

Conducting an Internal Investigation

**Seton Hall
Latin America Healthcare Compliance Certification
Program**

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Diana has been Director of Corporate Compliance for Merz Americas since joining the company in July 2018. In her role, she oversees Merz's compliance programs for the US and Latin America. Diana has close to 20 years of pharmaceutical compliance experience in areas such as compliance monitoring and auditing, global policy and program development, and investigations management. She has also held the role of Regional Compliance Officer for Latin America.

Diana has conducted numerous investigations involving fraud, potential bribes/kickbacks, regulatory violations, violations of company policies and procedures, and investigations involving governmental agencies.

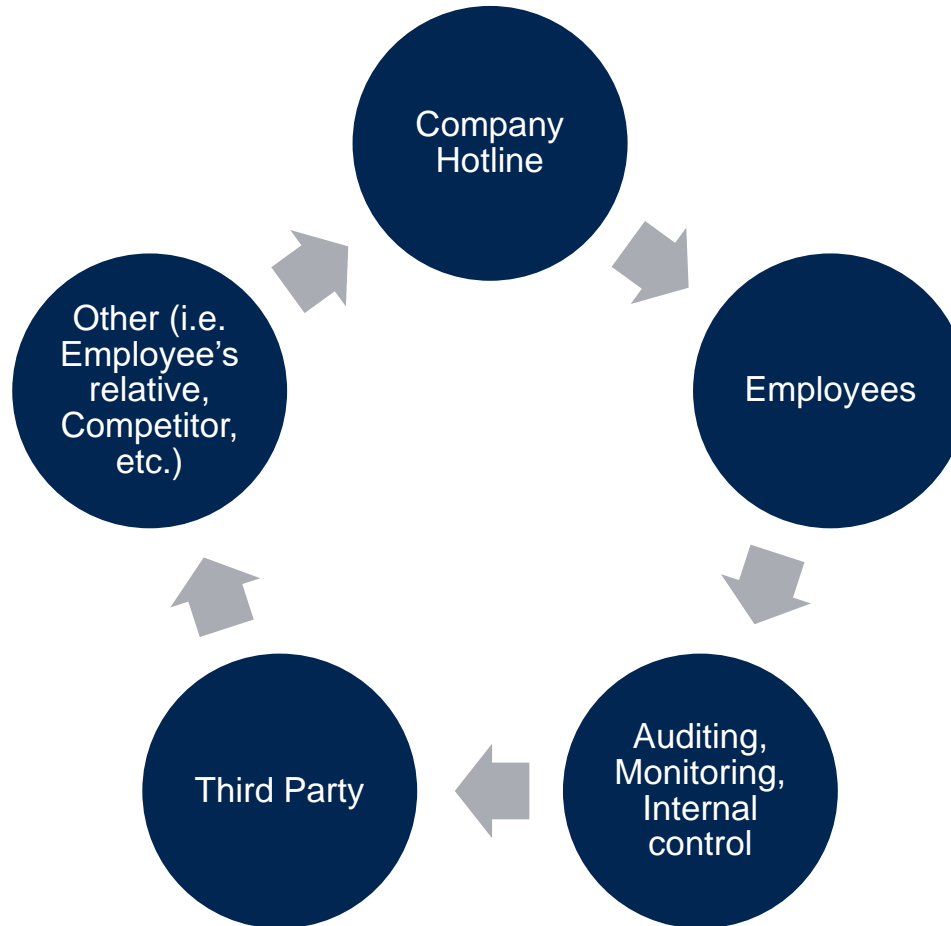


Gildas Durand, EY

Gildas Durand is a Life Sciences Principal at Ernst & Young LLP's Forensic Integrity Services (FIS) with over 20 years of experience. He specializes in assisting American and European companies with developing compliance programs, implementing anti-fraud and corruption tactics, as well as increasing awareness within their international subsidiaries in Latin America. He has performed and led multiple engagements throughout Latin America (from Mexico to Argentina including the Caribbean islands).

Over his career Mr. Durand has developed expert knowledge in compliance assessments; development and implementation of monitoring and auditing programs; prevention and investigation of fraud and corruption (ABAC); fraud risk mapping; internal controls, SOX 404; investigations relating to occupational fraud and embezzlement (e.g., channel stuffing, procurement fraud/ conflict of interests, stock shrinkage, bid rigging. etc.), third party due diligence and audits (e.g., distributors audits). He has been assisting life sciences companies (pharmaceutical and medical device) with distributor compliance audits in Asia, Europe and Latin America for the last 7 years.

Sources of Investigations



Types of Allegation

Fraud

- Bribery/Corruption
- Misappropriation of Assets
- Financial Statements

General compliance policy violations

Promotional (regulatory) violations

Non-compliance related violations (HR, Quality, etc.)

Determining Ownership

Is the allegation compliance related?

Who validates allegation?

- GCO, RCO, Triage Committee, Internal Audit, Legal, HR, Other

Assign to Dept/Lead Investigator

Document in case management system/internal log

Who should the Investigator involve?

HR?

- Consider employment laws in Latam

Management?

- Should the employee's manager always be notified?

Legal?

- Use of privilege
- Other legal challenges

External to the company – external counsel, forensic accountants, other specialists



Investigative Process

Develop investigation protocol

- Consistency throughout the organization
- Minimum requirement in terms of procedures
- Document retention
- Discard vs. retain

Develop a work program / checklist

- Must be fluid

Define the scope of the investigation

- Prove and disprove theories
- Flexibility due to changes or new findings
- How much is too much? Not enough?

E-discovery

Identify custodians:

Identify data available:

Logistics:

- Where and whom?
- Laws and regulations
- Remote / on site

Main steps:

- Collection
- Processing
- Search terms
- Review hits

Reporting:

- Outcomes / logs
- How to use outcome?

Data analytics

Document collection:

- Starts with data request depends on matter
- Knowing where the data is in a global organization and what data privacy and/or labor laws may affect the availability of information as well as the portability
- Hard copy documents – on-site / off-site, third party data
- Electronic documents (financial / other)

Analyze information gathered:

- Trends / identify outliers
- Time lines
- Gap analyses

Reporting:

- How to use outcome?

Interviewing techniques 1/ 2

Objective of the interview

- Informative vs. substantive

Who to interview and why?

Logistics

- Timing? Location? In person, via phone, via video conf?

Who will conduct the interview?

- Do you need witnesses?
- Planning
- Questionnaire, scripts, checklists
- To be used as guides only
- Use of closed end and open ended questions?
- What needs to be gathered / confirmed?
- Use of exhibits
- When should they be used?

Interviewing techniques 2/2

Conduct the interview

- Position in the room / number of people

Listen well.

- Don't feel the need to fill 'silence'.
- Don't feel the need to write down every word they say

Be respectful and considerate

- Build rapport. Try to be personable and make them feel at ease

Observing interviewee(s)

- Watch your body language as well as theirs

Document the interview

Finalizing your Investigation

Final report

- Should be standardized

Database or other mechanism for keeping track

What should you toss vs. keep?

- Draft versions, handwritten notes

Who gets copy of the report?

- Management, board, auditors, shareholders/investors, insurers?

Record retention policy

Other Considerations

Training your Investigators

Need for Independence?

Using external vendors or outside counsel

Tracking investigations for trends

Document preservation memos and data holds

