

1

2

3

4

5

6

7

8

9

10

# SOX Section 404 Compliance

*For Smaller Biotech, Pharmaceutical  
and Life Science Companies*

Presented by: Bob Benoit

# Big Picture



# What is Section 404?

- Sarbanes-Oxley Act
- PCOAB Auditing Standards
- SEC Standards
- AICPA Standards
- CoBIT
- COSO
- Small COSO

# *Step*

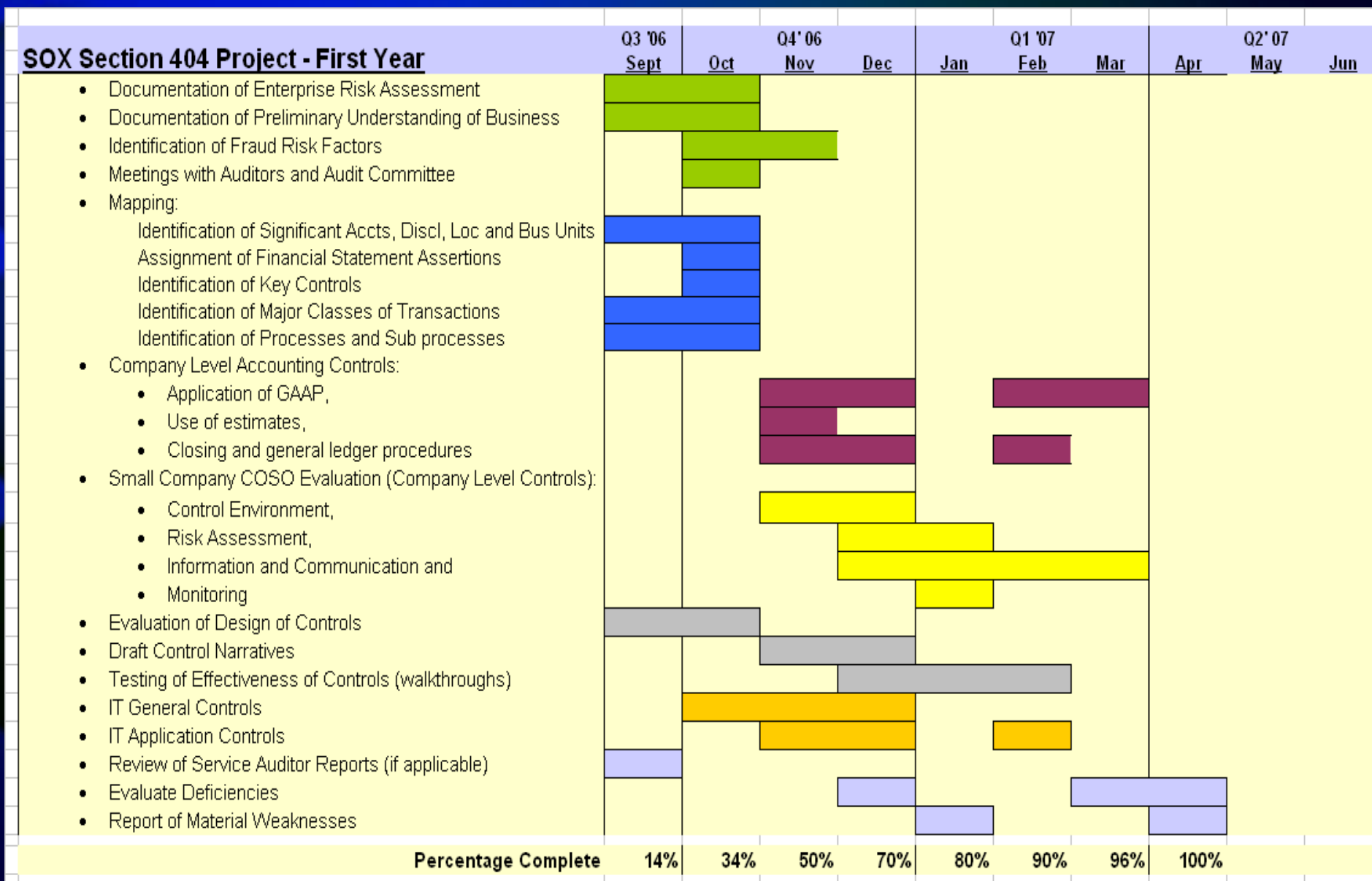
## 1

# Line Up Your Team

- Internal
- External
- Outside Auditors
- Management
- Upper Management
- Audit Committee

