

*The Thirteenth Annual* —————  
**Pharmaceutical Regulatory and Compliance Congress**  
————— *and Best Practices Forum*



**Pre-Conference III:  
A Comprehensive Overview of  
Pharma and Medical Device CIAs  
and Lessons Learned!**

November 5, 2012

# Pre-Conference III – Overview of CIAs

## THE PANEL

- **Wendy Goldstein, Esq.**  
Partner, Epstein Becker & Green, New York, NY (Moderator)
- **Tracy Mastro**  
Senior Director, Life Sciences, Huron Consulting Group, Washington, DC
- **Paul Silver**  
Managing Director and Practice Leader, Life Sciences, Huron Consulting Group, Atlanta, GA (Moderator)
- **Paige Slater, PA-C**  
Global CIA Program Director, Corporate Ethics & Compliance, Synthes, Inc., West Chester, PA
- **Bert Weinstein, Esq.**  
Vice President, Corporate Compliance, Purdue Pharma LLP; Former Member, PCF Executive Committee, Stamford, CT

*The views expressed today are those of the speakers and not necessarily those of the companies/firms they represent.*

# Agenda

WHAT WE WILL COVER

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8:30 – 9:45 am                      CIA Implementation – The First 120 Days

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9:45 – 10:30 am                    Additional Lessons Learned from New and  
Sunsetting CIAs and Case Study

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10:30 – 10:45 am                    BREAK

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10:45 – 11:45 am                    Additional Lessons Learned

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# Audience Survey

## QUESTIONS FOR YOU

- **Who is from Pharma? Medical Device? Other?**
- **Who is from Industry?**
  - Compliance?
  - Legal?
  - Marketing?
  - Sales?
  - Sales Ops?
  - HR?
  - R&D?
- **Government?**
- **Consulting?**
- **CIA or no CIA?**
  - 1<sup>st</sup> Year? 2<sup>nd</sup>? 3<sup>rd</sup>? 4<sup>th</sup>? Final Year?
- **Who has worked under more than one CIA?**



# CIA Implementation – The First 120 Days

GETTING STARTED – YOU CAN DO IT!

- First things first...

buy 3 bottles of champagne!

*Explanation to follow...*



# CIA Implementation – The First 120 Days

## GETTING STARTED – FOCUSING YOUR EFFORTS

- Don't wait for the 120-day clock to start
  - Selection of Outside Counsel
  - Selection of IRO
  - CIA Readiness Assessment Partner
  
- Communicate, communicate, communicate
  - Engage support from key stakeholders and assemble a leadership “CIA Steering Team”
  - Establish a “CIA Philosophy” (e.g., CIA activities become part of business routine)
  - Communicate importance of individual responsibility and accountability when it comes to compliance matters



# CIA Implementation – The First 120 Days

## GETTING STARTED – FOCUSING YOUR EFFORTS

- Plan, plan, plan...and plan some more
  - Break down the CIA requirements into manageable work streams
  - Conduct a gap analysis of policies, procedures, systems & processes
  - Assign work stream responsibilities to CIA Steering Team
  - Assign an experienced Project Manager to manage the overall CIA
- Anticipate resource challenges
  - CIA will absorb compliance resources
  - Compliance must continue to support both daily business operations as well as CIA
  - Consider headcount needs in terms of skills, capabilities



# CIA Implementation – The First 120 Days

## GETTING STARTED – STAFFING AND RESOURCES

- Identify important partnerships and understand their value under the CIA
  - Law & Compliance
  - HR Business Partners
  - IT (infrastructure and support)
  - Commercial groups (including Sales, Sales Management, Sales Operations)
  - QA/Regulatory Support (for FDA-related reporting)
  - Senior Executives & Management Team (e.g., Compliance Committee)
  - Certifying Employees (who are they? Are there sub-certifiers)
  - Board and Board certifications (if applicable)





