

SMB Validation: Four Ways To Do More For Less

BY JOHN AVELLANET



INTRODUCTION

For small to mid-sized businesses, validation of information technology systems is a great challenge. Resources are limited and quality controls often fall victim to daily operational issues. And for start-ups and pre-clinical stage firms facing the Food and Drug Administration's (FDA's) push for "Quality by Design" into the development arena, life is only about to become harder.

To deal deftly with daily demands and make steady validation progress, small to mid-sized businesses need a practical approach they can live with and afford. In the author's work over the past fifteen years, as Chief Information Officer for a mid-sized medical device firm, and now as an independent compliance advisor, four tactics have consistently provided high impact for low cost: defining a "validation box" or scope of work, re-using typical information technology (IT) tasks for validation purposes, implementing simple risk assessments and knowing when and where to look outside for help.

For the purposes of this article, small to mid-sized firms are defined as those with between 25 to 500 personnel, and those with total revenue under \$250 million. Micro-businesses (those with 10 or under employees) and start-ups should adapt the recommendations here to their situation.

The overall strategy is practical and can easily be put in place, be up and running, and be ready for auditing in 100 days or less. Here are four ways to do more with less:

DRAWING THE VALIDATION BOX

Ludwig Huber is one of the most popular proponents of the validation box approach, and detailed descriptions and analyses can be found in his writings and presentations.¹

However, for the small to mid-sized business, Huber's method may have two drawbacks: first, it can be a bit too

complicated, and second, if you are not well-versed in the nuances of information flow, technology, and regulations it can fall apart over time. Both of these drawbacks surface rather often in the small to mid-sized business.

With our clients and colleagues, the author advocates a simpler, more streamlined approach based upon how business tasks are actually accomplished within a client firm.

There are three overall steps:

1. Identify a regulated business process
2. Flowchart the process
3. Identify the IT components touched in the process

Drawing the box can be completed in a single meeting, and requires one management-level individual from IT, one from Quality Assurance (QA), the head of the business process department being mapped (Purchasing, Shipping & Receiving, Analytical, and so on), and either the Regulatory Affairs (RA) executive or the company's counsel. Because individuals in many small firms wear multiple hats, getting stuck on the numbers of individuals in the meeting is not productive; rather, focus on the roles each plays.

The role of the RA or counsel is to lay out the regulatory rules around the business process at a top-level, for example, he or she might state that proof of personnel qualification and training is required to verify competence to do a quality job. Next, the individual whose group handles training, such as Human Resources or QA, directs the flowcharting of the process, always noting two key items: decisions and how the process flows. This is where the IT individual is absolutely crucial, and not just for the identification of computer systems involved.

Rather, the primary IT role is to imagine that the process mapping discussion is actually for the full automation of the

process – whether that will occur or not is beside the point, the reality is, by acting as if it were so, the IT individual can bring into play his or her career experience. IT will need to repeatedly press for two key questions to be answered: “Is there anyone else involved in this decision?” and “Do we have to do that? Is there a way to streamline this?” Pushing these two questions will often cause informal processes to emerge, and given the goal of compliance and validation, to show control over the environment, it is far better to have these informalities appear now rather than during an audit.

Finally, the IT manager highlights the decision points and process flows that touch the electronic environment - the computer, the network path, the server and which software applications are involved.

The highlights are the boundaries of the validation project. Typically, such efforts involve many of the servers, much of the network, and most, but not all, of the desktop and laptop computers. Of all the software installed on these systems, typically only a small percentage are ever involved.

SIMPLE RISK ASSESSMENT

When working with small to mid-sized businesses, a fourth dimension is then added, risk assessment, to prioritize activities.

The key, however, is not just assessing risk based on compliance-relevance (patient safety, drug or device efficacy, etc.), but to also factor in technology plans. This is critical, because small to mid-sized businesses are renowned for osmosis-based, cross-functional communication and planning.

One firm the author worked with had hired a validation consultant and was midway through validating a laboratory data archival and retrieval system when it was “discovered” that IT was replacing the system within a month; the newer system had already been placed on order. Because the newer system was a component in a larger network upgrade, the IT Department had not even considered the quality ramifications. This situation cost the company significant resources and effort to resolve, and despite many efforts, seriously undermined the personal working relationships between the lab, IT, and QA leadership, something the company was still suffering from months later.

