Auditing for Business Risks in the World of Regulatory Compliance

By **Emma Barsky and Len Grunbaum**

Auditing should render more than sleepless nights and frayed nerves. There are business values to be gleaned from audits that a smart manager should know.

Have you, the regulatory compliance auditor, ever been questioned regarding the basis for your findings? Have you ever wondered whether some of your findings were even worth mentioning in a report? Have you ever felt that you would not be doing your job if there were no findings to present at the end of the audit? Have you ever been questioned as to the reason for your findings, especially after the auditee pointed out that previous Food and Drug Administration (FDA) inspections resulted in no 483s? Have you ever been questioned as to the business significance of your findings? Have you ever questioned the business significance of your findings?

If you answered "yes" to any of these questions, *read on*. This article provides guidance on how to avoid these professionally uncomfortable scenarios by presenting a somewhat different approach for what to look at (*audit focus*) and what to look for (*business risk areas*) during the audit.

If you have never been in these situations, you just might be comforted to learn that, in fact, there can be and should be a tangible business value to a regulatory audit. *So do read on.*

If you are a manager who is on the receiving end of audit reports or are in charge of the Quality Assurance Unit, *most definitely read on*. This article will identify certain expectations you should have – in fact should insist upon – from internal and external auditors. These expectations can be summarized in the following maxim:

> *"Providing a regulatory observation without the business context is like serving coffee without a cup."* [SM1]

What is an Audit

To some, the audit is an activity to be performed simply because there is the expectation to have one. In this case, the existence of the audit report is the end in itself, irrespective of the report's contents. To others, it is a function of merely identifying issues that are out of compliance with the current regulations and industry expectations. Under this scenario, the existence of regulatory observations is the end in

itself, irrespective of the operational, business context, or substance, of the observations. These views and approaches are quite common in our industry. However, if you perform an audit only for either or both of these reasons, the audit will be of limited value at best. You will miss the business risks which, for purposes of this article, are defined as *"operational issues that can threaten your company's financial success, competitive edge, and even survival."* In other words, you will miss the forest for the trees.

Consider the auditing function as a purposeful, intellectual exercise rather than a mechanical one. The auditing function then becomes a management tool designed to support the business by identifying regulatory issues (e.g., lack of Standard Operating Procedures SOPs) of potential harm (e.g., regulatory consequences, such as an FDA-483) so that operational remedies (e.g., establishing a consistent process) can be applied as soon as possible to correct the root of the regulatory compliance problems. With this approach, the regulatory audit now has a *business* value; the evaluation of existing regulatory deficiencies will tend to be predicated on focusing on underlying operational issues and deficiencies. These underlying operational deficiencies have the greatest impact on the company's prosperity, because they represent the true business risk to the company. Keep in mind that a company will have no chance or need to achieve regulatory compliance if it goes out of business.

Why Audit

You must have a clear understanding of the business need that drives the audit you are performing. Some audits, such as a pre-qualification or due diligence audit of a potential supplier or business partner, should be designed to assess the potential business risks (e.g., inadequate resources to complete work and/or to meet timelines) as well as the regulatory compliance status of the supplier or business partner. Other audits, such as a mock FDA inspection, should focus on readiness to deal with regulators. Yet others, such as "for cause" audits and investigations, should concentrate on identifying the cause and extent of problems. Still others, such as "in process" inspections or periodic follow-ups of an existing supplier, should be designed to monitor existing and on-going operations and relationships. If you can appreciate the differences between these business scenarios, you will understand intuitively that "one-size-fits-all" auditing just does not cut it; audits should always be designed to target a specific business need and the agenda should be developed accordingly.

When to Audit

For the audit to be of value, the timing of the audit is as important as the reason for the audit. You must have a clear understanding of the business need that drives the audit you are performing in order to know *when* to audit. Why is it that companies perform FDA mock audits before the FDA inspection itself, but might audit their vendors or suppliers for the first time after the contracts are finalized or, worse, when a specific project is almost finished? This scenario is both illogical and common. Problems that could have been relatively easy to remedy prior to the work start-up often end up being major issues, which result in delayed timelines and significantly increased costs due to the effort required to resolve them.

Who Should Audit

Some will argue that the mere knowledge of the regulations and experience in conducting audits using established checklists, independent of an understanding of the business' operations, is enough. We passionately, yet most respectfully, disagree. We feel that checklists, while helpful as a general roadmap and perhaps as a training aid, limit an individual's motivation and ability to identify and understand the true issues behind the regulatory deficiencies. They tend to inhibit the need or effort to ask questions and use logic to identify the operational issues because more time is spent on answering the checklist questions than on using common sense to evaluate how the answers fit into the overall operations. When completing the checklist becomes the end in itself, the quality or value of the information gathered undoubtedly suffers.

