

---

## Change Control and Risk Management: Recap Day 1

Jan 29, 2013 3:49 pm PST

It was a very successful beginning to IVT's 11th Annual Change Control and 3rd Annual Risk Management conference, hosted at the Sir Francis Drake Hotel in San Francisco!

Conference attendees floated between two educational tracks on either risk management or change control. Change Control was led by chairman and IVT 2012 Speaker of the Year Joe Zec, who discussed global regulations regarding change control. Discussing FDA requirements, warning letter surveys, CFR Title 21, conference attendees ended his session feeling informed and excited to implement a quality change control program in their manufacturing plant.

Alan Golden followed up Joe Zec's masterful presentation by giving conference attendees a brutally honest, but necessary, roadmap for an effective change control program. Goldman was quoted as saying "there are only two rules of change control. First, the only constant is change. Second, deal with it."

IVT Editorial Advisory Board Member, Gamal Amer, Ph.D., was the chairman for the Risk Management Track. On this track, attendees were reminded that risk is present in every part of the product lifecycle. There is a scientific and a compliance aspect of risk management and thus requires a holistic approach. This track featured validation and compliance professionals such as Roberta Goode, Stanley Bouma, and Karem Monge. A large and seemingly overwhelming topic, the speakers broke down risk management into global regulations, identifying and applying risk management, and corrective and preventative action (CAPA).

Amer's opening session entitled "CAPA: A Risk Mitigating Quality System," discussed risk in the context of CAPA, FDA requirements for risk-management, and risk level factors. Amer begins the presentation by describing the basics of identifying, evaluating, and assessing risk. Risk, within the CAPA system is integral, Amer explains, as the CAPA system should define the risk and implement the actions to mitigate said risk. Furthermore, with a nod to the other conference track, Amer described how change control and CAPA are intertwined. Examples are design changes and improvements, process changes, labeling changes, and operator training. This relationship is further indicated in ICH and FDA requirements. Amer concludes that "CAPA is a risk mitigating approach, which fulfills the promise of continuous improvement."

The IVT Network booth also made a strong appearance at the conference. Attendees and speakers were shown a tutorial of the new platform, and got to meet first-hand the publisher, John Kirchner, and the community manager, Cale Rubenstein, who were integral in the development. Speakers were happy to know that both of Joe Zec's presentations were filmed, and would be available on IVT Network in a matter of months. Observing the demonstration on a monitor, and surfing IVT Network on an iPad, IVT received great feedback, and a lot of fun was had!