

Approach to the Integration of Management Systems in a Pharmaceutical Organization

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ABSTRACT

This paper discusses how a system approach to management can be used for the development and implementation of an integrated management system (IMS) in a company producing medicinal products. It is argued in the paper that approaches to the solutions of how to integrate management systems all require two elements: a conceptual model and a supporting methodology. Although a large number of models has been developed that could provide the basis for integration, development of methodologies to achieve fully integrated systems is still stagnating. This paper presents the IMS model that can be used to integrate the requirements of existing and upcoming standards in the pharmaceutical industry, followed by a discussion on the issue of the IMS methodology.

Keywords: IMS, Quality, Management, ISO, GMP, PDCA.

INTRODUCTION

Socially accountable organizations engaged in medicinal products production are confronted with a challenge to establish a growing number of standards. All medicinal products manufacturers are obliged to have GMP certificate, and GDP certificate for distribution. At the same time, there are also management systems, such as ISO 9000 for quality,¹ ISO 14001 for environment,² occupational health and safety standard, OHSAS 18001³ and information security, ISO 27001⁴ standards, and ISO 17025⁵ for tests used in the quality control. These standards are quickly gaining international acceptance and are becoming a necessary condition for doing business.

Today, the most commonly implemented standards are in the ISO 9000, 14000, 17000, 18000, 20000, 22000, 27000, 31000 series and others. At this moment, the main question that arises is how to implement these standards integrated. The answer lies in integrated management systems which should link at least two, and preferably all relevant (from five to seven), standards.

This paper deals with the development of individual business standardisation models and with their integration with the aim of IMS design and application, from the perspective of requirements for quality management, environmental protection and occupational health and safety, and some others.⁶

The paper aims is to process basic factors of integrated management systems and to present proposals for designing integrated management systems in an organization producing medicinal products, in a manner that will be applicable in a wider domain.

MATERIAL AND METHODS

Working on this research, authors used professional and scientific sources that are related with the field of research. All the materials that have been used are listed in References. In making of this work great resource was authors experience in the field. Experience in manufacturing, quality control, quality assurance, regulatory affairs have been precious for conclusions that have been made. Authors are implementers

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and responsible persons for almost all management systems referenced in this paper. Problems in day-to-day practice were cause of thinking of solutions that are presented in this work.

RESULTS AND DISCUSSION

Pharmaceutical industry belongs to the most highly regulated industry branch, where application of quality management models for this field – Good Manufacturing Practice,⁷ Good Distribution Practice,⁸ and International Conference on Harmonization (ICH) Q10 guidelines is requested, which speaks of the Pharmaceutical quality system.⁹ The ICH Q10 guideline gives general postulates of Good Manufacturing Practice integration with the standardized quality management system ISO 9001, which should lead to a more efficient and effective product realization.¹⁰ Socially accountable companies in the pharmaceutical supply chain are faced with the fact that they must establish a growing number of standards which are a necessary condition for doing business and survival in the market. Globalisation and big competition in the pharmaceutical market work in favour of those organizations that will optimise their resources, reduce expenses and implement new, flexible management models.¹¹

Looking through the prism of requirements to be met, pharmaceutical organizations are found in a special zone. On one side, they should reply to demands of the market imposing ISO standards as control instrument, and on the other, they should reply to the legislation obliging them to GMP and GDP implementation. While ISO standards allow certain amount of freedom in fulfilling requirements, leaving to the organizations to find answers to the requirements on their own, Good Practices give concrete answers to the set requirements and impose them as the only ones acceptable. Reconciliation of these two currents that have an impact on the integrated management system architecture and, at the same time, continuous cost reduction to make the products available, represent a great challenge for the management and IMS engineers, and a field in which further research is expected.

Due to the proliferation of the function-specific management system models and the related costs, many organizations which already have or about to have these systems in place, have begun questioning the introduction of management system models as completely separate entities. Consequently, a growing need has emerged to somehow integrate both the standards and the internal management systems that they describe in order to reduce wasteful redundancies, facilitate implementation and possibly generate synergetic effects.¹³ However, practical experience and research

(e.g. Karapetrović, 2002¹⁴) shows that the integration of standards, on the one hand, and management systems, on the other, are two clearly separate issues.

