"Developing a New Employee Orientation Program for GXP Compliance," Journal of GXP Compliance, Vol. 13, No. 3 (Summer 2009), pp. 82-92.

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This article addresses several issues that emerge in the development of a new employee orientation (NEO) program for GXP compliance. There are two major sets of organizational expectations for the workplace performance of a new employee: compliance and productivity expectations. These expectations are operative from the new hire's first moment on the job; therefore, NEO is a timely setting for presenting these expectations. This article reviews the employment lifecycle, the comprehensive process every employee goes through from recruitment to separation, and situates NEO in that lifecycle. Next, various features of a typical NEO program are treated. A scenario based discussion of regulatory overlap is presented, as well as appropriate employee responses. This is followed by an episodic approach to the history of the US Food and Drug Administration. These episodes are employed as illustrations of the process of continuous improvement (i.e., identification of problems [deviations], investigation and root cause analysis, and remediations). Finally, several aspects of the organization of the NEO program are presented, including the necessity to coordinate the program across several departments.

INTRODUCTION

A new employee orientation (NEO) program can contribute to both GXP compliance and organizational productivity. New employee orientation can contribute to GXP compliance by indicating to the new hire or transfer that the organization (and the regulatory agency) has a series of expectations for employee performance in the workplace. These expectations are covered by the GXP regulations, corporate policies, and local procedures; are written and readily available to employees; and are mandatory. The new hire or transferred employee may not have experienced such regulation in his or her previous position.

The NEO program can contribute to organizational productivity by presenting new hires with the organization's process for assessing workplace performance (i.e., employee productivity). The organization's expectations are summarized in the specifics and criteria of the periodic performance review process. Again, new hires or transfers may not have experience with such process and can adjust their performance to meet the expectations.

On the one hand, both sets of expectations for workplace performance, compliance and productivity, are operative from the new hire's first moment on the job. Thus the NEO program is a timely setting for presenting these expectations. On the other hand, both sets of expectations are far too extensive to present in detail in the time available for new employee orientation. The question becomes: How to decide what to cover in the NEO program?

As a preliminary point, the term "new employee" should briefly be analyzed. The term is ambiguous. As Rollag points out, "everyone might agree that an arriving recruit is a 'new employee' on the first day, [but] when do members stop being considered as 'new employees?'"(1). Likewise, the "new employee" is frequently mentioned in discussions of "onboarding," even though "The most successful onboarding programs […] last one to two years" (2). This ambiguity may impact on the scheduling of new employee orientation programs (e.g., those that are scheduled on a biweekly

or even monthly basis). Thus the new employee can be on the job for days or weeks before participating in the NEO program. It will become clear that such scheduling practices can present serious GXP compliance issues or prevent the new hire from being assigned to a limited access area.

This article addresses five considerations that emerge in the development of a NEO program for GXP compliance. First, the article considers NEO programs in terms of what is called the employment lifecycle. Second, key elements of a typical NEO program, which are often overlooked, are described. The third section of this article presents a scenario-based discussion of regulatory overlap and appropriate employee response. Fourth, approaches to presenting the history of the US Food and Drug Administration will be reviewed. Fifth and finally, several aspects of the organization of the NEO program will be touched on, including the need to coordinate the program across several departments.

NEW EMPLOYEE ORIENTATION AND THE EMPLOYMENT LIFECYCLE

New employee orientation is a crucial element in the employment lifecycle. This section presents an overview of the employment lifecycle and its components, including new employee orientation, and two of the perspectives from which that cycle can be viewed: the organizational viewpoint and the viewpoint of the individual employee. Next, the contribution that participating in the NEO program can make for organizational and employee goals is considered. Finally, this section discusses the relationship between the overall process of employee socialization and the NEO program.

The employment lifecycle can be defined in terms of the following twelve elements:

- Advertising the position
- Recruiting
- Selection
- Hiring
- New employee orientation
- Probation
- Training and development
- Performance review
- Promotion
- Coaching and disciplining
- Separation
- Benefit entitlements.

This paper focuses on the importance of the NEO and its impact on subsequent elements.

Perspectives On The Employment Lifecycle

This lifecycle can be viewed from either the individual employee's perspective or the organization's perspective. On the one hand, there are differences between these two perspectives. For example, advertising a position will look differently from the organizational viewpoint versus the employee viewpoint. From the organization's viewpoint, the job posting will have content that is determined by a review of unit needs and resources; for instance, the position may require a bachelor's degree in chemistry and 5-7 years experience in FDA-regulated industry. From the individual employee's viewpoint, internal candidates may view the posting earlier than external candidates, may see the name and position of the hiring manager, etc. For another example of differences, from the individual employee's viewpoint, separation will mean different things in terms of benefits if the employee transfers, retires, or is terminated for cause. From the organization's viewpoint, the same separation will implicate issues of business continuity and succession planning, whether it is due to transfer, retirement, or termination.