Can one learn to sort out the critical findings from the less-than-critical ones, and eliminate the non-substantial ones altogether based on their impact on operations, without relying on the checklists too much? We say "yes", but, at a minimum,

the auditor must have a few basic qualifications to be able to do this.

One qualification is a thorough knowledge of current regulations (e.g., cGXPs), pertinent regulatory guidance, and industry trends; you need to know the rules of the game at least as well as those whom you audit if you are going to opine on their compliance status. For example, if you are auditing for 21 Code of Federal Regulations (CFR) Part 11 compliance, you must be able to comfortably speak about why the regulation was promulgated and what the FDA's current position is, as well as be well-versed about the potential, upcoming changes.[2,a] Of course, you also need to know what a "*predicate regulation*"[3] is and how it fits in the scheme of compliance.[b] Many auditors do not.

In addition, you must also be familiar with the technical aspects of the processes being audited; you need to understand the process, operational terminology, and operation itself to be able to assess it accurately. For example, if you are not technically comfortable with the analytical laboratory environment, you will not be able to assess the operational significance of the regulatory deficiencies in that type of environment.

Next, you must be able to apply at least a dollop of common sense and practicality to be able to distinguish between symptoms (i.e., the indication of the existence of something other than what you see) and problems (i.e:, the underlying issue). Do keep in mind that in order to permanently correct any regulatory deficiency, you must first evaluate the existing practices and modify them, if necessary, at the operational (core) level. For example, not following SOPs is undoubtedly a regulatory deficiency which should be noted and discussed. However, it is often only symptomatic of a much larger operational problem (e.g., lack of managerial discipline and/or oversight), which must be fixed first if the regulatory deficiency is to be permanently remedied.

And last but not least, always be polite, friendly, professional, and, above all, a good listener. These qualities will gain you the professional respect that you must have to be an effective auditor.

Auditing is not for everyone. Harsh but true. It is a tough line of work; the auditor is often challenged because people do not like to hear negative feedback, especially the type that reflects badly on them and/or will result in their having to do more work. But such (e.g., non-compliance with regulations and/or the existence of business inefficiencies) is what the auditor communicates more often than not. Some auditors have "earned" the reputation of being unfair, incompetent and, perhaps worse, a mere pusher of paper. How can you avoid such a reputation? *Read on...*

Audit Focus

As required, the FDA inspector has enough time to look at whatever deserves looking at. However, the regulatory compliance auditor will never have enough time to review in detail everything there is to review. As a result, you, the regulatory compliance auditor, are guaranteed to miss certain things. Understanding this reality, the concern on your part should be *"What constitutes 'important' parameters?"* and *"What can I do to ensure that all of them are adequately covered given the short time available?"* We believe that focusing on and auditing for business risk areas, in addition to the regulatory compliance areas, will provide answers to these questions.

We define *important parameters* as those aspects of the daily business conduct that impact the department's and/or the company's ability to produce at its maximum capacity and have quality deliverables at the same time. Using the Quality Assurance Department as an example, we will illustrate this point.

Footnote a: At a minimum, the auditor should have much more than a working knowledge of the Regulation itself as well as of Guidance Documents as noted in the References (see end of article) numbers 2 and 3.

Footnote b: As defined in Section 1 of the *Guidance for Industry: Part 11, Electronic Records; Electronic Signatures-Scope and Application,* "predicate regulations" (also known as "predicate rules") are "[t]he underlying requirements set forth in the [Federal Food, Drug, and Cosmetic Act]..., PHS Act, and FDA regulations (other than Part 11)..."

In a large number of companies, the Quality Assurance Department is directly responsible for overseeing the quality of both the individual departments' and the company's deliverables. However, sometimes this group spends a majority of its time on correcting grammatical errors and making sure that documents have been fully executed (e.g., no missing dates or signatures), irrespective of their contents or the logic behind generating those documents. Is the Quality Assurance group which operates in this manner using the time wisely and providing quality assurance that is of value? Hardly! If you see enough examples of such limited Quality Assurance scope, it is safe to assume that even if the Quality Assurance Unit exists, it may not be as effective as it should be.

