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Planning and Executing an Effective Records Review

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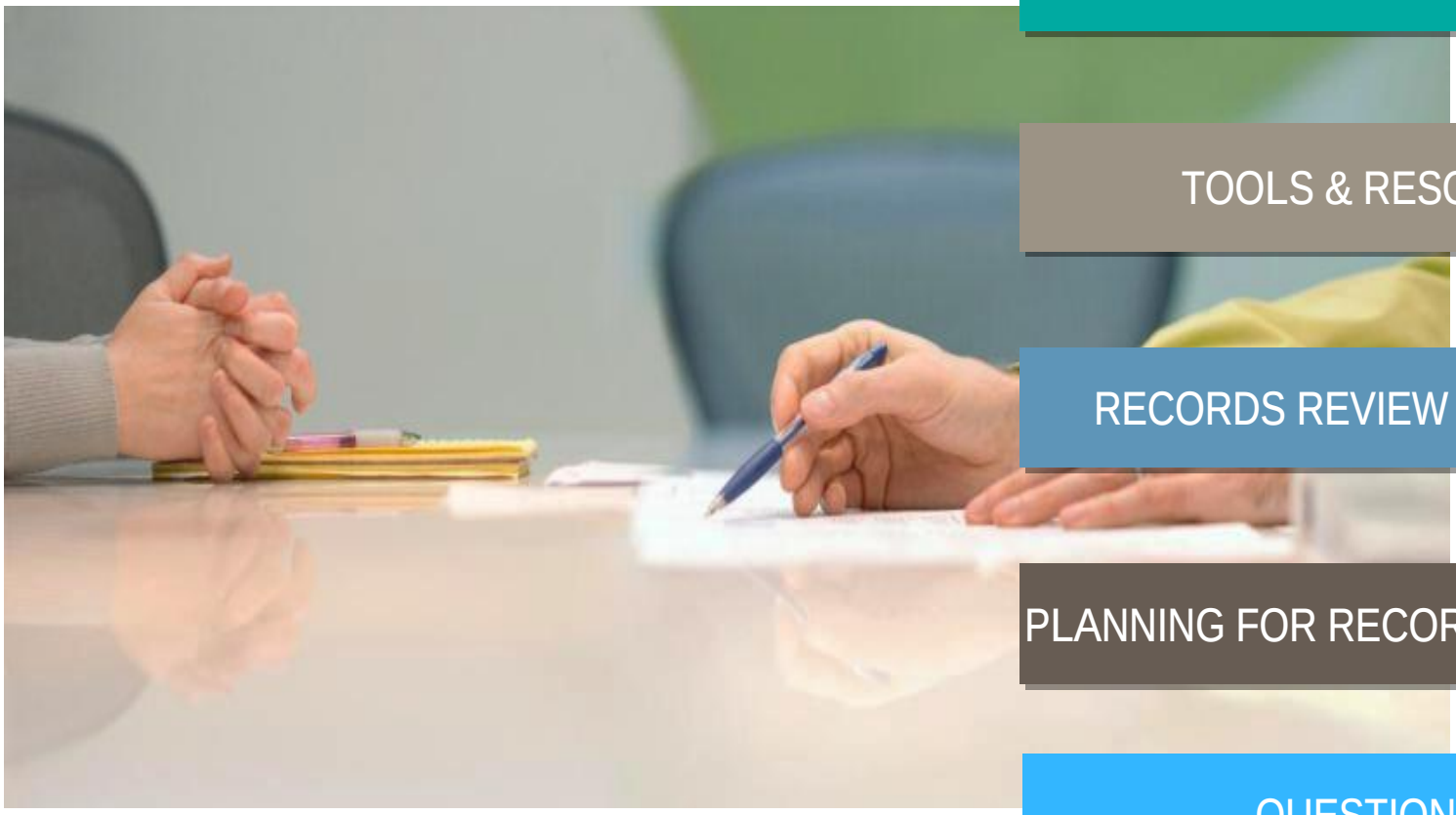
Agenda



- WHY RECORDS REVIEWS?
- TOOLS & RESOURCES
- RECORDS REVIEW RESULTS
- PLANNING FOR RECORDS REVIEWS
- QUESTIONS

Why Records Reviews?

Why Records Reviews?

