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Modelling the dynamics of products and processes requirements

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Abstract

This paper proposes a new modelling framework aimed at overcoming the current limitations of existing techniques for the representation of products and processes within a Technology Forecasting study. Starting from the review of the available modelling approaches, the authors define system requirements as the key elements to represent both drivers and barriers for the evolution of technical systems, analysed in the context of a business process. The new proposal allows such requirements to be mapped in an integrated and scalable model connecting finished goods with the related business processes, so as to collect the knowledge from different experts and stakeholders in a unified and manageable description, thus reducing the risks due to uncertain and partial representation.

The paper presents also an example of application in the field of pharmaceutical tablet manufacturing, focusing on the industrial processes requiring the granulation of pharmaceutical powders. An in-depth discussion about the emerged criticalities supports the definition of further developments to make this approach more repeatable and suitable for Technology Forecasting methodologies.

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Keywords: Product model; Process Model, Technology Forecasting, Technology Evolution; Decision Making;

1. Introduction

The rate of product innovation increased considerable in the last years. This situation forced companies to quickly adapt their organization, processes and products to better answer the emerging demands from the society. In such a continuous fight to survive the market competition, companies need to anticipate the main features of future products and related manufacturing processes [1]. In this context, the definition of reliable practices and supporting tools having this purpose allows driving with better effectiveness and efficiency the decision making processes at diverse organizations levels.

Several methods for Technology Forecasting (TF) exist, with different degree of reliability, depending on the domain of application, the available resources and the initial data and information available. Indeed, most of the TF methods require a clarified vision of the present situation and/or the historical context, so as to

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suitably research what is going to happen in the future. However, their applicability in different industrial domains is not always feasible: for this reason, there are more than one hundred methodologies with different characteristics and specific aims for TF analysis [2]. On the other hand, none of them can stand the test of repeatability [3].

One of the main reasons behind this issue stands in the logic behind these techniques, which collect information focusing on just products or processes. Indeed, Utterback and Abernathy have clearly pointed out that both the evolution of products and processes follow a common dynamics [4], thus implying that there exist important relationships both between their characteristic variables and with the context in which the technology is exploited.

To this purpose, this paper addresses the emerging need to map knowledge and information with a novel modelling technique, suitable to have a clear and integrated overview of the technology evolution from both the sides of product and process. The next Section briefly summarizes the most used and well-acknowledge modelling techniques for products and processes, with the intent to point out the relevant features to be integrated in the new proposal that is described in Section 3. Before the concluding Section, the authors present an application of the novel modelling approach in the field of tablets manufacturing and a discussions of those preliminary results.

Nomenclature

CP/EP	Control/Evaluation Parameter
EMS	Energy-Material-Signal
ENV	Element-Name-Value
IDEF3	Icam DEFinition for Process Description Capture Method
MTS	Minimal Technical System
TF	Technology Forecasting

2. Review of modelling techniques

The identification of relevant data and information, within the market and the industrial context under investigation, depends on the knowledge of experts and forecasters carrying out the analysis. Therefore, it is critical to organize, represent and highlight the relevant features concerning the specific technical domain. With this respect, many techniques are capable to describe very specific details of products or processes. Table 1 collects a non-exhaustive set of modelling techniques as they are proposed by their authors or as commonly used by scholars. The analysis focuses on the following set of techniques, even if not complete, because they cover all the main constructs and building blocks used for modelling. References, acronym meanings and more detailed descriptions, with examples of application, are available in [5].

Table 1. Summary (partial) of modelling techniques capable to represent Processes, Products as well as Problems to be solved. The fourth column collects modelling techniques suitable for different purposes. TRIZ-based techniques are in bold.

