Corporate Compliance for the Pharmaceutical and Medical Device Industries

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Agenda

- Current Compliance Environment
- Compliance Program Design and Evolution
- Internal/External Audits of Company Practices
- CIAs, IROs and Key Negotiation Points
- Using SOP 99-1 To Set Agreed-Upon Procedures
- Discussion and Questions & Answers

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Current Compliance Environment

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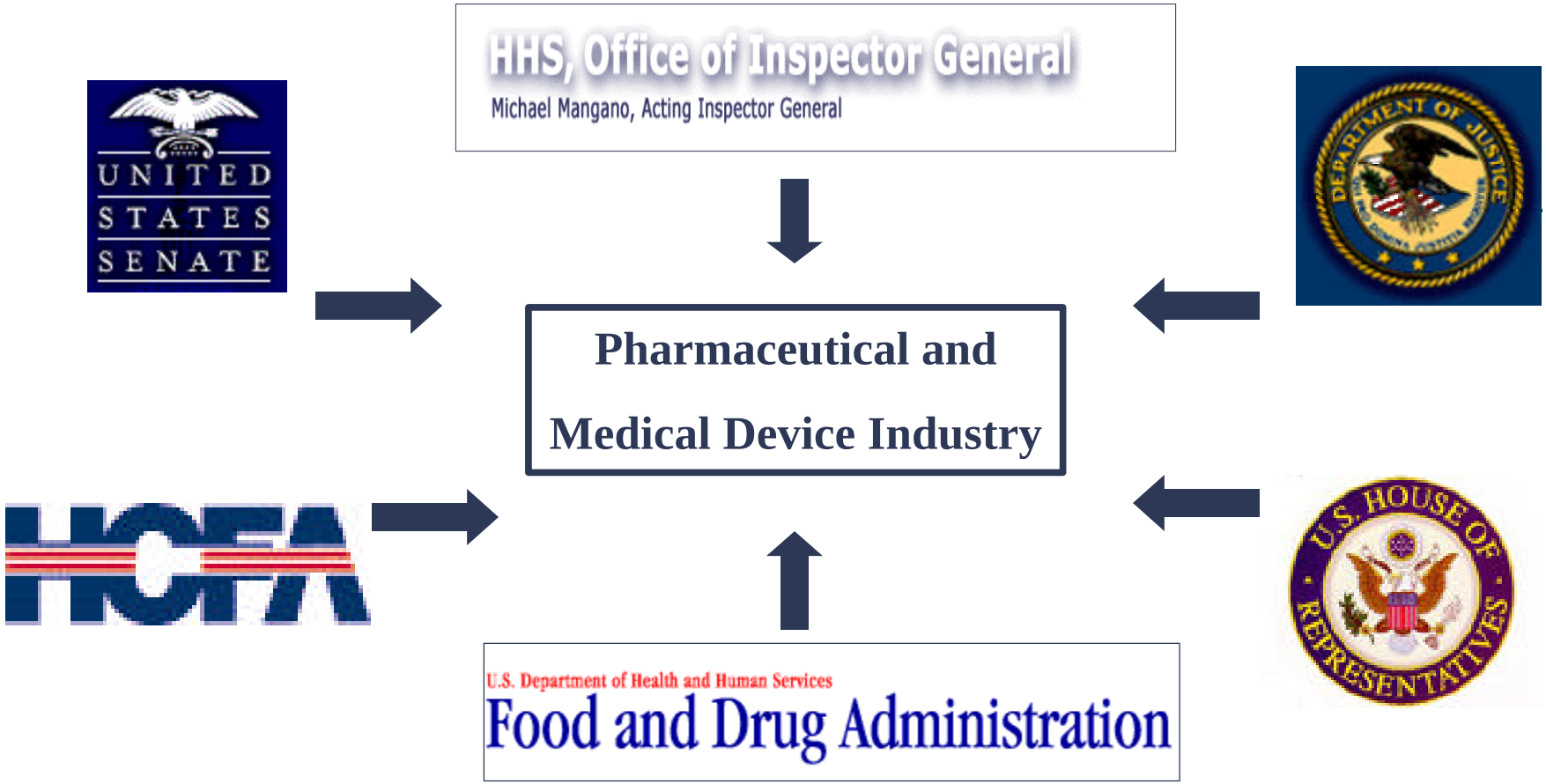
Current Compliance Environment



