

Perry's Solutions, LLC

Quarterly Newsletter

February 2023

Welcome to our quarterly newsletter. Since 2009 we have prided ourselves on providing you with clear and concise information that can be implemented in your daily operations. If you receive value from this, please share with a colleague.

RISK MANAGEMENT IN PROCESS DEVELOPMENT – MAPP TALK

Risk Management is a hot topic. With typical emphasis on design, are we losing track of our manufacturing operations? This presentation considers risk management during process development, for all industries. <https://bit.ly/3GjKzyj> Current ISO standard emphasis on risk for the medical device industry implies a huge value exists by improving any risk area. Call us to quickly gain an advantage for your organization.

FDA MODEL INTEREST

While attending the MDM conference, a presenter suggested the FDA may want Modeling & Simulation files in the future. As with many changes, there are advantages and disadvantages. The complexity of an FEA model could be challenging for an outsider to review quickly. Would we be expected to also provide a “user guide” to explain the logic? Could Design Of Experiments (DOE) files also be requested? Stating “we did a DOE” would no longer be adequate, but it could lead to needing to share the story of our development and exploration process. Interested in your reaction to this new idea.

DOE PROCESS – FUTURE BOOK IDEA

Using Design of Experiments (DOE) in R&D benefits from emphasis of certain steps, in a certain sequence. To ensure project success early in my career, I created a DOE process and carried it with me to meetings. When I was asked to teach DOE, sharing this process was important for future DOE user implementation. Someone suggested this process was a useful book idea – beyond these Youtube videos. <https://bit.ly/18nytx0> Thoughts?

Have a great day!



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