Process focused	*Product focused*	*Problem focused*	*General purpose*
• EMS • Petri Net • BPMN2.0 • EPC • IDEF0 • IDEF3 • NIST Functional Basis	• **TRIZ/OTSM-TRIZ Function** • SAPPhIRE • Soutbeach • **TOP TRIZ** • **TRIZ MTS (Law #1)** • **Su-Field** • DANE/SBF	• FMEA/FMECA • FTA • IBIS • Ishikawa Diagram • **TRIZ/OTSM-TRIZ Contradiction,** • **OTSM-TRIZ Network of Problems**	• ARIS • DSM • **ENV** • ERD & eERD • FBS Framework • Functional Tree • **System Operator**

From the analysis of Table 1, it clearly appears that there exist several alternatives going beyond the representation of just products or processes. However, on the one hand, some of them are just sufficient to represent problems (Table 1, third column). On the other hand, the ones having a general purpose (Table 1, fourth column) suffer from different lacks: DSM, for instance, can be used for both products and processes, but it misses their mutual connections; ARIS allows both product and processes to be mapped in the same static framework, thus missing the perspective on technical system evolution; etc… In other words, none of the existing modelling approach can currently capture the relevant facets of products and processes so as to support a TF methodology. Besides, the profile of the new modelling technique can be defined according to the lacks emerged from the analysis of the state of the art.

Therefore, such a modelling approach, beyond mapping products and processes in a unique framework, should also satisfy the following set of requirements:

- Versatility and ease of application to different industrial processes;
- Scalability to different detail levels, so as to map the knowledge of different experts and stakeholder of the industrial process;
- Capability to represent time dynamics with an evolutionary perspective on technology.

On this purpose, Table 2, the authors briefly present a limited number of modelling techniques capable of satisfying some of the above set of requirements. Some of their features are used as building blocks of the new modelling technique proposed in Section 3.

Table 2. Analysis of modelling techniques with relevant building blocks to be integrated within the original proposal of Section 3.

Modelling Technique	*What it is for*	*Relevant constructs*	*Relevance for the new modelling technique*
ENV model [6]	Framework to describe both material and immaterial entities	• Element (an entity) • Name of the parameter (description of a property or feature of the Element) • Value (quantitative or qualitative) of the Parameter	Representation of concrete and abstract concepts with both a qualitative and quantitative approach
System Operator [7]	Description of technical systems with hierarchies and time dynamics	• Time Dimension (x-axis) • Space Dimension (y-axis)	Time Dimension can be interpreted as historical time for mapping systems evolution
EMS model [8]	Description of functions as Input / Output transformations	• Input / Output flows of Energy, Material and Signal • Functions as black boxes	Function as an element transforming flows Fractal logic of function decomposition
NIST Functional basis [9]	Reference description for functions and flows	• Nouns for describing flows • Verbs for describing functions	Improvements in the repeatability of analysis with predefined textual terms
IDEF3 [10]	Description of processes and states of entities involved in the process with a time perspective (see activation plot)	• Process schematic diagram (for describing processes as a sequence of functions) • Transition schematic diagram (describing the states of entities along the process)	Characterization of functions with indexes and further references
OTSM-TRIZ Contradiction [6]	Problem description as a conflict between requirements	• Evaluation Parameters (as elements measuring satisfaction and dissatisfaction) • Control Parameters (design variables impacting with opposite results the EPs)	Elements measuring the satisfaction or the dissatisfaction of design choices

3. A novel integrated framework for product and process modelling

As mentioned in the introduction, the emergence of demands from the society drives the quick and frequent changes companies should introduce to their products and related manufacturing processes. In this perspective, requirements represent the link between market demands and technical issues [11]. Moreover, the satisfaction of requirements influences the decision-making process for both the choice of best alternatives and the search of new solutions as also suggested by the IEEE's definition [12]:

> *Requirement: a statement that identifies a product or process operational, functional, or design characteristic or constraint, which is unambiguous, testable or measurable, and necessary for product or process acceptability (by consumers or internal quality assurance guidelines)*

In this context, it appears clear that there exist a strong affinity between the concepts of system requirements and EPs, as presented in Table 2. Besides, each manufacturing technology has its own specific impact on some of the product characteristics as well as on the higher levels of the business process, determining the satisfaction or the dissatisfaction of their requirements. The changes of values or requirements, as well as the identification of completely new ones, represent one of the main evidences of technical systems evolution.

