SPECIAL REPORT
2009 Industry Outlook
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FDA Forecast
Nine recommendations to weather the new year.

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FDA Forecast 2009
Nine recommendations to weather the new year.

By John Avellanet, Managing Director, Cerulean Associates LLC

This year will bring a tougher attitude toward drug, biologic and device makers by the U.S. Food and Drug Administration (FDA). Congressional critics, long frustrated by an agency seemingly more enamored with manufacturers than public safety, will push forward legislation aimed at an "FDA accountability" stance that will last well into the next decade. The FDA will issue new regulations and update old ones to capture expectations that drug makers -- and their suppliers -- put a priority on public safety, product efficacy and policy compliance.

At a time when the global economy struggles, these changes will impact academic research organizations (CROs), contract manufacturers (CMOs) and pharmaceutical companies significantly. As the executives and business owner members of my SmarterCompliance™ regulatory intelligence peer advisory program have known since early last year, FDA changes for 2009 will impact their businesses' plans, strategies, resource allocations and product development programs.

This article summarizes nine key takeaways SmarterCompliance™ members felt were most important in three areas:

1. Enforcement
2. Regulatory changes
3. Guidance issuance

Each anticipated change is outlined below along with a corresponding recommendation for you to consider in your business.

A note of caution: these recommendations are not as tailored as the ones in my advisory program since this format is not conducive to a personal knowledge of your business and the specific challenges you face; instead, I've tried to capture one key recommendation broadly relevant to most FDA-regulated businesses. As such, these recommendations should not be the sole basis upon which you make your decisions, particularly when it comes to staying off the FDA enforcement radar screen.

ENFORCEMENT

1. Enforcement

The FDA will increase its enforcement this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability.

Personal Executive Accountability — Working with the Department of Justice (DOJ), the FDA will continue to enforce its greatest success thus far in a legal environment. The DOJ is now willing to bring criminal charges against individuals when the evidence warrants it. Furthermore, this year's settlement of the Ortho McIlroy case is a clear indication that both the FDA and DOJ recognize the need to cut off the financial flow to the bad actors.

2. Regulatory changes

The FDA will increase its enforcement this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability.

With this statement, the FDA is making a genuine effort to increase its enforcement efforts. The FDA is committed to ensuring that companies comply with the law and are held accountable for their actions.

3. Guidance issuance

While the FDA is increasing its enforcement efforts, it is also issuing new guidance and regulations. This is a strategic move on the part of the FDA to ensure that companies are aware of the requirements and are prepared to comply.

Recommendation: SmarterCompliance members should stay up-to-date with the FDA's guidance and ensure that their employees are trained to comply with the new requirements. This will help prevent any potential regulatory issues.

OVERSEAS INSPECTIONS

The FDA will increase its overseas inspections this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability.

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The FDA will increase its overseas inspections this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability.

RECOMMENDATION: SmarterCompliance members should ensure that they have established effective compliance programs with their overseas suppliers. This includes conducting regular audits and ensuring that employees are trained to comply with the law.

5. Price Controls and Efficacy

The FDA will increase its enforcement this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability.

Price Controls and Efficacy — The FDA will continue to address issues related to price controls and the efficacy of drugs and biologics.

RECOMMENDATION: SmarterCompliance members should ensure that they are aware of any new developments related to price controls and efficacy. This includes staying up-to-date with any new guidance or regulations.

Biosimilars

The FDA will increase its enforcement this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability.

Biosimilars — The FDA will address issues related to biosimilars.

RECOMMENDATION: SmarterCompliance members should ensure that they are aware of any new developments related to biosimilars. This includes staying up-to-date with any new guidance or regulations.

SUMMARY

The FDA will increase its enforcement this year in three areas: direct-to-consumer advertising and marketing, overseas enforcement, and personal executive accountability. SmarterCompliance members should ensure that they are aware of any new developments related to these areas and are prepared to comply with the new requirements.
Organization, and other not-for-profit agencies to factor out a maximum price per month a new drug or biologic can cost in the marketplace, and then help my client work backwards to derive a “not to exceed” development cost to stay under per month. In this way, a minor improvement in efficacy coupled with a significant decrease in cost can tip the FDA approval scales in your favor.

