Abstract

The quality management program in the Division of Transfusion Medicine at our institution had evolved to the point that the program generally was perceived to be the sole responsibility of our Quality Unit (which was administratively independent of day-to-day operations). It became clear that this administrative model was counterproductive to our new goal of instilling a responsibility for quality into every work level of our division. Such a culture change requires a considerable, organized educational effort. Quality School was established to meet these particular educational needs. The details of the modular structure of the courses and the initial results of their implementation are described. This Quality School approach was developed specifically for transfusion medicine, but the principles could be applied to any clinical laboratory.

Quality Control

In phase I (in the 1960s and 1970s), quality functions consisted primarily of quality control testing. The concept of error management emerged during those early years, with the introduction by H.F. Taswell, MD, of a remarkably innovative and successful program of “planted” intentional errors, which was aimed at predicting real error rates. During this phase, a system for characterization of real errors was used for analysis and trending. There was 1 technologist in charge of quality for the division, and the focus was clearly on the control of quality. This solitary quality control technologist reported to the medical director.

Quality Assurance

Phase II of our quality management evolution (in the 1980s and 1990s) brought enormous change. The work of 1 quality control technologist was performed by the 4-person Quality Unit, which, as prescribed by the US Food and Drug Administration, was administratively independent of the day-to-day work units of the division (“Operations”). The Quality Unit led divisional efforts to disseminate an understanding of and compliance with the current good manufacturing practices.
and developed an extensive quality plan based on the American Association of Blood Banks’ Quality System Essentials. Clearly, the emphasis during this phase shifted from simple quality control of tests or functions to a more comprehensive quality assurance of all processes.

**Quality Management**

By the late 1990s, we recognized that the quality assurance model was no longer adequate for our needs. The 4 staff members in the Quality Unit had become experts on quality, and they were fully responsible for all aspects of quality management in the division. They reviewed and approved all standard operating procedures (SOPs), forms, and validation protocols; they ensured compliance with all regulations; and they made decisions about the safety, purity, potency, and efficacy of all products, tests, and services provided in the division. In short, they were responsible for quality, and Operations was not. By this time, the division employed 200 people, and only the 4 in the Quality Unit were formally designated as responsible for quality, which resulted in a ratio of quality experts to technical experts of 1:49 [Figure 1]. The 4 Quality Unit technologists reported to the division chair (the medical director) without reporting to operations supervisors.

Many problems with that model began to surface. For example, the rapid growth in the volume, scope, and complexity of the work was making it virtually impossible for the 4 Quality Unit staff members to remain fully conversant with the myriad details of all procedures and processes. They were no longer applying their technical abilities on a daily basis, and they had become so removed from the actual work procedures in Operations that it became progressively more difficult for them to knowledgeably review and approve changes. The 4-person Quality Unit became a bottleneck when changes to procedures or processes were deemed necessary. The backlog of work in the Quality Unit slowed progress in Operations as well. Previously, the separation of functions led to the Quality Unit members being perceived as police rather than as partners of Operations. As a result of the bottleneck, the relationship between Operations and the Quality Unit became even more adversarial. [Figure 2I depicts how, in phases I and II, the members of the Quality Unit were spending so much time on the details of divisional quality management that they had only minimal time for critical oversight functions, such as internal assessments, regulatory review, and data stratification and analysis.

**Table 1**

**Evolution of Quality Management**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Years</th>
<th>Name</th>
<th>Responsible Party</th>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1960s-1970s</td>
<td>Quality control</td>
<td>Quality assurance technologist</td>
<td>Quality control testing; &quot;planted&quot; errors; characterization of real errors</td>
</tr>
<tr>
<td>II</td>
<td>1980s-1990s</td>
<td>Quality assurance</td>
<td>4-person Quality Unit</td>
<td>Regulation of current good manufacturing processes; quality plan; quality system essentials; change management; continuous improvement</td>
</tr>
<tr>
<td>III</td>
<td>2000-present</td>
<td>Quality management</td>
<td>3-person Quality Unit + 8 quality technologists</td>
<td>Phase II features + quality culture inculcated at all levels</td>
</tr>
</tbody>
</table>

**Figure 1** In the quality assurance phase (phase II), before Quality School was established, there were only 4 quality experts (all reported directly to the chair of the Division of Transfusion Medicine) on a staff of 200 (ratio of 1:49).

