

Tim Cooke



New England Meeting.

New England

The New England region held its spring meeting on May 13, 2015 in scenic Pepperell, Massachusetts.

Our host was Masy BioServices, a provider to the pharmaceutical, medical device, biotechnology, and regulated industries markets. Breakfast was provided by ProTEQ Solutions.

Our first speaker was Elizabeth Carbonella. Elizabeth is a Senior Accreditation Officer for the American Association for Laboratory Accreditation (A2LA). She regularly conducts training, on behalf of A2LA, for CABs, assessors and users of accredited organizations on a variety of topics related to the ISO/IEC 17025 and ISO/IEC 17020 standards.

Elizabeth provided a mini-tutorial on "Root Cause Analysis." She introduced terms associated with root cause analysis, and provided clarity on when a root cause analysis is required. We were provided tips and tools for performing root cause analysis. Pitfalls and common mistakes in performing a root cause analysis were also illustrated.

Real-world examples were cited, and methodology was discussed in providing objective evidence to resolve issues. The importance and processes of monitoring corrective actions were advanced as well.

Elizabeth provided an introduction and illustration of tools that should be used in a root cause analysis. These included techniques in interviewing, the concept of fish bone diagrams, and the "5 whys" to identify a root cause.

A non-metrology example of how to use the "5 whys" was illustrated as follows; A person borrows a bicycle from a friend to use for training for a bike run. The back tire goes flat (and it happens multiple times).



Elizabeth Carbonella.



George Rodriguez.

The first "why" is why did it go flat? The short answer is there was a hole in the tube. The person borrowing the bike replaces the tube. But to find out the reason(s) it keeps happening, there is a second "Why." That is, "Why is there a hole in the tube?"

This leads to group discussion. Was there a nail or foreign object found in the tire? Was there enough air in the tire? What were the road and environmental conditions?

Elizabeth taught us that by asking the right questions, and not being satisfied with just the obvious answer to the first "why," you can find the root cause!

George Rodriguez, PhD, Senior Scientific Manager for Artel, then provided a presentation on "Value Stream Mapping." Artel is introducing a new volume measuring instrument that is based on air space compression and the ideal gas law. It is an interesting technology, and Artel is in the process of value stream mapping to identify how metrology activities add value to the customer for this product. This includes the efficient application of standards, defining the calibration and testing processes, and adding value of importance to the customers for this new product. The process, and what Artel has learned in applying value stream mapping, with particular emphasis on the metrology component, was reviewed. We were able to have some group discussions on bringing this value to the customer... and were afforded the opportunity of putting ourselves in the customer shoes, to know what is really important to them. Eliminating showstoppers, or roadblocks, to the process of providing desired results to the customer was an important part of the dialogue.

After a hearty lunch (graciously provided by our hosts at Masy Bioservices), George Rodriguez continued at the podium with a new topic "The Business Case for Developing and Observing Voluntary Standards." George related that an ISO document for specifying and testing volumetric performance of automated liquid handling systems had recently been developed. It was an interesting case study of 18 different parties (inclusive of manufacturers, end users and third party services) getting together to find common ground and come up with a "prototype standard" that would benefit all stakeholders. The concept of International Workshop Agreements (IWA) was discussed. Those who participated had to weigh the cost of participation against the benefits. This session discussed key technical outcomes and what remained to be done. The advantages, as well as potential drawbacks,



Jun Bautista, Jr.

of participating in such a process were included in group deliberation.

Cesar D. (Jun) Bautista, Jr. PhD, Senior Director of Laboratory Operations at Masy BioServices rounded out a full day of learning with his presentations. Discussed were recent updates, proposed changes, and future initiatives in metrology regulations.

Jun acquainted us to the probable revisions to *ISO 9001:2015*. These include the additional management responsibilities contained therein. Management must ensure the risks that affect customer satisfaction are identified. There is additional focus on fault prevention... as opposed to correcting things *after* they go wrong.

The reason for the upcoming roll-out of the revised *ISO/IEC 17025* was also presented. The old standard references many documents that are now obsolete. The proposed and updated requirements contained in the new standard were also discussed.

Jun also provided highlights of the new RP-6 rewrite. Included in the 5 year review will be revised table of contents, reference to Good Automated Manufacturing Practice (GAMP), and relevance to *ISO/IEC 17025* and *ISO 13485*.

Jun delivered insight on the amendments to USP 41 /USP 1251. Proper test weight values are the source of some confusion, so this was clarified. Jun also shed some light on the topic of rounding errors and resolution definitions for calibration of balances.

Lastly, the Guide for the Determination of Uncertainty in Measurements (GUM) was deliberated. With dialog on the concept of the unification of type A and B uncertainties and less emphasis on degrees of freedom, there was interest in this topic by all who attended.

A tour of the Masy BioServices facility was then made available to the attendees.

We thank our host, and all the presenters, for what was a very interesting and informative day to the over 30 industry professionals in attendance. I hope to see you all again at the 2015 Workshop & Symposium, July 19-23 in Grapevine, Texas as well as at our next regional meeting in October.

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