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Validation Management Forum No. 1: Managing the Validation Quality System

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INTRODUCTION

Welcome to “Validation Management Forum.”

This feature provides a forum for validation managers to share information about how they manage the validation function in their facilities. Managing the validation function is a topic that is rarely discussed in professional meetings.

Validation Management Forum (VMF) will discuss specific topics relevant to the management of the validation function. The idea for this forum has come from validation managers. There is a need to share information and solutions to common problems associated with managing the validation unction. The information provided in these discussions should be helpful and practical so as to enable application in actual work situations. Our objective: Useful information.

VMF will build on the success of other current ongoing features in the *Journal of Validation Technology* (JVT) and *Journal of GXP Compliance (JGXP)* that focus on practical solutions to common problems. *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. *JGXP* ongoing features include “Compliance Case Studies,” which addresses technical compliance problems; “GXP Talk” (*JGXP*, Jerry Lanese and Tim Fields), which addresses reader questions about compliance topics, has discussed more than 50 reader questions during the last 5+ years; and GXP Training (David Markovitz), which has addressed all areas of compliance training.

VMF will address topics such as validation training, validation templates and model documents, Validation Master Plan administration, change management, document security, and so on – all of which were suggested by validation managers and various national and international meetings. In turn we will rely on successful solutions to validation management 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 VMF a useful resource.

WHY THE NEED FOR THIS FEATURE?

Validation managers in the US and Europe have told me that they simply do not have time to talk about managing the validation function. They are too busy “fighting fires” in their plants -- writing protocols, approving results, fixing problems, responding to emergencies, and so on -- doing the activities essentials to their respective site businesses and getting product out the door. They know that certain areas in the function are deficient or weak, but they simply do not have the time to fix their problems. The net of this dilemma is to keep going to maintain the business and find time to fix problems 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 and not receiving FDA 483 observations. Management therefore believes there is no

need to add staff or resources to enhance the validation program. As one manager described her situation, “I am like a hamster in one of those wheel toys – running all the time but not really making any progress.” Ultimately this person will change jobs due to overwork, frustration, and “burn out.” The site validation program will remain stagnant and will ultimately suffer as continuing problems remain while regulatory standards and industry expectations increase.

WHY VALIDATION MANAGEMENT PROBLEMS?

The validation function is unique in the manufacturing plant because it interacts with nearly all areas associated with product manufacturing. Validation is associated will all process validation including manufacturing, packaging, cleaning, analytical, and other processes. Any area that is responsible for equipment, facilities, utilities, control systems, and associated qualified systems must also deal with validation. HVAC systems and water systems must also be validated. Each of these validations/qualification has individual approaches and characteristics unique to the specific item of interest. Responsible individuals within these respective areas who submit validation/qualification protocols are equally diverse with differing education, backgrounds, and expertise. Originators of validation work include R&D scientists, technical support professionals, process engineers, facilities engineers, maintenance engineers, analytical R&D scientists, QA/QC professionals – literally everyone in the manufacturing plant. Each group is unique, each with specific education, expertise in their specific area, and each area with specific language and terminology. Each likely learned validation differently and has a different perspective on validation – all of which makes unifying the site approach to validation extremely difficult. The global pharmaceutical industry with an international workforce further complicates a unified and consistent approach to validation.

GENERAL APPROACH AND RESPONSIBILITY IN MANAGING VALIDATION

The FDA PV Guidance (1) has changed the scope, content, and responsibility of the validation function. Validation must now be involved with the entire lifecycle of manufacturing processes. Other regulatory documents have also embraced the lifecycle approach. FDA identified three stages in the validation process:

- Stage 1 – Process Design. This stage comprises development and scale-up activities, and is based on the Quality by Design (QbD) approach.
- Stage 2 – Process Qualification. This stage demonstrates reproducible manufacturing through conformance lots.
- Stage 3 – Continued Process Verification. This stage demonstrates monitoring and maintenance of the validated process by means of periodic reviews.

The lifecycle approach thus provides a new paradigm to validation in which emphasis is changed from primarily Stage 2, i.e., “three validation lots,” to Stage 1 and Stage 3. Validation must now ensure that design and development of the process by technical people yields good process knowledge and understanding (Stage 1). Actual process demonstration as in traditional process validation is relegated to a “snapshot in time” (Stage 2). Thereafter, the ongoing commercial process must be maintained and monitored as long as the product remains viable (Stage 3). Integration of manufacturing experience throughout lifecycle will results in product and process continuing improvements.

The lifecycle approach and its defined stages provide an opportunity to unify the site approach to validation and qualification across all areas of validation. The generalized lifecycle approach to validation, Design/development Performance Monitoring/maintenance, is now being applied to other processes, equipment, utilities, and even to quality systems. Should not all areas in the plant be appropriately designed and developed, demonstrated to perform as designed, and then maintained and monitored? And shouldn’t these areas be improved as experience dictates?

PROBLEM SOLUTION PROJECTS

Validation managers have described several specific projects that have successfully addressed various validation management problems. Some of these include

- Validation training program. Several managers described validation training programs that attempted to unify site strategies and approaches on validation. As mentioned above, the variety of site personnel with different backgrounds, education, expertise, and perspectives on validation made development of validation training programs a very useful endeavor. The net of this approach is to unify the approach to all validation, define expectations, and clarify language.
- Validation protocol writer training. Another useful program described by validation managers was training for writers of validation documents. This training unified structure, style, format, and content of respective validation documents. Validation documents should be written according to technical writing principles that are factual and impersonal. Clarifying this approach among the multiple writers in a manufacturing site provided standardized document formats that also facilitated internal approvals.
- Validation Approval Committee (VAC) responsibilities. The VAC has a key responsibility in the site validation program. Clearly identifying the responsibilities of the VAC assures appropriate focus of individual VAC members as well as providing standards for validation performance at the site. The members of the VAC must be a cross-functional group with broad competence. They must have the knowledge, experience, maturity, and training to fulfill the responsibilities of the VAC. The VAC should consider themselves to be a surrogate FDA auditor when they are reviewing validation documents – they should review documents from an outside perspective. The validation group leads the site validation program; however, the program will not be successful without the competence, responsibility, focus, maturity, and full commitment of the VAC.

FUTURE ISSUES OF VMF AND CONTACT INFORMATION

Future issues of VMF will discuss validation management issues associated with administration and support of the validation quality system – not specific protocols, not test results, not topics associated with the “product” of the validation function. Suggestions for future discussion topics are welcome. Readers are invited to submit manuscripts for publication. Readers are also invited to submit suggestions for discussion topics or other comments on future content. This feature will be most successful when the validation community submits ideas for improving the validation quality system. We need your help to make VMF a useful resource. Please contact coordinator Paul Pluta at ppluta@uic.edu or content specialist Melissa Carella at melissa.carella@cbinet.com with comments, suggestions, or topics for discussion.

REFERENCES

1. FDA. Guidance for Industry. “Process Validation: General Principles Practices.” January, 2011.