# Step 2

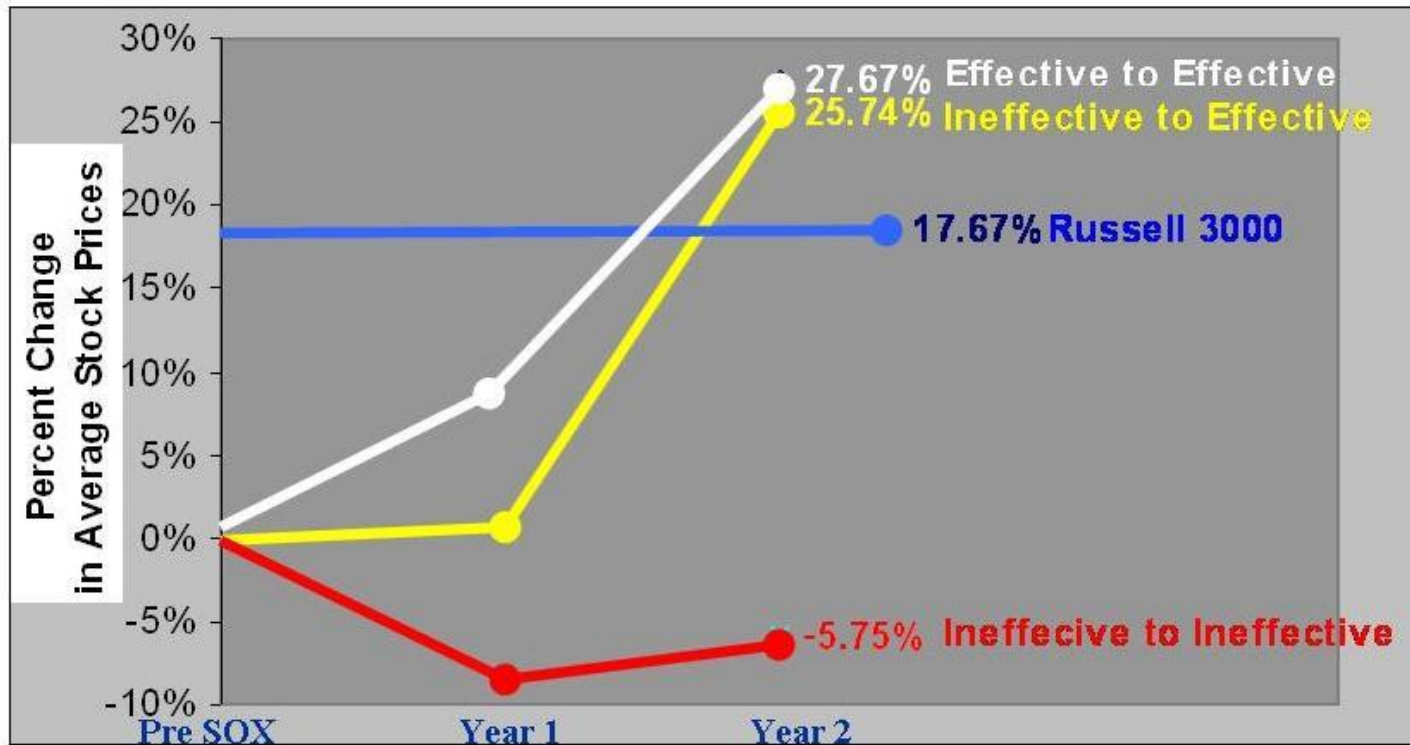
# Timeline



# PITFALLS to Avoid

Costs Exceed the Benefits

**Good Sarbanes-Oxley Section 404 Internal Controls  
Corresponded with Higher Share Price Movement**



Source: Lord & Benoit, LLC

# *Step*

## 3

# Understand Frameworks

- Examples:
  - COSO
  - COSO for Smaller Public Companies
  - CoBIT
  - ITGI Control Initiative for Sarbanes-Oxley
  - SAS 55

