



## Teleconference Course Materials

*You may duplicate this for each person attending the conference.*

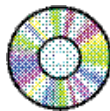
# FDA Compliance on a Budget: Avoiding FDA Trouble While Surviving Budget Cuts

**John Avellanet**  
Cerulean Associates LLC

**Date:** **Thursday, December 9, 2010**

**Time:** **1:00pm – 2:30pm Eastern Standard Time (GMT/UT 1800)**  
 12:00pm – 1:30pm Central Time  
 11:00am – 12:30pm Mountain Time  
 10:00am – 11:30am Pacific Time

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# FDA Compliance on a Budget

## Avoiding FDA Trouble while Surviving Budget Cuts



**John Avellanet**  
Cerulean Associates LLC  
[www.CeruleanLLC.com](http://www.CeruleanLLC.com)

an FOI Services teleconference

# Acknowledgements

## FDA

- Joseph McGinnis
- Michael Marcarelli
- Pablo Bonangelino
- Kim Trautman
- Barry Cherney

## DoJ

- Gene Thirolf

## Industry

- Mike Weber
- Dan O'Leary
- Anita Fauchier
- Roberto Guzman
- Brian Kaufman

# Agenda

- Costs and challenges
- Lean compliance framework
- Lean compliance techniques
- Quick cost-conscious compliance advice

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Industry hurdles  
FDA perceptions  
True cost of compliance

# **Costs** and Challenges

**- \$92,000,000,000.00**

# Industry Response in 2010

**Bayer to cut 4,500 jobs in global overhaul** - *reuters*

**Layoffs return with Abbott's 3,000 job cuts** - *pharmatimes*

**Roche details cuts, new buyout plans in global restructuring** - *wall street journal*

**Pfizer to slash 10,000 jobs** - *fiercepharma*

**Merck to cut 16,000 works, close 16 plants, labs** - *daily finance*

**AMAG Pharmaceutical to cut workforce by 24%** - *reuters*

**Biogen Idec axes 650 jobs** - *reuters*

**Pfizer plots more post-merger job cuts for 2011** - *dow jones*

# More **Costly** Challenges

- Rising healthcare price pressures
- Knowledge specialization
- Controlling virtual suppliers
- Generational conflicts
- Diversion of technology and regulation
- Globalization – marketplace, regulations, liability
- 20<sup>th</sup> century quality systems
- Increased compliance burdens
- RA and QM demographic shifts

Source:

*Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine (Logos Press)*



“Noncompliance always seems to boil down to **COMPETITIVE ECONOMICS** or deliberate ignorance.”

- Gene Thiof, Director, Office of Consumer Litigation, Department of Justice



“Manufacturers who **CHOOSE TO WAIT** until FDA investigators find violations rather than policing themselves will find that they have made a **POOR AND COSTLY DECISION.**”

- Dr. Lester Crawford, former FDA Deputy Commissioner



# 483 Observation Excuses

“It **cost too much to fix** and we didn't think you'd cite us for such a technicality”

“The **fix is too expensive** for such a low probability of this happening again”

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  
1 Montvale St., Stoneham, MA 02180 781-596-7700

DATE OF INSPECTION  
10/19/09 - 11/13/09

FBI NUMBER  
10003058

NAME AND TITLE OF INSPECTED PERSON  
President, and CEO

FIRM NAME  
Drug Manufacturer

CITY, STATE AND ZIP CODE  
STREET ADDRESS

10

confirms there is no... and the co... The

# 2002 FDA Survey

Surveyed

**1,566 firms**

Small businesses

**966 (61%)**

(less than 500 personnel)

Source:  
FDA Analysis of Economic Impact Presentation

# 2002 FDA Survey

## Annual Cost of FDA Compliance

Startup / micro firm → **\$ 38,000** *per product*

Small business → **\$ 61,000** *per product*

Large, multinational → **\$ 47,000** *per product*

# Annual Compliance Cost per Regulation

SOX, HIPAA, GMPs, QSRs, etc. **296 man-days each year**  
at \$2,000 per day

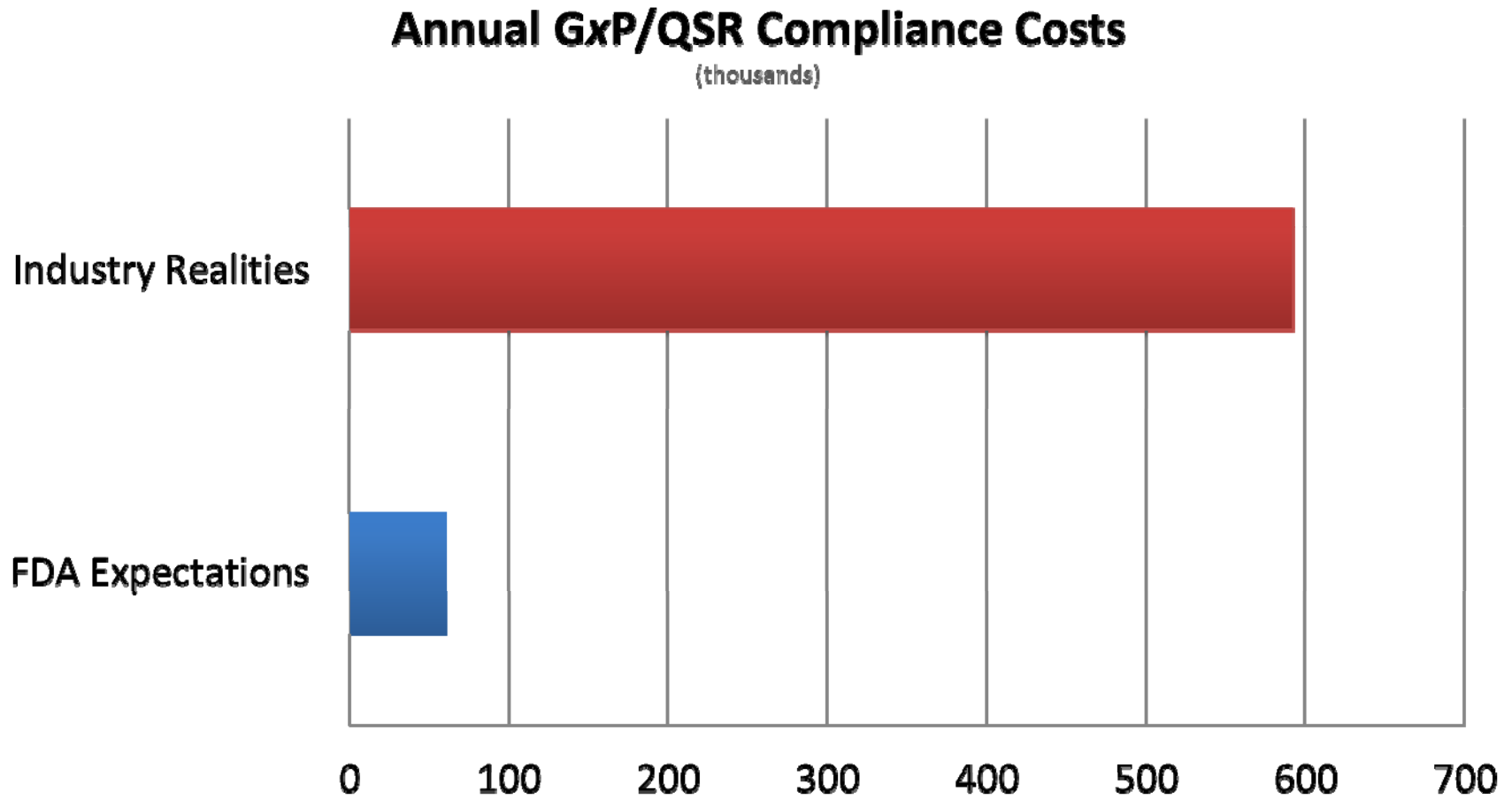
(i.e., 296 x 2,000)