Using the risk assessment process within the validation box is a perfect way to ensure broad-based understanding and coordination.

First, bring together each of the individuals who participated in the business process mapping. Next, utilize the risk assessment process prevalent in your firm for each of the identified technology systems.

Many smaller firms are just starting to adopt a risk management approach. In this case, a simplified Hazards Analysis and Critical Control Point (HACCP) based on the internal FDA training originally given to food inspectors might be of the most immediate use, with two clear end points on a risk spectrum. The highest risk systems are those that directly touch a patient, or otherwise might cause injury to an em-

ployee if the system has a malfunction. In most offices and pre-clinical environments, this level of risk is not present.

The lowest risk systems are those that might touch a regulated process, but typically do not, or those over which data flows, but there is very little input into its flow (such as a network cable). A typical example is the computer of the administrative assistant of the firm’s president. It is possible that the computer might be used to display and print out a “regulated” record, but the chance of it impacting the record’s integrity is dramatically lower than the risk associated with the computer actually storing the record in the first place.

In between, if there are no direct patient or personnel risks associated with the computer systems and software identified, the author recommends weighting two areas most heavily – data archival and retrieval, and security controls for the process and its data.

Using a simple purchasing process as an example, the security controls might focus on who has authority to submit purchasing orders electronically, what approvals are necessary, and how are they obtained, who can change the order after it is submitted, and who has access to the purchase order after the fact. The data archival and retrieval processes would key in on data integrity; how and where the purchase order is archived, who has access to the archived file, and what the process is (including the approvals required) for recalling the purchase order into the environment in other than a read-only mode.

The goal of the risk assessment is to prioritize those systems and software with the greatest chance of impacting data integrity or allowing the subversion of an approved process. By weighting these two considerations most heavily, the small to mid-sized business can then leverage their IT group (both internal and outsourced vendors) to effect much of the necessary validation.

IT TESTING AS VALIDATION

While this is the crux of a cost-effective approach to validation for small to mid-sized businesses, we need to be realistic and acknowledge the practicalities. There is never enough time, money, or manpower to validate systems to an ideal level in any company, much less in the small and mid-sized business. While most larger companies have at least some semblance of a dedicated IT QA function that can focus simply on maintaining validation, for the small to mid-sized organization, such a role is ephemeral at best. To effectively juggle the day-to-day with the long-term necessities of compliance, balance and compromise are critical, and innovation is crucial. By keeping the end goal in sight, we can look for opportunities to reframe what already exists.

At its essence, validation provides proof that the system does what it was intended to do, that any regulated information has integrity, and that the firm is in control of its operations.

Typical IT processes – functional testing, asset management, change control, electronic security, and so forth - have

a very similar goal in mind, and this can be leveraged to great advantage.

Typical IT functional testing is used to establish the suitability of a technology for its intended environment; whether it is a network component, a computer, or a software application, testing will occur. If the testing can meet industry-recognized criteria, is documented, and is reviewed and approved, the results can make-up a significant portion of the validation package.

A simple example is the process for displaying a regulated set of information to allow individuals to make decisions, e.g.: opening an Excel®-based purchase order form on your computer screen to review it before sending it to the vendor. In this case, three reasonable tests can be performed, and the results documented, in less than five minutes: first, create, open, and save a sample Excel®-based purchase order three different times – once by itself on the computer, once with several other applications open along with Excel®, and then third, with several applications open and saving it to a different physical location (a different server, the local computer hard drive, etc.); second, check any system application logs for errors (in addition to noting any errors displayed during the creation, opening, and saving processes); and third, run a display adapter and monitor test – typically the monitor will have a built-in self-test and you can also download and run the display adapter used by Ziff-Davis (publisher of PC Magazine and other IT periodicals) to conduct their testing. For further testing involving displaying information, such as a drawing file or a standard operating procedure, on the same computer hardware, you only need to run the first two tests.

These three tests are typical when an IT engineer configures a system, whether it is new or repaired. Document the results and then have either the department's supervisor or QA review the results and sign-off.

