
“Critical Issues Confronting Medical Device Manufacturers, their CEOs, CFOs, Managers and Developers”

Jerry Krasner, Ph.D., MBA

January 2010

Table of Contents

I. Introduction	4
II. Medical Device Accountability – Caught in the Current of the New Federal Laws and initiatives	4
III. Creating Value by Adopting Best Practices for Medical Device Developments	6
IV. Recommended Best Practices that your company should consider	7
V. What Medical Developers Need to Know – and What Tools They Need	8
VI. Modeling as a Development Attribute and Model Driven Development (MDD) as a Medical Device Development Best Practice	12
VII. EMF’s Guide for Medical Device Developers – Suggested Best Practices	14