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Current Compliance Environment

Names in the News

1. TAP Pharmaceuticals

2. Bayer Corporation

3. Schering-Plough

4. Bristol-Myers Squibb

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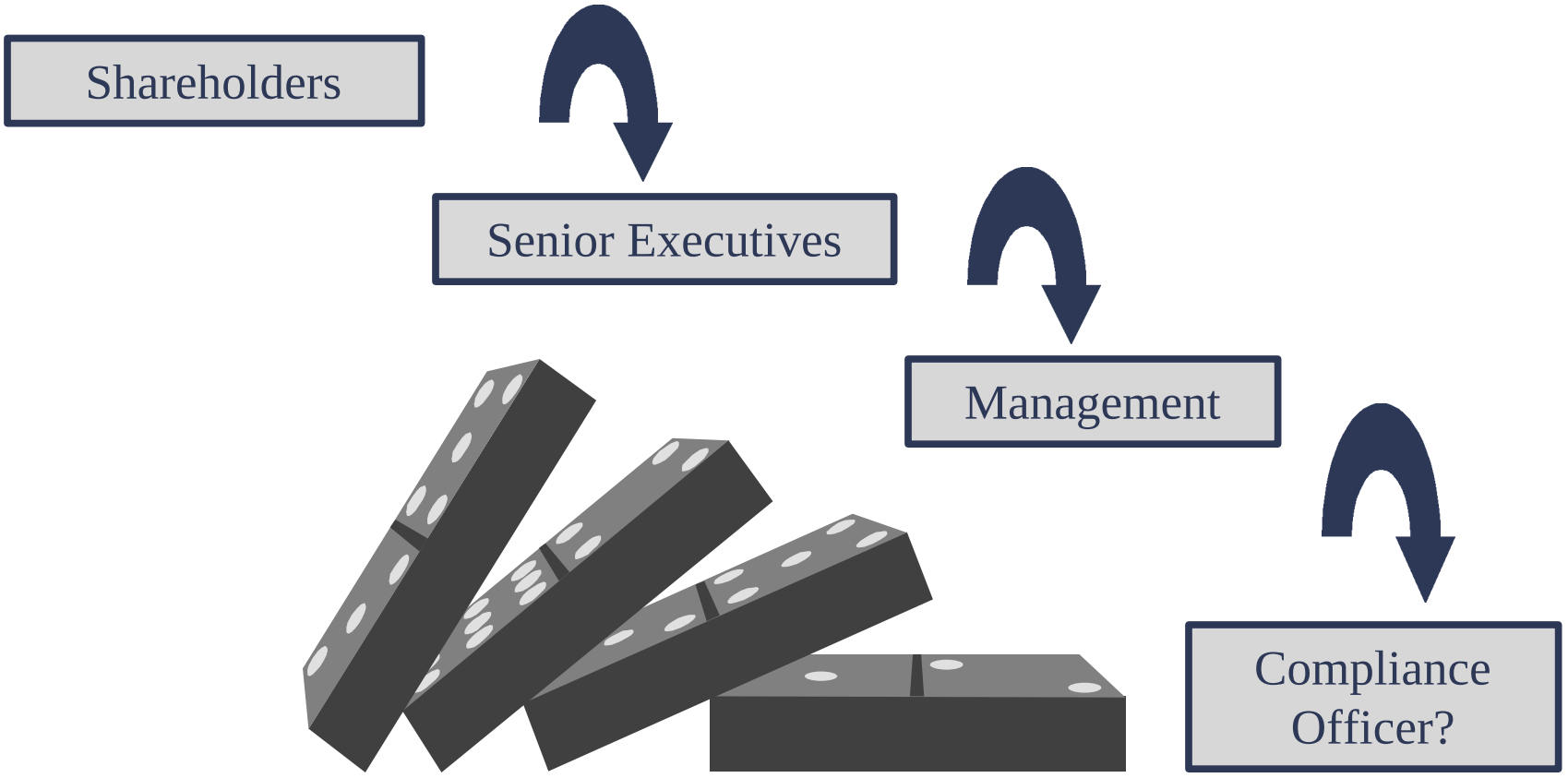
Current Compliance Environment