Another tactic: using the IT process of asset tracking and inventorying to demonstrate control over the environment. While many firms conduct inventory audits either on an as-needed or yearly basis, consider holding them quarterly to focus on aspects directly relevant to the validation process other than equipment presence and serial numbers.

Develop a simple checklist that calls for the review of items such as error logs, security access, software patches, and software revision documentation. Deviations should then be addressed in a "mini-project" under change control.

Taken together, the inventory audits and the completed checklists show a pattern of control and on-going monitoring of the environment. Combined with a mini-project to resolve deviations or improve an area of repeated weakness (such as automatic virus-updates), the result is demonstrated effort of continuous improvement. This will put a small to mid-sized business in good stead for any audit.

Further IT tactics to leverage include troubleshooting logs, configuration management records, data back-up logs, disaster recovery test results and even several on-line websites that pro-

vide web-based performance scans of your computer.

By drawing upon, and maturing, many typical IT processes, a small to mid-sized company can validate its systems to its best abilities. However, in the case of home-grown software applications, this becomes more difficult. The principles hold true, but typically firms insistent upon developing applications rather than buying them off-the-shelf, will find the going a bit more difficult. Thus, the final key to doing more for your limited resources is knowing when, and where, to ask for help.

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LOOKING OUTSIDE

When further expertise is called for, such as independent code reviews or temporary boosts in manpower, consider calling in either validation consultants, or as a less costly alternative, value-added resellers, or VARs. These companies are typically regionally based and sell and support well-known information technology products and services.

VAR personnel are well-trained and certified in the products they resell, and because they are small to medium-size companies themselves, they understand the trade-offs and

compromises necessary. If you can provide the quality direction, they can provide the expertise.

If you do not utilize a VAR, consider asking your software or hardware manufacturer whom they recommend and certify in your area. Most manufacturers maintain a list of value-added resellers with whom they work regionally.

Software code review can be handled similarly, but in this case, look for independent programmer consultants or contractors; use the online databases of not-for-profit associations like the Independent Computer Consultants Association (ICCA) or N-TEN to search for local expertise. You do not necessarily need someone skilled in your precise code version or code quality review, but rather someone experienced in coding with good client recommendations.

Both the VAR and the independent computer consultant can also serve double-duty as technical expert advisors, bringing their experiences in different environments and various projects to bare and help you further improve your processes. If you document and follow their recommendations, even in a simple "memo to the file" form, you again have proof of continuous improvement to your quality environment.

Some small and mid-sized businesses also work with independent consultants to craft a long-term strategy that builds the organization's capabilities. Typically, the most cost-effective approach is one that relies upon a mix of remote work with on-site meetings. Such a strategy should blend the company's technology plans, electronic compliance and information management tactics, and identify various VARs and other local experts for the organization to draw upon over the next three to four years. In the best of circumstances, such an advisor will outline suggestions and checklists for the business to ensure it gets the best results out of its VARs and other technical experts, and will work with the QA or RA folks to select internal training that will not unduly impact IT's day-to-day support responsibilities.

Down the road, this type of partnership provides a small to mid-sized business with an individual knowledgeable about their organization who can be quickly drawn upon for advice and help over the years in rare situations like a due diligence audit or an independent review of a large-scale technology change-over (in the case of leased computers or major upgrades).

FINAL THOUGHTS

Ironically, for all the struggles inherent in compliance for small to mid-sized businesses, such firms often have a better

handle on their business processes, their technology in-house and where their "regulated" data resides - all of which can be the Achilles' heel of larger corporations.

By reframing these three key aspects as strengths, then applying the entrepreneurial skills of ingenuity and compromise, and leveraging already existent IT processes and local service providers, small to mid-sized businesses have the opportunity to significantly ease their validation burden. The result is less stress, lower costs, continued productivity, stronger compliance and better business.

Are you ready? ☐

ABOUT THE AUTHOR

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Article Acronym Listing

FDA	Food and Drug Administration
HACCP	Hazard Analysis and Critical Control Point
ICCA	Independent Computer Consultants Association
IT	Information Technology
PC	Personal Computer/Computing
QA	Quality Assurance
RA	Regulatory Affairs
VAR	Value Added Reseller

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