# CIA Implementation – The First 120 Days

## GETTING STARTED – MANAGING RELATIONSHIPS

- Manage Relationships with External Groups
  - OIG Monitor
  - Independent Deferred Prosecution Agreement (DPA) Monitor
  - Independent Review Organization (IRO)
  - Mock IRO/CIA Readiness Assessment Reviewers
  - Independent Board Expert Reviewers



# CIA Implementation – The First 120 Days

GETTING STARTED - IDENTIFY WHAT EXISTS, WHAT IS NEEDED

- Reports
  - Understand what company needs to report each year through its Annual Reports and Implementation Report
  - Develop processes and systems that will be able to provide Compliance with what it needs to develop each report
- Policies & Procedures
  - Existing/New Policies need to reflect CIA requirements
  - Work instructions/work flows should be reviewed or developed to reflect processes and satisfy CIA language
  - Consider developing an SOP on management of the CIA and training relevant employees on the SOP

# CIA Implementation – The First 120 Days

GETTING STARTED - IDENTIFY WHAT EXISTS, WHAT IS NEEDED

- Systems/Data Repositories – understand the operational limitations in meeting CIA requirements and quickly address them
  - Training Systems
    - Do you have a Learning Management System (LMS) that can handle CIA requirements?
    - Can you get timely, accurate reports on training?
    - Do you have a training and communication strategy that will continue throughout each year of the CIA?
    - Does the system allow for automated messages to remind employees of incomplete training?
    - Do your HR systems interface with the LMS (e.g., changes in employee jobs require changes in training curricula)?
    - Are job profiles linked to a training platform in LMS?



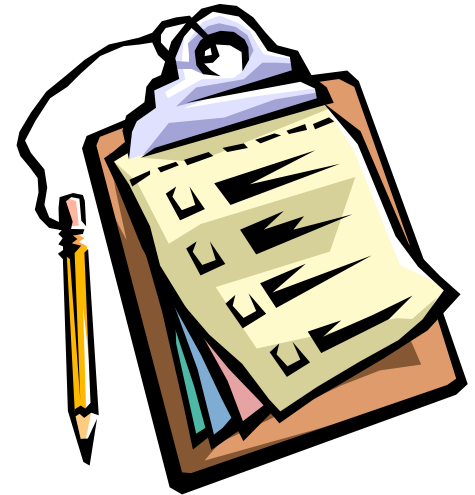
- Systems/Data Repositories (cont'd)
  - Software/Data Systems
    - Are data/software systems sustainable and do they operationally address the CIA requirements?
    - The more manual the processes, the higher the potential error rates
    - Reduce risk and error by improving processes and automating them as much as possible



# CIA Implementation – The First 120 Days

IDENTIFY WHAT EXISTS, WHAT IS NEEDED

- Other Important Processes
  - Covered Persons
  - Compliance Monitoring & Auditing (commercial and non-commercial activities)
  - Management Certifications
  - Needs Assessments, Budgeting Plans and FMV
  - Ineligible Persons Screening
  - Transparency
  - Sales representative incentive compensation



***15 Minute Break***

# **Additional Lessons Learned from New and Sunsetting CIAs**

# Additional Lessons Learned

## CASE STUDY – COVERED PERSONS

### Goal:

Meeting the obligations of your CIA regarding the identification, notification and training of “Covered Persons”

### Considerations for Achieving Goal:

1. How will you identify your existing Covered Persons (i.e., U.S. and global employees, contractors, vendors)?
2. How will you notify your Covered Persons regarding their CIA and training obligations?
3. How will you train your Covered Persons?
4. Who will be responsible for Covered Persons on a go-forward basis?



### Potential Topics:

- The challenges, obligations, and impact on the Compliance organization and business functions
- Biggest unanticipated obstacles/challenges implementing a CIA
- Insights from the OIG Roundtable discussions
- What is OIG hoping to accomplish through CIAs?
- FDA Components of Recent CIAs
- Maintaining an effective Compliance Program post-CIA
- *Friedman vs. Sebelius* and Executive exclusions from Federal programs

# Today's Panel

## CONTACT INFORMATION

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