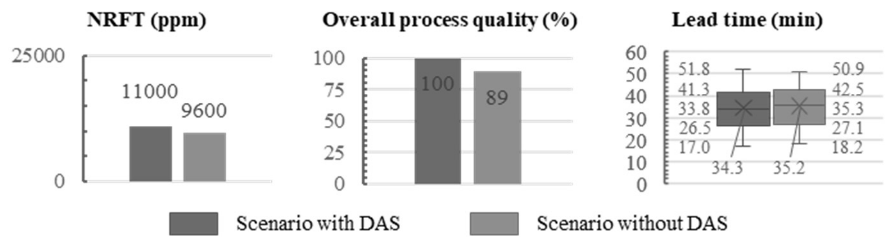


***Figure 6:*** *Simulation results comparing simulation scenarios with and without DAS*

Since the detected failure probability with the DAS increases at the secondary packaging process step, the NRFT indicator increases as well. However, the final overall process quality increases in comparison to the scenario without the DAS. With increasing simulation runs, it is only stochastically justified that the overall process quality will decrease to 95 % as this is the probability for the failure detection with the implementation of a DAS. The lead time is mainly influenced by the (pre-/post-) processing times and the failure detection rate. The first is shorter for the DAS and the second results in longer lead times per product, due to the fact that the products have to be produced again. The shorter (pre-/post-) processing times have a higher influence on the lead time and therefore the lead time is reduced slightly.

It has been shown that with the implementation of the DAS in the changeable PS, the overall process quality and the lead time improves, while the NRFT has worsened. This information is particularly of interest for the production planner and helps to decide on the implementation of the DAS.

## 5 Conclusion and outlook

In order to cope with the increasing complexity of changeable PSs, production planners are faced with the challenge of successfully implementing lean and I4.0

measures. This paper presents a simulation-based framework for planning and assessing lean and I4.0 measures in changeable production systems. The framework evaluates I4.0 measures in a systemic context. Therefore, not only direct impacts but also potential cross-impacts between measures and inside the process chain (e.g. shifting of bottlenecks) are evaluated with regard to relevant performance indicators. Based on VDI 2870, simulation-relevant indicators were determined that address the different dimensions of quality, cost, time and sustainability. While the approach can be flexibly applied to evaluate KPIs from all dimensions, the case study primarily focused on the benefits of employing a digital assistant system in individualised pharmaceutical production on quality indicators. The results indicate that the implementation of the DAS not only increased the quality but also reduced the lead time of production, which together leads to a better customer satisfaction. Based on the above findings, further studies can be conducted to quantify the effects of I4.0 measures on other KPIs. Likewise, consideration of other I4.0 measures is of great importance in order to obtain an overall view, especially when combining different measures. Finally, the extension of the approach to include the parameters for determining product quality is useful in order to take into account other influences in addition to the process and production. Further research should be made on the impact assessment of individual I4.0 measures to allow building an I4.0 data base.

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