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*

11.00 Risk Management in the Pharma Industry
Magdolna Morvai, Teva Pharmaceutical Works Private Limited Company, Hungary

Morvai, Magdolna (Hungary)

Mrs. Morvai got her university degree as pharmacist in 1985 at Semmelweis Medical University. In 1988 she finished her postgraduate study at Eötvös University Department of Analytical Chemistry and got her Ph.D. degree in 1991. Between 1985 and 1991 she worked as an assistant professor at Eötvös University and gave lecture in analytical chemistry. From 1992 she joined to the Chinoin Pharmaceutical Company, later on Sanofi-Aventis and worked as a stability manager and Head of the Product Development Department. During this period she introduced and established the ICH guidelines in the validation processes and stability management. Since 1999 she has been working for TEVA Pharmaceutical Works Plc. first as the Head of Quality Control Department and from 2004 as the Director of Quality. The site is one of the Sterile Manufacturing Center of TEVA Pharmaceutical Industries. She has managed several product transfers, especially aseptic manufacturing technologies and prepared expert reports for the FDA or EU submissions. From 2005 she has been acting as Qualified Person. She has given several lectures on the IIR Conferences in the topic of Risk Management and she is a lecturer at Semmelweis University for porstgaruate students of Quality Assurance.

Risk Management in the Pharma Industry

Magdolna Morvai
TEVA Pharmaceutical Works PLC, HUNGARY

21st century's quality assurance system is based on the analysis, evaluation and criticality classification of the effects influencing product's quality for increasing and preventing risks and thereby adequate actions can be determined/implemented for sustaining the product's quality.

It is well known, that risk is defined as combination of the probability of occurence and severity of harm.

The manufacturing and use of a pharmaceutical product by necessity comprise multiple level of risks.

The effective risk control ensures excellent quality of the product along its whole life cycle for the patients by providing proactive tools for recognising and contolling possible quality problems during the development and the manufacturing.

Risk control can be adapted in each steps that impacting pharmaceutical products' quality. E.g. in the development phase of the product, or rather already at planning the manufacturing sites and equipments, furthermore it is practical to take into concideration the possible effects, risk factors when establishing the qualification process, validation, in-process controls, maintenance, quality investigations, quality control parameters.

The quality risk evaluation needs to be based on scientific knowledge and first of all it has to serve the patient's protection, but at the same time it is an effective tool for maintaining business compliance.

In this presentation main steps, main methods of risk assessment, focusing on the FMEA mode of the quality risk management and the latest ISPE guidance will be discussed and evaluated.