*Step*

4

# Risk Assessment



# Internal Control Weaknesses

## *for Bio/Pharm/Life Sciences*

4

<u>Internal Control Material Weaknesses:</u>	<u># Co.s</u>	<u>%</u>
Accounting documentation, policy and/or procedures	22	91.7%
Material and/or numerous auditor /YE adjustments	14	58.3%
Accounting personnel resources, competency/training	12	50.0%
Restatement or nonreliance of company financials	12	50.0%
Segregations of duties/ design (personnel)	10	41.7%
Untimely or inadequate accounting reconciliations	6	25.0%
Information technology, software, security & access issues	4	16.7%
Restatement of previous 404 disclosures	3	12.5%
Senior management competency, tone, reliability issues	3	12.5%
Ethical or compliance issues with personnel	1	4.2%
Ineffective or understaffed audit committee	1	4.2%
Insufficient or non-existent internal audit function	1	4.2%
Scope (disclaimer of opinion) or other limitations	1	4.2%

**Macro Level**

# Accounting Weaknesses

4

## *for Bio/Pharm/Life Sciences*

<u>Accounting Material Weaknesses</u>	<u># Co.s</u>	<u>%</u>
Revenue recognition issues	11	45.8%
Inventory, vendor and cost of sales issues	8	33.3%
Tax expense/benefit/deferral/other (FAS 109) issues	8	33.3%
Accounts/loans receivable, investments & cash issues	7	29.2%
PPE , intangible or fixed asset (value/diminution) issues	7	29.2%
Foreign, related party, affiliated and/or joint venture issues	5	20.8%
Liabilities, payables, reserves, contingencies & failures	4	16.7%
Debt ,quasi-debt, warrants (BCF) security issues	3	12.5%
Fin Stmt/ footnote/ US FASB, segment disclosure issues	3	12.5%
Acquisition, merger, disposal or reorganization issues	2	8.3%
Income statemt classification, margin and EPS issues	2	8.3%
Lease, FAS 5, legal, contingency & commit issues	2	8.3%
Deferred, stock-based or executive comp issues	1	4.2%
Depreciation, depletion or amortization issues	1	4.2%
Gain or loss recognition issues	1	4.2%
Intercompany/Investment w/ sub/affil issues	1	4.2%

**Macro Level**

# 4 Enterprise Risk Assessment

Risk Assessment:		
Assets and Liabilities	<ul style="list-style-type: none"> <li>- Nature of the company's <b>significant</b> inventory</li> <li>- <b>Significant</b> assets or liabilities subject to estimation processes.</li> <li>- <b>Significant</b> assets subject to impairment</li> <li>- <b>Significant</b> product warranty liabilities.</li> <li>- <b>Significant</b> potential liabilities from litigation or other significant contingent liabilities.</li> </ul>	<ul style="list-style-type: none"> <li>x</li> <li>x</li> <li>yes</li> <li>x</li> <li>x</li> </ul>
Revenue Risks	<ul style="list-style-type: none"> <li>- <b>Significant</b> revenues are dependent on primarily a few large customers.</li> <li>- <b>Significant</b> business with customers that are not financially sound.</li> <li>- <b>Significant</b> slowdown in cash and accounts receivable.</li> <li>- <b>Significant</b> change in the company's bad debt experience.</li> <li>- Aggressive marketing in economic conditions, loss of major customer</li> <li>- Difficulty meeting demand or in generating sales orders.</li> <li>- <b>Significant</b> revenue recognition policies.</li> <li>- Industry (highly competitive, cyclical, significant changes)</li> <li>- <b>Significant</b> sales contracts</li> <li>- Noncancelable sales contracts that are unprofitable</li> <li>- The trend in sales orders.</li> <li>- The life cycle of the company's products.</li> <li>- Technology trends that could impact the company.</li> <li>- Unusual terms or conditions for sales offered to certain customers or markets (for example, volume discounts)</li> <li>- Whether management's bonuses are significantly affected by the company's earnings results</li> </ul>	<ul style="list-style-type: none"> <li>yes</li> <li>x</li> <li>x</li> <li>x</li> <li>x</li> <li>x</li> <li>yes</li> <li>x</li> <li>x</li> <li>x</li> <li>x</li> <li>x</li> <li>yes</li> <li>x</li> <li>x</li> </ul>