On the other hand, there are similarities between the individual employee's and the organization's perspectives. In particular, reaching the first performance review is obviously important for the employee, especially if that review is positive. Similarly, it is important for the organization, because it validates the resources expended in advertising the position, recruiting, and interviewing those persons in the applicant pool, and then selecting and hiring the particular employee whose initial performance review will prove to be positive.

Objective Of The NEO Program

Regardless of the differences of perspective, it is important for both the organization and the individual employee that their views come to be aligned, to whatever extent possible. A well-focused NEO program can contribute to that goal. A NEO program seeks to engage

new hires or transferred employees more rapidly with the organization. It seeks to ensure that their behavior aligns more rapidly with the organization's culture and expectations for the workplace. Such a program intends to lengthen employees' tenure at the organization, as well as their motivation to perform successfully in the new position.

The NEO program is thus a specific, programmatic component in the overall process of socializing the employee to fit into the organization. It is limited in time, occurring within the first few days of hiring or transfer, in contrast to onboarding, which occurs over months or even years, or the process of employee socialization that takes place throughout the entire employment lifecycle. New employee orientation is a program, with a more or less well defined set of participants and agenda, in contrast to the disparate set of formal and informal activities and interactions that comprise onboarding or employee socialization in general (3).

A TYPICAL NEO PROGRAM

A typical NEO program includes the following elements:

- A welcome and mission statement from an officer of the organization
- Presentation(s) on expectations for the workplace
- A presentation on organizational structure, history, and culture
- A series of transactions facilitated by a representative of the human resources (HR) department, based on resources (whether available online or in a binder) containing information about employee benefits, beneficiaries, HR policies, confidentiality agreement, and standards of business conduct (4).

Moreover, in regulated industry, the NEO program can include regulatory elements (e.g., safety and GXP topics). The NEO program is an appropriate occasion to present material that immediately impacts most or all employees. Thus an official greeting, as well as the organization's mission statement, structure, history, culture, and resources on employee benefits, are relevant to all employees. For example, the mission statement could include the following:

An organization in FDA-regulated industry is responsible for products that can directly affect customers' health and quality of life. Product failure could result in sickness or death. Working for an organization where products help preserve and sustain life comes with the responsibility to know one's job and perform one's job correctly at all times.

An official greeting can contribute substantially to a new hire's integration into the workplace as well as to an organization's success. As an illustration, Don Mayne, the CEO of Dorothy Lane Markets in Dayton, OH, has personally greeted every new employee for the 20 years he has been CEO. He wants all the company's new hires to understand the company's culture, customers, and competitors. And Dorothy Lane Markets has margins twice as high as the industry average (5).

Content that does not immediately impact the new hire, or only impacts new hires in several departments or units, is better deferred until departmental or unit training activities. More generally, material that is task specific tends to be appropriate for technical training at the departmental or unit level, while content that is domain (or context) specific tends to be appropriate for the NEO program and other, subsequent regulatory training (6). Thus the good manufacturing practice (GMP) regulations stipulate that "training shall be in the particular operations that the employee performs," which is to say technical training that tends to be more task specific. The regulations go on to say that training shall also be "in current good manufacturing practice (including current good manufacturing practice [CGMP] regulations in this chapter and written procedures required by these regulations)," which is to say regulatory training that tends to be more domain specific (7).

The following are several examples of domain specific content. The first illustrations involve Occupational Safety and Health Administration (OSHA) regulations. In any industry, a presentation of workplace expectations will include a review of environmental, health, and safety (EHS) issues that directly impact employees. This review will ensure, for example, that all employees can respond appropriately to various industrial safety warnings and alarms that may be encountered from their first moment on the site (8). By way of illustration, OSHA regulations stipulate, "Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial

assignment" (9). Because of the immediate need new employees have for this information, the NEO program is a good occasion to present this information (10).

As another example, employees must have immediate and continuing access to material safety data sheets (MSDS). The significance of the MSDS for employee safety can be covered in the NEO program; the process of accessing this information can be addressed as well. If the organization uses an electronic document management system (EDMS) to capture the MSDS, this portion of the NEO program can be conducted in a networked computer classroom, where the new employees can be stepped through the process of logging on to the organization's intranet, accessing the EDMS, and retrieving a MSDS. The presentation of employee safety issues in a NEO program is typically facilitated by a representative of the EHS unit.

In FDA-regulated industry, another presentation of workplace expectations will include a review of relevant GXP regulations to ensure that the employee will be compliant in each assigned task according to regulations, corporate policies, and local procedures. Again, these compliance issues may arise from the first moment the employee is on the site. This GXP review will ensure, for instance, that the new employee is "instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products" (11).

An important topic that should be covered in the GXP review is the FDA requirement that employees have immediate and continuing access to relevant standard operating procedures (SOPs). Good laboratory practice (GLP) regulations, for instance, stipulate, "each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed" (12). Because new employees may have an immediate need to access procedures, the NEO program is a timely occasion to address this issue.