On the basis of these considerations, the authors propose a new modelling approach suitable to map the requirements at different detail levels, considering technological alternatives and their potential impact on the definition of product characteristics. Figure 1 summarizes the overall framework of the modelling technique: the EPs concerning different facets of technology are represented by different colours. The identification of requirements goes beyond the purpose of this paper, however a set of criteria for their elicitation from experts is available in [13]. The following subsections aim at describing the main characteristics of the model.

3.1. Sustainability level

This level has been included consistently with the importance of the concept of Sustainable Development (SD) in many facets of technology. Moreover, SD is increasing its influence on policies, laws and regulations, resulting in a growing number of context-based constraints for technology evolution. Indeed, according to the Brundtland report [14], three main pillars give the direction for the SD: Social, Economic and Environment. Therefore, the introduction of these elements within the model should help analysts to properly identify the context in which the future of technology is investigated, considering the impact those pillars may have on the organizational level of the business process. The model allows the analysts to flexibly add the representation of internal company hierarchical levels, if necessary for the completeness of the representation.

Figure 1 presents, as an example of perspectives that can be embedded in the model, two different levels of analysis: Environment and Organization (orange arrow). With reference to the legend of Figure 1, the boxes describing these stages are divided in two parts: the upper part contains a specification of the function, the lower part collects the relevant requirements (EPs) impacted by that function. As for the EMS model, such functional stages aim at transforming flows of energy, material and/or signals.

3.2. Process Technological Alternatives Level

The model also details one of the organizational stages as a process according to a hierarchical logic (blue arrow). This part of the model aims at representing in a unified picture the different available technological alternatives (green arrow) according to the state of the art. In other words, one of the stages of the whole business process gets decomposed into a set of elementary functions whose sequence represent the technical process at the core of the investigation.