International organizations for standardization are thinking of establishing an international “integrated standard” which would be capable of covering several functions in an organization, for instance quality and environment, but it would be unrealistic to expect any time sooner a fully integrated standard. Any new function-specific management system model would consequently require its revision and expansion.

Therefore, what organizations really require is not an integrated standard in itself, but a conceptual model that is able to accommodate the inclusion of any currently existing and potentially emerging management system standards. At the same time, this model should be able to harmonize the differing requirements of function-specific management system models.¹⁵ Different and, not that seldom, even contradictory system objectives, make the realization and, in general, will for integration difficult. System management does not have the purpose for itself only, but it is oriented towards the success of a company. Standards require the management to clearly formulate the company policy thus providing a precise framework for action. An organization should be established as an integrated system in which managers manage relationships between elements, which are integrated above the individual goals.¹⁰ Integrated management system enables the management and employees to clearly understand different requirements of individual field management and to fulfil them in accordance with the organization values.

A common denominator of the integration of management systems in organizations contains two parts:¹⁵

A model to analyse, harmonise, align and integrate specific standard requirements.



Figure 1: Pharmaceutical organization specificities in view of the IMS approach.

A methodology to support the conceptual model and to guide an organization towards the integration of internal management systems.

The model and methodology discussed here are analysed within the systems approach to management. A description of the systems model for the integration of management systems is given, followed by a brief analysis of the methodology to accomplish an IMS.

A systems model for IMS

A system is a composite of inter-linked elements that make a whole and serve together a purpose. The systems approach provides the basis for grouping of different elements into one common framework. The most appropriate model for use should be able to meet a number of criteria crucial for the development of a solid IMS in an organization. The model should be (Karapetrović, 2002¹⁴):

- Able to incorporate all the common elements of function-specific management systems.
- Generic, in other words, universally applicable to all organizations. This characteristic is important for the provision of the possibility to include management systems emerging in the future.
- Flexible, meaning that it must have the ability to meet the specific requirements of quality, environment, safety, social accountability or any other management system.
- Fully compatible with the function-specific management system models in order to provide seamless transition from the generic to the specific model, and vice-versa.
- Supportive of the related methodology to implement, assess, maintain and improve an IMS in an organization. For instance, allowing for the inclusion of appropriate auditing practices is extremely important, since no true IMS can exist without a simultaneous alignment of audits. In fact, many benefits of an IMS come directly from the reduction of auditing resources.

Developing an IMS model in pharmaceutical environment

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Developing an IMS model in pharmaceutical environment

The systems model suggested by Karapetrović and Willborn (1998 a, b)¹⁵ that complies with the stated requirements can be found in the literature.

The model follows a universal cycle of stakeholder satisfaction, from the determination of stakeholder and company goals, to the design and implementation of processes and incorporation of resources to achieve those goals. Since it contains processes as one of its three main elements, and continuous improvement as one of its primary objectives, the systems model is compatible with the process and PDCA¹⁶ approaches of the current MSS.¹⁵

For the particular application of integrating the requirements of the function-specific management system, the system approach provides the basis for grouping of different elements into a common framework. In this manner, we can combine the requirements of, for example, “product quality” and “sustainability” standards. Karapetrović and Willborn illustrate how this is possible for the ISO 9001 (ISO, 2000) and ISO 14001 (ISO, 1996) standards.¹⁵

Jonker and Klaver¹⁹ state that the integration of standards lacks a methodology, and consequently lacks a model, so they propose integration at different levels: policy, conceptual, system, normative and pragmatic. A common policy based on a strategic decision on integration is necessary, otherwise a number of parallel policies for each new system appear. The EFQM model can be adapted as the conceptual model. The development of a model in a step-by-step way leads to integration.