Min. Yearly Compliance Cost *per Regulation*

= **\$ 592,000**

Source:  
IDC Compliance Automation Analysis

# Comparison



# Two Compliance Questions

1. How much is **too much** to spend on compliance?
2. How much is **too little** to spend?



**\$ 5,400.00 per person**

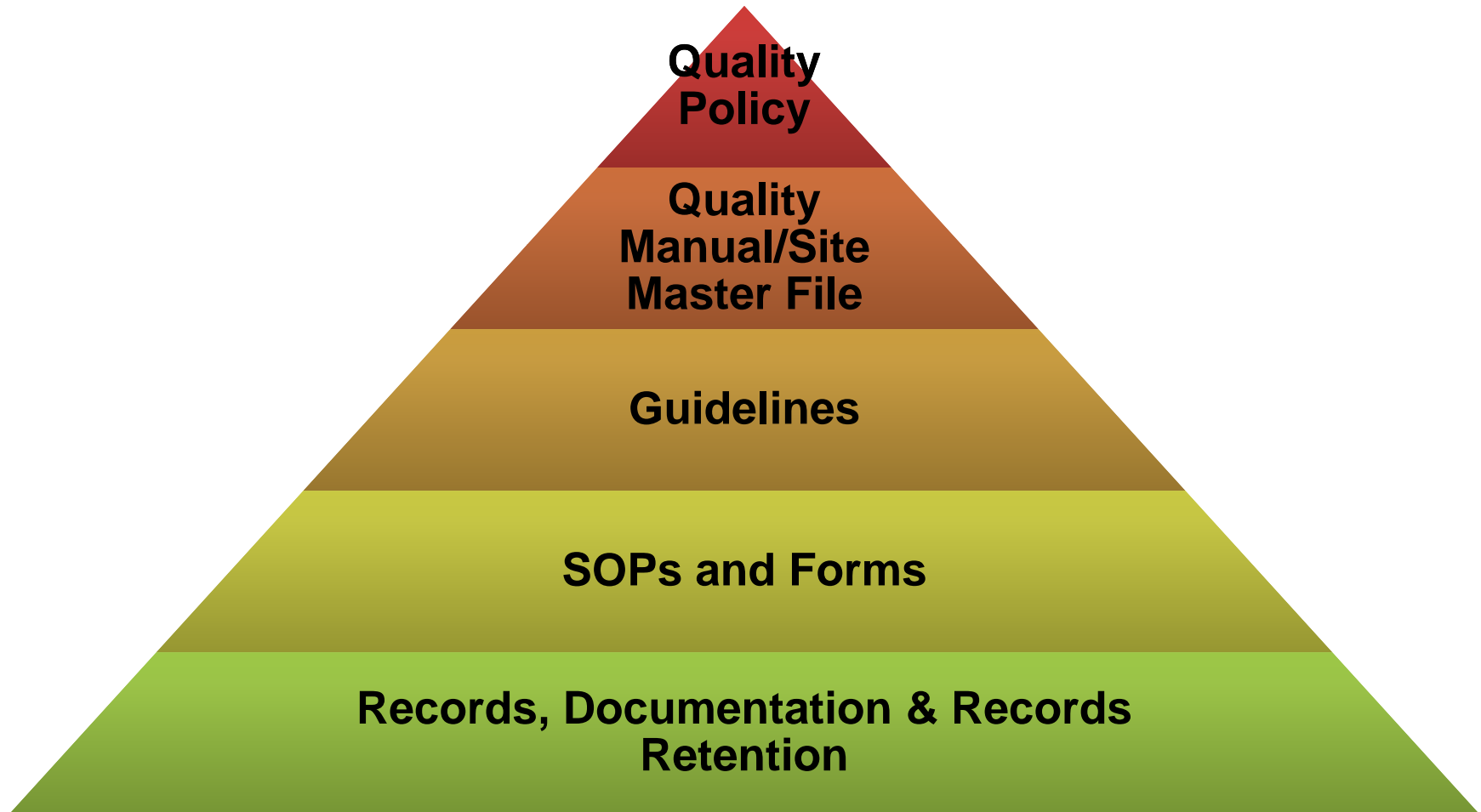


Source:  
"Lean Compliance for Midsized Companies,"  
*Journal of GxP Compliance*

Lean quality management system  
Lean regulatory affairs program  
Lean cross-compliance coordination