**Figure 2** In phases I and II, Quality Unit members spent most of their time on details of quality management (represented by the shading). In phase III, they spent most of their time on oversight functions. From Foss and Moore. Used with permission of the American Association of Blood Banks.
Our quality management structure clearly needed to change. Thus began phase III, in which the responsibilities for various quality functions (hitherto performed only by the Quality Unit) became the duties of newly appointed quality technologists in each of our 8 work units within the Division of Transfusion Medicine. The concept was that these 8 quality technologists would be subject matter experts in their work units and also would assume responsibility, on a half-time basis and after adequate training, for various quality functions. They would not be members of the Quality Unit. Instead, they would remain members of their own work units and continue to be a part of Operations rather than the Quality Unit. They also would retain their subject matter expertise while acquiring new quality-related knowledge and skills.

Figure 2 depicts the desired outcome in phase III of having Operations, as well as the Quality Unit, responsible and accountable for the management of quality. Our goal was to fully inculcate a quality culture into all levels of work.\textsuperscript{7-9} To reach that goal, education for the newly appointed quality technologists would be essential. It was necessary that they become familiar with basic quality principles and many regulations and accreditation requirements. It also was necessary to give them detailed instructions and training to enable them to effectively fulfill their new job descriptions. This would require training in how to distinguish between Operations functions and quality management functions and how to fulfill the associated responsibilities in each domain. To achieve this level of training, Quality School was developed.

**Quality School**

Quality School was designed to provide systematic training in quality principles and practices. The 40-hour course curriculum was developed by the division’s administrator, Quality Unit, and Education Resource Team. The primary resource documents were the quality system essentials of the division’s previously developed quality program and associated SOPs.

**Curriculum**

The curriculum includes a series of formal training modules, each of which includes learning objectives, published resource materials, didactic classes on the practical application of the material, student assignments, and training verification assessments. Comprehensive tests are administered before and after training to measure overall learning. **Table 2I** outlines the modules included in Quality School. The modules were designed to provide the student with a step-by-step understanding of the general principles of quality management, the importance of current good manufacturing practices, regulatory expectations, our division’s quality program, and practical application of quality management principles in the performance of daily functions within Operations.

**Training Modules**

The format of the training modules is standardized **Table 3I**. Each of the 13 training modules is a controlled document that is linked to its associated SOPs. Consequently, when SOPs are modified, the affected training modules are modified; implementation of the new versions occurs simultaneously. Each training module includes a “Training Verification Evaluation” form **Figure 3I**, the instructor’s key **Figure 4I**, and the official record **Figure 5I** to document the student’s successful completion of that module.

**First Day of School**

During each 2-week session, Quality School classes are held for 4 hours each day. Before the first class, the division chair and administrator welcome the students and discuss the following topics: (1) attitudes about quality of service to patients; (2) the need for division-wide understanding of quality principles

### Table 2I

**Quality School Modules**

<table>
<thead>
<tr>
<th>Training Module</th>
<th>Description</th>
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<tbody>
<tr>
<td>Organization</td>
<td>Explanation of the need for a defined organizational structure</td>
</tr>
<tr>
<td>Current good manufacturing practices</td>
<td>What are current good manufacturing practices, and why must we follow them?</td>
</tr>
<tr>
<td>Process control</td>
<td>What is the relationship of process control to patient safety?</td>
</tr>
<tr>
<td>Validation</td>
<td>Description of initial and summary validation documents, including when and how to use them</td>
</tr>
<tr>
<td>Writing quality documents</td>
<td>Examples of how to write quality documents, including standard operating procedures, forms, validation protocols, etc</td>
</tr>
<tr>
<td>Document and data management</td>
<td>Explanation of the need for complete records, archival traceability and trackability, and maintenance of thorough documentation</td>
</tr>
<tr>
<td>Critical materials</td>
<td>Definitions, including supplier qualification</td>
</tr>
<tr>
<td>Personnel</td>
<td>Discussion of qualifications, competence assessment, etc</td>
</tr>
<tr>
<td>Equipment</td>
<td>Description of necessary records</td>
</tr>
<tr>
<td>Facilities and safety</td>
<td>Description of necessary records</td>
</tr>
<tr>
<td>Events</td>
<td>Discussion of event reporting, identification, categorization, and trend analysis</td>
</tr>
<tr>
<td>Assessments</td>
<td>Description of internal and external assessments and how to prepare for them</td>
</tr>
<tr>
<td>Process improvement</td>
<td>Description and discussion of process improvement opportunities, the ultimate goal of the quality management program</td>
</tr>
</tbody>
</table>
and their applications in daily work; (3) expectations of the students, including diligence in attending every class, actively participating in class activities, completing all assignments, and successfully completing the training verification assessments (which are formal tests); and (4) the concept, which they emphasize, that quality is everyone’s responsibility and that the ultimate importance of the course is its direct linkage to good outcomes for patients.