The system based on a model brings the requirements such as preparation, assessment, improvement and assurance into one system. The model development, the method and the system form a cyclic development pattern. The normative approach involves taking into account the main standards and their norms and values, and handling the differences in an explicit manner, which makes integration easier. At the pragmatic level, integration is viewed from the employee's point of view. There is a need to make one set of questionnaires, instructions and routines, as having separate documents for each system will only serve to confuse workers, who would consequently make mistakes, get confused and lose motivation. Employee training is therefore a key element in integration. Training on the standards and their approaches, along with task-related training, is necessary if the system is to succeed.

QuEnHeSa model¹⁷ developed by Dr Divya Singhal and Keshav Ram Singhal, was first issued as draft in September 2010, and thereafter 200 different experts and organizations worked on it. It integrates quality, environment, health and safety management systems' requirements into a single document. The model

incorporates 12 principles: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making, mutually beneficial supplier relationship, environmental performance, prevention of pollution, health and safety performance, prevention of accidents. The "QuEnHeSa" model is organized into eight elements: integrated management systems, management responsibility, resource management, design and development, purchasing, implementation and product realization, emergency preparedness and response, monitoring, measurement, analysis and improvement. The model implementation must not neglect important factors of each organization, such as: specific environment, specific organization goals, legislation, size, type and structure of the organization.

The "Sun" model as shown in the Figure 2 was designed by the authors of this paper, as a reply to the requirements stated in Karapetrović, 2002.¹⁴ By following system approach, the model is presented within its closer and wider environment. It was initiated by the stakeholder satisfaction, starting from the society, through community and owners on one side, clients on the

