June 22, 2011 (Wednesday) 55th EOQ Congress

CONCURRENT SESSIONS **Wednesday 8:30 – 12:30**
KEMPINSKI HOTEL CORVINUS **Erzsébet tér 7-8, Budapest V.**

REGINA BALLROOM III. **Wednesday 11:00 – 12:30**

22.1. QUALITY IN PHARMA INDUSTRY

Session Chair: ***Vilmos Berényi****, WIL-ZONE Consulting Office, Hungary*

12.00 Integrated Management System in Pharmaceutical Industry: The New Approach in Capital Project Management
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Marinković, Valentina (Serbia)

Valentina Marinković got PhD degree in Faculty of Pharmacy in Belgrade in 2003. Now she is Ass. Professor there at the Department of Social Pharmacy and Pharmaceutical Administration as well as Ass. Professor in Faculty of Technology, Leskovac at the Department of Pharmaceutical Technology. She has wide practical experience in the following two multinational pharmaceutical companies as Quality Management Director:In Actavis, she was responsible for the development of Quality Management Systems and Integrated Management Systems (GMP, ISO 9001, 14001, OHSAS 18000, ISO 22000, HACCP), implementation and validation. She was also an accredited expert for registration of drugs and Qualified Person for batch release on Balkan's market.In Alvogen, she was responsible for Project Management for the Packaging Center in Serbia and development of IMS (Integrated Management Systems) in Supply Chain in West Balkan. Valentina Marinković published 42 scientific papers in international and national journals and presented more than 80 expert and scientific papers in International and National Conferences. She is member of the Serbian Pharmaceutical Association, European QP (Qualified Persons) Association and International Pharmaceutical Federation; Vice President of Serbian Quality Association. She is member of the International Editorial Board of International Journal "Total Quality Management and Excellence". Also, she is co-chair of Balkan Quality Conference ''Balkan as region of Quality'', which was at first held in 2005. Valentina Marinković has been involved in many national scientific and development projects by the Ministry of Science, Republic of Serbia and also, until now she is involved in several International Projects (Tempus, ets.).

INTEGRATED MANAGEMENT SYSTEM IN PHARMACEUTICAL INDUSTRY- THE NEW APPROACH IN CAPITAL PROJECT MANAGEMENT

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Summary: *The current versions of ISO 9001, ISO 14001 and OHSAS 18001 have increased the similarities among standards. Also, the current revision of EU GMP, mandatory requirements for pharmaceutical industry, has made them more compatible with TQM principles. The developments of those standards enhance the integration of management systems in practice. Integration of the Quality Management System (GMP, ISO 9001), Enviromental Management System (ISO 14001), Ocupational Health and Safety (OHSAS 18001), as well as Energy Management System (ISO/CD 50001), in the project phase is preferable. This paper discusses the new approach of IMS through Capital Project Management: facility construction design, organization design and documentation design. International standard (ISO 10006)- Guidelines for quality management in the project have been implemented in pharmaceutical industry.*

Keywords: *IMS, capital project management, pharmaceutical industry*

1. Introduction

Th current versions of ISO 9001, ISO 14001 and OHSAS 18001 have increased the similarities among standards [1-3]. Also, the revision of EU GMP, mandatory requirements for pharmaceutical industry, has been made more compatible with TQM priciples [4]. The developments of those standards enhance the integration of management systems in practice. On the other hand, liability in connection with quality, environmental, occupational health and safety and social accountability is increasingly important for the company image [5]. Recently, we have the new standards for business continuity management [6], risk management [7], and energy management [8], to support the company to survive in tough economic environment. By having certified management system covering these areas, the companies give a signal of liability and concern for stakeholder relation.

Applying the concept of multidimensional quality at the organization level, understanding of the ” expectation and needs” of all interested parties are preferable [9].

With the revision and new editions of the different standards for management systems, the systems have an increased number of similarities [10]. All of those impacts were a good starting point to integrate the standard management systems into the Integrated Management system. The new Integrated Management System will enable the organization to achieve the ultimate goal of avoiding the risk of negative impact on the organisation objectives [9].