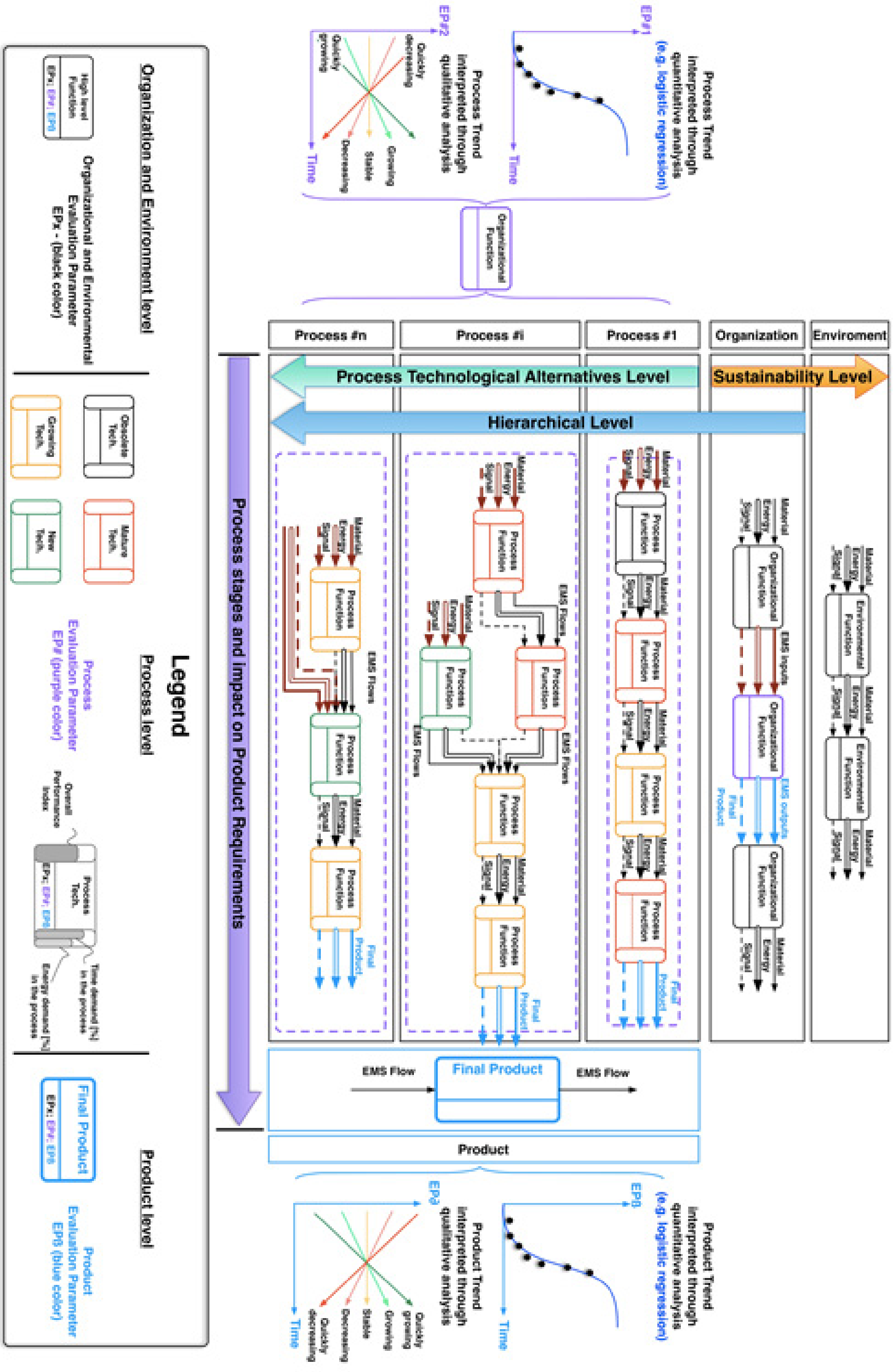

Fig. 1. The novel framework for mapping requirements of both product and processes with an evolutionary perspective.

Figure 1 shows that the elementary stages of the process are described consistently with EMS model logic and the repeatability of this decomposition can be improved through the combined adoption of the NIST functional basis, as suggested in [15]. On the contrary, consistently with what is classically proposed for this modelling approach, e.g. [8], since this novel proposal aims at representing the available technical alternatives, the EMS flows involved in the industrial processes should be represented with reference to the real situation, thus including those flows that are not just "desired", but also "required" by the system for working. The functional boxes, similarly to the ones of IDEF3, are further subdivided into 4 parts. In this original modelling approach, they assume the following meaning:

- top (function specification) and bottom (EPs) parts follow the same logic presented for boxes at sustainability level;
- the left side presents a qualitative indicator about the performance level at which the technology is exploited within the process, with regards to its full potential (as emerged in lab tests or in different contexts);
- the right side of the box collects two bars representing the relative time and energy consumption by the technology with respect to the overall process under investigation.

With the purpose of easing the readability of the model and the decision-making process, a colour scale defines the maturity of the different technologies involved in the industrial process: obsolete (black), mature (red), growing (yellow) and new technology (green).

3.3. *Product Functional description and related requirements*

The functional description of the product makes use of two complementary approaches. The product is represented as a set of EMS flows (light blue) from both the perspective of the organization and the technological alternatives, considering it as the final outcome of the specific process under investigation. Moreover, since for TF and the anticipation of product future features it is relevant to map its requirements as well, the authors include a specific level, which is orthogonal (purple arrow) to the process and shown inside a light blue rectangle. This specific product model takes into account its function and describes it with the EMS model. Even this functional box is subdivided into two parts following the same rationale presented for the Sustainability level, with the exception that the textual description just reports the product name as for the flows at the Organization and Process levels.

3.4. *Monitoring the evolution of Evaluation Parameters with time perspective*

The above parts just provide a rich description of the technologies, even considering the mutual relationships between product and process requirements. However, this representation is static, thus neglecting the evolution of the values that the requirements are occurring along time. As for Figure 1, the authors have included evolutionary analyses with both a quantitative and a qualitative approach. The former is carried out with historical data so as to define the future behaviour of an EP according to statistical regressions (linear, logistics, etc.). The latter, on the contrary, defines the evolutionary trends for an EP on the basis of historical evidences and/or experts' judgement. Such a qualitative trend is represented through a straight coloured line (5 levels, from "*Quickly growing*" -dark green- to "*Quickly decreasing*" -dark red). Such option is most suitable also when the source data are scarce and not sufficient to define a significant statistical regression.