On the other hand, a well organized, traceable, easy to follow and technically meaningful documentation suite, with accurate data contained therein, points to sound and reliable Quality Assurance oversight even if there are a few spelling or punctuation errors, or missing dates or signatures. Having confidence in the department's or company's ability to adequately meet the regulatory and industry expectations is far more meaningful than a documentation suite that is complete with respect to signatures and dates but which has little technical or operational value.

Every effective audit should have two objectives – to identify regulatory deficiencies and to identify business risks – and therefore should be approached from two perspectives. One perspective should be geared towards answering the question of whether the auditee complies with applicable regulations and industry expectations within the areas of their expertise. To achieve the first objective, one will need to ensure that the auditee consistently and continuously produces quality products and data. This is exactly the confirmation that the FDA itself is looking for – that the product is not adulterated and that the data used in support of any submissions (e.g., New Drug Application (NDA), Investgational New Drug (IND), 510K) are accurate, complete, and valid. The lack of either one of these quality attributes may result in potential citations from the Agency, placing existing or future clinical studies and/or products on hold, delaying approvals, removing products or devices from the market, and in the company's poor standing with the Agency in general. In addition, basing the internal go/no go decisions on the unreliable data will slow your company's progress for moving forward in the right direction quickly and steadily. Furthermore, some outcomes (e.g., an adulterated product, poorly documented clinical studies) will have a significant financial impact on the company. None of these things will be conducive to the company's growth, success, and visibility in a fast-paced and highly competitive market.

The second audit perspective is something that most auditors tend to overlook because they do not associate this aspect of auditing with their direct area of responsibility. And, perhaps, it is not. However, with the increasing trend to outsource and due to continuously limited internal resources, you, the regulatory compliance auditor, often become the only "eyes" of the company when it is time to make assessments as to whether other parties are suitable or continue to be suitable for providing services and products. Therefore, it is critical that you are able to accurately identify business risks, in addition to regulatory risks. Not assessing whether the auditee is capable of adequately supporting the operations in terms of the business needs, such as having technically competent personnel, a strong and committed managerial team, and an efficient project management approach, will negatively impact the success of any study and/or project, even if the regulatory requirements are met.

A weak management team will result in lack of proper guidance and direction, as well as poor decision-making regarding hiring, promoting and, if need be, firing staff. Since people are the most important resource the company has (and after all, it is the same people who will be implementing and executing the company's procedures, documents, activities, etc.), it is critical that this factor be assessed with the same degree of diligence as the company's compliance status.

Inefficient project management will affect the individual projects' and the overall company's objectives of identifying the proper resources, allocating the sufficient budgets, and meeting the always strenuous timelines. And, of course, the lack of competent technical personnel speaks for itself in terms of the negative impact it will have on overall operations.

All these symptoms of business risks can be easily detected during the regulatory audit, if the auditor makes it a point to look for them. Concentrating on the business risk areas creates a much

Figure 1

Audit Focus Example Types

Audit Type	Why	When	Selected Areas of Audit Focus to Identify Significant Operational/Business Risks
Due diligence	Pre-qualification	Prior to formalization of agreements	• Adequacy of facilities, equipment, and resources • Adequacy of quality infrastructure • How disciplines are enforced re: meeting timelines or budget • Efficiencies of processes • Effectiveness of departments • Project team qualifications • Adequacy of Quality System
Mock FDA inspection	NDA submission - awaiting approval	Prior to the FDA site visit	• Adequacy of CAPA processing if applicable • Existence and adequacy of objective evidence of compliance to regulations and company SOPs
Investigation	For cause (e,g., OOS, medically impossible clinical data, drug mix-up)	Immediately after the issue has been discovered	• Adequacy of personnel training and qualifications • Adequacy of management involvement or oversight • Adequacy of Quality System • Level of turnover in management and staff • Indications of control breakdown (e.g., unauthorized processing)
Periodic internal and vendor audits	In-process inspections	In accordance with established Master Audit Schedule	• Responsiveness to previous audit findings • Changes in operations, personnel, and/or management • Changes in business structure or business model (e.g.: merger, acquisition, outsourcing) • Changes in financial picture (e.g.: severe cost cutting required)
Follow-up	Assess effectiveness of planned remedial actions	As required	• Consistency of actual remedies with planned or expected activities • Acceptability of remedial activities if different from planned or expected activities • Impact of remedial actions on budgets and timelines

more valuable and comprehensive picture of the department's and/or company's overall stand and status not only for the audit report author, but also for the subsequent audit report readers, as well as for the recipients of the audit observations. Again, in addition to the compliance status of the department and/or company, your focus should be on whether the auditee's operational components, such as people, technology, facilities, etc., are able to support the needed processes and services. Do remember that the documentation gaps are much easier to fix than the core operational deficiencies. After all, it is the operations that reflect on the departments' and/or company's ability to provide services and support products.

