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Reflections about Quality Control and Quality Assurance in clinical trials

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The changing environment in which clinical research is conducted invites new approaches in quality management to all stakeholders. Legal and regulatory requirements lead to collect information that is valuable to improve the efficiency and effectiveness beyond regulatory compliance, and incorporating proven methodologies usually used in other areas opens new perspectives in the sector. The most actual approaches to systems for quality management are based on processes evaluation. The basic concept is that well controlled processes produce best results and the quality control should be focused on those instead on the final results. This strategy is used in many industrial areas; but it is also very useful in activities that produced intangible products, as the clinical research. Evaluating the performance of processes and risk assessment are being introduced in the day to day monitoring and is acquiring an important role in the management systems of quality in clinical research. The presentation will discuss the applications of some of these tools in the environment of clinical trials.

Biography

Fernando Geijo has a PhD in Organic Chemistry from Barcelona University and Master in Quality Management from Polytechnic University of Catalonia. He has worked in R&D in the pharmaceutical industry since 1985 and within the Quality Management area since 2000, acting as consultant since year 2000. Currently he is Product Manager for Quality Assurance services in R&D of Azbil Telstar Projects, S.A.U.

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