IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

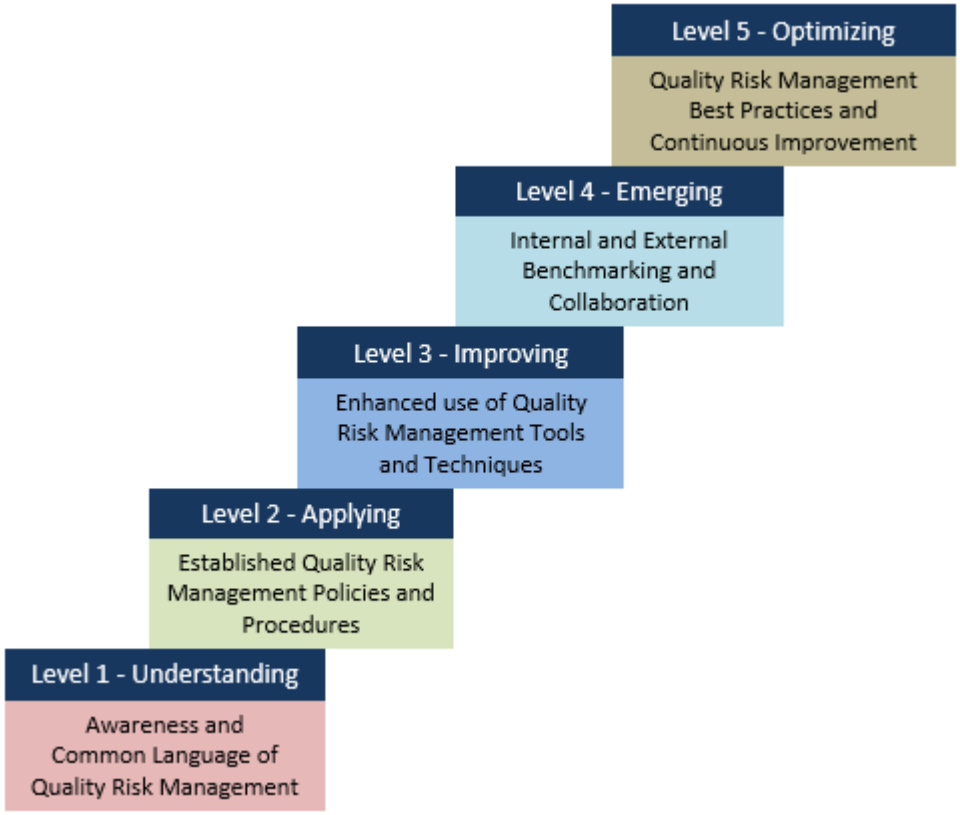
Reaching the Next Plateau in Quality Risk Management

By **Willis H. Thomas Jan 24, 2018 8:00 am PST**

Ahead of February's Quality Risk Management & Change Control conference in San Diego, let's take a peek at emerging concepts that will be discussed to help organizations implement robust quality metrics and achieve quality systems excellence.

As you look at your business in terms of quality risk management, it is important to consider where you are on the maturity ladder and what your next steps might be to achieve a higher level of performance to meet and exceed stakeholder expectations.

The model below summarizes some key concepts that will be discussed in the session entitled "Practical Qualitative and Quantitative Approaches to Quality Risk Management."



As we consider the origins of quality risk management, it is important to keep in mind that the application of both quality management and risk management have becoming increasingly important concepts to the life sciences. The synergy of these knowledge domains necessitates that we periodically review emerging concepts in this area. Industry regulations and guidance, relevant research from professional organizations and association bodies of knowledge can provide fresh perspectives on quality risk management tools and techniques. It is not necessarily that we need to do things different, but we need to consider how to do things better. It is the quest for both efficiency and effectiveness.

Quality risk management is no longer limited to quality operations, but has become a responsibility of employees throughout

the organization and many times engages the extended enterprise to include vendors and suppliers. Therefore, it is incumbent upon those who have a vested interest that there is a short and long term strategy to address this very important topic. It is imperative that we demystify how to perform quality risk management so that people understand that qualitative approaches are straight forward and may involve the use of a risk matrix, Probability X Impact assessment, fault tree, cause and effect diagram or SWOT analysis. On the other hand, qualitative methods are more complex and may involve mathematical models such as a decision tree, simulation or sensitivity analysis. By attending IVT's education sessions, organizations become better equipped to understand their true capabilities so they know where they need to get assistance to meet their requirements for quality risk management.

This interactive session will give participants an opportunity to engage with other professional and discuss their skills in this area. Over the past 15 years, I have been a full-time practitioner in life sciences education as well as a college professor teaching concepts in risk management. This presentation will provide an interesting balance of theory and application of quality risk management.