Figure 1 provides high-level examples of the audit focus for potential operational or business risks associated with different types of audits.

How to Audit

While you should structure your audit around general policies, procedures, training, interviews, and documented evidence of such, effective auditing tactics and strategy should not stop at that. For example, a review of specific, project-related records will often provide as much information regarding the regulatory and business risks as a review of only the general documentation (e.g., SOPs, training records, protocols). In fact, more often than not, the details in the documents may provide more information about the business risk areas than any other documentation because they show what has happened and is happening and not just what should happen.

Lack of attention to detail on the part of the auditee, which often shows up as non-compliance issues, may potentially uncover operational issues that one normally would not detect during the customary review of the high-level or general documentation. For example, an execution of a physically impossible number of test scripts for a computerized system by the same individual on the same day – with no exceptions and no objective evidence – is a regulatory issue in that the actual test results cannot be accurately confirmed. On the operational level, this symptom points to the fact that this individual needs closer managerial oversight. In the extreme, this symptom may point to fabrication (i.e., the tests were not performed at all). Unless this problem or business risk (i.e., lack of management oversight and, perhaps, authority), is addressed and corrected, not only the validity of the test script execution and of the resulting data collected from that system will continue being questioned, but also other regulatory deficiencies will continue showing up in the processes for which the department is responsible.

You should also remember that there is a reason for every regulation. It is important that you not only know what the reason is, but are also able to explain it in simple and practical terms. The latter skill of addressing the reason for concerns regarding a particular regulatory deficiency is yet another useful tool for an auditor. For instance, instead of pointing out that a cross-out is not initialed and dated, it is more meaningful to indicate that lack of such information may impact one's ability to reconstruct the chronology of events, should this ever become necessary. Your ability to communicate to others the in-depth practical understanding and application of the regulations will gain you professional respect amongst peers and colleagues.

Other things to look out for while auditing are non-compliance trends. It may be difficult to see operational or business risks related to isolated non-compliance instances, but not when trends of such are identified. These trends do not have to be of the same nature, but do have to have a common denominator. For example, multiple delays with project document reviews (a regulatory issue) may be a direct result of the poor communication between the sponsor and the vendor (an operational issue). Unless the root of the problem is identified (e.g., is the vendor or sponsor responsible for the poor communication?) there may be a relatively high business risk regarding delays in other operational areas related to that vendor or department.

When you identify a potential regulatory deficiency, make sure to ask enough questions to confirm the validity of what you saw. Whenever possible, try to get enough information to understand the business risks associated with the confirmed regulatory deficiency. After the observation is confirmed and the relationship to the business risk is established, it should end up on the list of observations.

Relating a regulatory deficiency to a business risk may seem to be more time consuming than the conventional regulatory compliance audit, but it

is really not. If anything, it is challenging, strenuous, and intense on your professional self. However, if you intuitively know what question to ask next, if you can see the value of assessing regulatory compliance through the business-risk prism, and if you strive for professional excellence, you will adapt to it quite easily.

How to Present Findings

You should always present your findings in the context of current regulations; that is, be specific as to which regulation is being violated. However, do not stop there. To ensure that your audit findings do not become subject to lengthy discussions and arguments, always explain the significance of your findings in light of the company's operations.

We believe grouping regulatory findings into categories, rather than listing them individually and out of context, will help to put all the findings into a business perspective, as well as help to better address larger operational problems and not just the regulatory symptoms. Doing so will give you and your audience a better sense as to where the weak operational areas are. If you cannot tie the regulatory deficiency to an operational or business issue, then the regulatory deficiency is not of a high risk and should only be briefly mentioned at the close-out meeting.

From our experience, everyone is concerned about weaknesses in their operations, even if they are found as part of the regulatory compliance audit. This grouping strategy will not only make the close-out audit meeting shorter and more productive for everyone, but it will also increase your chances of getting management's attention.

We believe that if you follow the auditing tips presented in this article, you are sure to at least minimize, if not avoid completely, the negative reception of your findings.

One more thing, please remember that the readers of the audit report were probably not with you on the audit; therefore, your writing should be factual, simple, unambiguous. and let us not overlook the importance of "understandable."