For example, a newly hired animal care technician must have immediate access to the lab's procedures for the identification of test animals. The process of accessing this information can be addressed in the NEO program (13). If the lab makes the SOPs available in an EDMS, this part of the GLP review can be conducted in a networked computer classroom, where the technician can go through the process of logging on to the organization's intranet, accessing the EDMS, and retrieving the relevant SOP. This material is typically facilitated by PharmOps staff.

In addition to the OSHA and FDA regulatory areas, other corporate policies addressing workplace expectations (e.g., security, intellectual property rights, corporate intranet access) must be presented.

REGULATORY OVERLAP AND ITS IMPLICATIONS

Another important topic that should be covered in the NEO program is the complexity of regulatory regimes and regulations that impact the organization, as well as the individual employees. These regimes include such agencies as the FDA, Drug Enforcement Administration (DEA), Department of Transportation (DOT), Environmental Protection Agency (EPA), OSHA, and others, each with its own set of regulations. As already noted, the new hire or transferred employee may have an employment background that was not subject to regulation by some of these agencies, or to such complexity of regulation.

On the one hand, the sheer number of these disparate regulations means that they cannot be considered in any detail in the NEO program. They will need to be addressed, on a timely but "as needed" basis, during training subsequent to new employee orientation. On the other hand, the various regimes can present the problem of regulatory overlap, where different agencies have differing regulations covering the same situation. This complexity can be raised during new employee orientation, and several ways the affected employee can appropriately respond can be highlighted.

An Illustrative Example Of Regulatory Overlap

The following is an example scenario and guided discussion that can be incorporated into a NEO session. It has three parts. The first is the presentation of the scenario and an invitation to the new hires to share their responses. The second part is a facilitated discussion of the way SOPs provide guidance for most situations the new hires will confront in the workplace. The third part presents the principles that control the situation when procedures don't suffice. This allows

the new employee orientation program to comfortably introduce new hires to issues of regulatory complexity, appropriate and inappropriate ways to respond to that complexity, the role of SOPs in regulated industry, and the necessity of problem escalation and change control when the current procedures are clearly inadequate.

The scenario is as follows:

> Newly hired employees, Francine and Frank, have been duly screened and certified for work with a controlled substance. During their first hour on the job, while processing the controlled substance, the fire alarm sounds in their area.

Ask the participants in the NEO session: How should Francine and Frank respond? Points to discuss include the following:

> • On the one hand, the chain of custody required by the Drug Enforcement Agency stipulates that "manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area" (14).
> • On the other hand, evacuation requirements of the Occupational Safety and Health Administration call for "procedures for emergency evacuation, including type of evacuation and exit route assignments" (15).

Do Francine and Frank remain in the limited access area and maintain the chain of custody for the controlled substance, complying with DEA regulations. Or do they immediately evacuate the area with all due speed, complying with OSHA regulations?

When this scenario is presented to line personnel in a new employee orientation session, the responses vary widely. Many participants simply say, "Francine and Frank should get out quickly." Some say, "They should use their good sense." Others say, "They should ask Joe," or "Follow Joe," Joe being a fellow worker in the controlled substances area, a twenty-year veteran employee, or other employee.

Some participants point out that in the case of a fire, or even a fire alarm, a notice of event (NoE) will be required, so evacuating (i.e., breaking the chain of custody for the controlled substance) will be covered by the NoE anyhow.

A few suggest that the relevant SOPs should be consulted, presumably in advance of the fire alarm.

It is important in the new employee orientation session for the facilitator to point out that no known organization in regulated industry has a procedure that states, "Use your good sense" or "Ask Joe." It is also important to explore further the point about a NoE. What does a "notice of event" mean? Because some of the new hires in the orientation session may not have employment experience in regulated industry, they may not know that this means that a deviation has occurred, a deviation that may involve non-compliance with an SOP. This will help focus the discussion of the scenario on the topic of relevant SOPs. Clearly the facilitator of this portion of the new employee orientation session will have already reviewed the local procedures that address the issues brought out in the scenario.

When the discussion focuses on the role of written procedures, the point can be reinforced that the FDA requires employees have direct and continuing access to relevant SOPs. SOPs that cover such situations typically indicate that line personnel such as Francine and Frank should comply with the emergency evacuation plan for the area. But the procedures go on to say that their supervisor is responsible for maintaining the chain of custody for the controlled substance. This seems to accord with the stipulation in §1301.73(b) that an employee, "specifically authorized in writing, shall be responsible for the area.

Of course this does not resolve the question initially posed: How should Francine and Frank respond to the scenario? It simply shifts the question from all employees certified for work with controlled substances to their supervisors. The employees, including Francine and Frank can evacuate, but what about the supervisors? Do they remain and maintain the chain of custody for the controlled substance, complying with DEA regulations, or do they too evacuate the area, complying with OSHA regulations?

