



# **Sarbanes Oxley**

## **Impacts in 2005 and Beyond**

Presented by

**Robert Rausch, CPA**

Consultant

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

# Presentation Topics

- Key Areas to focus, Risks & Controls - Pharmaceutical Companies
- Strategies to move from “Project” to “Process” for Sustainable Compliance
- Best Practices for Future Compliance Efforts

## Key Issues for SOX Compliance – Pharmaceutical Companies

- Revenue Recognition
- Inventories
- Medicaid Accruals
- Product Revenues & Trade Accounts Receivable
- Environmental Liabilities
- Pension, Other Post Retirement Benefits Assets, Liabilities, & Related expenses

## Revenue Recognition-Areas to focus

- Income derived from new revenue streams like licensing, co-marketing & co-development contracts
- Thorough review of both the detailed agreement and the appropriate accounting procedure
- Review the proposed agreement with the legal team & external auditor before it is signed
- Documenting the process due to the unique nature of each “deal”

# Revenue Recognition-Key Risks & Controls

Key Risks	Controls
Income from new revenue streams	<ul style="list-style-type: none"><li>• Company accounting personnel are consulted throughout the negotiations</li><li>• Management reviews the agreements and documents the appropriate accounting treatment</li><li>• The final contract and accounting instructions are sent to the appropriate individuals to appropriately record the transaction</li></ul>
Income is misclassified in the income statement	<ul style="list-style-type: none"><li>• Evaluation &amp; determination of whether such income represents revenue or other income</li></ul>
Disbursements or receipts made in accordance with the contract are inappropriately recorded in the financial statements	<ul style="list-style-type: none"><li>• Perform account reconciliations</li><li>• Non standard journal entries should be subject to review &amp; approval</li></ul>

# Inventory- Areas to focus

- Controls over inventory procurement and monitoring of approved vendor listings
- Physical existence controls
- Assumptions to calculate inventory reserve and frequency of updates
- Documenting & justifying inventory reserves

# Inventory- Key Risks & Controls

Key Risks	Controls
Vendor, product master files not controlled	<ul style="list-style-type: none"> <li>• User access &amp; program change controls to be set in place</li> <li>• Periodic review of user rights</li> </ul>
Goods received, inventory not recorded	<ul style="list-style-type: none"> <li>• Cycle count, physical existence testing</li> <li>• Inventory recording requires identification, PO number before receipt</li> </ul>
Purchase price variance (PPV) is not calculated upon receipt of inventory	<ul style="list-style-type: none"> <li>• System verifies 2/3 way match and records, reports PPV</li> </ul>
Incorrect inventory at third party locations	<ul style="list-style-type: none"> <li>• Cycle counts performed at significant third party locations and results are reviewed and approved by management</li> </ul>
Excess & obsolete reserves are inaccurate	<ul style="list-style-type: none"> <li>• Reserves assumptions are compared to previous quarter &amp; reviewed</li> </ul>
Inventory per GL not agreed to sub ledger	<ul style="list-style-type: none"> <li>• Monthly book to physical reconciliations</li> </ul>

## Medicaid Accruals- Areas to focus

- Appropriate estimation of Medicaid rebates that are due to state agencies
- Historical rebate/discount payments by various customer groups
- Evaluating current Medicaid rebate laws/interpretations
- Estimating products sold to Medicaid participants, and other pricing/discount contracts

# Medicaid Accruals- Key Risks & Controls

Key Risks	Controls
Relevant assumptions are not updated or utilized in the ending accrual analysis	<ul style="list-style-type: none"><li>• Management to review assumptions quarterly</li><li>• Ending accrual analysis is reconciled to the TB monthly</li></ul>
Appropriate rebate amounts are not recorded in a timely manner	<ul style="list-style-type: none"><li>• The system automatically records the rebate % based on information developed from the accrual model</li><li>• Sales rebate amounts are reconciled to the GL monthly</li></ul>
The remittances of rebates are not authorized, not accurate, and not made in a timely manner	<ul style="list-style-type: none"><li>• All disbursements are reviewed &amp; reconciled to the supporting invoices</li><li>• An analyst reviews the payment trend report</li><li>• Cash &amp; Medicaid liability accounts are reconciled monthly</li></ul>

## Product Revenues & Trade Accounts Receivable - Areas to focus

- Build controls around reserves for inventory returns & other rebate programs
- Revenue recognition issues-channel stuffing, consignment sales etc
- Establish processes to estimate returns and determine the appropriate value of the sales transactions

# Product Revenues & Trade Accounts Receivable- Key Risks & Controls

Key Risks	Controls
Revenue & accounts receivable do not represent valid claims against the customer	<ul style="list-style-type: none"> <li>• Shipments are only recorded to customers with a valid order form and the appropriate license</li> <li>• Management reviews the level of inventory in the channel, compared to prior periods &amp; expectations to detect indicators of "channel stuffing"</li> </ul>
All amounts chargeable to customers have not been recorded in the financial statements	<ul style="list-style-type: none"> <li>• IT system automatically invoices all items which have been shipped</li> <li>• Daily reconciliation of quantity shipped to quantity billed</li> </ul>
Pricing is not approved or is inaccurate	<ul style="list-style-type: none"> <li>• Management reviews all new contracts on a monthly basis to ensure appropriate pricing is utilized</li> <li>• All pricing changes are reviewed &amp; approved by the appropriate supervisor</li> </ul>