Audit Recommendations

Some industry organizations and companies believe that regulatory auditors should not provide recommendations regarding how to remedy deficiencies noted during the audit. However, company management often appreciates not only practical recommendations but also a statement of impact as to why the respective finding and recommendation should be taken seriously. For example, a finding such as *"There is no training SOP in place"* may be true, but the auditee would probably better appreciate the following presentation:

> *"There is no training SOP in place. While this is in violation of 21 CFR Part <xxx>, the impact of the issue is that the staff may not be qualified to perform their assigned responsibilities. This in turn may jeopardize existing submissions such as <nnn> and future submissions such as <yyy> should FDA inspect the respective study processes. Management should evaluate the organization's training needs and formulate policies and procedures to ensure staff qualifications to perform their assigned responsibilities."*

Additionally, you position yourself as someone who can identify significant problems and knows how to most effectively remedy them. The latter is what will gain you further respect amongst your peers and those whom you will audit.

A cautionary note: *It is important to be realistic about the fact that the departments and/or companies will not necessarily increase their staff to correct the regulatory deficiencies and implement the recommendations. With that in mind, the recommendations should be such that the departments and/or companies are able to bring their operations back in compliance using their existing resources. Therefore, your recommendations should be customized to the company's culture and business needs. For example, instead of suggesting that a small company complies with existing cumbersome procedures, suggest that the procedures and/or respective forms be simplified to maximize chances of compliance.*

CASE STUDIES

This section illustrates our premise in a greater level of detail by providing several real-life examples of how it shows up in the real world. As you will see, creativity and flexibility on the part of the regulatory compliance auditor make the difference between a run-of-the-mill deliverable and a valuable one.

CASE STUDY #1

Scenario

A couple of days before a scheduled one-day "in process" inspection, the regulatory compliance auditor learned that there were very specific problems that the client had with a vendor. For example, study data were changed without explanation, some values were not medically possible, and some values were out-of-trend.

Challenge

The challenge was to address a multitude of identified issues and discrepancies in only one day, as well as to provide respective explanations.

Solution

The auditor:

- Viewed this as an "investigation" and focused strictly on the records and processes surrounding data collection, processing, and distribution.
- Doubled the number of people to conduct the investigation.
- Invited a subject matter expert from the client to assess the vendor's technical answers.
- Requested that the available information be provided before the site visit to promote familiarity with the discrepancies.
- Prepared a detailed list of discrepancy-specific questions.
- Supplied the site, in advance of the visit, with a list of specific records to be reviewed.

Result

The auditor identified three root causes which resulted in and/or exacerbated the discrepancies:

- Inadequate system validation for study-specific functionality and requirements
- Inefficient Quality Assurance Group
- Ineffective project management

A regulatory focus alone would have identified the validation issues. However, such a focus would not have connected the validation issues to the Quality Assurance Group and project management issues. These issues impact the vendor's overall operations and they exacerbated the vendor's initial problem of not identifying the data discrepancies, much less addressing them.

The regulatory compliance auditor was able to recommend timely and effective remedial actions which were completed to the client's satisfaction.

CASE STUDY #2

Scenario

A pharma company contracted with a software vendor to license software and the vendor, in turn, is using the hosting facilities of a third party through a cross-licensing agreement. The regulatory compliance auditor was hired by the pharma company to perform a standard regulatory due diligence assessment regarding regulatory compliance of the parties. The pharma company had not yet formalized a contract with the vendor at the time of the audit so no study activity had begun.

Challenge

At the start of the audit, the auditor was informed that agreements between the vendor and the hosting facility had not yet been formalized and that the hosting facility was in the process of doing its own due diligence regarding the vendor. This came as a surprise to the pharma company personnel as well. The challenge thus became determining what issues were more significant to the pharma company: the issues regarding the formalization of the business relationship between the vendor and the hosting facility or regulatory compliance issues that might exist with the software or hosting environment.

Solution

The auditor suggested that the pharma company rely on the hosting facility's capability to do the due diligence of the vendor. The rationale was that the hosting facility would not go through with the relationship with the vendor if it determined that significant business or regulatory risks were identified. This eliminated the need to perform a thorough review of the vendor's compliance status. Instead, the auditor was able to focus on the more risky areas of the overall business relationship between the pharma company, its vendor, and the hosting facility. The auditor, therefore, assessed the quality assurance and technical capabilities of the hosting facility staff that was to perform the due diligence. The auditor's assessment included (1) the nature and scope of the due diligence from the system validation, 21 CFR Part 11 compliance and quality assurance perspectives, and (2) the qualifications of the hosting facility staff performing the due diligence.

