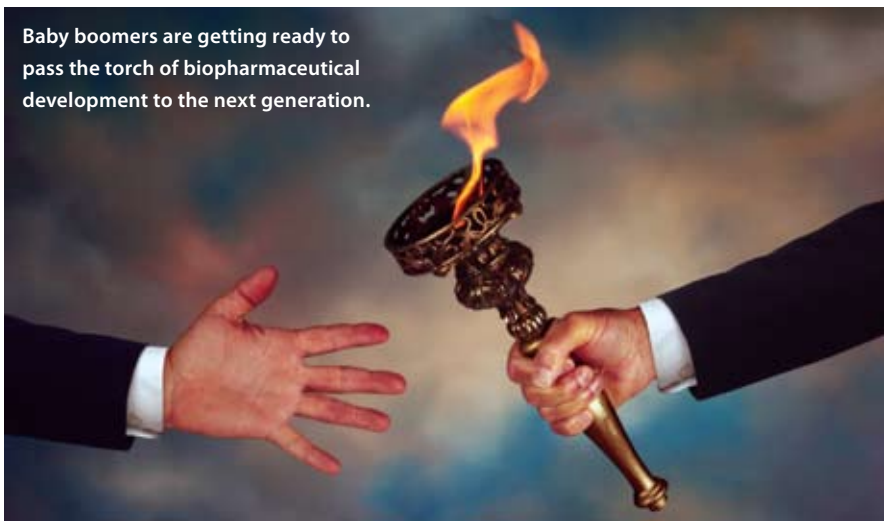
Building Compliance for Personalized Medicine

by John Avellanet



Baby boomers are getting ready to pass the torch of biopharmaceutical development to the next generation.

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Regulatory compliance is the means by which biopharmaceutical companies bring new medicines to market. But as we embark on developing and bringing to market more complex, more personalized medicines in the 21st century, we are about to find that our most experienced sources of compliance know-how and intelligence are getting ready to leave for the comforts of retirement. Demographics are working against the biopharmaceutical industry.

Survey Results

A 2006–2007 survey by the University of Southern California (USC) found that two-thirds of experienced regulatory compliance professionals in the United States — those with over 10 years of experience — are preparing to retire within the next five to nine years (**1**). Some of these people will stay engaged in the field through speaking and advisory roles. But how interested will those semiretirees be in accumulating new skills for navigating regulatory expectations, reimbursement strategies, and globally harmonized regulations governing personalized medicine?

In writing my new book, *Get to Market Now,* I conducted a topic review of industry certification and graduate degree programs available to rising professionals within quality systems and regulatory affairs. The survey results were not encouraging (**2**). Few of these major trends affecting the regulatory landscape ahead are given any attention, if they're discussed at all:

- a need to incorporate reimbursement elements within new drug and biologics regulatory strategies
- FDA's expectation for companies to incorporate quality by design (QbD) in new drug and biologics development
- the agency's increasing enforcement of regulatory harmonization rules,
- rising criticality of records retention and integrity,
- a growing need to balance compliance controls with flexibility and the corporate bottom line.

Already those trends are beginning to have an impact. Nearly 49% of companies surveyed admitted difficulty in filling vacancies for regulatory affairs, quality, and clinical departments with personnel who have experience beyond the traditional textbook view of regulatory affairs, quality systems, and new drug or biologics development. Open positions at all levels — entry, midmanagement, and senior — revealed a dearth of candidates who had any familiarity with global supply chain management, QbD, risk-based decision making, postmarket monitoring or improvement strategies, risk communication, virtual suppliers or product development partners, regulatory requirements in preclinical or early clinical stages, records integrity, or a host of other topics increasingly critical to compliance and commercial success in the 21st century.

Ironically, nearly half the job applicants flagged as having insufficient knowledge and real-world experience held numerous industry-association sponsored certifications. In talking with study author Dr. Frances Richmond, I was reminded of a similar phenomenon in the computer industry. In the 1980s, holding a certificate such as "certified network engineer" (CNE)

or "Microsoft-certified systems engineer" (MCSE) translated to deep technical expertise that employers could count on. By the mid-1990s, however, certification "boot camps" had arisen that focused on getting people to simply pass the tests. The end result was a plethora of information technology (IT) job applicants who looked good on paper but couldn't handle technical challenges in the real-world. Their expertise ran only as deep as what the certification test makers had quizzed them on.

Handling applicants who wallpaper over a lack of real-world experience with certifications is only one challenge facing the biopharmaceutical industry in the coming decade. Compounding our struggles will be the large knowledge loss companies will face as senior job holders retire. As baby boomers leave the workforce, this demographic wave of real-world knowledge loss threatens to significantly disrupt the industry's ability to respond to evolving regulatory health-agency expectations and intentions. No publication, expert-led web seminar, or consultant's counsel will help if, as regulators discuss QbD 2.0, your company is still coming to grips with whether quality by design even applies to your products. The key is to craft a long-term strategy to build your strength and expertise in compliance; companies without a long-term plan will lose the race to market in the 21st century.

Four Real Tactics

To kick-start your efforts and give your company the time necessary to craft a cohesive strategy, consider four immediate steps right now: growing internal knowledge, cross-training staff, starting a compliance intelligence program, and building a partnership with local academia.

Grow Internal Knowledge: Industry conferences, expert-led webinars and teleconferences, and on-site corporate workshops are all means by which you can expand the expertise of your current team. Rather than the usual "best practices" approach, however, focus on learning about new regulatory expectations that need to be applied to current projects or new ways to better tackle current activities.

