

Management Roundtable #1: Invitation To Participate



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Invitation to Participate

WELCOME TO MANAGEMENT ROUNDTABLE (MR).

MR is a new IVT feature that will provide quality and validation managers a mechanism to share information about how they manage their function responsibilities. This forum will address non-technical function management including contemporary personnel topics. Management topics are rarely addressed at technical professional meetings; discussion of these topic is needed more than ever at this time. Management-related discussion topics have become increasingly important as the modern pharma work environment undergoes significant change.

MANAGERS WANT THIS FEATURE

Managers wholeheartedly agree on the need to discuss non-technical management topics. They are frustrated with the management aspects of their company responsibilities. They simply do not have time to talk about management, leadership, company culture, personnel, staffing, and associated issues. They are “fighting fires” in their plants – approving batches, doing investigations, fixing problems, CAPA, 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 the function need improvement, but they simply do not have the time to do the desired work. The net of this dilemma is to keep going to maintain the business and find time to address issues as they occur – without doing anything more substantive to thoroughly and completely correct problems. Because they are doing a good job at avoiding serious regulatory problems, senior management sees no need to add staff or resources – why add to the “cost of quality?”

MANAGEMENT IN THE CHANGING WORKPLACE

Work life in pharma and many other industries has been significantly affected during the past year. COVID-19 has caused

organization changes, working remotely, virtual meetings, civic lockdowns, service interruptions, and other changes intended to minimize health risks associated with the pandemic. All employees in the workplace have been affected. Many workers will never meet colleagues “face-to-face” under virtual Zoom and Skype circumstances. Workers require new skills to succeed in the modern corporation. Management under these conditions is not the same as under the normal workplace. Successful managers may have difficulties when required to function under virtual conditions. Talking about these new work conditions and exchanging successful approaches was mentioned by several managers in support of the MR effort.

PAST EVENTS

The IVT Network has conducted several very successful forums addressing workplace issues during the past few years at the annual Validation Week meeting. Topics discussed at this meeting included workplace stress, the “glass ceiling,” corporate hierarchy, bias and discrimination, work-life balance, competing family responsibilities, and other relevant topics. Participant reviews of these discussions were extraordinary. Suggestions for continued discussions and expansion of IVT efforts in this area were numerous. New focus on diversity, equity, and inclusion may be easily integrated with prior efforts. IVT plans to expand these discussions in future meetings.

MR SCOPE AND APPLICATIONS

The content scope of MR will be broad -- management objectives, strategies, programs, workforce diversity, inclusion, virtual workplace (Management by Zoom), implementing changes, and others -- all of which are supportive to the quality and validation work of the respective compliance functions. The virtual workplace is a new topic to which we have all been exposed. JVT recently published “CF#5. Team Member Traits in Virtual Project Teams – Emphasis on Personal Attributes” (1).

The title “Management Roundtable” was selected to represent the multiple applications available through IVT as well as to emphasize interactive sessions. Journal submissions for publication in the *Journal of Validation Technology* and *Journal of GXP Compliance* on management topics are most welcome. Blog discussions posted on the IVT Network are more informal and are also very welcome. IVT “**Voices in Validation**” podcasts provide verbal discussion by individuals and groups. Some recent Voices in Validation podcasts addressing diversity, equity and inclusion, as well as leadership include the following:

- Women in Science, Technology, Engineering, and Mathematics – What’s the Real Deal? (2)
- Top 3 Trending Topics in Pharmaceuticals – Data Integrity, AI, and Leadership (3)
- Workplace Diversity and Gender Parity In Life Sciences (4).

The IVT Network is currently experiencing tremendous growth in each of our communication vehicles. Information sharing through IVT podcasts has been very well received and especially successful. Applying their outreach to management and personnel topics will contribute to general website value as well as providing contributing individuals with global visibility and recognition.

WE NEED YOUR HELP

Future issues of MR will discuss management issues associated with administration and support of the respective areas of a site quality and validation functions. Readers are invited to submit suggestions for discussion topics or other comments on future content. Readers are also invited to submit manuscripts and blogs for publication as well as to participate in podcasts. MR will be most successful when the quality and validation communities submit ideas for improving management and associated personnel programs. We need your help to make MR 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.

REFERENCES

1. Marinelli, Allan. CF#5. Team Member Traits in Virtual Project Teams – Emphasis on Personal Attributes. *Journal of Validation Technology*, Volume 26, #6, 2020.
2. King-Bailey, Valarie. Voices in Validation. Women in Science, Technology, Engineering and Mathematics – What’s the Real Deal? 11-26-2019.
3. Ford-Rice, Felicia. Voices in Validation. Top 3 Trending Topics in Pharmaceuticals – Data Integrity, AI, and

Leadership. 12-2-2019.

4. Raimondo, Raechelle. Voices in Validation. Workplace Diversity and Gender Parity In Life Sciences. 7-14-2020.

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