# Step

# 4

# Fraud Risk Assessment

Fraud Risk Assessment:	Level of Risk			Test?
	Impact	Fraud	likelihood	
1. Discuss the susceptibility of the financial statements to material misstatement due to fraud. Specifically discuss the following:				
• How and where the company's financial statements				
• Which accounts or transaction classes might be susceptible to material misstatement due to fraud.				
• How management could perpetrate and conceal fraudulent financial reporting.				
• How the company's assets could be stolen.				
• External and internal factors that might create incentives/pressures, provide opportunities, or enable rationalization of fraud.				
• The nature and risk of management override of controls.				

# *Step*

## 4

# Risk Assessment

- **Other Risk Documentation:**
  - Materiality
  - Analytical Review
  - Preliminary Understanding of Business
  - Identify Significant Estimates

# *Step*

## 5

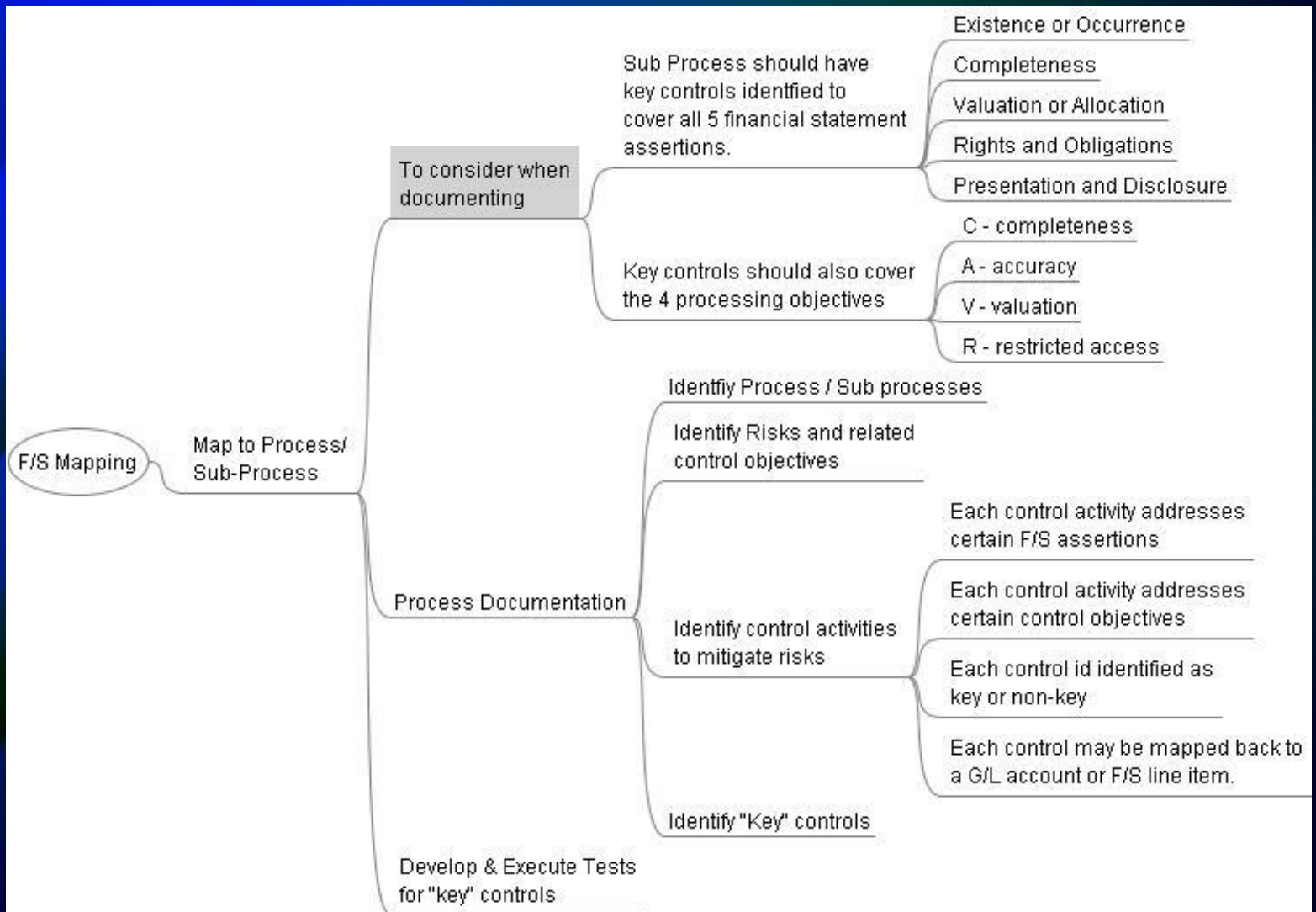
# “Mapping” PCAOB AS#2

- Significant Accounts and Disclosures
- Significant Business Units or Locations
- Relevant Assertions
- Major Classes of Transactions
- Significant Processes and Sub processes over major transactions
- Internal Controls over major classes of transactions
- Evaluate likelihood, magnitude and other controls.
- Determine which controls should be tested

# Step

# 5

# “Mapping” PCAOB AS#2



**Step**

**6**

# Company Level Controls

- **COSO Control Environment**
  - Integrity & Ethical Values
  - Commitment to Competence
  - Board of Directors/Audit Committee
  - Management's Philosophy and Operating Style
  - Organizational Structure
  - Assignment of Authority & Responsibility
  - HR Policies and Procedures



# Step

# 6

# Company Level Controls

## COSO Risk Assessment

### COSO:

Risk Assessment	Has management developed a fraud risk assessment and monitoring program that is appropriate for the size and complexity of the entity, including identifying fraud risks and taking appropriate action to reduce or eliminate the risks?	yes