If the relevant SOPs do not provide guidance for the fate of the supervisors, this helps to further focus the discussion on the topics of problem escalation and change

control in regulated industry. Once it is evident that there is no SOP that covers the supervisors in the scenario, and once the inadequate answers "Ask Joe," "Use good sense," have been dispensed with, the participants can be introduced to the principles that control the situation. Two important principles, management notification and change control, can be discussed.

> Most organizations have the following workplace expectation: Employees shall escalate any problem that they don't know how to deal with, to their supervisor.

This escalation process can be proceduralized; call the SOP "Alert Management, Notification, and Escalation." This procedure can be referred to and summarized at this point in the NEO session.

> Moreover, organizations have another workplace expectation: Employees shall deal with unexpected situations in an orderly fashion, i.e. situations for which currently implemented SOPs do not provide guidance, or SOPs that are clearly inappropriate.

This expectation that change will be controlled is captured in the organization's change control procedure. This procedure also can be referenced and summarized at this point.

Overall, discussion of this scenario in the NEO session should give new hires the following takeaway:

> The web of regulations is complex, but distinct processes and procedures are operative even in the most complex situation.

At this point, having presented the scenario and discussed topics of the complexity of regulations, appropriate and inappropriate responses to that complexity, the role of procedures, and the necessity of problem escalation and change control when the current procedures are clearly inappropriate, the agenda can move to broader areas of organizational history and culture.

PRESENTING THE HISTORY OF THE FDA

In regulated industry, the history of FDA is usually presented in a NEO program as part of organizational culture and history. The historical account might be summarized in four or five critical episodes, including the origin of federal regulations, the development of drug safety regulations, and other episodes (see the Table). Several threads can be drawn from these illustrative episodes, and presented in the NEO program.

Critical Episodes in the History of FDA	
Upton Sinclair's **The Jungle**	1906
Elixir Sulfanilamide	1937
Thalidomide	1960s
Tylenol tampering	1982
Salmonella contamination	2000s

Reaction To Public Concern

The first focus on FDA's history presents public concern and official responses to crises—legislative responses such as the Food, Drug and Cosmetic Act of 1938, as well as regulative responses such as 21 CFR 58 and §211. This discussion provides an opportunity to summarize the history of FDA for new employees.

Upton Sinclair's Novel. As an important episode in the origin of federal regulation, take Upton Sinclair's *The Jungle*. It was based on Sinclair's own investigative journalism in late 1904 in the Chicago stockyards and meatpacking industry. This book was serialized in the journal *Appeal to Reason* in early 1905, and was published by Doubleday in early 1906. It graphically recounted the plight of workers and the adulteration of food that characterized the meatpacking industry. This book dramatically disclosed the problems in the industry, and its publication and popularity contributed to the signing of the Pure Food and Drugs Act in June 1906 (16).

The book is an iconic factor in the emergence of the 1906 legislation. It should be stressed that there had been widespread concern about adulterated food and drugs in the United States even before 1904. President Theodore Roosevelt had called for legislation to regulate "misbranded and adulterated foods, drinks, and drugs" in his State of the Union statement in late 1905. Many factors combined to lead to the passage and signing of the legislation, including Sinclair's book (17).

Elixir Sulfanilmaide. This was also the case with the Elixir Sulfanilamide disaster of 1937, which was a critical episode in the emergence of drug safety regulations. When the sulfa drugs first came to market, they were distributed in tablet form. Soon, the S.E. Massengill Company developed a liquid preparation. This was the Elixir Sulfanilamide, with diethylene glycol (DEG), water, and sulfanilamide as the main ingredients. The solvent, DEG, was not listed as an ingredient, nor were existing animal studies of the solvent consulted. The Elixir was distributed across the United States in late 1937, and resulted in over 100 deaths due to diethylene glycol poisoning (18).

This tragedy contributed to the introduction of a bill that eventuated in the Food, Drug and Cosmetic Act, signed into law in June 1938. Among other provisions, it required that a new drug application (NDA) provide evidence of drug safety. As FDA Commissioner Walter G. Campbell had argued in October 1937, "In the interest of safety, society has required that physicians be licensed to practice the healing art. Pharmacists are licensed to compound drugs. […] Certainly a requirement that potent proprietary medicines be manufactured under license can be justified on the ground of public safety " (19). Once again, many factors, including the tragedy itself, combined to lead to the passage and signing of the legislation (20).

Thalidomide. Another episode involves Thalidomide, which was manufactured and marketed in Europe by Chemie Grünenthal of (West) Germany as a tranquilizer in the late 1950s, and was used to relieve morning sickness. Soon thalidomide was associated with peripheral neuritis. A letter from Dr. Leslie Florence to the *British Medical Journal* suggests that, "these symptoms could possibly be a toxic effect of thalidomide" (21). Next, a letter from Dr. W.G. McBride was published in *The Lancet* suggesting that thalidomide, when used for morning sickness by pregnant women, was accompanied by a pattern of severe birth defects (22). Finally, thalidomide was withdrawn from the West German market because of safety concerns. Thalidomide was not commercially distributed in the United States during this episode, although it was distributed for clinical trials (23).