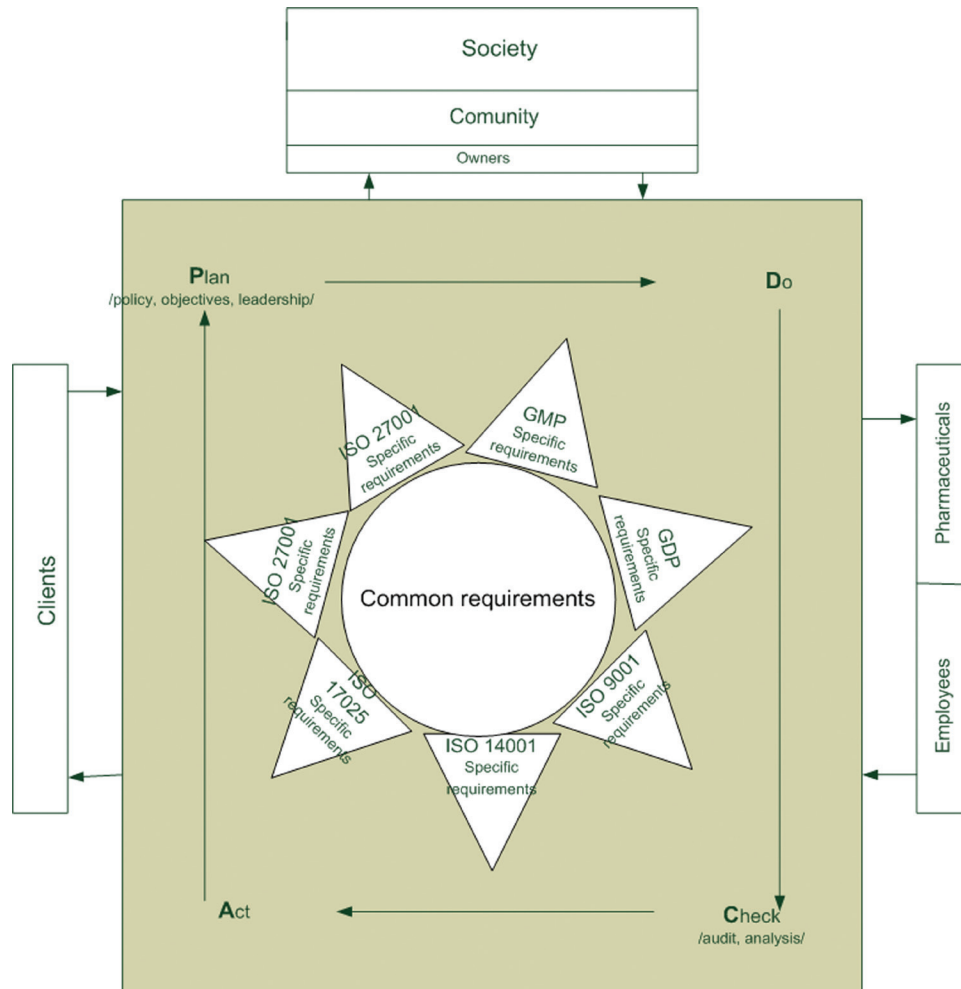


Figure 2: The IMS "Sun" model.

other, to employees and requirements referring to pharmaceuticals. The model is nested in the Deming feedback loop, the so called PDCA cycle (Plan, Do, Check, Act) according to Deming D. Edwards (1986), *Out of the Crisis*, MIT Center for Advanced Engineering Study.¹⁶ However, this model is robust enough to also integrate other standards relevant for pharmaceutical business. This means that we can expand pharmaceutical chain of supply to the parts referring to design of new business systems, whether these systems are new factories, new contractors, new products or new information systems.¹²

The analysis of each management system and mutual comparison brings us to a common denominator of requirements, which can be viewed as a whole, and thus it can be managed as a separate entity. It is presented in the Figure as the sun core. The result obtained by taking this common entity away from the single management system requirements is a separate beam representing the new entity that is approached as a separate whole. It is presented in the Figure as the sun beam. The central part of the model is occupied by the common requirements of all systems to be integrated, while the single requirements add to the common requirements thus each forming a separate IMS sub-unit.

In the specific case, the IMS sub-units consist of: ISO 9001 for quality, ISO 14001 for environment, OHSAS 18001 occupational health and safety standard, ISO 17025 for testing laboratories, ISO 27001 information security, GMP for pharmaceuticals and GDP for pharmaceutical distribution. The sub-units comply with the external requirements and internal needs that a pharmaceutical organization should fulfil.

In order to identify common requirements, it is suitable to make a comparative overview of all management system requirements which should be implemented in the specific organization. Two sets of requirements stand out in the analysis of the comparative overview: those identical, i.e. very similar and those specific to each particular management system. The common requirements include: documentation management, records management, organization's policy, objectives, competency, awareness and training, responsibilities and authorizations, resource provision, communication, planning, operation control, monitoring and measuring, audits, non-conformities management, corrective and preventive actions, review, etc.

An example of specific requirements can be ISO 17025 technical requirements, stated in the point 5, or control objectives and controls stated in the ISO 27001 Annex I. The "Sun" model integrates the current requirements within the pharmaceutical organization environment

and provides to the management system engineers a quick insight into the management systems which are expected to be implemented in a pharmaceutical organization. Taking into account that the model integrates a larger number of management systems than are present in practice or literature in pharmaceutical organizations, the application of the model is feasible in the future also, since it complies with the needs and tendencies of a pharmaceutical environment. On the other hand, visual interpretation of the model gives by itself an indication of the way how integration is to be approached, that is, what is the direction of activities for establishing an IMS.

For the needs of this paper, the Sun model was compared to the model suggested by Karapetrović and Willborn, 1998.¹⁵ One can observe similarities, but differences as well.

Similarities can be observed by looking at inputs and outputs of the presented systems. Both models are exposed to requirements and needs, which the organization implements as inputs in its goals and processes. Inputs depend of the specific management systems comprising the IMS. Both models identify the same external factors generating inputs, with the one difference that the model presented in Figure 2 also has specific requirements related to the field of work, i.e. to pharmaceuticals. Since the model should represent a system with feedback, external factors generating inputs represent the output target.

Both models recognize the PDCA cycle as the infrastructure for establishing feedback within the model.

Differences between the models compared are visible at first sight.

