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*

11.20 How Pharmaceutical Companies Leverage Quality and Quality Certifications to Achieve Competitive Advantage
Eize de Boer, SGS, Systems & Services Certifications, Switzerland

de Boer, Eize (Switzerland)

Dr. de Boer was appointed Global Manager for Life Science Auditing at SGS in the beginning of 2007. Previously he served as site director for Wyeth, a leading global pharmaceutical company, which he joined in 1997. There he was responsible for manufacturing and supply chain operations, including the development and maintenance of a wide variety of pharmaceutical quality management systems.
Dr. de Boer is a frequent speaker at international conferences on global pharmaceutical compliance programs. He is a member of the editorial board of advisors of PharmaAsa, the leading resource provider to the pharmaceutical industry in Asia. Active member of the International Society of Pharmaceutical Engineering (ISPE) with several presentations delivered on vaccines Manufacturing Quality Compliance.
He holds a PhD in biochemistry from the University of Amsterdam, The Netherlands.

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How companies leverage quality and quality certifications to achieve competitive advantage

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Flexibility is the key word in Pharmaceutical Supply Chains today.

Current operations and logistics cycles are comprised of traditional manufacturing of primary and secondary components, labelling and packaging of finished product, and the distribution of the medicine to the patient. This more or less straight forward working model is part of a changing mechanism, where the Pharma product portfolio gets more diverse, and manufacturing & distribution chains increasingly become more complex in nature. Undisputable safe and secure deliveries to healthcare are more vital then ever.

Product diversification, where companies are focussing on biologics and others, will bring advanced technologies like nanotechnology, tissue re-engineering and recombinant vaccines. Pharma organizations will have to combine these new technologies with existing manufacturing lines in multi-functional units and / or partner with others. All in all, there is a clear demand for manufacturing units that are capable to deliver the required high-tech innovative services and at the other side of the spectrum low-cost providers for traditional generics and over-the-counter (OTC) products continue to remain part of the supply chain as well.

Budget restricted governments and insurance organizations in mature economies are putting pressure on Pharma to reduce prices of medications. In emerging markets patients are getting more financial ability to affort medicines, but not up to the same spending of those in mature markets. Further pressure on revenues created through generic competition challenging the Big Pharma ‘Blockbuster’ concept with billions of USD worth in sales of expiring patents over the coming years. The resulting cost awareness in combination with emerging global markets is spreading the traditional Pharma Supply Chain into diverse geographies.

The combination of product- and supply chain diversification is challenging to maintain proper quality levels for medications delivered to patients. A wide variety of incidents have been reported and over recent years the number of stolen and illegally diverted medicines, reported cases of counterfeits, adulteration, and the number of recalls have increased dramatically. Pharma supply chain security is now on the agenda of regulators, associations, and the sector itself. Several initiatives have been organized or are pending to improve controls over manufacturers and their suppliers of raw materials and intermediates.

Clearly the number of quality guidance and regulations is increasing. Driven by incidents of counterfeiting and adulteration regulators are publishing guidelines and directives how to control these. Most recently, the European authority for example, have amended existing directives to include anti-counterfeiting measures to prevent fake medicinal products entering the commercial chain. On the other hand, independent bodies like the International Committee on Harmonization (ICH) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S) are active in publishing new quality guidance that reach out to manufacturers in the global community. These schemes are aiming to harmonize Pharmaceutical quality around the world and are adopted by the regulators in order to 1) improve on their national supply chains and 2) put exports at ease for recipients in – mostly – 'western' countries.

Regulators are clear about their actions to enhance controls of the Pharmaceutical supply chain. For example the US Food and Drug Administration (FDA) to challenge importers of medicinal products and medical devices through a five year strategic plan to increase the number of foreign inspections and examining these products at the US border. This *Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century: A Risk-Based Approach,* as it has been nominated is aiming to make the companies more responsible for their deliveries to patient healthcare programs but on the other hand also foresees the hiring of several hundreds of inspectors focussing on drug imports. With the ultimate goal to harmonize inspection programs authority agencies are also joining forces to decrease the number of duplicate inspections and so increase effectivity of their overall capacities. For a few years now US FDA, EU EMA/EDQM, and Australian TGA are collaborating on the inspections of API manufacturers worldwide. This program is aiming to exchange information on manufacturing sites that is of interest to multiple regions. In doing so the benefit to the manufacturing site is to get less authority inspections and on the other hand make inspectors more available to a broader base of facilities to assess.

Industry associations are taking their marks too. For example, the International Pharmaceutical Excipients Council (IPEC) / Pharmaceutical Quality Group (PQG) have published quality guidance for some years now. Clearly driven by incidents where non-active Pharmaceutical Ingredients (or excipients) caused severe adverse reactions in patient populations, this program has now developed into a quality scheme where the organization is promoting their membership and beyond to upgrade facilities up to an acceptable quality level to ensure secure deliveries of non-active ingredients to finished dosage manufacturers.

Government agencies making the Pharmaceutical industry more responsible for the quality of their products and the industry sector itself creating new quality guidance for better control of suppliers is a perfect synergy to improve healthcare systems. The actual realization of such programs, however, is far from straightforward. The number of eligible organizations to undergo these controls (i.e. the suppliers to the Pharmaceutical industry) is tremendous and several evaluation reports already have pointed out that the combination of official agency inspections and audits performed by the Pharmaceutical organizations by far cannot cope with these numbers. This is actually the point where third party organizations are bringing a perfect addition to the Pharma supply chain. Provided that auditors are trained and experienced to work in an environment that aligns with requirements as set out by the regulators GMP certification of manufacturers of Active Pharmaceutical Ingredients and Excipients is an excellent tool to impose controls effectively. A brief overview to ensure an efficient system for accredited GMP certifications in Pharma:

- Qualified, experienced, and well trained auditors capable to understand the specifics of the Pharmaceutical organizations they are auditing very well.
- Independency and objectivity of the certifying organization, avoiding conflicts of interest of the auditing organization towards the Pharmaceutical organizations that are audited. In this regard a certification body being independent in itself is to be preferred over these auditing initiatives and platforms that temporarily recruit GMP auditors from Pharma organizations as competition issues challenging independency and objectivity could easily occur.
- Impartiality, where an advisory board sets out the rules for the accredited GMP certification system and structure. This advisory board e.g. composed of the regulators

establishing directives, regulations, and guidance for GMP, in combination with Pharma industry representatives and the third party auditing organizations as ‘scheme holders’.

- Robust organization for GMP certifications present within the third party auditing organization, to allow for:
    - Clear and transparant decisions on observed non-conformities and resolutions thereof.
    - Translation of GMP guidance and regulations into auditable and certifiable processes that can be deployed by the competent auditing teams efficiently.
    - Guaranteed program to follow the rules as set out by the GMP accreditation program as established by an effective scheme of external and internal audits within the certifying body.

In conclusion, the addition of third party auditing organizations to the combined efforts of government agencies and pharmaceutical organizations to control manufacturers of (non-)Active Pharmaceutical Ingredients creates the necessary flexibility Pharma needs in today’s complex Supply Chains to ensure that high quality medicines are delivered to healthcare programs around the world.