

PRESENTATION ABSTRACT**Presentation topic: GMP – new documents and thoughts and considerations****Speaker:**Andrey Meshkovsky
expert of World Health Organization**Presentation abstract:**

- Recently the need to implement GMP standards has been confirmed once again. Last July a draft GMP Guide has been presented for comments. This text is a translation of the EU GMP Guide. However, it has advantages over GOST P 52249-2004 in that it has been updated up to the middle of 2008.
- This is not to say that the draft is free of errors. Thus, the term “medicinal products” is translated as “medicines”, even though it means industrially manufactured finished pharmaceuticals. As a result some important provisions of the original text are wrongly interpreted. In the EU GMP, for instance, Part I covers manufacture of medicinal products, while Part II refers to APIs. After translation Part I become relevant both to products and active substances.
- From that Russian readers may wrongly conclude, that in Europe e.g. batches of APIs are released in the same way as products, that is through certification by Qualified Person. In actual fact this is not required by EU legislation, and in most cases APIs are released by Quality Departments.
- It seems that under the circumstances the draft text merits support and prompt approval (subject to correction of obvious errors). Otherwise there is a risk of adoption of other, much less reasonable decisions.
- In this context one thinks, in particular, of an alternative translation of the EU GMP Guide, appeared in September as an annex to the draft Technical Regulation “On safety of Medicines”. This text contains most of mistakes found in GOST P 52249-2004 and has no annexes.