In general terms, the quantitative approach should be preferably chosen in a TF context, since it is necessary to predict when a certain expected changes occur, also by identifying the current stage of the technology lifecycle, as well as the gaps with the competing alternatives, so as to support the decision-making processes about technology substitution [16, 17].

This approach can be carried out for EPs concerning both products and manufacturing processes in order to define, on the one hand, the time-gap before the affirmation of a certain process technology and, on the other hand, the future and possible changes that can appear in the or the market behaviour, and thus in the set of product requirements.

4. An example of model: pharmaceutical granules for tablet compressions

Pharmaceutical tablets are products aimed at healing sick people or at preserving people's health conditions (Product level). A tablet is the result of process transforming the Active Pharmaceutical Ingredient(s) (API) and excipients from a powder status into pills. Excipients are required to improve the manufacturability and the conservation properties of the drug. Whereas a direct compression can be directly applied to API/excipient mixtures, the largest majority of current pharmaceutical compounds need an intermediate step of granulation to confer the powders the required characteristics for making them mouldable. This section presents an example of application of the modelling approach exclusively focused on processes requiring powder granulation, as presented in [18]. Figure 2 shows the model about four alternative technologies for tablet manufacturing (black rectangles spanned by the green vertical arrow): Dry Granulation (DG), Pneumatic Dry Granulation (PDG), Fluid Bed Granulation (FBG) and High Speed Granulation (HSG). In the past, granulation was performed through the production of a solution to be homogenized, dried and eventually reduced to granules. After the introduction of severe limitations about solvents usage, wet granulation technologies started using water instead of solvents, but still keeping the same equipment. More recently, the dry granulation processes have been proposed to reduce the harmful impact of water residuals into the tablets and to improve the efficiency of the overall production process. With reference to Figure 2, one can note that the incoming EMS flows (in dark red) present some differences among the four alternatives: wet-based granulation processes include the use of both *water* to agglomerate the pharmaceutical compound and *heat* to dry it after a first fragmentation.

Moreover, each of the process alternatives has been decomposed into elementary phases employing specific technologies so as to concur to the production of granules, before compressing them in a pharmaceutical tablet. Besides, note that the same technology can be employed independently from the process (e.g.: Vibrating sieves are used in DG, FBG and HSG). In addition, the specific process technologies shown in Figure 2 have different maturity levels. For instance, Wet and Dry mixing are, respectively, an obsolete and a mature technology, thus marked in black and red. The fluidization-based technologies are coloured in yellow because they are relatively recent and still growing. The Smart sifting technology of PDG, on the contrary, is completely new in the field of Tablet manufacturing and it is, thus, depicted in green.

The indexes pertaining time and energy consumptions (functional boxes at process level - right side) have been normalized within each of the alternative processes, in order to clarify the different impact of the elementary stages on the whole process. For what concerns the *overall performance index* (functional boxes at process level - left side), some stages use technologies without exploiting them at their full potential. This may even depend on the need of reducing some side effects in the object to be transformed, as in the case of *roller compaction* and *convection drying*. In the first case, higher compressing forces would produce harder granules resulting in higher time for bioavailability of the tablet. The lowest exploitation of drying performances is related to the need of reducing the water content in granules to the level they do not re-absorb water from the environment, resulting in a worsened shelf-life for tablets.

Moreover, 13 EPs, among the most relevant ones in this domain, are described and linked to the different levels and stages of the analysis:

- 5 EPs (in blue) are mostly related to the final product or its semi-finished stages;
- 6 EPs (in purple) are mostly focused on specific characteristics of the process;
- 2 EPs (in black), at last, focus the attention on two relevant requirements at the organization and environmental level.