Graduation Day

At the conclusion of the Quality School session, a graduation ceremony is held. The division chair and administrator address the students, acknowledge their important achievements, reemphasize their particular new authority and responsibilities for management of quality in the division, and present each participant with a certificate of completion. A celebration with refreshments, class photograph, and time for fellowship follows the ceremony. This formal ceremony with participation by senior management staff reemphasizes for the students the fundamental importance of what they have learned.

Quality School originally was established to educate and prepare the work unit quality technologists for their new responsibilities. However, we quickly realized the value of this school for individuals at all levels and, after the initial session, opened enrollment to everyone in the division.

Accountability

One of the most important concepts taught in Quality School is that personal accountability accompanies the performance of quality functions. Throughout the session, the instructors weave the concept of personal accountability into virtually every training module. They often refer to “putting on your quality hat” to help the students visualize the important responsibility and accountability they will have after graduation when they begin performing designated quality functions.

<table>
<thead>
<tr>
<th>Table 3</th>
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</thead>
<tbody>
<tr>
<td><strong>Example of a Training Module: the “Process Control” Module</strong></td>
</tr>
</tbody>
</table>

**Training Event: Process Control**

| Purpose: to help the participant understand |
| 1. Necessity for process control |
| 2. Implications of uncontrolled change |
| 3. Process of change control (process control) in transfusion medicine |

**Training format:** lecture (2 h)

**Associated SOPs and policies**

- SOP 4107—Process Control
- SOP 5430—Process Change Control
- SOP 5195—Process Validation
- SOP 5296—Application and Software Change Control
- SOP 5619—Application Software Validation
- SOP 5620—Computer Hardware Validation

**Prerequisite training:** none

**Objectives**

1. Trainee will define the following terms: process control, change control, validation
2. Trainee will understand the implication of uncontrolled processes
3. Trainee will review the 6 associated SOPs and policies

**Trainer’s guide**

- Order laptop
- Obtain data projector
- Reserve room (be sure room has a network connection)
- Obtain large poster paper, markers, and masking tape
- Make copies of the following for each trainee:
  - Learning objectives
  - Assignment sheets at end of T-3500 document
  - Training verification
  - PowerPoint handouts
- Make copies—marked “Uncontrolled Copy”—of the following for each trainee:
  - Quality Program (System A)
  - Operational Systems (ie, SOP 4112 System B: Suitability)
  - Associated SOPs

**Prepare for process control game**

**Training session:** train from PowerPoint presentation and notes page

**Training verification:** no special preparation needed

**Assignment 1**

Locate validation records and documentation performed in your work unit

Prepare to report back to the group

Were you able to find those documents?

Did the storage location meet the criterion of a “designated, single location for filing documentation”?

**Assignment 2**

Read the 6 associated SOPs and policies

**SOP, standard operating procedure.**

* PowerPoint, Microsoft, Redmond, WA.
Accountability can be defined as having personal moral responsibility for something for which one may be answerable. In Quality School, the students are taught that they will be accountable (answerable) to various individuals and groups. We devote considerable time to teaching accountability to ensure that the students understand what it must mean to them personally and to ensure that they thoroughly comprehend how their new responsibilities for quality will directly affect care and outcomes for our patients. The primary value of our institution, “The needs of the patient come first,” applies to all personnel. We repeatedly remind our students that every function they perform potentially affects patient care (directly or indirectly) and that the optimal care they would want for themselves or their loved ones is the goal of all we do each day. Because the concept of “putting on your quality hat” is a reminder of accountability and a key principle taught in Quality School, on graduation day, each student is awarded a purple quality hat as a visual reminder.