# **Lean** Compliance Framework

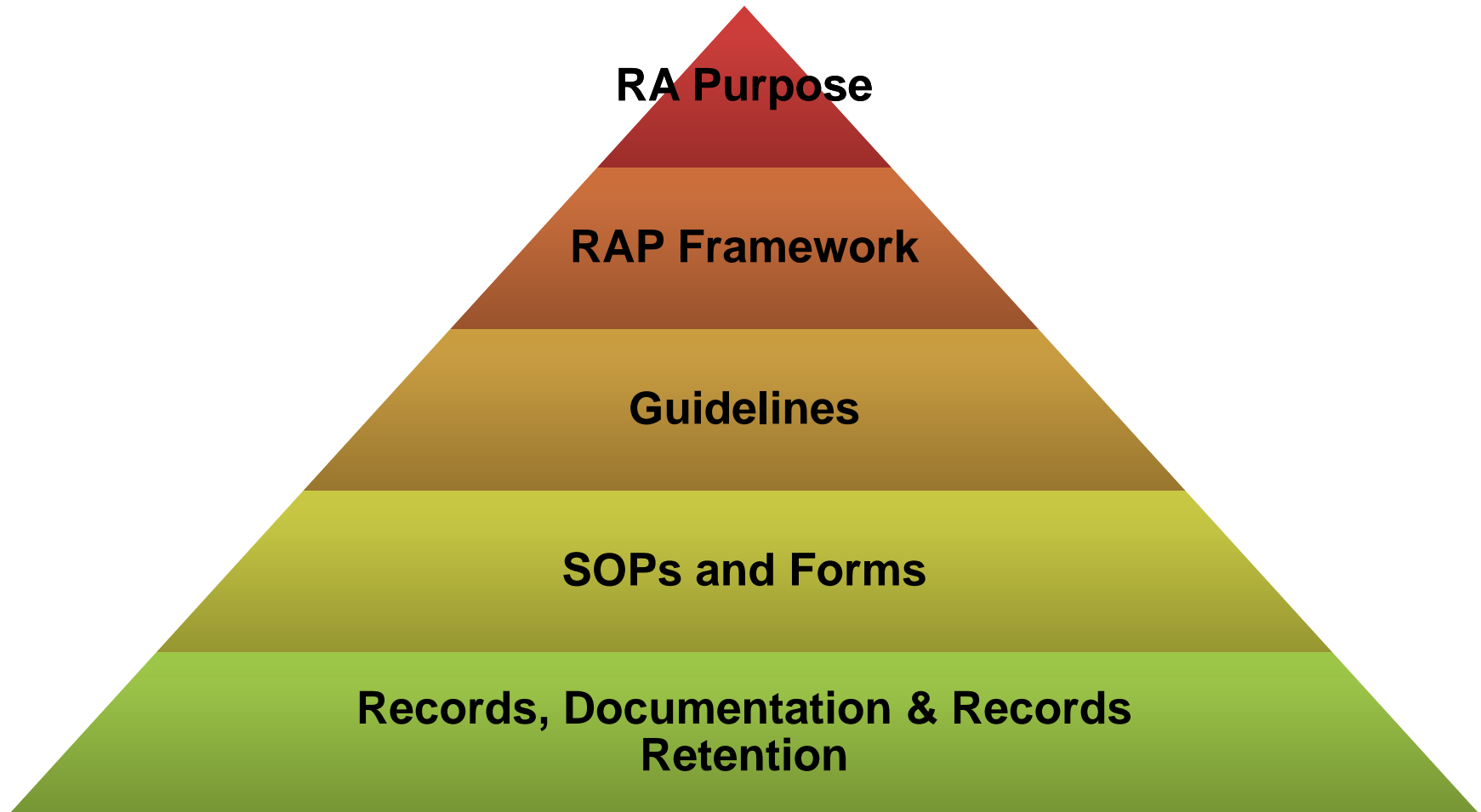
# Lean QMS Framework



# Practically Speaking

- Speed SOP incorporation into day-to-day
- Written procedures compete for mental focus in an increasingly fragmented work day
- Focus efforts around ensuring comprehensibility and flexibility

# Lean RAP Framework

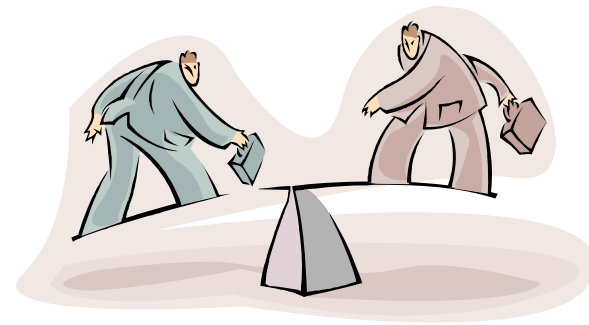


# Practically Speaking

- Fill out framework with:
  - annual RA management review
  - compliance radar
  - cross-functional roles RA plays
- Build a regulatory requirements matrix
- Use a CRISP for better cross-functional planning

# Cross-Compliance Coordination

- Leverage other compliance efforts in company
  - sarbanes-oxley audit committees
  - integrated audits of critical suppliers
  - sampling rationales
  - internal audit plans
  
- Leverage vendor compliance



# Practically Speaking

- Improves influence with senior management
- Helps avoid “silo mentality”
  - is focus on **ensuring regulatory adherence** *or* **ensuring business success ...?**
- Minimizes risk of being seen as overhead
  - integral part of operational and strategic success
  - see “Bucking the Regulatory Affairs & Quality Outsourcing Trends” in *Regulatory Affairs Journal*, May 2010



Prioritizing with risk

Writing lean SOPs

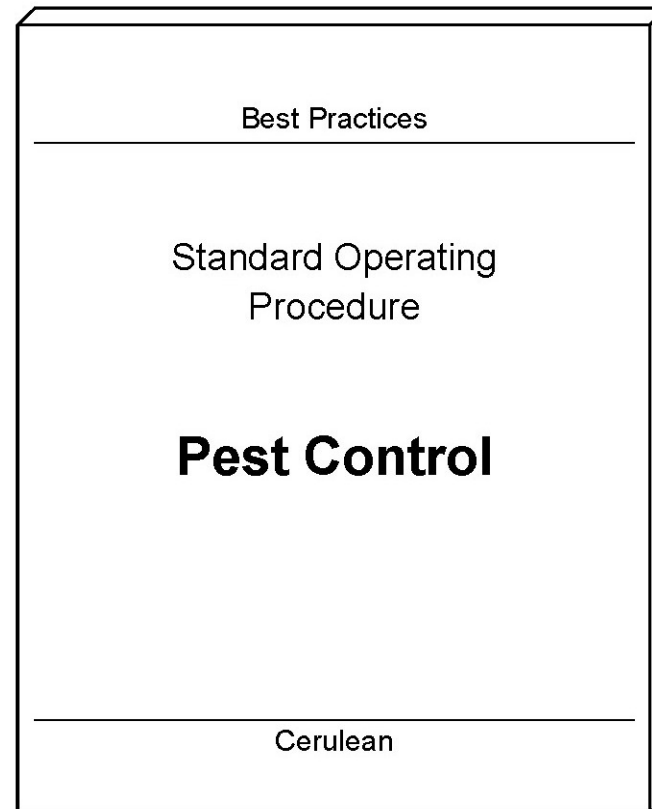
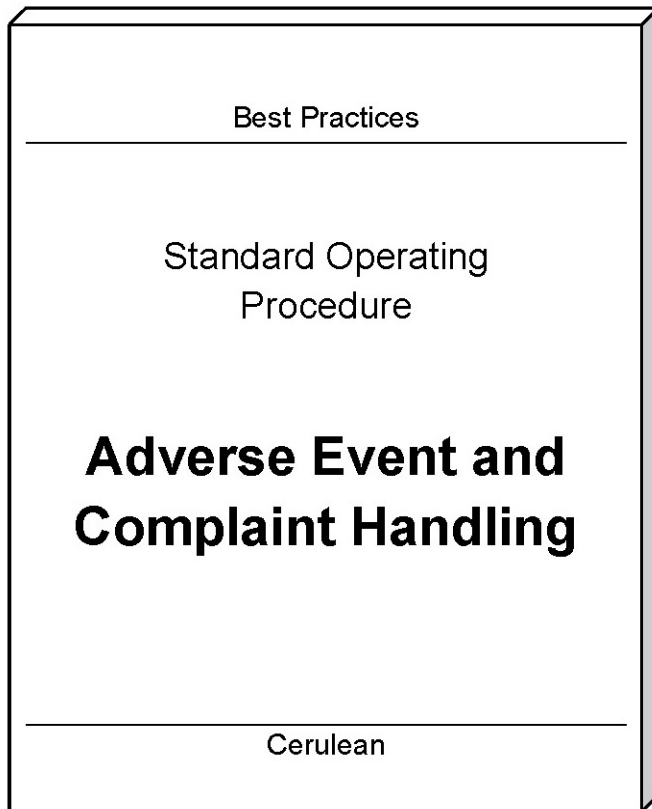
Using a clinical regulatory integrated strategic plan

