

Title: Managing Risk - ISO 14971: 2007

Abstract: Are you managing risk or simply taking your chances? Do you want to reduce liability? These are significant topics concerning most businesses. Unfortunately, they're often misunderstood, applied poorly or completely ignored. This clinic (I of III) will use the framework described in the newly revised 82-page ISO 14971 document for understanding key concepts and their application in the industry. The ISO document is expected to serve as the basis of risk management in the medical industry; it can apply to other industries as well.

This will be an *interactive session* so please bring your questions to the clinic. Additionally, to receive adequate response, please email them to Jack now.

Take-away: You'll leave with a clear understanding of the why it pays to understand the value of risk management and how to actually do it! You'll see the value of going beyond *FMEA* and decisions based upon *RPN* which is a common practice in many companies. (Note: The information will not be crammed into one clinic.) Specifically, you'll leave with answers to the following:

1. What's in it for me?
2. Big picture
3. Key concepts
4. Key techniques including *bottom-up* and *top-down* approaches

(Additional clinics will get into more nut-and-bolt details of risk analysis, risk mitigation, updates on this ISO revision as well identify *opportunities to reduce liability*.)

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Jack is an expert trouble-shooter specializing in the medical industry. He has been problem-solving in R&D, manufacturing and quality areas. Since 1992, he co-founded JD Consulting, a firm specializing in medical industry.

Jack specializes in design control, risk management, root cause analysis and CAPA. He has developed risk management programs and reduced risk for his client companies. He is a guest lecturer at UCI and USC on quality and regulatory issues. He has published several articles on CAPA, problem solving, productivity and communication. He has spoken on Root Cause Analysis and CAPA during FDA-OCRA events. He enjoys sharing his knowledge and public speaking.

He serves as the Membership Chair for the Orange Empire Section of ASQ. He is a member of the executive board of OCRA, a professional organization for quality/regulatory affairs. He is a recipient of the National Performance Review Hammer Award.

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