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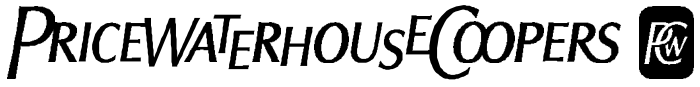
Compliance Program Design and Evolution



Compliance Program Design and Evolution

A compliance program is a management process comprised of formal reporting structures and risk mitigation systems designed to motivate, measure, and monitor an organization's legal and ethical performance around complex business practices.

-- It's More Than GXP

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Compliance Program Design and Evolution

Simply Put - Compliance is Reaffirming Your Commitment to Uphold the Laws Which Govern

- **Federal agencies**
  - Consumer Product Safety Commission,
  - Drug Enforcement Administration,
  - Department of Transportation,
  - Environmental Protection Agency
  - Federal Aviation Administration,
  - Federal Trade Commission,
  - Food and Drug Administration,
  - Nuclear Regulatory Commission
  - Occupational Safety and Health Admin
  - Security and Exchange Commission
- State Laws
- International Laws

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Compliance Program Design and Evolution

Factors Driving Pharmaceutical and Device Compliance Program Evolution:

1. Healthcare industry spill-over
2. Enhanced scrutiny
3. Qui Tam activity
4. Market competition
5. The wildcard: Medicare drug benefit

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Compliance Program Design and Evolution

Elements of Model Compliance Program Initiatives

1. Written Standards of Conduct
2. Written Policies and Procedures
3. Designate a Chief Compliance Officer
4. Education and Training for All Employees - At Least Annually
5. Audit to Monitor Compliance
6. Discipline Employees Who Have Engaged in Wrongdoing

Compliance Program Design and Evolution

Elements of Model Compliance Program Initiatives

7. Investigate and Remediate Identified Problems
8. Promote Compliance as an Element in Evaluating Managers and Supervisors
9. Policy to Include Termination as an Option for Sanctioned Individuals
10. Maintain a Hotline to Receive Complaints and Ensure Anonymity of Complainants
11. Create and Maintain Required Documentation

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Internal/External Audits of Company Practices

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Internal/External Audits of Company Practices

U.S. Sentencing Commission
Vice Chair, John R. Steer

"I think the guidelines may need to say something more about the need to have ongoing auditing and testing of a compliance program on paper to ensure that it is effective in practice."

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Internal/External Audits of Company Practices

Why Perform Ongoing Auditing and Testing?

1. Need to know the strengths and weaknesses of your program

2. Effectiveness measurement can help with fiscal decision-making and management of resources

3. Need to demonstrate to outside observers that your program is working (helpful when negotiating settlements/CIA)

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Internal/External Audits of Company Practices

Current Area of Scrutiny - Sales and Marketing

1. Contracting and Incentives
2. Marketing and Promotional Activity
3. Samples Management

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Internal/External Audits of Company Practices

Contracting and Incentives

- Interview staff from contract marketing, sales and product marketing to understand and map established controls. (Can field sales write contracts/make deals?)

- Select a representative sample of contracts by customer class (GPOs, Specialty Distributors, IDNs/Hospitals, Home Care, Renal, etc.)