As a consequence of the Thalidomide tragedy, the Kefauver-Harris drug amendments to the Food, Drug, and Cosmetic Act were signed by President John F. Kennedy on October 10, 1962. These regulations mandated an investigational new drug application (IND) for the trials. Moreover, the regulations include informed consent of subjects of clinical trials, qualified investigators to conduct the trials, Institutional Review Board (IRB) approval of changes to a study protocol, and reporting of adverse events (AEs) (24).

Further episodes might include Tylenol tampering (1980s), and, if it there is a desire to highlight current events, Salmonella contamination (1990s; 2000s).

Continuous Improvement

A second focus on the history of FDA treats each of the historical episodes as the occasion for continuous improvement (i.e., problem identification, investigation, root cause analysis, and remediation through corrective action and preventive action). This focus can familiarize the new employees with regulated industry's approach to continuous improvement and risk management. The episodes illustrate this continuous improvement through the logic of investigation and remediation.

The Jungle. *The Jungle* can represent the issue of problem identification and triage. What is the evidence for a problem, and how important is it? What is the risk, what is the severity associated with the problem? When Sinclair's book was published, there was substantial dispute in the press about the accuracy of his account (25). President Roosevelt sent Charles P. Neill and James Bronson Reynolds to Chicago to ascertain and report the truth of the book's claims. Roosevelt delayed releasing their report, which basically substantiated Sinclair's claims. As Sinclair expressed it about the meatpacking industry, "The packers worked on the President's sympathy […] in order to keep the true conditions from the public." Sinclair went on to insist that the Neill-Reynolds report be made public (26). The report was finally made public and contributed to the signing of the Pure Food and Drugs Act in June 1906 (27).

Elixir Sulfanilamide. The Elixir Sulfanilamide poisoning episode can represent the issue of investigation and root cause analysis. What factors might have contributed to a problem, and which is most likely the fun-

damental, or root cause? A few days after October 11, 1937, when the first cases of poisoning were reported from Tulsa, OK, the American Medical Association (AMA) had begun to investigate and suggested that it was the solvent, diethylene glycol, that was the cause (28). S.E. Massengill, the company that had manufactured and distributed the Elixir, continued to argue that the solvent was not the cause, that the poisoning was the result of interaction of the Elixir with other drugs (29). By carefully identifying the potential factors (e.g., the active ingredient, the solvent, the other excipients, and other factors ["other drugs"]), then weighing their actual effects, the chemists were able to identify the root cause, the toxicity of ethylene glycol. As a byproduct of the root cause analysis, Samuel Massengill himself was charged with mislabeling and misbranding the elixir and fined $26,000 (30).

Thalidomide. The thalidomide tragedy can be considered an example of corrective action. In West Germany, a pediatrician named Widukind Lenz began to suspect that thalidomide was associated with a dramatic increase in birth defects. Lenz presented his findings at a medical conference in 1961. This account was picked up by a widely read newspaper, *Welt am Sonntag* (November 26, 1961) that called for the withdrawal of the drug. Under pressure from West German government officials, while still contesting the findings, Chemie Grünenthal withdrew thalidomide from the German market a few days later. Further evidence accumulated and the public outcry increased. This lead to criminal indictments filed in 1967 against Chemie Grünenthal officials. The trial lasted three years. It finally ended when the company agreed to establish a substantial fund to provide for the victims of thalidomide, and the defendants were released from further liability (31). This is an example of a corrective action, where steps are taken (i.e., establishing the fund for the victims) to in part remedy the problem (i.e., the administration of a dangerous drug during pregnancy).

The heroic role of an FDA medical officer, Frances Kelsey, to prevent Thalidomide marketing in the United States represents a somewhat more oblique instance of corrective action. When Wm. Merrill Co. submitted a NDA for thalidomide to FDA on September 12, 1960, the documentation included evidence of drug safety based on the distribution of the drug in Europe. Frances Kelsey and her colleagues at FDA noted omissions in the application. Merrill responded to requests for further evidence. As Kelsey continued to delay approving the application, awaiting further safety evidence, Merrill became increasingly impatient. Finally, Dr. Kelsey corrected the misperception of responsibilities that had crept into the situation. "In the consideration of an application for a new drug, the burden of proof that the drug causes side effects does not lie with the FDA. The burden of proof that the drug is safe—which must include adequate studies of all manifestations of toxicity which medical or clinical experience suggest—lies with the applicant" (32). While this corrective action does not focus on the victims of the unsafe drug, it does focus on the responsibility for evidence regarding drug safety.