WHY MORE COMPANIES ARE DOING THEM

- The Office of Inspector General (OIG) considers compliance monitoring and auditing to be one of the seven elements of an effective compliance program.
- OIG has **increasingly incorporated field force monitoring and auditing provisions in Corporate Integrity Agreements** (CIAs) with medical device and pharmaceutical manufacturers because of the business and compliance **risks associated with product promotion** related to the **False Claims Act** and the **Anti-Kickback Statute**.

Why Records Reviews?

RECENT CIA REQUIREMENTS

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Below is a list of Monitoring requirements from recent CIAs, all of which (except for one) require some form of Sales Representative Records Reviews

	Company	Commercial/Promotional Activities															
				Observations/ Ride-Alongs		Sales Representative Records Review											
		Effective Date of CIA	Speaker Programs/ Other FFS Programs	Sales Reps	Other Employee types	Sales Rep Speaker Program Activities	Recorded Results of Ride-Alongs	Emails/ Electronic Communication	Call Notes	Sales Rep Expenses/ Meals	Sales Rep Corporate Credit Card Charges	Sample Distribution by Sales Rep	Tutorials/ Preceptorships	Medical Info Inquiries/ Requests	Message Recall Studies/ Verbatim	Manager Communications	Promotion Materials
	2013																
1	Par Pharmaceutical Companies, Inc.	3/4/2013	✓	✓			✓	✓	✓	✓		✓		✓	✓	✓	
	2012																
2	Amgen, Inc.	12/19/2012	✓	✓			✓		✓					✓			
3	Boehringer Ingelheim Pharmaceuticals, Inc.	10/22/2012	✓	✓			✓	✓	✓	✓		✓	✓	✓	✓	✓	
4	Abbott Laboratories	10/11/2012	✓	✓		✓	✓	✓	✓	✓		✓		✓	✓		
5	GlaxoSmithKline LLC	6/28/2012	✓	✓			✓	✓	✓	✓		✓		✓	✓	✓	
6	Orthofix International, N.V.	6/6/2012		✓													
	2011																
7	Merck & Co., Inc.	11/22/2011	✓	✓		✓	✓	✓	✓	✓		✓		✓	✓		
8	UCB, Inc.	6/20/2011	✓	✓			✓	✓	✓	✓				✓	✓		✓
9	Novo Nordisk, Inc.	5/31/2011	✓	✓			✓	✓	✓	✓	✓	✓		✓	✓		
10	EMD Serono, Inc.	4/29/2011	✓			✓	✓	✓	✓	✓		✓	✓	✓	✓		
	2010																
11	Novartis Pharmaceuticals Corporation	9/29/2010	✓	✓				✓	✓	✓	✓	✓		✓	✓		
12	Synthes, Inc.	9/23/2010		✓	✓												
13	Forest Laboratories, Inc.	9/15/2010	✓	✓		✓	✓	✓	✓	✓				✓	✓		
14	Allergan, Inc.	8/30/2010	✓	✓		✓	✓	✓	✓	✓				✓	✓		
15	Ortho-McNeil-Janssen Pharmaceuticals, Inc.	4/28/2010	✓	✓			✓	✓	✓	✓							✓
16	AstraZeneca Pharmaceuticals LP/ AstraZeneca LP	4/27/2010	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓		

Why Records Reviews?

CIA AUDITING & MONITORING REQUIREMENTS

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Field Force Monitoring Program (FFMP)

- Many CIAs now require manufacturers to establish an FFMP to evaluate and monitor field sales force representatives' interactions with healthcare professionals (HCPs).
- The FFMP is a formalized process designed to assess the appropriateness of field sales force representatives' interactions with HCPs and to identify potential off-label promotional activities.
- Sales Representative Records Reviews is typically a component of FFMP CIA Requirements and consists of a "deep dive" into selected sales representatives' records and documentation to assess appropriateness of interactions with HCPs.

FFMP Critical Components	Type
Sales Representatives Observations (Ride-Alongs)	Monitoring
Promotional Speaker Program Monitoring	Monitoring
Sales Representative Records Review	Auditing

Why Records Reviews?

REQUIREMENTS

- Consists of a review of data and documents associated with selected sales representatives and their interactions with HCPs for any suspected or potential compliance violations of federal laws and regulations and company policies and procedures
- Sales representative sampling can be random or targeted, such as based on geography, product, sales, performance issues, previous compliance violations, etc.

Why Records Reviews?