- Review contracts for key issues such as:
  - Volume Discounts (Divisional Participation, Early Participation, Participation, Performance, Shareholder Compliance, Standardization, Tiered Pricing)
  - Special GPO Payments (Administrative Fees, Commitment/Marketing/Growth Fees)
  - Conversion/Trade-In Allowances
  - Free Goods/Services (also hidden as trials)

Internal/External Audits of Company Practices

Contracting and Incentives

- Bundled Programs
- Temporary Price Promotions (Introductory Pricing, Special Deal Pricing)
- Chargebacks
- Other (Capital Acquisition, Depreciation, Trademark Agreement, Data Agreement, Contract Extension)

- What's in the DMs filing cabinet?

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Internal/External Audits of Company Practices

Marketing and Promotional Activity

- Interview staff from sales and product marketing to understand and map budgeting process and controls, as well as major CME and promotional programs.
- Interview training and education to understand extent to which representatives are trained on regulatory requirements and organizational policies and procedures.
- Select a representative sample of sales representative expense reports to understand true use of promotional/educational funds
  - Check Compliance with AMA Guidelines
  - Check Compliance with Government Gratuity Regulations
- What's in the DMs war-chest?

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Internal/External Audits of Company Practices

Marketing and Promotional Activity

- Program Sponsorships (Health Fairs, Assoc. Meetings, Educational Programs)
  - Check No Preferential Status for Products
  - Check Direct Payment for Cost of Programs
  - Check Focus on Business, Not Recreation
- Educational Grants
  - Check Objective Presentations
  - Check Control by Educational Provider

Internal/External Audits of Company Practices

Samples Management

- Review existing procedure manuals, SOPs, reconciliation data, flowcharts, sample management documents, other pertinent materials, and interview key managers, staff, and sales representatives to gain a deeper understanding of the existing process.
  - Labeling of samples,
  - Process for requests/receipts for samples,
  - Content of requests/receipts,
  - Internal controls for receipt non-compliance,
  - Inventory & reconciliation processes,
  - Investigation of falsified records/diversion,
  - Distribution of samples to charitable institutions, and
  - Threshold established for significant loss.

Internal/External Audits of Company Practices

Samples Management

- Compare actual field sales and sales administration activities being performed against SOPs, PDMA regulations, and industry best practices.

- Based on the results of the steps above, perform a gap analysis between existing practices and the PDMA regulations and develop a risk assessment of any identified gaps.

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Corporate Integrity Agreements, Independent Review Organizations and Key Negotiation Points

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Corporate Integrity Agreements

- Over 420 CIAs on record
- Typically 3 to 5 years in duration (precedent being set for 8 years for high-profile providers)
- Requires corporate integrity program
  - Compliance oversight structure
    - senior management
    - not the CFO or GC
    - regular reports to the CEO and/or Board
    - Compliance Committee
  - Written policies and procedures to be established
    - Code of Conduct (content & distribution)
    - element in evaluating performance
    - policies for complying with all laws & regulations

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Corporate Integrity Agreements

- Training & Education
  - General Training (within 120 days, 2 hours, all employees)
  - Specific Training (within 90 days, 4 hours, covered employees)
- Annual audits reported to OIG (internal/external)
- Confidential Disclosure Program (24hour/7days)
  - non-retribution, promotion, anonymous
- Pre-screening of potential hires (excluded, suspended, debarred)
- Audits of billings to Federal health care programs

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Independent Review Organization

- IRO independence can be an issue
- Ensure that the IRO is expert in your business
- Two types of reviews -
  - Performance or Billing review
  - Compliance review
- IRO function can be “negotiated”
  - Ambiguity
  - Attach a work plan
  - Transition work away from IRO to organization