Tylenol. The Tylenol tampering case can be considered an example of preventive action. What steps can be taken to prevent the recurrence of a problem? In 1982, Tylenol was the nation's leading non-prescription painkiller. In late 1982, a number of persons in the Chicago suburbs died from cyanide poisoning after swallowing Extra-Strength Tylenol in capsule form (33). It was quickly determined that the capsules had been opened somewhere along the distribution chain, possibly in the retail outlet, and the cyanide was added. The capsules were then reassembled and sold by the unsuspecting retailer to the unsuspecting consumer. Within a month, the pharmaceutical industry had asked FDA to develop regulations for tamper evident packages (34). FDA prepared new regulations requiring tamper evident packaging that went into effect in early 1983 (35). While the preventive action seems to have been reasonably effective, there has never been a criminal conviction in the case (36).

Salmonella. Finally, the current episodes of Salmonella contamination could represent the need for robust maintenance and diligent implementation of the system of investigation and remediation. The contamination of peanuts has taken eight lives and sickened some 19,000 people in more than 40 states (37).

ORGANIZATIONAL ISSUES

The breadth of topics that must be covered in a NEO program means that there must be close coordination

and buy-in of each department that is involved. This usually includes HR, EHS, and the GMP training unit, as well as other units. A representative of each of these units should be a member of a coordinating committee for the whole program. This committee should work closely with the business owner of the NEO program, whether that business owner is located in HR or some other department. In addition, if senior management is to be involved in welcoming new hires, that activity must also be closely coordinated. It may also require coaching the officer in this role as some are good at it and others are not.

The high visibility of the NEO program means that all facilitators must be fully engaged in their assignments. None of the facilitators can behave as though they feel that their time would be better spent elsewhere. None of the facilitators can behave as though they feel that they will never see the new hires again, once the sessions are completed, no matter how large the organization. Each facilitator must recognize the value of the program and be willing to help welcome the new hires to the organization. These points about facilitator performance are important because they may be overlooked due to the cross-functional nature of the program. The coordinating committee should be responsible for reviewing not just program content but facilitator performance as well, to ensure these contents and performances are aligned with organizational goals.

Because of the breadth of topics addressed in a NEO program, the multiplicity of departments involved, and the crucial need to convey the information in a timely fashion, the NEO program should be proceduralized. This SOP can be developed from several sources, including the charter for the coordinating committee, the various subject matter experts involved from the several departments, and the agenda for the NEO program that has been approved by the various departments, with all the times, facilities, materials, and responsibilities clearly delineated.

CONCLUSION

This article has addressed several issues that emerge in the development of a NEO program for GXP compliance. New employee orientation is a critical step a new hire or transferred employee takes in an organization. This is a step on the path to reach his or her first performance review. The path itself is an early segment of the employment lifecycle, the comprehensive process every employee goes through from recruitment to separation. This article reviewed the employment lifecycle, and various features of a typical NEO program were treated. A scenario-based discussion of regulatory overlap was presented, as well as appropriate employee responses. This was followed by an episodic approach to the history of FDA. These episodes were employed as illustrations of the process of continuous improvement (i.e., identification of problems [deviations], investigation and root cause analysis, and remediations). Finally, several aspects of the organization of the NEO program were presented, including the necessity to coordinate the program across several departments.

ENDNOTES

1. Keith Rollag, "Defining the Term 'New' in New Employee Research," *Journal of Occupational and Organizational Psychology*, Vol. 80, 2007, pp. 63-75, esp. p. 64.

2. B. M. T. "Onboarding Success," *Workforce Management*, Vol. 87, Issue 15, September 22, 2008, p. 29.

3. John P. Wanous and Arnon E Reichers, "New Employee Orientation Programs," *Human Resource Management Review*, Vol. 10, Issue 4, Winter 2000. For further discussions of NEO programs, see Doris Sims, *Creative New Employee Orientation Programs*, NY: McGraw-Hill, 2001, and Karen Lawson, *New Employee Orientation Training*, Alexandria, VA: ASTD, 2002.

4. For checklists of topics included under resources and information, see Kathryn Tyler, "Take New Employee Orientation off the Back Burner," *HR Magazine*, Vol. 43, Issue 6, May 1998 or David K. Lindo, "New Employee Orientation is Your Job!" *Supervision*, Vol. 60, Issue 8, August 1999.
The new employee orientation program should not be restricted to these HR activities; as Garvey has pointed out, recent "NEO initiatives are getting more creative and comprehensive, and they are moving away from those painful sessions with stacks of HR forms and dusty videos." See Charlotte Garvey "The Whirlwind Of A New Job," *HR Magazine*, Vol. 46, Issue 6, June 2001.

5. Keith McFarland, "Getting Personal with Your Staff," *Business Week*, April 19, 2006, p. 4

6. Thus it is a GXP requirement that employees must be appropriately gowned for an assignment in a limited access area of the site, but gowning procedures may vary in terms of different limited

access areas. For gowning in GMP sites, see 21 CFR 211.28(a), for gowning in GLP sites, see §58.29(e). Subsequent regulatory training includes "training in cGMP [that is conducted] on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them;" 21 CFR 211.25(a). This implicates quarterly or annual CGMP refresher training, etc. as a follow-up to the GMP content in the NEO program.