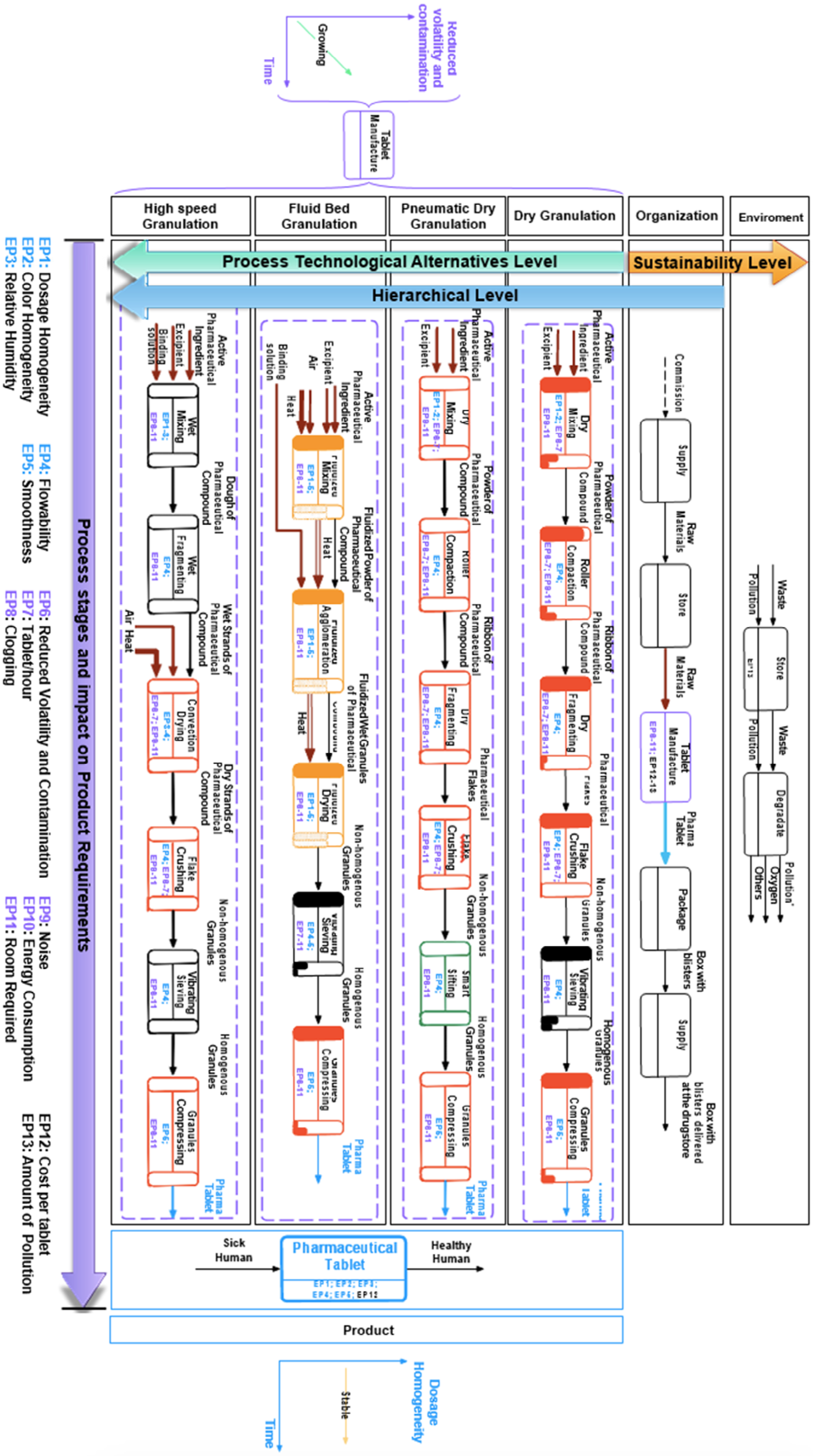

Fig. 2. Illustrative model of Products and Process requirements in the domain of Pharmaceutical Tablets manufacturing.

For two of them (*Dosage homogeneity* -EP of the product- and *Reduced Volatility and Contamination* -EP of the process) a qualitative indication of their evolutionary trend in time is provided at the sides of Figure 2.