Leveraging vendors

Metrics that matter

# **Lean** Compliance Techniques

# Which Should You Do First?



# Prioritize Based on End Risks

## FDA Concerns

1. Patient safety
2. Product safety
3. Product efficacy
4. Regulatory / statute compliance
5. Product quality

## Your Proof ...?

# Leave a Trail of Risk Control

## FDA Concerns

1. Patient safety
2. Product safety
3. Product efficacy
4. Regulatory / statute compliance
5. Product quality

## Your Proof

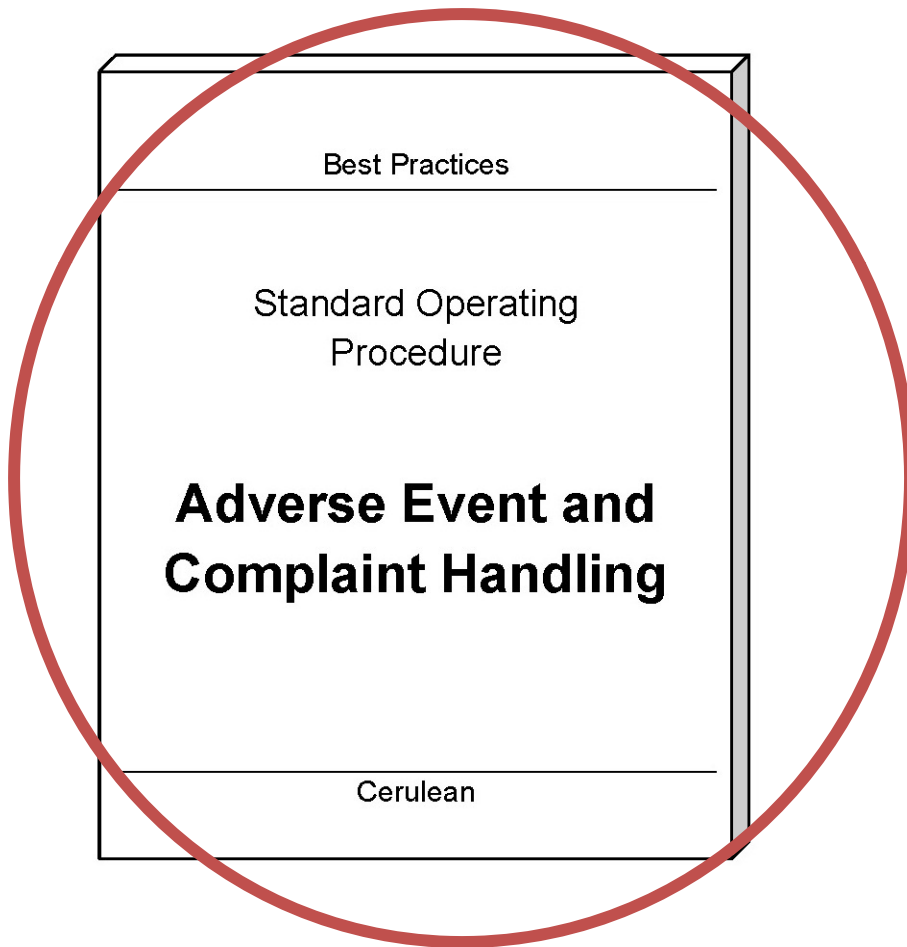
1. Clinical trial plans, implemented SOPs
2. Consumer complaint files, critical supplier audits
3. Clinical / nonclinical results, postmarket studies
4. Advertising and marketing materials, validation plans
5. Equipment calibration records, PAT trend analyses

# Lean Compliance Tactic #1

Prioritize based on *proximity* to patient



# Which Should You Do First?



# Lean SOPs

“This SOP applies to all regulatory and technical staff responsible for authoring and compilation of annual reports, recognizing that IND Annual Reports are to be submitted within 60 days of the effective date of the IND as stipulated in 21 CFR 312.33, and covering the information cut-off date.”

# Lean SOPs

“This SOP applies to all regulatory and technical staff responsible for authoring and compilation of annual reports, recognizing that IND Annual Reports are to be submitted within 60 days of the effective date of the IND as stipulated in 21 CFR 312.33, and covering the information cut-off date.”

**There are 5 problems with this scope statement that will cause the firm headaches within 1 year – *can you find them?***



# Lean SOPs

“*ONLY* authoring and compilation...?”

“So anyone else that might actually be involved doesn't need to follow any part of this SOP...?”

“This SOP is for all **regulatory and technical staff** responsible for **authoring and compilation** of annual reports, recognizing that **IND Annual Reports** are to be submitted **within 60 days of the effective date of the IND as stipulated in 21 CFR 312.33**, and covering the information cut-off date.”

“Why specify the **current** regulation and its **current** timeframe in the scope of the SOP...?”

“So you only follow this process when you have to do an IND annual report for FDA – what about reports for EMA, HC, MHRA, *et al.*...?”