7. FDA, 21 CFR 211.25(a), "Personnel Qualifications."

8. Audrie Armes, "Safety Begins on Day 1," *Safety and Health*, Vol. 173, Issue 3, March 2006, pp. 36-38.

9. See "Occupational Safety and Health Administration," 29 CFR 1910.1200(h)(1).

10. It is suggestive that Peter M. Smith and Cameron A. Mustard report that only one-fifth of Canadian employees received safety training during their first year of a new job; moreover, the provision of safety training does not seem to be more prevalent among workers or in occupations with increased risk of injuries. See their "How Many Employees Receive Safety Training During Their First Year of a New Job?" *Injury Prevention*, Vol. 13, Issue 1, February 2007, pp. 37-41. This included safety training during orientation.

11. FDA, 21 CFR 211.28(d), "Personnel Responsibilities." Either the EHS presentation or the GXP presentation (or both) should make clear that the former presentation addresses the safety of the employee, while the latter addresses the safety of the product or the non-clinical lab materials. For issues of regulatory overlap, see G. Welty, "The 'Design' Phase of the ADDIE Model," *Journal of GXP Compliance*, Vol. 11, No. 4, July 2007, pp. 45-46.

12. FDA, 21 CFR 58.81(c), "Standard Operating Procedures." See also *Organisation for Economic Co-operation and Development (OECD) Principles of GLP*, Geneva: OECD (1997), §7.2: "Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein." As Jürg Seiler has put it, "the distribution of SOPs is on the one hand governed by the requirement that the relevant SOPs should be immediately available at the workplace, and on the other hand, that work should be performed only according to approved and current SOPs." Jürg P. Seiler, *Good Laboratory Practice—the Why and the How*, Berlin: Springer-Verlag, 2005, p. 248; see also p. 39.

13. The actual content of the SOPs will probably be better addressed in later training at the departmental or unit level.

14. FDA, 21 CFR Part 1301.73(b), "Security Requirements."

15. FDA, 29 CFR §1910.38(c), "Emergency Action Plans."

16. Anthony Arthur, *Radical Innocent: Upton Sinclair*, NY: Random House, 2006. See also Upton Sinclair, *The Autobiography of Upton Sinclair*, NY: Harcourt, Brace and World, 1962.

17. Arlene F. Kantor, "Upton Sinclair and the Pure Food and Drugs Act of 1906," *American Journal of Public Health*, Vol. 66, No. 12, December 1976, pp. 1202-1205. See also James H. Young, "Food and Drug Regulation under the USDA, 1906-1940," *Agricultural History*, Vol. 64, No. 2, Spring 1990, pp. 134-142. As Daniel Carpenter and Gisela Sin have aptly put it in their "Policy Tragedy and the Emergence of Regulation," *Studies in American Political Development*, Vol. 21, Fall 2007, pp. 149–180, esp. p. 149, Sinclair's book "eased the path for the Pure Food and Drugs Act of 1906." Scott Sutton points out that the *United States Pharmacopeia* (USP) was "recast from its traditional focus of how to make medicines to the role it would eventually take as a book that describes the safe making of medicines," in its eighth revision, in 1900. This provides further evidence that the regulatory climate was ready for the passage of the Act. See Sutton, "USP <1211>: The Compendial Informational Chapter on Sterility Assurance," *Pharmaceutical Technology* (Sterile Manufacturing Suppl:), May 2009, s16-s21, esp. page s16

18. Paul M. Wax, "Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act," *Annals of Internal Medicine*, Vol. 122, Issue 6, March 15, 1995, pp. 456-461. DEG is used as antifreeze.

19. Quoted in Carpenter and Sin, "Policy Tragedy and the Emergence of Regulation," op. cit, p. 168.

20. As Carpenter and Sin, op. cit. p. 177 have put it "Had the sulfanilamide tragedy occurred at another time, when FDA regulation as the dominant alternative to the status quo was not advanced by bureaucratic leaders, the Act would either not have passed or would have taken a much different form." Thus the tragedy was perhaps a necessary condition, but hardly sufficient, for the passage of the act.

21. A. Leslie Florence "Is Thalidomide to Blame?" *British Medical Journal*, Vol. 2, December 31, 1960, p. 1954.

22. W.G. McBride "Thalidomide and Congenital Abnormalities," *The Lancet*, Vol. 2, December 16, 1961, p. 1358.

23. See also Steven Spencer, "The Untold Story of the Thalidomide Babies," *Saturday Evening Post*, Vol. 235, Issue 37, October 20, 1962, pp.19-27. Also Rock Brynner and Trent D. Stephens, *Dark Remedy: The Impact of Thalidomide and Its Revival as a Vital Medicine*, NY: Perseus Books, 2001.

