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Welcome to The June Issue of JVT - The Journal Of Validation Technology

By **Stacey L. Bruzzese**

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We are all familiar with the regulations and requirements inherent in the pharmaceutical industry. Each manufacturer shall have appropriate personnel based on education and background to assure that all activities are completed properly. Personnel performing work impacting conformity to product requirements must be competent based on appropriate education, training, skills, and industry experience. Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. But still problems occur for a variety of reasons.

This current issue of the JVT Journal will highlight why regulations and guidelines are critical to ensuring the highest degree of quality across a range of topics and systems. We highlight how to properly implement best practices - the philosophy of our activities - as well as the reality of practice and approaches of how to make continuous improvements. Highlights of this issue include:

- **Dr. Young-Lin** Chen discussing Medical Device Process Validation.
- **Dr. Tim Sandle** describing method verification and validation in microbiological studies.
- **Ivan Soto** addressing the risk-based analytical instrument qualification programs through USP <1058>.

The reality is that we all encounter problems in our day-to-day world. We discuss some common problems and how to fix them. Enjoy the insights of**Dr. Paul Pluta**, as he describes Validation Approval Committee problems in Compliance and Quality in Validation #6, and Validation Approvers and Documents in PQ Forum #12, two of our ongoing regular features reflecting the input of validation and quality managers.

As always, we welcome your comments, questions, and suggestions on any of the above. The validation community only becomes stronger through the contributions of its participants.

Happy reading!

Stacey Bruzzese, Managing Editor