

Perry's Solutions, LLC

Quarterly Newsletter

August 2010

Welcome to our newsletter. Tell us things you would be interested in hearing more about. Please pass this along to others who might be interested.

FDA 510K PROCESS REVIEW - PERSPECTIVE

With a majority of my business in Medical Device, keeping up with industry trends is important. In May, the Director of CDRH was in Minnesota and I attended the meeting with him. He expressed concern with “lack of predictability”, and his dedication to Promote and Protect Health. Otherwise, it was hard to read him. This month an agency panel released a report of potential changes to the new product approval process. Reading the actual reports and media summaries, I believe the point is going to be in handling “extreme” products. Those that are simple need a better “simple” process. Those products that are riskier need guidelines established for clinical, manufacturing, and design data expectations. The Director summarized it by “fostering innovation with predictability and safety”. Expect more product categories, more guidance, and more learning.

BOOK REVIEW – TAKING A NEW JOB

For those of you that know me well, I am an avid reader. I recently came across a book to share. It is called “The First 90 Days”. It helps new leaders identify situations and create a transition plan whether it is a turn around or to sustain growth. If this sounds like you, pick up the book and share your thoughts with me regarding how you benefited.

MORE NETWORKING

Last newsletter, I talked about “Good Networking”. If you are looking for a job, let me know. There are 2 hot positions I have heard about. One is for a Project Manager for complex ME, EE, SW equipment. The other is for a Quality person with medical systems knowledge, vendor interactions and ability to still do the dirty work for this start up role.

Have a great day!



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