

## PRESENTATION ABSTRACT

**Presentation topic: GMP yesterday, today, tomorrow  
(Development of quality management systems in the manufacture of medicines)**

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**Presentation abstract:**

- Medicines are a special kind of commodity. Market forces alone cannot adequately regulate the medicines market ("market failure"). The third party is normally involved in such regulation: professionals (doctors, pharmacists) and/or Government.
- Traditionally the quality of medicines had been assured by pharmacopoeias, initially through description of processes, i.e. methods of preparation. With time analytical procedures for testing ingredients and dosage forms increasingly have been included in compendia. Gradually methods of preparation disappeared from pharmacopoeia standards.
- These methods appeared in other types of regulatory documents. While more specific ones were included in the registration dossiers, general requirements formed the basis for GMP rules.
- GMP rules are needed to protect consumers, to enhance export potential of medicines manufacturers and to improve economic performance of medicines manufacture.
- Three levels of GMP may be considered: low level – simplified national GMP standards, "normal" level - EU GMP Guide or PIC/S Guide, and advanced level – so called "GMP+".
- Presently in Russia the low level of GMP is achieved. Recently, however, steps have been made in the right direction: adoption of the EU GMP Guide coupled with creation of an Inspectorate.
- "GMP+" at the moment is implemented by some multinationals on a voluntary basis. It should be noted, however, that voluntary improvements in quality systems tend to become obligatory.
- "GMP+" involves new approaches such as: Pharmaceutical development, Product design and realization, Quality risk management, Pharmaceutical quality systems, Process analytical technology (PAT), real time release etc.
- These new approaches are not enough considered and discussed in Russia which may result in continuous lagging behind industrialized world.