

PRESENTATION ABSTRACT

Presentation topic: Risk analysis execution during designing and validation of pharmaceutical manufacture

Speaker:

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NNE PHARMAPLAN

 nne pharmaplan**Presentation abstract:**

- Quality risk is just one component of the overall risk in drug manufacturing, but it is considered as major issue for the patient' health and safety. At present risk-based approach is moved from the area of just actual trends to the regulatory requirements level. Thus, in 2004 FDA USA assigned risk analysis as basis for critical factors estimation regarding quality during inspections. Furthermore, ICH Q9 document "Quality Risk Management" is adopted as Annex 20 of GMP-EC since March 2008.
- According to GMP rules risk assessment approach should be used, but this point is often interpreted by the pharma producers in practice as just formal execution of regulatory requirements. In reality risk analysis should be considered not only as obligatory external demand, but also as an effective tool, which can be useful for manufacturers themselves during solving of production tasks. Risk analysis enables identifying of risk sources and most critical factors, assessing and preventing of possible problems, saving resources and achieving of higher quality.
- An effective risk analysis should combine formal approach and empirical methods (ICH Q9). Herewith experience and practical skills are very important, they provide usage of proved and endorsed methodologies and schemes on the one hand, and reasonable and considered approach to the application of these methods in each specific case - on the other hand. NNE Pharmaplan has many years experience and proven methods of risk analysis application when designing of new facilities and developing of existing ones, in qualification and validation on working pharmaceutical manufactures. This expertise is used successfully during execution of engineering and consulting projects in pharma and biotech industries. The lecture expounds procedures of risk analysis conduction and documentation during facilities designing, equipment procurement and qualification and process validation.