Karapetrović-Willbourn model distinguishes three main elements: goals, processes and resources, and gives an example of the specific application of the model to integration of ISO 9001 (ISO, 2000) and ISO 14001 (ISO, 1996). The "Sun" model is initially oriented towards the application and starts immediately from the common and specific requirements. This model refers to a larger number of management systems which should constitute an IMS and gives a clear starting point for the management system engineers. It also includes the systems not conceived as ISO standards, which will make integration process more complex: Good Manufacturing and Good Distribution Practice. The three elements of Karapetrović-Willbourn model: goals, processes and resources, the Sun model has implemented through the IMS sub-units, comprised of the individual management systems, and at the same time grouped within the common requirements.

The models compared do not exclude each other and do not represent extremes in view of the answers to the

set requirement of management system integration, but they represent guidelines according to which integrated management systems for specific circumstances can be planned.

A methodological analysis of IMS

As described in the previous section, the system approach can provide the foundation for aligning function-specific management system model, and consequently help in establishing an IMS within an organization.

The required levels of integration, the sequence of systems to be added to the common core, the actual elements to be integrated, and a myriad of other factors differ from one business to another. It is not possible to develop “the universal methodology” that will work in all cases.

Instead, contingent approaches based on a common (system) model and a set of principles that will guide an organization towards an IMS are required.

The elements of integration according to Marinković i Majstorović¹¹ are:

1. management commitment;
2. documents and records management;
3. planning objectives and key performance indicators;
4. corrective and preventive actions/continual improvement;
5. training of employees;
6. audits;
7. reviews by the management.

Crucial questions to the development of a methodology for the integration of management systems:

- What are the required integration levels? For example, Jonker and Klaver (1998)¹⁹ mention five: policy, conceptual, system, normative, and pragmatic.
- How should an IMS be developed? Integrating documentation, followed by aligning of internal objectives, processes and finally resources is one possible approach. The interested reader can consult Karapetrović (2002)¹⁴ for a more thorough discussion on this issue.
- What elements of each management system should be included? Some companies integrate parts of MS documentation (e.g. policy), others aim for full integration of objectives, processes and resources. Therefore, both partial and full integration are possible.
- What management systems should be included? This depends on the need and the availability

of supporting standards. Quality, environment and safety are the most common, as the underlying standards are readily available. Corporate social responsibility is also around the corner. Additional management systems and corresponding standards will inevitably appear.

- In what sequence should the chosen management systems be introduced? This depends on the existing systems and focus. Quality, followed by environment and safety is the most common order. Other possible sequences are discussed by Karapetrović and Willborn (1998),¹⁵ as well as Karapetrović (2002).¹⁴
- What should be the underlying organizational philosophy? Probably, full integration is required at the top and bottom organizational levels, while in the middle aligned but still separate systems may suffice. However, full integration across all levels is also possible. This would essentially create a single system with multiple functions, which is theoretically possible and even desirable. However, the practicalities of this ultimate level of integration will probably be debated for a long time.

The methodology looking at ISO 9001 as a platform for building an IMS⁶ appears at the moment, to be the most acceptable from the standpoint of an organization facing the integration of management systems. The methodology is useful in the cases where management systems are mostly from the ISO family, making it relatively simple to establish a common foundation for IMS.

In the Sun model example, since management systems belonging mostly to the ISO standards family are discussed here, and taking into account the structure of ISO standards, the model core will belong mostly to the requirements stated in the ISO 9001. This way a foundation for ISO management systems will be formed, while the common requirements with GxP can be determined without any greater difficulties .

CONCLUSION

The integration of management systems is imposed as a necessity of modern business dealing. On the one hand, IMS should be the tool for achieving the set organization goals, while on the other the IMS complexity should be optimised in accordance with the available resources of the organization.

Although there is no single, universal solution for the set request, it can be said that the development of a systems model, considering and adopting a methodology for its realization is the approach that currently seems to be the most acceptable.

If an organization chooses IMS, in order to manage it efficiently, it is necessary that the organization establishes a set of common requirements according to which it will plan activities to fulfil the common denominator for all management systems, while the fulfilment of the specific requirements will be planned within separate modules.

In this way, the organization builds an infrastructure which can meet the current needs of an IMS and also its development into a complex form.

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