# Five Steps to Lean SOPs

1. Map the process
2. Strive for readability
3. Stay silent
4. Put the process up front
5. Take advantage of everyday technology

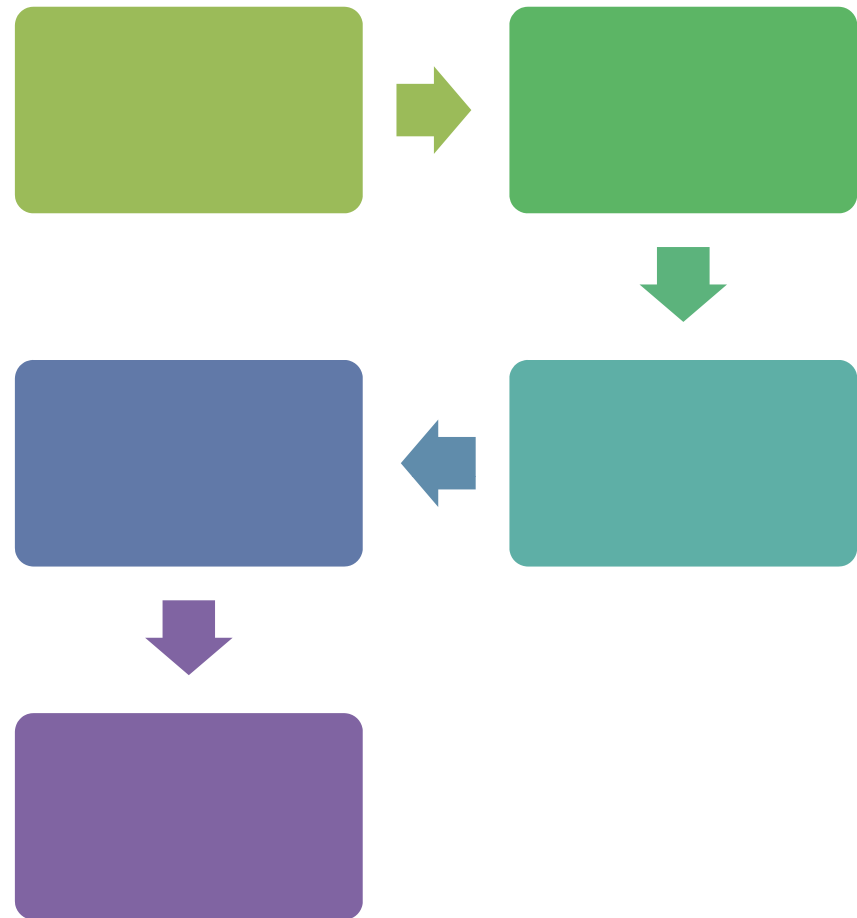
“The first thing we’re training new inspectors to look for is a **workflow or process map.**”

- Kim Trautman, QSR Author, FDA

**Map the process**



- Information flow
- Handoffs
- Decisions
- Approvals
- Records generated



## Map the process



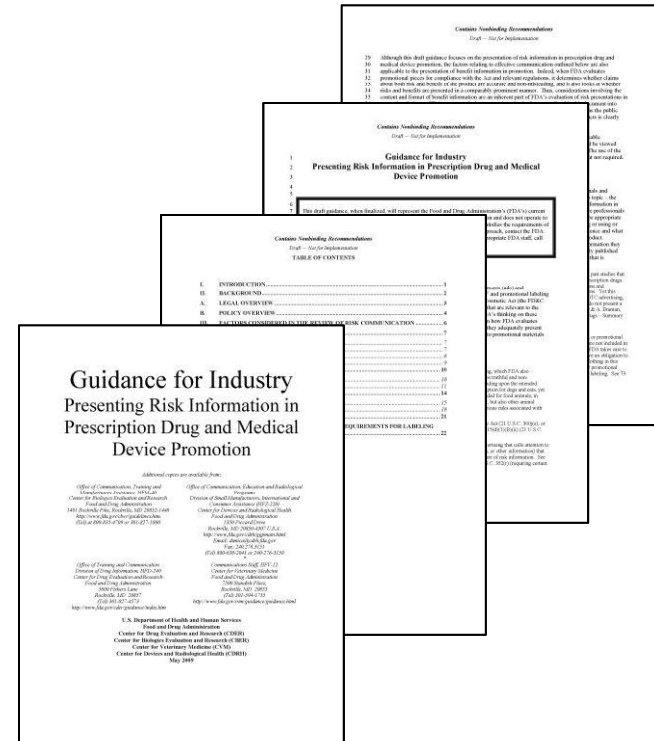
- Training aid
- Speed audits or CAPA investigations
- Process reinforcement
- Rapid prototyping implementation
- Procedural consolidation
- Cross-functional coordination
- Avoid analysis paralysis
- Eliminate non-value added activity

## **Process map benefits**



# FDA Guidance on Presenting Risk Information

May 2009



Strive for readability

Avellanet, December 2010



## Manual formulas

[http://en.wikipedia.org/wiki/Flesch%E2%80%93Kincaid\\_readability\\_test](http://en.wikipedia.org/wiki/Flesch%E2%80%93Kincaid_readability_test)

## Automated in Word-Processing

- Google Docs
- Microsoft Office Word
- WordPerfect
- WordPro
- Kword

**Strive for readability**



## Original

“This SOP applies to all regulatory and technical staff responsible for authoring and compilation of annual reports, recognizing that IND Annual Reports are to be submitted within 60 days of the effective date of the IND as stipulated in 21 CFR 312.33, and covering the information cut-off date.”

## Revised

“This SOP applies to all personnel responsible for authoring, compiling, reviewing, and/or submitting annual reports to regulatory health agencies.”

**Strive for readability**





- More conducive to how people work
  - “Scannable”
- Easier to understand and follow
  - Day-to-day applicability is simpler
- More streamlined
  - Cost-effective
  - Flexible

## Readability benefits



“If we don’t need to say it,  
it’s best to simply **stay silent**  
on the matter.”

**Stay silent**



## Original

“This SOP applies to all regulatory and technical staff responsible for authoring and compilation of annual reports, recognizing that IND Annual Reports are to be submitted within 60 days of the effective date of the IND as stipulated in 21 CFR 312.33, and covering the information cut-off date.”

## Revised

“This SOP applies to all regulatory and technical staff responsible for authoring and compilation of annual reports, recognizing that IND Annual Reports are to be submitted within 60 days of the effective date of the IND as stipulated in 21 CFR 312.33, and covering the information cut-off date.”

**Stay silent**



- **More flexibility**
  - Avoid inadvertently confining ourselves
- **Less chance of typos and other errors**
- **Easier to achieve readability**
- **Minimizes risk of having un-provable steps**

**Silent benefits**



Procedure  
**STARTS** on  
page 5 !

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**MEDICAL DEVICE REPORTING**

**4.0 DEFINITIONS**

4.1 **5-Day MDR:** report of an adverse event to the FDA on Form 3500A upon written request from FDA or for an event necessitating remedial action to prevent unreasonable risk of substantial harm to the public health within 5 days of the alert date.

4.2 **30-Day MDR:** report of an adverse event to the FDA on Form 3500A for a device related death, serious injury, or malfunction within 30 days of the alert date. (See MDR Reportable Event.)

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**MEDICAL DEVICE REPORTING**

filing the original report or when new facts or information are discovered affecting the information provided in the original report.

4.22 **Work Day:** Monday through Friday, excluding Federal holidays.

**5.0 RESPONSIBILITIES**

5.1 **All Company Employees:** responsible for notifying the personnel in the MDR Processing Unit when they become aware of an incident or product problem that may necessitate an adverse event report.