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CIA Challenges

- Agreed upon procedures should be agreed upon at signing date
- OIG resources and understanding
- CIAs must be written so that they may be objectively tested
- Difficult to do for entities that have not implemented compliance programs
- Requires evaluation of current processes and controls and planned or future processes and controls

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Negotiation Points

- Sampling - the OIG is considering a change in position on sampling. Could go to a SAS program rather than RAT-STATs to reduce sample sizes.
- Trigger Clauses - build triggers into your probe (usually 5% error before need to go to full sample).
- Compliance Engagement - should only be for one year
- Transition work from IRO to compliance or internal audit in later years

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Stipulated Penalties

- $2,500 per day fine for failure to have...
  - Compliance Officer
  - Compliance Committee
  - Code of conduct
  - Polices and procedures
  - Training program
  - Confidential disclosure program

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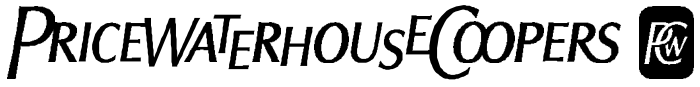
Stipulated Penalties

continued

- $2,000 per day fine for failure to…
  - Hire or contact with ineligible person
  - Employ or contact with an ineligible person who deals with Federal programs or who is paid by such programs
  - Employ or contract with an ineligible person who has been charged with a criminal offense or is suspended or proposed for exclusion
- $1,500 per day fine for failure to…
  - Grant OIG access to information or documentation

Using SOP 99-01 to Set Agreed Upon Procedures



Objective of SOP 99-01

- Guidance for conducting and reporting on an "Agreed-upon procedures" engagement to assist health care organizations in evaluating effectiveness of its corporate compliance program

- ***Objective***: Perform procedures and present findings, if applicable, to assist users in evaluating compliance

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Evolution of SOP-99-01

OIG

Signing of CIA

Compliance Assessment and Annual Reporting Requirements

Resolution or settlement to establish or promote compliance with Federal health care programs

Organization

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Conditions for Agreed-Upon Procedures

- Management's assertion regarding compliance with the CIA
- Management ***accepts responsibility*** for such compliance
- Management evaluates compliance or the effectiveness of internal control over compliance

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Conditions for Agreed-Upon Procedures

continued

- IRO is independent
- Specified users must take responsibility for sufficiency of procedures
- Criteria to determine findings is agreed-upon
- Use of the report is restricted to specified users (the OIG and the health care organization)

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Key Points for the Engagement Letter

- Confirms arrangements and procedures to be performed
- Delineates responsibilities regarding sufficiency of procedures
- Management's responsibilities regarding compliance and the assertions
- "Substantially less in scope than an examination"
- Limits distribution of report
- Working papers: Who owns and who has access?
- Involvement of a specialist

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Prior to Performing Agreed-Upon Procedures

- IRO must understand requirements of the CIA
- Develop agreed-upon procedures to be performed
- Circulate draft report - agreement by all parties
- No obligations beyond agreed-upon procedures

CIA Requirements

→ **Management's Assertions**

→ **Procedures**

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Example of Agreed-Upon Procedures "Linkage"

CIA Requirement	Assertion	Procedures
Confidential Disclosure Program (CDP) Within 90 days: ➢ Establish a program to enable employees, contractors, agents or other individuals to disclose identified issues in question ➢ Publicize the existence of the hotline	Confidential Disclosure Program (CDP) Our CDP: ➢ Was established within 90 days ➢ Enables any employee to disclose practices or billing procedures ➢ Provides a toll-free telephone line ➢ Has been publicized to be maintained 24 hrs/day, 7 days a week	Confidential Disclosure Program (CDP) We read documentation of the CDP and noted: a) Includes effective date within 90 days of CIA b) Enables any employee to disclose practices or billing procedures c) Provides toll-free telephone line 2. We made five test calls and noted: a) Each call was recorded in logs b) Anonymity is not discouraged

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Using Outside/Inside Resources for Monitoring