Result

The pharma company was appreciative that the auditor identified the true area of business risk; if the business relationship did not work out, a new software vendor would have to be selected.

CASE STUDY #3

Scenario

A pharma company hired the regulatory compliance auditor to review the policies, procedures, and associated documentation of a Contract Research Organization (CRO) at the start of a study and before data was collected.

During the course of the audit, the regulatory compliance auditor noted several falsehoods (e.g., the project manager was a consultant, but was represented as an employee) and perceived other "red flags" (e.g., no admittance permitted - even if escorted - to an unmarked room described as the "document archive," where study data were kept).

Challenge

The challenge became one of determining the veracity and effectiveness of CRO's project team and even company management with respect to their ability to support the pharma company's project requirements.

Solution

The auditor elected to confirm the study and process information with project and company management (e.g., asked several people the same set of questions to be able to compare responses) against the available documentation.

Result

On the surface and on paper, the CRO seemed to be in a good regulatory compliance shape for the following reasons:

- The policies and procedures were current, approved, and appropriate to the nature of the business
- Personnel that were part of the CRO's project team seemed to have proper training
- Training records were complete
- Quality Assurance involvement was evident

However, cracks appeared as the auditor started reviewing the detailed records regarding training, site qualifications, investigators, problem resolution, quality assurance involvement, etc., and asking personnel to clarify the details of the process. The CRO staff was reluctant to provide information, answers were incomplete and contradictory, and the CRO personnel seemed disorganized and defensive.

None of the observed regulatory compliance deficiencies were of immediate concern because the CRO had not yet generated substantive study-related data for the pharma company. However, it became obvious that unless corrected, the observed deficiencies regarding the business operations (remember the regulatory compliance issues were minor) would ultimately compromise the study's timelines as well as the quality of its data (both findings constitute significant business risks).

Post-audit note: The CRO did not meet the project timelines but, given the findings of the audit report, the pharma company was able to plan for this eventuality and compensate for it effectively.

CONCLUSION

Industrialist Charles F. Abbott once said, *"Business without profit is not business any more than a pickle is candy."*[4] Profit, of course, is a reflection on the intricate interrelationship of multiple and complex operations. And everyone knows that if operations suffer, so does the business.

We see regulatory compliance auditing as a valuable tool that, if used wisely and with practicality, may help identify and correct operational issues. We hope that you, the auditor, will start viewing your role in the industry along the same lines.

If you are in a position of hiring regulatory compliance auditors, you may agree, after reading this article, that auditors should have certain critical professional and personal qualifications or have those further developed, and that some individuals - please, no offense – should simply consider looking for another professional path within industry.

We also encourage those of you who are heading the Quality Assurance function, and those managers who are the recipients of regulatory compliance observations, to challenge auditors as to the business significance and impact of their regulatory findings. Once you are in that mode, you may be pleasantly surprised at how much you can learn from practical and competent auditors who have business sense and vision. ❑

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ABOUT THE AUTHORS

Emma Barsky and Len Grunbaum are Partners in The Practical Solutions Group, LLC. Ms. Barsky leverages her proven expertise in the areas of GXP Quality Assurance and Project Management. Since the time the business was launched, Ms. Barsky has performed multiple overall quality and computer validation assessments, conducted multiple field investigations, helped start-up companies to build a quality infrastructure in order to successfully pass client audits and managed multiple projects that required the assistance of subcontractors. She can be reached at 609.683.0756 or at ebarsky@practicalsolutionsnj.com.

Mr. Grunbaum is a recognized expert in the industry, particularly in the areas of Validation, Quality Assurance and Compliance with 21 CFR Part 11, the electronic records/electronic signatures final rule. He has written extensively on these subjects and has delivered numerous tutorials and training sessions to clients and industry groups. He has also provided validation and compliance enforcement training to the FDA and developed quality plans and validation strategies for software companies planning to begin operations in the Pharmaceutical Industry or to work with pharmaceutical clients. He can be reached at 609.683.0756 or at lgrunbaum@practicalsolutionsnj.com.

Article Acronym Listing

CAPA	Corrective And Preventive Action
CFR	Code of Federal Regulations
cGXP	Current Good Clinical, Laboratory, Manufacturing, etc., Practice
CRO	Contract Research Organization
FDA	Food and Drug Administration
IND	Investigational New Drug (application)
NDA	New Drug Application
OOS	Out Of Specification
SOP	Standard Operating Procedure