24. See 21 CFR 312.23 "Investigational New Drug Application," §50.20 "General Requirements for Informed Consent," §312.23

(a)(6)(iii)(b) "The name and qualifications (curriculum vitae or other statement of qualifications) of each investigator," §56 "Institutional Review Boards" (IRB), and §56.108(b)(1), §312.53(c)(1)(vii), and §312.66 on AEs.

25. The critiques of Sinclair's book by a leading meatpacker, Armour, were published in a series of articles in the *Saturday Evening Post*; collected in J. Ogden Armour, *The Packers, the Private Car Lines and the People*, Philadelphia: Henry Altenus, 1906.

26. Upton Sinclair, as quoted in "Worked on President's Sympathies – Sinclair," *New York Times*, May 29, 1906.

27. See also Gabriel Kolko, *The Triumph of Conservatism*, NY: The Free Press, 1963, esp. pp. 98-110.

28. According to Dr. Morris Fishbein, editor of the *Journal of the American Medical Association* (JAMA), "the solvent, diethylene glycol […] rather than the sulfanilamide was responsible" for the poisoning; see "Drug Preparation Blamed in Deaths," *New York Times* (19 Oct 1937). This statement was made a few days after the first reports of poisoning; the editorial was published as "Deaths following Elixir of Sulfanilamide – Massengill," *Journal of the American Medical Association*, Vol. 109 (23 Oct 1937), p. 1367. The AMA later published a report on the investigations; see Paul N. Leech, "Elixir," *Journal of the American Medical Association*, Vol. 109 (06 Nov. 1937), pp. 1531–39.

29. James H. Young, "Three Southern Food and Drug Cases, Part II," *The Journal of Southern History*, Vol. 49, No. 1 (Feb. 1983), p. 24.

30. See "Manufacturer Accused," *New York Times*, June 12, 1938.

31. Arthur Daemmrich, "A Tale of Two Experts," *Social History of Medicine*, Vol. 15, Issue 1, April 2002, pp. 144-146.

32. As quoted in Daemmrich, "A Tale of Two Experts," page 154. See also Frances Kelsey, "Problems Raised for the FDA by the Occurrence of Thalidomide Embryopathy in Germany, 1960-1961," *American Journal of Public Health*, Vol. 55, No. 5, 1965, pp. 703-707.

33. "Five Die After Taking Tylenol Believed to Contain Cyanide," *New York Times*, October 1, 1982, page A12.

34. Thomas J. Lueck, "Drug Makers Suggest U.S. Packaging Rules," *New York Times*, October 15, 1982, page D1; also Ernest Holsendolph, "U.S. To Issue Rules On Capsules Soon," *New York Times*, October 16, 1982, page A7. Meanwhile, the demand for surveillance cameras in retail outlets grew, see Dorothy J. Gaiter, "More Stores Seek Camera Monitors," *New York Times*, October 20, 1982, page A23.

35. Michael Decourcy Hinds, "U.S. Sets Up Rules On Drug Packages To Bar Tampering," *New York Times*, November 5, 1982, page A1. The various deadlines established by the regulations were met; Pamela G. Hollie, "Drug Rules Met on Time," *New York Times*, February 7, 1983, page D1. See 21 CFR 211.132, "Tamper-Evident Packaging."

36. There were further cyanide poisonings using Tylenol capsules. See Peter Kerr "Tylenol Is Linked to a Cyanide Death in Yonkers," *New York Times*, February 11, 1986, page A1; also Robert D. Mcfadden, "Maker of Tylenol Discontinuing All Over-Counter Drug Capsules," *New York Times*, February 18, 1986, page A1. According to Abby Goodnough et al., "F.B.I. Searches Building Where Man Linked to 1982 Tylenol Poisonings Lives," *New York Times*, February 06, 2009, page 1, "The poisonings in 1982, which killed seven, terrified the nation and changed the way drugs are packaged, have never been solved."

37. Dahleen Glanton "Peanut plant in Georgia linked to salmonella had earlier problems," *Chicago Tribune*, January 3, 2009; Ben Meyerson, "Senators push for better food regulation: Agencies accused of moving too slowly on salmonella outbreak linked to peanuts," *Chicago Tribune*, February 6, 2009; and Michael Moss "Peanut Case Shows Holes in Food Safety Net," *New York Times*, February 9, 2009, Page A1. As President Obama has recently acknowledged in his speech, "Tougher Food Safety Measures" (14 March 2009): "the FDA has been underfunded and understaffed in recent years."

ARTICLE ACRONYM LISTING

CGMP Current Good Manufacturing Practice
DEA Drug Enforcement Administration
DOT Department of Transportation
EDMS Electronic Document Management System
EHS Environmental, Health, and Safety
EPA Environmental Protection Agency
FDA US Food and Drug Administration
GLP Good Laboratory Practice
GMP Good Manufacturing Practice
HR Human Resources
MSDS Material Safety Data Sheets
NDA New Drug Application
NEO New Employee Orientation
OSHA Occupational Safety and Health Administration
SOPs Standard Operating Procedures

ABOUT THE AUTHOR

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