[Company Logo] **STANDARD OPERATING PROCEDURE**

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**MEDICAL DEVICE REPORTING**

**1.0 PURPOSE**

To describe the procedure for the mandatory reporting of adverse events and product problems to the Food and Drug Administration according to the FDA's Medical Device Reporting requirements.

**2.0 SCOPE**

Applicable to all medical device products, as designated in the applicable statutes and FDA regulations, manufactured or distributed by [Company Name].

**3.0 REFERENCES**

21 CFR Subchapter H, Part 803, FDA Medical Device Reporting

21 CFR Part 820, FDA Quality System Regulation for Medical Devices (cGMP) Final Rule, §201.189 Complaint Files

ISO 13485:2003, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

ISO 14971, Medical Devices - Application of Risk Management to Medical Devices

FDA Guide to Inspections of Quality Systems, Quality System Inspection Technique (QSIT), [http://www.fda.gov/oc/inspect\\_ref/sqis/qsit/qsitguide.pdf](http://www.fda.gov/oc/inspect_ref/sqis/qsit/qsitguide.pdf)

Medical Device Quality Systems Manual: A Small Entity Compliance Guide, FDA, December 1996, <http://www.fda.gov/cdrh/cer/contol.html>

Instructions for Completing the MedWatch Form, 3500A, (2004), <http://www.fda.gov/medwatch/REPORT/instnuc.html>

FDA MedWatch Program Home Page, <http://www.fda.gov/medwatch/index.html>

FDA Information about Medical Device Reporting, <http://www.fda.gov/cdrh/mdr/>

MedWatch Form 3500A, <http://www.fda.gov/medwatch/safety/3500a.pdf>

MedWatch Mandatory Reporting Form Coding Manual, <http://www.fda.gov/cdrh/mrccode.pdf>

FDA Medical Device Reporting, Baseline Report, Form 3417 <http://www.fda.gov/cdrh/mdr/fda-3417.pdf>

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ure of a device to meet its performance specifications, including whether the device performs as intended.

**Alert Number:** unique number that identifies each Individual Adverse Event Report (MDR) and is in the form "1234567 - YYYY - #####" where "1234567" is a registration number for the site, "YYYY" is the year in which the report was filed, and "##### is a unique, 5-digit sequence number assigned by the Company.

**Individual Adverse Event Report (MDR):** FDA MDR Form 3500A.

written or electronic files maintained by the Company that contain or reference all records, documents, and information associated with the MDR process. MDR files shall be prominently identified as such and filed to ensure that this file shall also contain any documentation or record of the actions and decision making processes used to determine if a device is known as MDR, Individual Adverse Event Report, Event Report, Form 3500A, or Medication and Device Experience Report.

(1) statements made in the 510K, PMA or other applications filed with the FDA for approval of products or (2) performance specifications provided verbally to customers in such formats as websites, e-mails, brochures, catalogs, booklets, tear sheets, brochures, instruction manuals, service manuals, advertising claims, etc.

Individuals who are (1) licensed, registered, or certified to administer a drug, or (2) receive a diploma or degree in a professional or scientific discipline, applicable for receiving and evaluating adverse event reports or to a persons.

4.17 **Reasonably Suggests:** information such as professional, scientific, or medical facts, observations, or opinions that would reasonably suggest that a device has caused or contributed to a reportable event.

4.18 **Remedial Action:** for the purposes of this procedure, any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

4.19 **Serious Injury:** an injury or illness that: (1) is life threatening, (2) results in permanent impairment of a body function or permanent damage to body structure, or (3) necessitates medical or surgical intervention to preclude permanent damage to a body structure.

4.20 **Shelf Life:** the maximum time a device will remain functional from the date of manufacture until it is used in patient care.

4.21 **Supplemental Report:** a report sent to FDA after the original 5-Day or 30-Day MDR has been submitted. This report contains information not known or not available at the time of

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to manage the complaint handling process and provide a feedback system according to the approved Company policies and regulatory requirements.

qualified to analyze and compile information regarding potential risks and document the determination about whether to file such 0-Day, Baseline and Supplemental reports with FDA, and to ensure that the information is reported in a timely manner. If product is sold outside the US, these reports are for reporting including the timing, and to whom the reports are sent shall call upon additional assistance from medical, legal, regulatory, or technical personnel as needed. The MDR Processing Unit shall be in charge of this procedure, except where noted otherwise.

baseline Reports, Annual Reports, and any other records that are maintained by the Company shall be retained to prevent loss, damage, or destruction for a period of 2 years from the date of the event or a period of time equivalent to the device, whichever is greater, even if the device is no longer marketed in the United States.

reported to the FDA that satisfy the reporting criteria even if the device is no longer marketed in the United States.

to be reported to the FDA electronically with written consent from FDA. Any reports not meeting reporting standards, guidance documents, or other information received by the FDA for MDR reporting will be deemed to have prior written consent from FDA.

It shall be evaluated according to the requirements of 820.186, Designated Unit.

Medical Device Reporting Form Coding Manual shall be used to prepare the MDR report in accordance with MedWatch reporting standards.

6.0 **DEFINITIONS**

6.0.1 **Alert:** notification of a reportable event.

6.0.2 **"N/A":** no information at this time, but may be available at a later date

6.0.3 **"UNK":** unknown, not provided

**7.0 PROCEDURE**

7.1 **Gather Information about the Adverse Event**

7.1.1 Adverse events may come from a variety of sources including, but not limited to:

- Health care professionals
- Health care institutions (hospitals, labs, nursing facilities, etc.)
- Abusers
- Literature, journals, trade magazines
- News reports
- User facility reports
- Customers or customer representatives
- Company complaint trending
- Company corrective and preventive action system analysis
- The Company's own research, testing, evaluation, servicing, installation, maintenance, repair activities, etc., for devices.

7.1.2 These reports may come via phone, fax, e-mail, web contact form, direct mail, MedWatch Reports, personal contact with Company employees, etc. Gather as much information as possible from the reporter. Important information to gather includes, but is not limited to:

- Reporter information (name, address, phone, etc.)
- Customer/Patient information (name, address, phone, age, date of birth, gender, weight, etc.)
- A detailed description of the problem including how the device was involved
- Date the event occurred
- Alert date
- Device information (brand, type, lot, control number, expiration date, etc.)

Place process upfront

Adult  
comprehension  
**STARTS** fading  
after page 3...

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**MEDICAL DEVICE REPORTING**

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**MEDICAL DEVICE REPORTING**

4.22 **Work Day**, Monday through Friday, excluding Federal holidays.

**5.0 RESPONSIBILITIES**

5.1 **A. Company Employees**: responsible for notifying the personnel in the MDR Processing Unit when they become aware of an incident or product problem that may necessitate an adverse event report.