To clearly declare the significance we attach to successful graduation from Quality School, graduation is a prerequisite for performance of certain defined quality functions in our division. By providing education on quality practices and principles first, we are providing the tools necessary for good assessment, judgment, problem solving, and decision making in the work unit. In other words, the quality principles can be (and should be) readily applied to day-to-day operations.

Advanced Classes

Quality functions that are technically or organizationally more complex require more extensive instruction, which is offered in advanced classes. These classes use the standardized training module format, which includes specific detailed instructions for the function and, generally, a follow-up period for hands-on practice under the supervision of individuals in the Quality Unit.

An example of an advanced class is “Writing and Reviewing Standard Operating Procedures.” The 3 objectives of this class are to (1) review the process for writing SOPs, (2) define the roles and responsibilities for the quality assurance reviewer of SOPs, and (3) review the process for SOP review and approval. The training verification evaluation includes assessment of whether the student attended the SOP lecture series to review the process for writing SOPs and the role and responsibilities for SOP reviewers, attended the mentoring session with the Quality Unit, reviewed the criteria for SOP review,
and completed a thorough review of at least 3 SOPs under the supervision of Quality Unit personnel, who subsequently reviewed and approved them. Some training modules include a checklist of items to consider when performing a complex procedure \textbf{Figure 6}. Students who complete advanced classes to learn a new function must demonstrate competency before they are authorized to perform the new function.

**Outcome**

The number of people in the Quality Unit has decreased from 4 to 3, and they continue to report to the medical director. This organizational model better conforms with the US Food and Drug Administration’s intent that there be a distinct separation of quality oversight and Operations. The Quality Unit members now devote substantially more time to divisional oversight functions, such as internal audits, management of data and documents, process control and change control, and identification of potential ways to improve processes. Each Operations work unit has a quality technologist who works approximately 20 hours per week on quality management functions. With the support of their Operations work unit supervisory staff, these technologists have assumed many of the duties formerly performed solely in the Quality Unit, including SOP content review and sign-off, validation content review, maintenance of equipment tracking logs, collection of work unit data, and participation with the Quality Unit in investigation and characterization of all reported events. They also participate in work unit–specific management of the divisional process for change control.

Now a strong partnership exists between the quality technologists and the Quality Unit, which fosters a collegial, non-adversarial, collaborative team approach to the management of quality in the division. The roles and the boundaries of responsibilities of each group are well delineated and understood. The quality technologists in Operations are primarily subject matter experts; the Quality Unit members are primarily regulatory experts. Working together, they accomplish all the necessary quality functions more efficiently. For example, previously the Quality Unit had sole responsibility for SOP review and sign-off. Now the quality technologists in Operations review SOPs for content and accuracy, and the Quality Unit members review them for regulatory compliance only. As a result, the turnaround time for SOP review in the Quality Unit has decreased by at least 50%. With the incorporation of quality experts into Operations, the ratio of quality experts to technical experts in the division increased from 1:49 to 1:17 \textbf{Figure 7}.

The evolution of our quality program during several years created problems because the responsibility for quality was widely perceived to reside solely in the 4-person Quality Unit (which was, and continues to be, administratively independent of Operations). To alleviate those problems, a quality technologist was appointed in each operational work unit to coordinate quality management functions and to help establish a quality culture at all levels in the organization. Quality School (formal,
systematic training on quality principles and practices) provides the fundamental education for this new structure of quality management and for the establishment of a quality culture to help ensure that quality is understood and accepted as everyone’s responsibility. Although this Quality School was developed specifically for transfusion medicine, the principles could be applied to any clinical laboratory.

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Acknowledgments: We gratefully acknowledge the following people for their ongoing efforts in teaching and continually improving Quality School: Brenda Bendix, Jill Kruger, Barbara Litsenberger, Rebecca Reisner, Jennifer Talmo, and Craig Tauscher.

References