	Does management assess the effect of the following conditions on the company's ability to prepare financial statements that are free from material misstatement:	x
	Changes in the company's operating environment?	x
	New personnel?	yes
	New or revised information systems?	x
	Rapid growth?	x
	New technologies in production processes or information systems?	x
	New business models, products, or other business activities?	x
	Restructuring or reorganization and resulting staff reductions, changes in supervision, or segregation of duties?	
	Is sufficient timely information available to assist management in identifying and managing risks relevant to financial reporting?	
	If there are risks relevant to financial reporting that management has decided to accept because of cost or other considerations, are the effects considered to be immaterial to the financial statements?	
	Does management make assessments of new accounting issues or pronouncements?	
	Does the company have a disaster recovery plan?	
	Does the company's risk assessment process include an assessment of the company's vulnerabilities to fraudulent activity and whether any of those exposures could result in material misstatement of the financial statements?	
Has the company attempted to identify the processes, controls, and other procedures needed to mitigate identified fraud risks?		

***Step***

**6**

# **Company Level Controls**

- **COSO Information & Communication**
- **COSO Monitoring**

# *Step*

## 7

# Accounting Controls

- **Company Level Controls**
  - Period End Closing Activities
  - Significant Estimates
  - Application of GAAP
  - General Ledger

***Step***

**8**

# **Design of Controls**

- **Narratives**
- **Evaluation of Design**

# *Step*

## 9

# Operating Effectiveness

- **Test of Controls**
  - Daily
  - Monthly
  - Quarterly
  - Once a year
  - Establish sample size

# *Step*

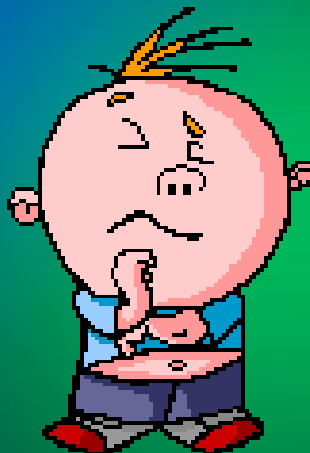
## 10

# IT Controls

- **General Controls**
  - Design of IT environment
- **Application Controls**
  - Effectiveness of controls