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**MEDICAL DEVICE REPORTING**

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**MEDICAL DEVICE REPORTING**

6.0.2 **"N"** - no information at this time, but may be available at a later date.

6.0.3 **"U"** - unknown, not provided.

**7.0 PROCEDURE**

7.1 **Customer Information about the Adverse Event**

7.1.1 Adverse events may come from a variety of sources including, but not limited to:

- Health care professionals
- Health care institutions (hospitals, labs, nursing facilities, etc.)
- Attorneys
- Literature, journals, trade magazines
- News reports
- User facility reports
- Customers or customer representatives
- Company complaint tracking
- Company corrective and preventive action system analysis
- The Company's own research, testing, or a lab test, servicing, installation, maintenance, repair activities, etc. for product

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21 CFR Part 820, FDA Quality System Regulation for Medical Devices (QSP) Final Rule, 3003.189 Compliant Files

ISO 13485:2003, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

ISO 14971, Medical Devices - Application of Risk Management to Medical Devices

FDA Guide to Inspections of Quality Systems, Quality System Inspection Technique (QSIT), [http://www.fda.gov/oc/inspect\\_ref/qsit/qstguide.pdf](http://www.fda.gov/oc/inspect_ref/qsit/qstguide.pdf)

Medical Device Quality Systems Manual: A Small Entity Compliance Guide, FDA, December 1996, <http://www.fda.gov/ocdhr/center.html>

Instructions for Completing the MedWatch Form, 3500A, (2004), <http://www.fda.gov/medwatch/REPORT/index.htm>

FDA MedWatch Program Home Page, <http://www.fda.gov/medwatch/index.html>

FDA Information about Medical Device Reporting, <http://www.fda.gov/cdrh/mdr/>

MedWatch Form 3500A, <http://www.fda.gov/medwatch/safeby3500a.pdf>

MedWatch Mandatory Reporting Form Coding Manual, <http://www.fda.gov/cdrh/mdr/code.pdf>

FDA Medical Device Reporting, Baseline Report, Form 3417 <http://www.fda.gov/cdrh/mdr/fda-3417.pdf>

Place process upfront



- Aids comprehension
- Supports important information retention
  - Which is more important – the process or definitions?
- Encourages people to actually look up the SOP

**Upfront benefits**



- Hyperlink appendices
- Hyperlink definitions
- Use a simple intranet webpage with links
- Send out emailed reminders
  - “Did you know that if you’re working on an annual report, there’s an SOP that can help? Here’s the link...check it out.”

**Leverage technology**





- Easier outreach to Gen X and Y
- Simpler maintenance
- Helps encourage a culture of compliance
  - SOPs becomes more than just paperwork

## Technology benefits



✓ Prioritizing with risk

✓ Writing lean SOPs

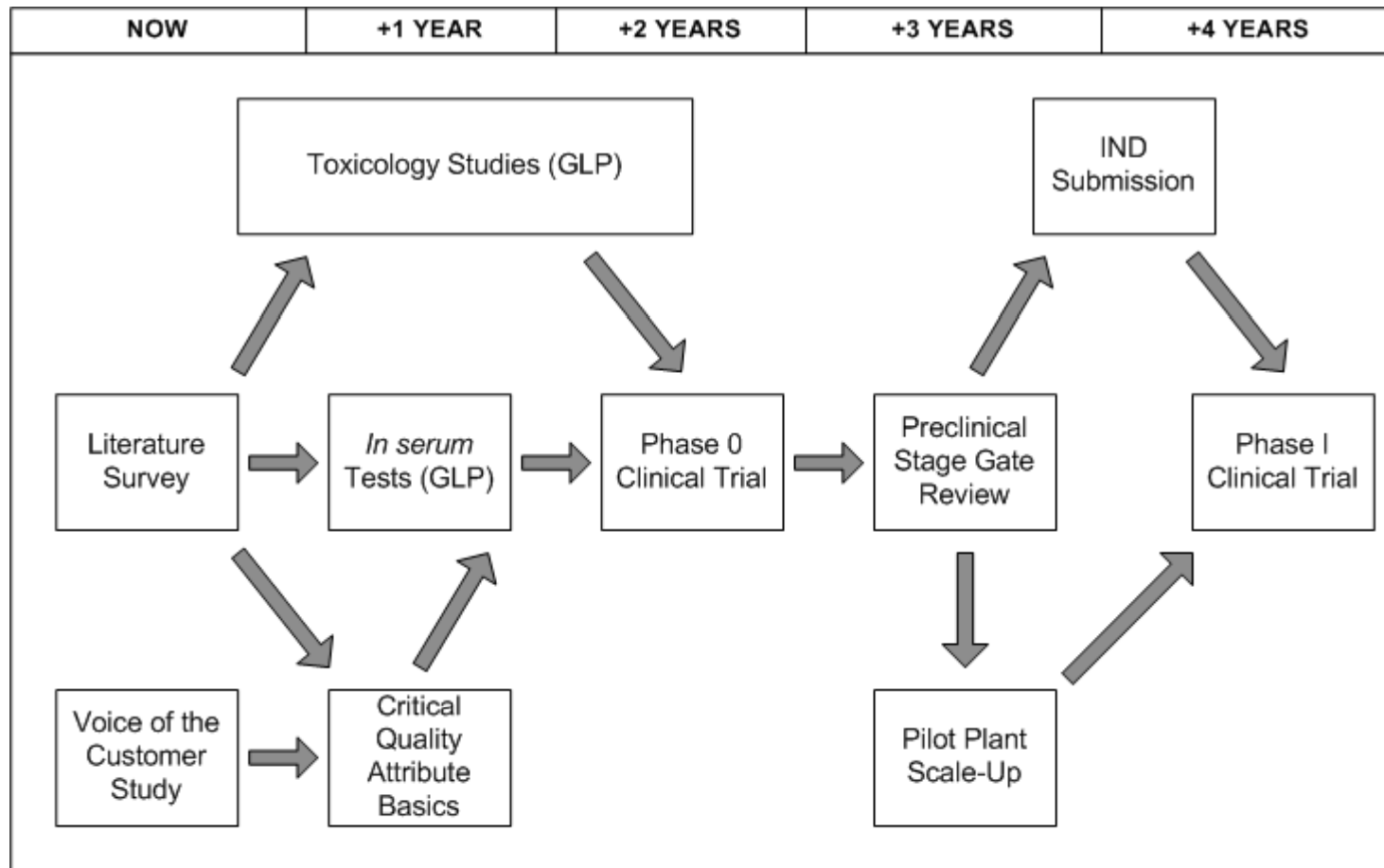
Using a clinical regulatory integrated strategic plan

Leveraging vendors

Metrics that matter

# **Lean** Compliance Techniques

# CRISP



Source:  
*Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine* (Logos Press)

