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Published on *IVT Network* (http://www.ivtnetwork.com)

Consultant Forum #1 - Invitation to Participate

Allan Marinelli

Paul L. Pluta

By ,

Aug 22, 2018 3:57 pm EDT

Welcome to “Consultant Forum.”

This feature will provide a forum for pharmaceutical industry managers and consultants to share information about their interactions in the daily work environment. Consultant interactions is a topic that is rarely discussed in professional meetings, but is a topic of vital importance in the industry. Validation organizations in particular are often able to survive only by using a cadre of validation consultants – sometimes with numbers of consultants exceeding the number of staff members in the validation department. Quality managers are likewise employing increasing numbers of consultants.

The idea for “Consultant Forum” came from multiple sources. Industry people -- Validation and Quality managers – heartily agreed on the need to discuss the many individual topics associated with consultant interactions. At the same time, consultants have suggested a need for dialogue to address their issues with industry clients. Both sides in this relationship are interested in sharing their complaints and ideas to improve relationships.

Why is This Feature Needed?

Validation and Quality managers in the US and Europe have told me that they simply do not have time to talk about managing consultants. They are too busy doing day-to-day work in their facilities. When they need consultant help, it is usually during a crisis situation. There is simply no time to plan, interview, define rules, communicate, and other “normal” work activities during a crisis. They know that certain areas in the consultant relationship 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. At the same time, they are doing a good job at avoiding serious problems, meeting deadlines, and accomplishing commitments. Senior management therefore believes there is no need to change the consultant approach.

Consultant Management and Interactions are a “Two-Way Street”

While Validation and Quality managers comment on problems and deficiencies with their consultants, similar viewpoints are heard from consultants about their industry clients. Industry people should also be aware of their responsibilities in consultant relationships – they are not completely innocent of any problems in these relationships. Consultants comment that industry people, because they are paying for services, do not listen to consultants, ignore requests, and are otherwise uncooperative. Consultants must not be treated as “second-class citizens.” Consultants have needs and expectations in order to do a good job for the client -- and sometimes it is the fault of the client that the consultant fails to meet project goals.

Content

“Consultant Forum” (CF) will discuss specific topics relevant to the management and interactions with consultants. Perspectives from both sides of these relationships will be addressed. There is an overdue and unmet need to share information and solutions to common problems associated with consultant relationships and performance in an organization.

The information provided in these discussions should be helpful and practical so as to enable application in actual work situations. Our objective: Useful information.

CF will address topics such as objectives-short term and long term; communication and its frequency; honesty, political correctness, favoritism, consistency, and other topics. These topics were suggested by validation managers, quality managers, and respective consultants at various national and international meetings in the US and Europe. 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 CF a useful resource. If CF is successful, these discussions will help readers – industry clients and consultants -- to better manage their respective responsibilities. Again, as stated above, our objective for CF is useful information that is applicable to actual work situations.

Building On Success

CF 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. JGXP ongoing features include “Compliance Case Studies,” which addresses technical compliance problems; “GXP Talk” (Jerry Lanese and Tim Fields), which addresses reader questions about compliance topics, and has discussed more than 70 reader questions during the last 5+ years; and GXP training (David Markovitz), which addresses all areas of compliance training. JVT ongoing features that routinely elicit positive comments from readers include “PQ Forum,” which addresses PQ documentation problems; “Validation Case Studies,” which addresses technical validation problems; “Medical Device Forum” (John Lincoln), which addresses all areas of medical device design, development, and commercialization; and “Cleaning Validation,” (Rizwan Sharnez, Jenna Carlson, and other authors) which addresses all areas of cleaning validation. Several new features have been introduced in the IVT Journals again in response to reader comments. These include “Validation Management Forum” which will discuss managing the validation function, and “Validation Documents Forum” which will discuss specific documentation topics relevant to the expanded requirements for validation in the lifecycle approach to validation. Reader input is currently being assembled for both these new features.

We Need Your Help

Future issues of CF will discuss management issues associated with consultants in validation and quality functions in the organization. Readers are invited to submit suggestions for discussion topics or other comments on future content. Readers are also invited to submit manuscripts for publication. This feature will be most successful when the quality and compliance community submits ideas for improving consultant interactions. We need your help to make CF a useful resource. Please contact coordinator paul.pluta@comcast.net or Managing Editor, Stacey Bruzzese at stacey.bruzzese@informa.com with comments, suggestions, or topics for discussion.