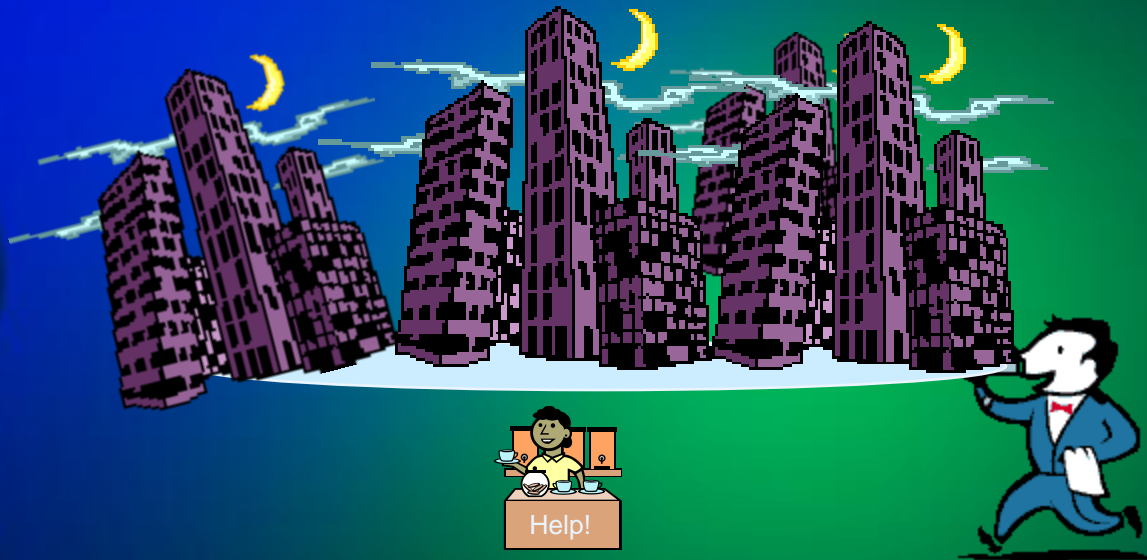
# PITFALLS to Avoid

- Plenty of Time



# PITFALLS to Avoid

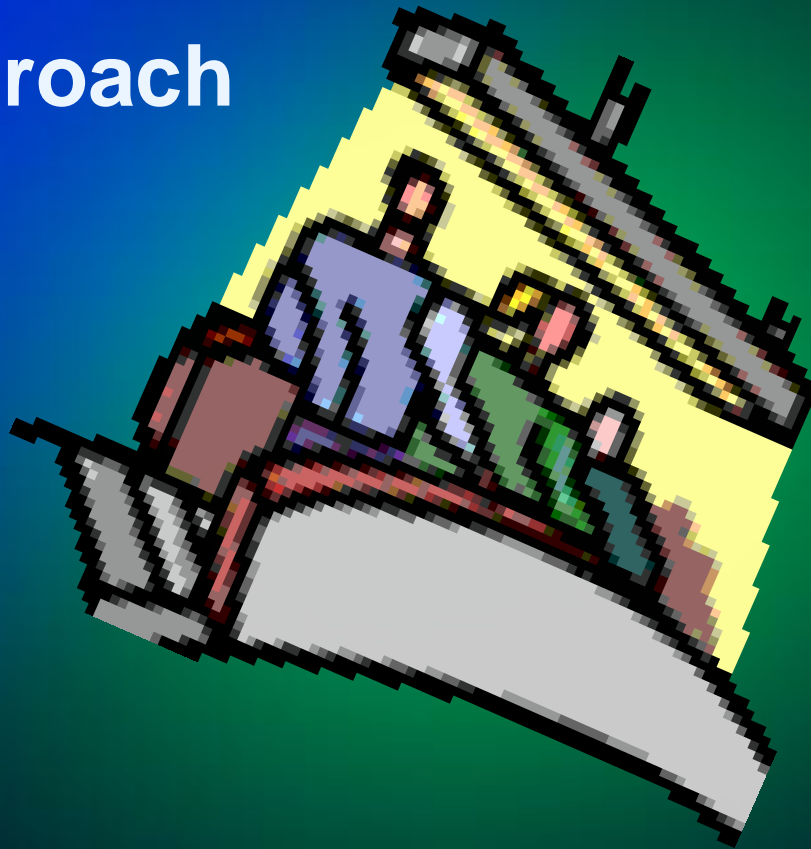
- Framework





# PITFALLS to Avoid

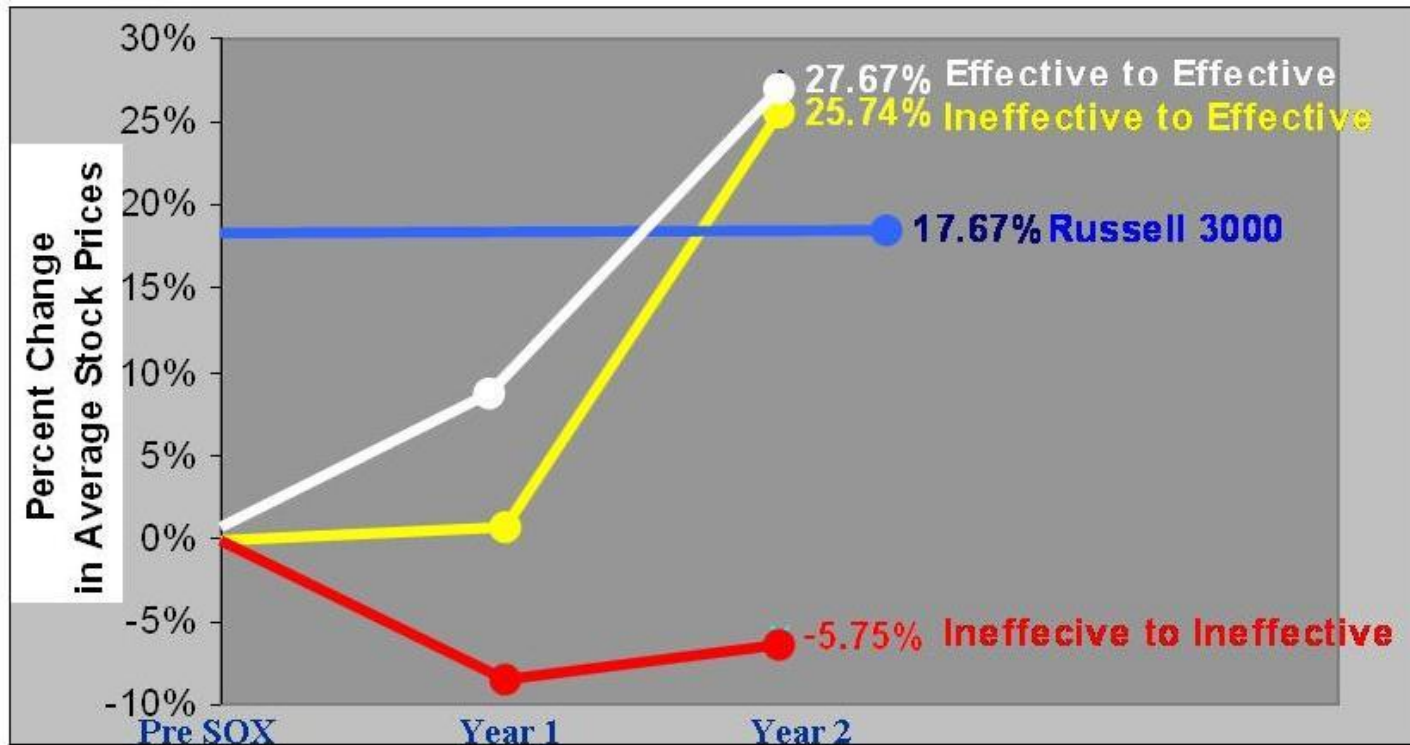
- Approach



# PITFALLS to Avoid

Costs Exceed the Benefits

**Good Sarbanes-Oxley Section 404 Internal Controls  
Corresponded with Higher Share Price Movement**



Source: Lord & Benoit, LLC

# SOX Section 404 Compliance

*For Smaller Biotech, Pharmaceutical  
and Life Science Companies*

Questions?



[www.Section404.org](http://www.Section404.org)

Bob Benoit 800-404-7794x204