For instance, a teleconference on risk evaluation and mitigation strategies (REMS) and their role in postmarket monitoring is something that should be undertaken long before the FDA asks you to submit a proposed REMS. Is there an article you can share with colleagues that summarizes the new certifications required to accompany submissions under the 2007 Food and Drug Administration Amendments Act (FDAAA) or Health Canada's revisions of good laboratory practices? In my process mapping workshops, I show clients how to save significant effort when it comes to creating and maintaining standard operating procedures (SOPs), as well as using process maps to demonstrate proof of compliance and bottom-line benefits. Consider searching the Internet for compliance seminars, teleconferences, or published articles and blog postings on topics such as improving record integrity in regulatory submissions or putting in place a supplier management tool kit that balances risk, cost, and compliance.

Cross-Train Staff: As I noted in an article last year on personalized medicine product development, we inadvertently limit our flexibility and capabilities when we allow knowledge and expertise specialization to flourish. Two ways to minimize risks associated with specialization are cross-team project assignments and cross-functional educational sharing.

Cross-Team Project Assignments: Personnel can be assigned to help out on project activities outside their "comfort zones." For example, a common technical document format specialist could be assigned to a labeling design activity or a supplier due diligence audit. This allows real-world, hands-on skills to develop and grow, strengthening a team for the long term.

Cross-Functional Educational Sharing: Team members can be asked to share knowledge gained from conferences, offsite workshops, and even meetings with regulatory health agencies. To prevent generic "knowledge dumps," consider confining such sharing sessions to analyzing and answering three questions: What were the three to five most important takeaways? What were the one to three most surprising pieces of information learned? and What regulatory expectations (and industry responses) are still evolving? All answers should be given in the context of your company's current projects and products.

Start a Compliance Intelligence Program: A biopharmaceutical company needs to develop a formal compliance intelligence program designed to give functional departments and senior company management heads-up information to better plan, forecast, and allocate monies, personnel, and time.

Gathering basic compliance intelligence is not unduly difficult. Hundreds of articles, blog postings, warning letters, guidance documents, special presentations, and other materials are widely available on the Internet. Beyond-the-basics analyses, forecasts, and recommendations denote good regulatory and quality systems intelligence; basic who-said-or-did-what information has become a commodity. Focus your compliance intelligence program on analyzing trends and providing practical recommendations geared to your colleagues and the challenges your company either already faces or soon will. Such perspectives should be well-thought out, logical, and relevant.

In a traditional approach to gathering regulatory and quality systems intelligence, you should be cognizant of three problems: First, it takes time to sort through the volumes of information available; second, there is never going to be enough time; and third, striking a balance requires a long-term mindset. You will need to make tradeoffs. One to consider is whether or not it is worthwhile to first outsource this type of compliance intelligence and thus better understand the time involved. This would also provide an opportunity to assess the types of information most relevant in both the immediate short term as well as to help long-term planning.

Craft a Partnership with Local Academia: The fourth step you can take as part of an initial plan to overcome the looming knowledge and expertise gap is to partner with an accredited university or college (preferably near your facilities) to help develop a workforce with real knowledge currency. When I interviewed the USC's Dr. Richmond, she made five concrete suggestions to keep such "partnerships" away from mere platitudes and focused on tangible actions instead:

• Identify a specific knowledge need (e.g., how QbD applies to active pharmaceutical ingredient development) and ask universities to design a short course on it;

• Provide speakers who can talk to students about real-world challenges to getting tasks done (for instance, when I talk to business school students about compliance, in addition to the basics I cover how to deal with them in the context of budgets, egos, and organizational politics);

• Hire interns throughout the year, each one to work on a specific real-world project such as creating an index of a drug history file or helping your staff prepare for and report on supplier due diligence;

• Reimburse tuition for staff members to take courses at the local university;

• Donate designated-use monies for the local university to purchase new texts, bring in a regulatory health agency speaker or industry expert for a guest lecture, or design a new course to track an evolving subject area (such as qualifying and managing virtual suppliers).

My book covers a significant number of additional ways companies can inexpensively (and compliantly) leverage universities when it comes to new drug and biologics development under an open innovation collaboration model. But a book will not help your company face the future without the staff strength to match. The four steps outlined above are only a first set of tactics to implement in a longer-term strategy.

Ultimately, building a strong compliance staff that can succeed in the personalized landscape of 21st-century medicine requires a long-term view. Given that new drugs and biologics routinely take 10–13 years before they are ready for market launch, recognize that many senior colleagues around you may be basking in the warm glow of retirement when it comes time to for phase 3 clinical trial decisions to be made or a regulatory submission to be finalized. Now is the opportunity to step, even momentarily, beyond short-term considerations and proactively tackle problems on the horizon before it is too little, too late.

Whether we share new knowledge with colleagues; ask specialists to help out on nonspecialist projects; design a systemic, reliable regulatory and quality systems intelligence program; or work with universities to develop our future new hires; we need to recognize that business success and bottom-line profitability come from gathering, applying, and adapting to new knowledge and expertise. Companies that broaden their staff's expertise and achieve smarter compliance will invariably surpass their competitors. These are the companies on whom 21st-century drugs and biologics rely and tomorrow's patients depend. Are you ready?

References

1 Richmond, Frances J and Nancy Singer. *Hiring and Training Needs in the Medical Products Industry: Focus on Regulatory, Quality and Clinical Professions.* School of Pharmacy, University of Southern California: Los Angeles, CA, 2007.

2 Avellanet J. *Get to Market Now.* Logos Press: Rockford, IL, May 2010. C

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