

Title of Paper

Software Process Improvements in Regulated Industry

Presenter

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Level

Introductory Intermediate Advanced

Abstract

Improving software process is recognised as one of the ways in which companies can improve the quality of their software, and consequently, many companies implement models such as Capability Maturity Model Integrated © and ISO 15504 (SPICE). Furthermore, the growth of software development for safety-critical industries such as the automotive and medical device sectors, has introduced other, sector-specific regulations, into the software industry. These include DIN 31000 (Schauffele and Zurawka, 2005) within the automotive industry and Food, Drugs and Administration regulations (FDA, 2006) within the medical device industry. Software companies moving towards safety-critical software development need to be aware of the issues that these non-software-specific regulations impose on their software processes.

This talk will discuss software process and how it can be implemented to improve the quality of software developed. It will further examine how industry-specific regulations can be used to focus on software development and, using an example of Risk Management in the medical device industry, discuss how recognised software process models can be used to ensure that companies meet regulatory standards.

FDA Regulations. "Code of Federal Regulations 21 CFR Part 820." April 2006.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1> (accessed September 2007)

Schauffele. J and Zurawka. T. Automotive Software Engineering: Principles, Processes, Methods and Tools. U.S.A., SAE International (2005).

Biography

Dr. Ita Richardson, BSc, MSc, PhD, CPIM, CDipAF, MBCS, CEng is a senior lecturer in the Department of Computer Science and Information Systems at the University of Limerick. She is project leader on the Global Software Development for Small to Medium sized enterprises project, which is funded by Science Foundation Ireland and operates within Lero – the Irish Software Engineering Research Centre. Her research focuses on global software development, software processes within the Medical Device industry and software process improvement and involves qualitative research with companies. Some of her post-graduate students are in full-time employment with software development companies