21 CFR Part 11 — Everyone’s favorite tug of war, a minor improvement in efficacy coupled with a significant decrease in cost can tip the FDA approval scales in your favor.

Recommendation: To determine if your Part 11 efforts and monies are being spent on the right things, I advise you to do two things: first, review the EU’s drafted Annex 11 revisions (and associated Chapter 4 revisions of the European GMPs); and second, make sure you and your team know the answer to three simple questions:

* How long do “burned” CDs/DVDs last versus so-called “pressed” or manufactured CDs/DVDs?

* Why?

* How do I recognize a degraded CD/DVD on sight alone?

These and other questions — including the typical failure rates of backup tapes, and so on — are ones you can use to vet Part 11, Annex 11 or validation consultant: those that do not know the answers are unlikely to be able to help you comply with FDA’s new focus on data integrity and quality. The old “validate everything” misinterpretations will not help you prove record integrity.

**GUIDELINE ISSUANCE**
Along with new regulations and increased focus on executive accountability, 2009 will see the FDA release at least three new guidance documents covering process validation, third-party certification programs, and a Quality by Design guidance on design space.

**Design Space —** FDA guidance for design space will layout Quality by Design manufacturing concepts for drugs and biologics entering clinicals and for medicines already on the market.

**Recommendation:** Design space is complicated, and among the many recommendations discussed in the SmarterCompliance™ programs I’ve outlined when it comes to delineating design space. I spend significant time on this in my workshops and in my industry report on modern quality systems under Quality by Design. You can get a good head start on your competition today by combining a review of my report with a study of the draft International Conference on Harmonization (ICH) Annex R to Q8 entitled “Pharmaceutical Development” (especially pages 3-5). Use your pilot production as a perfect testing ground to layout Quality by Design manufacturing concepts for drugs and biologics entering clinical and phase I clinical production and testing. Under the new guidance, the old approach of three batches is no longer acceptable.

**Recommendation:** If you have not already adopted a risk-based approach to process validation, now is the time; I expect tight to be issued on this by the end of the year. Couple your risk-based priorities with a valid-statistically sound approach (see any of my recent “Lean compliance” webinars for a detailed walk through on how to do this). The key is to make your approach consistent, straightforward, and systematic. Inspectors will expect to be able to follow your logic.

**Third-Party Certification —** The FDA is also set to release a major revision of its 1987 process validation guidance. Keeping in line with international efforts to harmonize and modernize quality systems and product development, the guidance will encourage increased emphasis on quality and compliance oversight of preclinical and Phase I clinical production and testing. Under the new guidance, the old approach of three batches is no longer acceptable.

**Recommendation:** If you have not already adopted a risk-based approach to process validation, now is the time; I expect tight to be issued on this by the end of the year. Couple your risk-based priorities with a valid-statistically sound approach (see any of my recent “Lean compliance” webinars for a detailed walk through on how to do this). The key is to make your approach consistent, straightforward, and systematic. Inspectors will expect to be able to follow your logic.

**Final Thoughts**

Other FDA initiatives to keep an eye on this year include a continuation of GMP modernization (think Quality by Design and ICH), the modernization of Good Laboratory Practices (think Quality by Design in preclinical and phase I clinicals), guidance on good importer practices, and a push by Congress to give FDA the power to force recalls. Much noise will also be made of splitting the agency into two — a food agency and medicinal agency — but do not expect anything to come of this over the next year. Regulatory compliance has always been a necessary cost of doing business. Executives who continuously learn more about what regulators want in the very near future and who tackle problems in the here and now with new thinking and original directions are executives who will reap huge benefits of wealth and market position. Most of your competition will engage in stale habits, expecting the regulatory landscape of 2009 to be the same as that of the 1980’s or 90’s. Armed with the knowledge in this article, plus the references materials cited, you can turn your compliance program from a competitive edge, leaving your competition, stuck in last century’s past, mired in the mud.

**Are you ready?**

About the Author:

John Avellanet is the founder of the regulatory intelligence and lean compliance program for executives and business owners, SmartCompliance™. He is the author of more than 30 articles on lean compliance and quality systems, a co-author of a book on biotech business development, and a frequent speaker with FDA officials.

He can be directly reached through his independent advisory firm, Cerulean Associates LLC, on the web at www.ceruleanllc.com.

**References:**


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**References:**