## Environmental Liabilities- Areas to Focus

- Assessment of the accounting impact of outstanding environmental liabilities
- Consideration of FAS 143 for environmental matters involving asset retirement obligations
- Provisions for environmental cost as part of the budgeting & forecasting process
- Increased use of environmental engineering and consultants to prepare cost estimates

# Environmental Liabilities- Key Risks & Controls

<b>Key Risks</b>	<b>Controls</b>
Contingent Liabilities are not identified	<ul style="list-style-type: none"><li>Plants are required to submit quarterly environmental assessment</li><li>Communication with EPA or other agencies is discussed with management</li></ul>
Contingent liabilities are not properly measured or recorded	<ul style="list-style-type: none"><li>Factors considered &amp; assumptions used in the assessment of the probability and the basis for conclusions reached are documented, reviewed &amp; applied consistently</li></ul>
Contingent liabilities are not properly monitored	<ul style="list-style-type: none"><li>Meetings between legal and accounting management teams are conducted prior to each 10-Q/K filing</li></ul>

## Pension, other post retirement benefits (OPEB) assets, liabilities, & related expenses-Areas to Focus

- SEC focus on accounting for and disclosure of certain pension/OPEB assets, liabilities & related expenses
- Estimating the expected long term rate of return on investment based on a earnings of a portfolio with a similar asset allocation
- Discuss in MD&A the uncertainties associated with the underlying significant estimates, and the potential for material impacts on either the results of operations or cash flows

# Pension, other post retirement benefits (OPEB) assets, liabilities, & related expenses-Key Risks & Controls

Key Risks	Controls
Expenses are not identified & recorded in the proper period	<ul style="list-style-type: none"> <li>• Standard list of procedures/calculations is used</li> <li>• Pension/OPEB journal entries are reviewed prior to posting</li> <li>• A reconciliation between the balance sheet and actuarial statements is performed</li> <li>• Accrued benefit obligation is compared to the fair value of plan assets</li> </ul>
Calculations are based on inaccurate underlying data	<ul style="list-style-type: none"> <li>• Actuarial data and submissions received from the actuary are compared to prior periods</li> <li>• Actuaries report is reviewed by accounting &amp; HR departments for reasonableness</li> </ul>
Plans are inadequately funded	<ul style="list-style-type: none"> <li>• Reconciliation of balance sheet accounts to actuarial report</li> <li>• Segregation of responsibilities- approving plan funding and recording plan funding</li> </ul>

# Strategies to move from “Project” to “Process”

- Think long term
  - Achieve sustainability of compliance efforts
  - Achieve value add
  - Achieve cost effectiveness

# Think long term

- Achieve sustainability of your compliance efforts
  - Build a compliance approach that will withstand scrutiny over time as change occurs
  - Build the right organization structure to facilitate ongoing compliance
- Achieve Value Add
  - Improve financial processes quality, time & cost performance

# Examples of Value Add Areas & Opportunities

- GL close times significantly below peers
- Increasing demand for timely analytical information
- High error rates in financial transaction processes
- Unusually high number of manual JE's
- High dependency on spreadsheets
- Limited return on investments in IT assets
- Cost reduction pressures to offset SOX compliance cost

# Think long term-Achieve cost effectiveness

- Increase the effectiveness of entity & process level monitoring
- Improve the mix of controls ( both automated Vs manual & preventive Vs detective)
- Complete the remediation of prior year deficiencies
- Improve the anti fraud program
- Increase the effectiveness of period end financial close process

# Best Practices for future compliance efforts

- Improve the quality of the internal control structure & then design the compliance process around the improved structure
- Revisit SOX compliance organizational infrastructure
  - Integrate SOX 404 & 302 compliance processes
  - Assess change readiness
  - Formulate the current year's compliance approach
  - Understand & select appropriate technology solutions

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# Best Practices for future compliance efforts

- Clarify responsibility & accountability
  - Define roles, responsibilities & resource program support
  - Align audit plan with SOA related management & audit committee expectations
  - For organizations with outsourcing relationships- clarify responsibilities around SAS 70 assurance process

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# Best Practices for future compliance efforts

- Design change recognition process
  - Define the “as is” policy and processes for recognizing change
  - Evaluate the effectiveness of disclosure controls & procedures
  - Define responsibility for evaluating the reporting implications of change
  - Define responsibility for updating controls documentation for change

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# Best Practices for future compliance efforts

- Employ filtering to focus primarily on the key controls
- Use self assessment
- Focus risk assessment on business risks rather than on financial reporting risks

**Thank You**

