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

IVT Management Roundtable #1: Invitation To Participate - Written, Audio, Visual, And In-Person


Paul L. Pluta

Stacey L. Bruzzese

By , **Jun 25, 2020 7:00 am EDT**

Welcome to IVT Management Roundtable.

IVT Management Roundtable (IMR) is a new feature for the IVT journals, podcasts, webinars, and meetings that will provide a communication forum for pharma managers to share information about how they manage their respective technical functions. Managing these function is a topic that is rarely discussed in professional meetings. The idea for this forum came from several quality and validation managers at IVT meetings – they heartily agreed on the need to discuss the many individual topics in management applied to their responsibilities. IVT provides multiple opportunities to facilitate this communication.

WHY THIS FEATURE?

Pharma managers in the US and Europe have expressed that they simply do not have time to talk about management. They are too busy “fighting fires” in their plants – approving protocols, releasing batches, doing investigations, fixing problems, responding to emergencies, and so on -- doing the activities essential to their respective site businesses and getting product “out the door.” They know that certain areas in their functions need improvement, but they simply do not have the time to do the desired work. They “treat the symptoms, but not the disease.” The net of this dilemma is to maintain the business and address issues as they occur – without doing anything more substantive to thoroughly and completely correct problems. They are doing a good job at avoiding serious problems and not receiving FDA 483 or other agency observations – a good thing. But then senior management believes there is no need to add staff or resources to enhance the respective functions at the site – adding to the cost of quality. As one manager described her situation, “I am a hamster in one of those wheel toys – running all the time but not really making any progress.” Ultimately this manager will change jobs due to overwork, frustration, and exhaustion. Site programs will remain stagnant and ultimately suffer as continuing problems remain while regulatory standards and industry expectations evolve.

DISCUSSION TOPIC CONTENT

IVT Management Roundtable (IMR) will discuss specific topics relevant to the management of various site technical functions – validation, quality assurance, quality control, training, operations, compliance, analytical labs, and other site functions. There is a need to share information and solutions to common problems associated with managing operating functions in an organization. The information provided in these discussions should be helpful and practical so as to enable application in actual work situations.

IMR will address topics such as function objectives, strategies, business processes, infrastructure, monitoring performance, implementing changes, and others -- all of which are supportive to the technical and business work of the site. These topics were suggested by managers at various national and international meetings. In turn we will rely on successful solutions to problems communicated by our readers. Suggestions for future discussion topics are invited. Readers are also invited to participate and contribute manuscripts for this column – please share your successful practices with others. We need your help to make IMR a useful resource. If IMR is successful, these discussions will help readers to better manage their respective responsibilities. Our objective for IMR is useful information that is applicable to actual work situations.

Building On Previous Success

IMR will build on the success of other current ongoing features in the ***Journal of GXP Compliance (JGXP)*** and the ***Journal of Validation Technology (JVT)*** that focus on practical solutions to common problems and which are supported by journal readers. Ongoing features include “Compliance in Quality and Validation,” which addresses technical compliance problems; “GXP Talk” (Jerry Lanese, Rich Poska, and contributors), which addresses reader questions about compliance topics, and has discussed more than 80 reader questions during the last 10+ years; Regulatory 101 (Karen Zimm and contributors), which addresses all areas of regulatory compliance; and PQ Forum (Paul Pluta), which has discussed topics related to validation documentation. Many of the content topics discussed in the above features were suggested by journal readers and by participants in various IVT meetings. “Senior Think Tank” discussions at various IVT meetings have been especially useful in stimulating topics that have been previously discussed in the respective IVT journals.

COMMUNICATION METHODS – WRITTEN, AUDIO, VISUAL, AND IN-PERSON

IVT provides multiple communication media and methods for dissemination of IMR information. Content in IMR will be published in either the ***Journal of Validation Technology*** or the ***Journal of GXP Compliance*** as appropriate for topic content. Contributors may provide audio content through Voices in Validation, the IVT network podcast. IVT webinars and in-person presentations and discussions at IVT meetings in the USA and Europe on IMR topics are also potential communication methods. A recent webinar (Karen Ginsbury) discussed Taking Control of Change, CAPA and COVID, with overviews of regulatory and supply chain protocols during and post-pandemic. Some recent ***Voices in Validation*** podcasts discussed Building a Culture of Compliance, Change Management: Beyond the SOP, Pharmaceutical, Device, Biotech: Building a Smart Business - Part 1 and Part 2, Compounding. Compliance. COVID. The impact of temporary FDA guidance now, and in the future, and Managing Data Integrity in GCP Environment.

WE NEED YOUR HELP

Future issues of IMR will discuss management issues associated with administration and support of the respective functional areas of a pharma manufacturing site. Readers are invited to submit suggestions for discussion, topics or other comments on future content. Manuscripts for journal publication are always welcome. This feature will be most successful when the pharma community submits ideas for improving function management. We need your help to make IMR a useful resource. Please contact coordinators Paul Pluta at paul.pluta@comcast.net or Stacey Bruzzese at Stacey.bruzzese@informa.com with comments, suggestions, or topics for discussion.