5. Initial analysis of the outcomes after the application in the domain of Pharmaceutical Tablets

The hitherto described application of the modelling approach shows that the different characteristics of both products and process can be represented consistently with the proposed approach. Moreover, the novel framework allows the system requirements (here expressed as EPs) to be linked with the different technologies impacting them. In this context, this model also supports decision makers in better understanding the impact of their choices and strategies on the satisfaction of the requirements at the diverse levels of description. To this purpose, it is also worth mentioning that the overall amount of requirements, for both the product and the whole set of different technologies examined within the model, is not manageable inside the proposed visual framework. So as to keep it readable and usable by experts and decision makers, the authors propose to rely on the experts' judgement to fill the model with just the most relevant and important requirements, in order to focus just on the most critical issues preventing or driving the evolution of such technical systems.

Moreover, the availability of data for carrying out trend extrapolation about specific EPs represents one of the main issues to be faced. At the current stage of development, there is a current lack in defining which EP (among the whole subset of those embedded within the model) should be chosen for mapping the evolution of both the process and the product. For this reason, the model proposed in Figure 2 presents just qualitative trend description based on experts' opinion.

For what concerns the functional description of the product (blue rectangle, product level), the model shows a consistent limitation: it can be properly applied just for those products having a clear function (as for Pharmaceutical Tablets). On the contrary, some semi-finished goods that just have a property to be further exploited (e.g. the better compressed of Pharmaceutical Granules) rather than a defined function per-se, cannot be properly represented with an EMS model.

As for the Sustainability Level, the definition of the context (Organization and, more specifically Society and/or Environment), as a sequence of functions is not intuitive. In order to obtain more truthful descriptions here, a better specification of the meaning of functions for the Sustainability level appears as a primary need to be satisfied.

Moreover, it is important to add some considerations with respect to the repeatability and usability of the model: to develop the analysis at different levels, the competences of the teamwork should span from management to technology. Moreover, the lack of teamwork's experience in modelling can significantly affect the time consumptions to develop the whole analysis.

Finally, with respect to the set of characteristics presented in the subsection 2.3, different panels of experts should apply the model in diverse contexts and technical domains so as to test its versatility and ease of application, together with the effective scalability to different detail levels. Moreover, the model should be also checked against other modelling techniques according to appropriate criteria for quantitatively measure its effectiveness in representing products, processes as well as their mutual relationships with an evolutionary perspective.

6. Conclusion

This paper presents a research for defining the overall framework of a novel modelling technique suitable to support Technological Forecasting methodologies and the subsequent Decision-Making processes. In this context, the authors stem from the analysis of existing modelling techniques so as to identify their current lacks and define the desired characteristics of the new modelling approach.

The original proposal allows the representation of relevant information for both product and processes considering the mutual relationships between manufacturing technologies and system requirements, declined at different detail levels. Moreover, different alternatives can be represented according to a scalable and hierarchical logic embedding also the main sustainability pillars (Economic, Social and Environmental) that drive or prevent the evolution of technical systems.

Such a model can support the decision makers with a visual representation that ease understanding the consequences of their technological decision in the perspective of planning the future strategies for their company. A preliminary example of its application in the field of pharmaceutical tablet manufacturing has shown the possibility of mapping the required information in an easy and comprehensive way. Nevertheless, some complications in defining the context in terms of functional stages, as well as the identification of quantitative data from carrying out statistical regression highlighting technology trends should be mentioned as well. However, the complete evaluation of the effectiveness of the approach, so that it can be proficiently used within a Technological Forecasting methodology, should be carried out on a wider number of case studies. To this purpose, an intensive testing activity has been planned in the forthcoming future, also with the purpose of fine-tuning the overall model framework and eliminating the emerged limitations.

In terms of expected further development for the modelling technique, the authors also aim at providing a detailed set of guidelines that overcome the current description of the main constructs, so that the model can be more meaningfully enriched with detailed information about the performances and resources consumption. Moreover, these guidelines should also aim at supporting both comparative analyses among competing technologies and the selection of the appropriate EPs to be used as reference parameters for trend extrapolation and logistic growth analysis.

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