But, when the Pharmaceutical Industry makes a decision to invest in a new facility we have a strategic dilemma, **when** and **how** to start the management system integration.

In this paper, the new model of IMS through Capital Project Management has been proposed.

The proposed model has been applied during the project of Packaging plant in Serbia of **Alvogen Pharma Serbia.**

2. Capital Project Management and PDCA model

International Standard Organization provides guidance on quality management in projects – ISO 10006:2003 [11]; this standard is based on eight quality management principles [1].

They are intended to be used by the personnel who have knowledge and experience in QMS, as well as managing in projects. It is recognized that there are two aspects to the quality management in a project: a) Process approach and b) Project product. The creation and maintenance of process and product quality in a project requires a systematic approach.

In this paper, the integration of management systems (GMP, ISO 9001, ISO 14001, OHSAS 18001, ISO 10006) has been implemented, through PDCA model [10].

Project product - **Alvogen Pharma Serbia -Packaging plant** has to achieve the expectation and needs of all interested parties (stakeholders, regulatory authorities, contractors, municipality, suppliers, customers and employees).

Basic elements of management systems are presented in Table 1.

Table 1. Management Systems elements through PDCA cycle

Standard	***ISO 9001:2008***	***ISO 14001:2009***	***OHSAS 18001:2007***	***„Concept paper"- GMP***	***ISO 10006:2003***
Plan (P)	**Quality policy Quality objectives planning**	**Enviroment policy Enviroment objectives planing**	**Occupational Health & Safety policy OHS objectives planning**	**Quality, sefety, efficiency of pharmaceutical Quality objectives planning**	**Quality plan for the project Time –relation processes Resource planning**
Do (D)	**Product realisation**	**Operation and implementaion of EMS programs**	**Operation and implementaion of OHS programs**	**Product realisation**	**Project product realisation**
Check (C)	**Analysis and continual improvement**	**Audits and CAPA**	**Audits and CAPA**	**Analysis and continual improvement/ CAPA**	**Measurement, analysis and improvement**
Act (A)	**Management review**	**Management review**	**Management review**	**Management review**	**Management reviews and progress evaluation**

3. Project Management phases and integrated process

The "originating organization" – **Alvogen West Balkan** has been assigned to a "project organization" led by Quality manager. Project phases divided the project life cycle into manageable sections, such as conception, development, realization and termination [11]. Implementation of different standards elements was a part of all project phases.

- Management responsibility

It was a direction – setting process, which includes planning the establishment and implementation of QMS, EMS and OHSAS principles. The management team made a decision about documentation structure, QEHS policy and Risk management policy. Validation Master Plan was approved. Risk assessment formal documents have been raised to facilitate project outcomes.

- Resource management

Management team has identified, estimated, scheduled and allocated all relevant resource-contractors, suppliers in project organization and provided human resources during the packaging process start up. In this phase it was very important to develop individual and team skills and the ability to enhance project product realization.

In this phase, GMP/ ISO/ OHSAS /regulatory/ legal requirements have been evaluated. All interaction and integrated elements have been managed. Standardized Management System SOPs were prepared to assure the broad outlines of what the Packaging facility will do.
42 SOPs have been approved. Change management has been assessed through Change Control System. Project Manager has ensured that contractor's performance met contractual requirements. Project schedule control has been reflected by controlling the realization of the project activities, for confirming the proposed schedule or for taking corrective actions for recovering from delay.

- Measurement, analysis and improvement

The organization learned from the project - Knowledge Management is in place. Collection and validation of data for continual improvement have been established. Common internal audit has been performed, lead by corporate Operation head.

4. Conclusion

The presented results of the possible model of IMS have been based on the process approach implemented in PDCA cycle. The process approach is the basic characteristic of QMS (GMP and ISO 9001), as well as Project management (ISO 10006). In this paper, the process approach has been reflected in PDCA model, using the key management enablers - Risk management and Knowledge Management.
A strong recommendation is to apply the proposed model in the earliest phase in Capital Project investment. The benefits of the IMS, through project management are: a) cost reduction b) resource optimisation and c) efficacy improvement.

References:

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