

ROLE OF IT

IN EFFECTIVE REGULATORY COMPLIANCE

John Avellanet
Cerulean Associates LLC
www.ceruleanllc.com
john@ceruleanllc.com
+1.757.645.2864

© 2010 Cerulean Associates LLC

IT Compliance Realities

Reasons My Company might Undergo a Regulatory Investigation / Inspection (check all that apply)

- We have more than 50 employees
- We make products that we sell or distribute
- We make products / provide services that fall under FDA jurisdiction
- We make products / provide services that fall under DOE jurisdiction
- We make products / provide services that fall under SEC jurisdiction
- We make products with components under DEA, EPA or state Boards of Pharmacy
- We have operational activities that fall under OSHA
- We outsource company activities (accounts payable, IT, manufacturing, R&D, etc.)
- We are publicly traded on a stock exchange

Regulatory agency I hear the most concern about from colleagues _____

I believe that regulatory compliance is a... (circle one)

- A. ... significant distraction to a company's operations
- B. ... significant part of a company's financial results

Average Cost to Clean-Up IT Compliance Problems _____

What does that number assume? _____

More Notes

Defining IT Compliance

Which of the following Practices, Behaviors and Beliefs have I Observed? (check all that apply)

- A policy that is not enforced
- System documentation that is significantly out-of-date or non-existent
- An expectation of privacy when sending email through the company email system
- Lots of system log files being gathered with no apparent review or trending
- Significant business decisions with systems impact that IT learns about after the fact
- An assumption that firewalls and anti-virus software makes our e-records safe
- Almost every system has a different username/password schema
- An assumption that IT's data backups are for long-term data archive and retention

Why are written policies and procedures only subjective proof? _____

Define "IT Compliance" _____

List the 5 characteristics of data that has Integrity (e.g., will be accepted by an investigator)

List the 4 components of Effective IT Compliance

IT Compliance Challenges

What are some reasons why lawyers are unlikely to be able to tell IT what to do (*i.e.*, what controls to put in place to ensure IT Compliance)?

What might IT be able to do or rely upon instead? _____

What tool makes IT compliance easier? _____

List the 7 most common mistakes IT executives make when it comes to IT Compliance

What two key external challenges do IT executives have to handle in the IT Compliance space?

What percentage of a company's cost to comply with regulations comes from IT? _____

More Notes

Starting a Lean IT Compliance Program Today

List two Powerful, Measurable Benefits that Effective IT Compliance provides

Can you think of other benefits to your organization? _____

Steps to Kick-Start an Effective IT Compliance Program _____

Ideas on How to Get Support for IT Compliance in My Organization _____

What are some additional Best Practices to consider? _____

More Notes

Executive To-Do Checklist

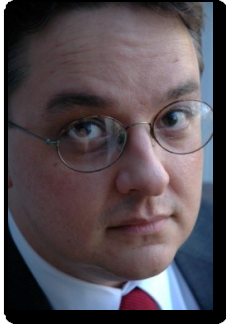
- Download and read the reference articles at www.ceruleanllc.com/MISRC/ available until September 30 (“Cost-Effective IT Outsourcing” and “Why CIOs Should Commoditize IT”)
- Download and review the list of IT compliance resources
- Download and complete the IT compliance self-assessment checklist (a good exercise is to pass this out to multiple colleagues and compare scores)
- Summarize today’s session for your team or department
- Schedule one hour a week on your calendar to focus on IT compliance issues
- Determine if your company has a records retention schedule / matrix (RRS) and get a copy of it
- Create your own plan to kick-start an effective IT compliance program
- Define IT compliance training and workshop opportunities for your team and management (on-site workshops, webinars, etc.)

More Notes to Remember

Lean IT Compliance Expert

John Avellanet

author of



Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine, contributing author to **Best Practices for Biotechnology Business Development**, publisher of the monthly *SmarterCompliance* executive newsletter, and author of the blog, *Compliance Zen*, recently selected one of the top 50 biopharmaceutical blogs in the world.

John Avellanet solves compliance worries for his clients. He has a breadth of experience designing, implementing, and maintaining **IT, records retention, quality management systems** and **compliance programs** for FDA 21 CFR 58, 210/211, 820/822, Part 11, the ICH and GHTF, plus ISO 13485, 17799, 17025, and 15489.

For more than 15 years, John served as an executive accountable for compliance, records management, and information technology. He was trained as a Part 11 inspector and spent 5 years as a CIO for a *Fortune 50* combination medical device subsidiary.

To have Mr. Avellanet speak for your event or

To enquire about his specialized compliance services

Contact him through his website at www.Ceruleanllc.com

JOHN AVELLANET

CERULEAN ASSOCIATES LLC

PO Box 498

WILLIAMSBURG, VIRGINIA 23187-0498 US

+1 757-645-2864 • JOHN @CERULEANLLC.COM

LEAN COMPLIANCE CONSULTING

WWW.CERULEANLLC.COM

Feedback Request

I value your honest feedback and suggestions for improvement. Please take a moment to provide it. Fill this sheet out – tear it off – and provide to me (or mail to John Avellanet, PO Box 498, Williamsburg, VA 23187-0498, US).

Compared to your original expectations, how well did this meet your objectives?

- Exceeded objectives: learned more than I can immediately apply
- Met objectives: all promises were kept; I can apply everything I learned within 30 days
- Did not fully meet objectives: I did not learn anything new to apply

To what extent was I responsive to your needs?

- Exceeded needs: provided specific answers and examples, responded to questions, tested to ensure points were understood and provided follow-up opportunities
- Met needs: responded to questions and used appropriate examples
- Did not meet needs: avoided some questions and/or did not use pertinent examples

To what degree were the handouts, reference material and presentation useful?

- Exceeded needs: relevant, informative with suggestions and good long-term value tied directly to the issues I (and my organization) face
- Met needs: sufficient and useful for the immediate, 30-45 day short-term
- Did not meet needs: weak, generic and full of self-promotion

If you were to present this yourself, is there one aspect you would change? How?

How do you feel about this topic after our work together today?

If you've been completely satisfied with this presentation, please take a moment to write a 1-2 sentence personal testimonial I can use in my publicity efforts to help other executives who might be considering inviting me to speak.

Name: _____
 Title: _____