# CRISP Components

- Regulatory strategy
  - Core region
  - Global
- Clinical strategy
- Nonclinical strategy
- Safety and efficacy strategy
- Postmarket surveillance elements
- Quality by design coordination strategy
- Timetable of strategic elements

# CRISP Lean Benefits

- **Encourages cross-functional coordination**
  - Reduces waste and duplication
  - Better, simpler, easier adoption of quality by design
- **Allows for long-term planning horizons**
  - “Development” no longer ends at Phase III
  - Provides flexibility points based on regulatory intel
  - Makes partnering milestones and timelines easier
- **Encourages valuable strategic role for RA**
  - Minimizes risk of RA being seen as expensive submitters

companies have an average of  
**651 suppliers** each

Sources:

*International Journal of Purchasing and Materials Management*  
Institute for Supply Management

Avellanet, December 2010



# Three Ways to Leverage Vendors

1. Focus on oversight
2. Use their SOPs
3. Look for learning opportunities

- Do not duplicate their processes
- Focus on **oversight** of their processes
  - Audit to their SOPs and policies
  - Audit those SOPs and policies to FDA *minimum* expectations
- Document what you did
  - Write your SOPs as “Oversight of [*vendor process*]”

**Oversight focus**





- **As records**
  - CMO's site master file in your vendor dossier
  - Their master SOP index in dossier
- **As a starting point for your gaps**
- **As an independent benchmark**
  - Number of SOPs
  - Types of SOPs
  - etc.*

**Use their SOPs**



- **Ask “Why?” ... a lot**
  - Why did you choose to do \_\_\_\_\_ this way?
  - Why did you reference that industry standard?
- **Compare and contrast**
  - Forms are a great place to find better ways
- **Look for items to identify for future revisions**
  - Regulators like to see “continuous improvement”

**Learn from vendor**



# Lean Benefits

- Avoids re-creating the wheel
- Allows easier record-keeping
- Offers opportunities to strengthen compliance
  - Use learnings to “continuously improve”

# Metrics that Matter



# Metrics that Matter

<b>Goals</b>	<b>Measures</b>

# Metrics that Matter

1. How we **made the company money**
2. How we **saved the company money**
3. How we **minimized risk** to the company

# Metrics that Matter

Goals	Measures
Implement QMS	<ul style="list-style-type: none"> <li>Action schedule v. plan</li> </ul>
Stakeholder learning of SOPs	<ul style="list-style-type: none"> <li>Time from approval to training completion</li> </ul>
Success of quality policy	<ul style="list-style-type: none"> <li>Randomly survey personnel</li> </ul>
Reduce overhead	<ul style="list-style-type: none"> <li>Time to process change requests</li> <li>Time to move received goods between quarantine and inventory</li> </ul>
Success of QMS	<ul style="list-style-type: none"> <li>Mock FDA audit results</li> </ul>

# Metrics that Matter

- Time between SOP draft to implementation
  - Avg. hourly wage X No. of days = cost to company
- Number of mock FDA audit critical findings
  - Roughly equivalent to at least an FDA Form 483 observation
  - Three or more = risk of public warning letter
  - WLs cause 6+ mos. decline in stock price of 3%
  - How much does a 3% stock price decline cost the company?



# Metrics Benefit

- **Speak the language of senior management**
  - Provide greater visibility and strategic importance
  - Draw direct line between *compliance* ↔ *revenue*
  - Connection leads to budgetary importance
- **Clearly demonstrate continuous improvement**
  - To senior management
  - To regulators
  - To investors, business partners, et al

Three keys to budgeting buy-in

Find automated tools

Better ROI for training

**Quick Cost-Conscious Advice**

# Three Keys to Budgeting Buy-In



Assess operational costs **quarterly**



Show at least a **3-to-1 ROI**



Give back at **2RF**

# Find Automated Tools

- Vendor whitepapers touting **ROI** or **TCO**
  - ROI: 3-to-1 in 6 months, 5-to-1 in 12 months
- Google “[*vendor name*]” and “FDA”
- Tools that save time
  - Portable scanners for on-site supplier material testing to save back and forth with labs

# Better ROI for Training

- Focus on getting an ROI within 6 months
  - As a result of the training, what will you implement that will save money, make money, reduce risk?
- Utilize off-the-shelf
  - Teleconferences and webinars
  - Recorded audio CDs from conferences
  - Slidecasts

<http://www.get2marketnow.com/free-resources/mini-presentations/>

# Better ROI for Training

- Average training expenditure per person
  - \$1,041 (2010 Training Industry Report, *Training Magazine*)
- Bring an external training inhouse
  - Typical in-house workshop is **\$10K**
  - For 10 attendees = \$1K each person
  - For 100 attendees = **\$100 each person**
  - Consider partnering with local college or association

# Want More?



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# Agenda Summary

- ✓ Costs and challenges
- ✓ Lean compliance framework
- ✓ Lean compliance techniques
  - Prioritizing with risk
  - Writing flexible SOPs
  - Planning with the CRISP
  - Leveraging vendors
  - Picking metrics that matter
- ✓ Quick cost-conscious compliance advice



# Executive To-Do List

- Download reference material in link from follow-up email
- Take the 38-point lean compliance self-assessment
- Share the results with your team and discuss next steps
- Determine how many SOPs have process maps
- Identify at least 3-5 metrics that matter
- Schedule your first operational expenditure review
- Regularly read the monthly *SmarterCompliance* newsletter trial

# About Your Presenter



[www.Ceruleanllc.com](http://www.Ceruleanllc.com)

[www.ComplianceZen.com](http://www.ComplianceZen.com)

**John Avellanet** solves complex compliance problems for clients. Winner of the 2009 Best of Business award by the Small Business Commerce Association, Mr. Avellanet has earned international acclaim for his business-savvy, practical compliance advice.

His latest book, **Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine**, has earned multiple five-star reviews in industry publications, blogs, and Amazon.com.

He has a breadth of experience designing, implementing, and being accountable for quality systems and compliance programs for FDA the ICH and GHTF, and ISO. For more than 15 years, John served as an executive accountable for compliance, records management, and information technology, most recently as a C-level executive for a *Fortune 50* combination medical device and biotech subsidiary.

In 2006, Mr. Avellanet founded his private FDA compliance consulting firm, **Cerulean Associates LLC**.

thank you



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- lean FDA compliance
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# Training Evaluation Form

TC001517

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John Avellanet, Presenter – December 9, 2010

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(1 = Poor; 2=Fair; 3=Good; 4=Very Good; 5=Excellent – please circle your answers)

What is your overall rating of the course?	1	2	3	4	5
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Were course materials clear and understandable?	1	2	3	4	5
Was the length of the course adequate to cover the content?	1	2	3	4	5
Was the instructor knowledgeable about the subject matter?	1	2	3	4	5
How would you rate the instructor overall?	1	2	3	4	5

### Other comments:

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