

DEVELOPMENT OF THE PROFILE-FORMING BASE STANDARTS FOR THE COMPLEX ASSESMENT QUALITY AND SAFETY OF THE MANUFACTURING EXECUTION SYSTEM (MES) OF PHARMACEUTICAL ENTERPRISE

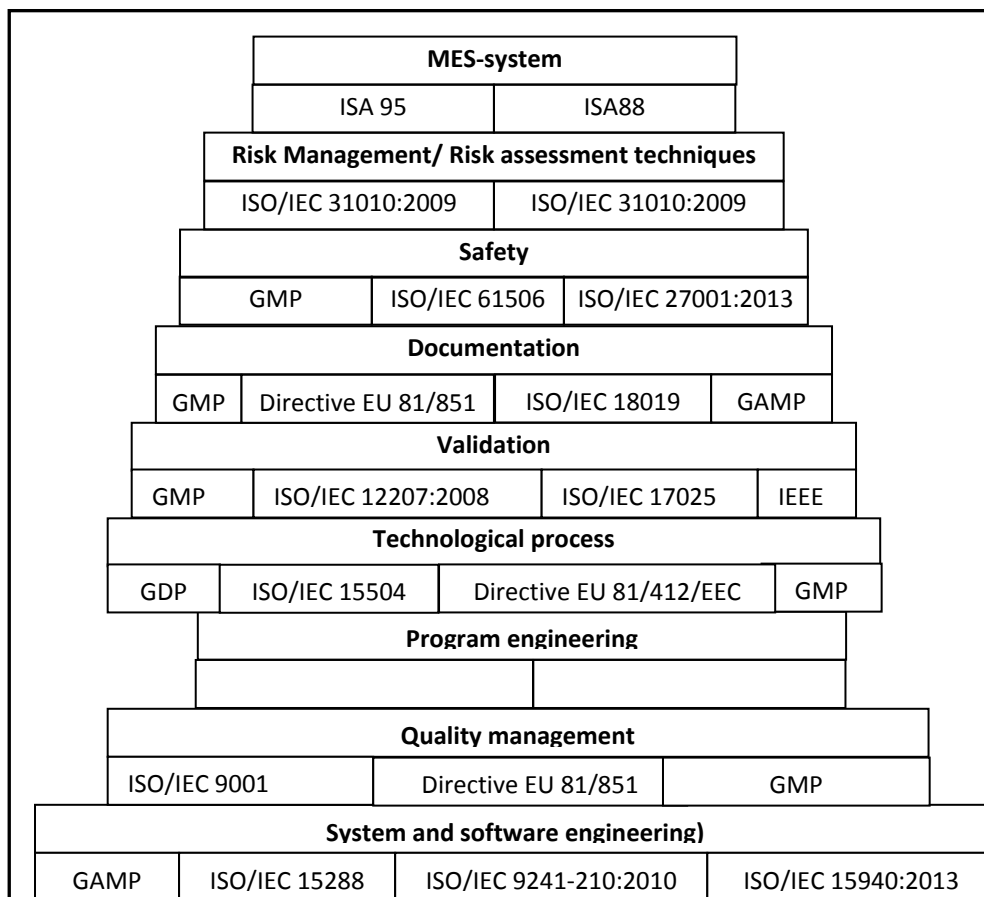
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Using MES-systems becomes increasingly hot topic in pharmaceutical manufacturing environments. This is due primarily to the fact that quality assurance of medical products and drugs is critical from the standpoint of patients safety.

For the creation safety model of the MES-system of pharmaceutical enterprise is necessary to conduct profiling (analysis) normative base. Profile-forming base should be include the normative documents and standards, which affect the technological process of the manufacturing drugs (pic.1).



Pic.1. The profile-forming base

A represented profile-forming base standard allows a comprehensive assessment of MES-system of pharmaceutical enterprise. This is will enable build the model of safety and quality of MES-system of pharmaceutical enterprise and select the standards, which link with usability.