IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Robust Knowledge Management Activities in Process Validation to Ensure Intrinsic Compliance

By **Cliff Campbell**

Aug 26, 2020 3:05 pm EDT

In this episode, Stacey and Cliff speak about new ways of thinking across the industry that aim to ensure appropriate, risk-based, least burdensome validation, with a focus of validation activities, instead of the traditional “are we compliant” mentality.

Read Cliff's article on this topic.

For more information on this topic:

- Intrinsic Compliance Matrix, http://www.ivtnetwork.com/sites/default/files/ntrinsic%20Compliance.pdf
- Intrinsic Compliance: A Model for Process Validation Optimisation, by Cliff Campbell; https://www.ivtnetwork.com/article/robust-knowledge-management-activities-process-validation-ensure-intrinsic-compliance
- ICH Q10 Feedforward, https://www.fda.gov/media/71553/download
- Process Validation Systems Based Inspection, https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf
- Operation Warp Speed, https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html
- Continuity Bill of Materials MBOM, https://www.cbsi-corp.com/wp-content/uploads/2012/02/NA50_03_Bill_of_Materials2.pdf

Cliff is a highly experienced consultant with a proven track record in efficient, agile and flexible compliance. His strengths include validation strategy, process mapping and gap analysis projects, both short and long term. He is exceptionally well regarded, and has worked collaboratively and co-authored with regulatory agencies, such as the FDA and HPRA, providing leadership training and advisory services. In addition to FDA, projects and workshops have been successfully completed for the following companies: Aveo, Amgen, Bayer, BioMarin, Celgene, Janssen, Kite, Lonza, Novartis, Parexel, Pfizer, Prolong. Cliff is also a long time contributor to the IVT Network, publishing articles in the Journal of Validation

Technology since 2010. Cliff was awarded the Kenneth G. Chapman Award in 2017 in recognition for his long standing efforts and contributions to validation.

Source URL: http://www.ivtnetwork.com/article/robust-knowledge-management-activities-process-validation-ensure-intrinsic-compliance-0