- OIG, at its discretion, may permit the organization to utilize internal auditors subject to a review of their work
- Internal or Compliance auditors or other personnel may perform tasks
- Negotiate this up-front

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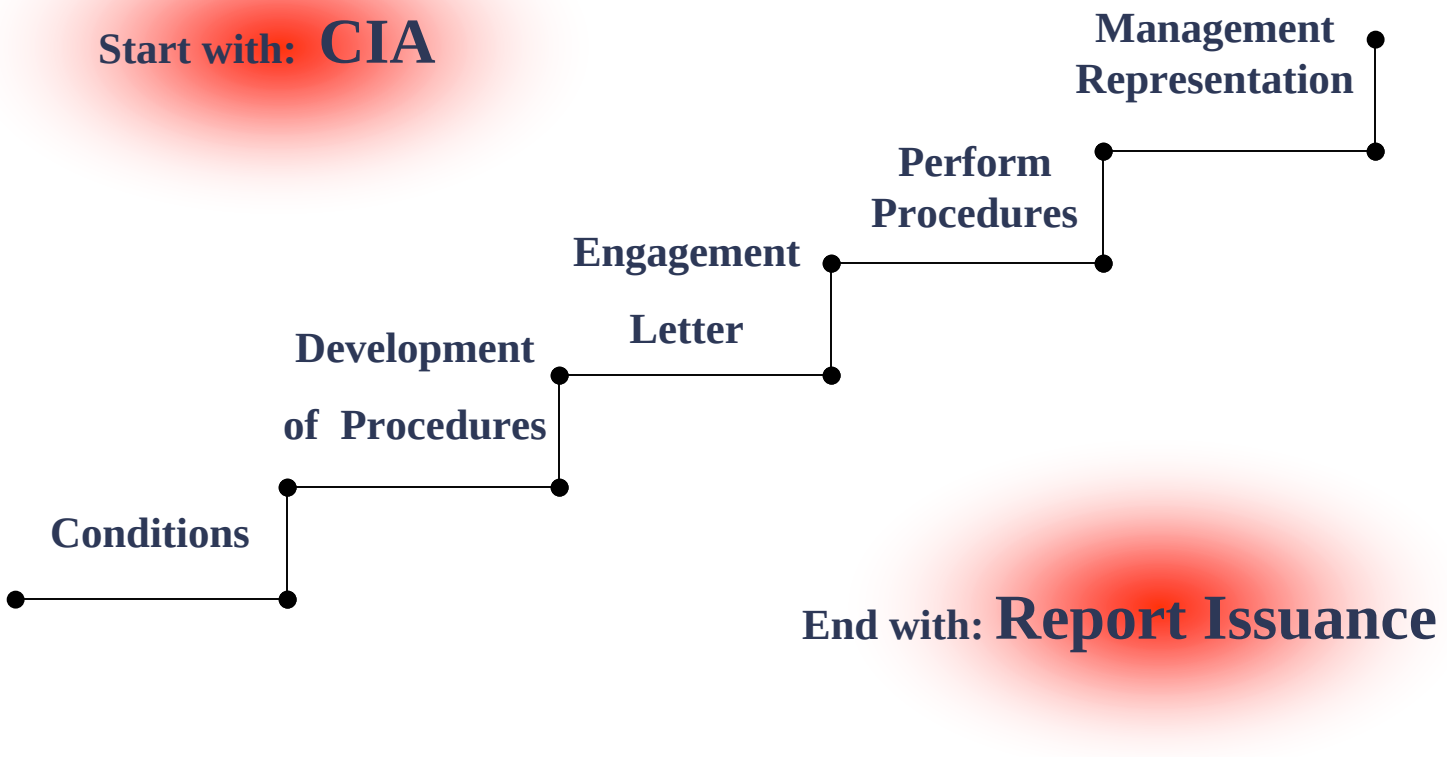
Summary of the Process



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