SOURCES OF INFORMATION

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CIA Language	Sources of Information
"Records and systems relating to sales personnel interactions with HCPs and HCIs (including records from any call reporting system used by sales personnel), including sales communications from managers, coaching reports, sample distribution records, and expense reports"	• Call Notes/Call Records • Sample Distribution/Inventory Records • Travel & Expense Reports/Expense Documentation (i.e., receipts, HCP attendance sheets, etc.) • Speaker Program Documentation • Manager Field Coaching Reports • Educational Items/Gift Distribution
"Requests for medical information about, or inquiries relating to, Relevant Government Reimbursed Products"	• Medical Information Request database export
"Message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales personnel interactions with HCPs and HCIs"	• Verbatims • Message recall surveys
"Sales personnel e-mails and other electronic records"	• Email Records • Exhibit/Display Requests • Investigation/Compliance Hotline Records
"Recorded results of the Observations of sales representatives and applicable notes or information from the sales personnel managers"	• Compliance Ride-Along Results • Manager Field Coaching Reports

Tools & Resources

Tools & Resources

DOCUMENTS/RESOURCES FOR SUCCESS

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It is important to have sufficient documentation in place to guide the records review process. Written controls such as an SOP, Work Instruction, and Evaluation Template will help to ensure consistency of the process.

Resource	Purpose
Control documents *(i.e., SOP, Work Instruction)*	• Guides overall process • Ensures consistency across all reviews • Defines scope and responsibilities • Defines sales representative selection process
Records Review Template	• Provides a guide for recording all results and observations for each Records Review • Provides documented evidence that the review was completed
System Owner Spreadsheet	• Identifies the systems and system owners who are able to provide the relevant records for each review
Results Database	• Provides summary level information • Allows for ease of reporting and summarizing results • Identifies trends across sales forces, regions, products, etc.
Investigation / Corrective Action Protocol	• Ensures there is a process in place if a potential violation is uncovered through Records Review auditing

Tools & Resources

TEMPLATE EXAMPLE

A records review template is used to document the monitors' review of each sales representative and any observations and/or potential compliance violations.

Activity Information	
Monitoring Activity Number	
Name of Monitor	
Review Date(s)	
Record Review Period	

Sales Representative Information	
Name of Sales Representative	
Sales Representative's Title	
Territory Number	
District	
Region	
Products Promoted	

Records/Data Reviewed (check all that apply)	
☐ Promotional Speaker Programs	☐ Travel and Expense
☐ Sample Distribution	☐ Exhibit/Display Requests
☐ Educational Items/Gifts Distribution (T&E)	☐ Emails
☐ Field Coaching Reports/Observations	☐ Medical Information Requests
☐ Sales Force Call Records	☐ Message Recall Studies
☐ Other Records (describe)	

Evaluation Criteria	Yes	No	N/A
Speaker Program Data:			
Were any potential or actual compliance violations noted in review of speaker program data?	☐	☐	☐
What is the total number of speaker programs hosted during the review period?			

Tools & Resources

INVESTIGATION/CORRECTIVE ACTION

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- If a records review surfaces compliance-related issues, the Company is obligated to address and appropriately remediate potential compliance violations as necessary.
- Corrective action plans help Companies respond to instances of confirmed non-compliant behavior in a manner that is both appropriate for, and proportional to, the type of behavior surfaced by the records review.

1

Determine appropriate action by categorizing the monitoring observations by type:

> Isolated versus systemic

> Active versus passive (commission or omission)

> First offense versus recidivist

> Individual versus organizational

> Magnitude of the problem (frequency, size, impact)

2

Determine the type of control gap that led to the observation:

> Gap in policies or procedures

> Lack of organizational support / buy-in

> Ineffective training

> Technology gap

> Lack of company response to previous violations

3

Determine appropriate response:

> Individual disciplinary action

> Individual re-training

> Broader re-training (division or company-wide)

> Re-drafting internal guidance documents, policies or procedures

> Communication of senior level expectations regarding compliant behavior

> Evaluating adequacy of current technology solutions

Records Review Results

Records Review Results

SPEAKER PROGRAMS – EXAMPLES OF FINDINGS

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Records Review Findings	• Sales Representatives not using Company sign-in sheets • Sales Representatives not accurately capturing attendee information • Incorrect HCPs listed • HCPs listed who had RSVP'd but did not actually attend • HCPs not physically signing sheet • HCPs not listed on the sign-in sheet, yet listed as an attendee on the speaker program's expense summary
Potential Impact	• Improper documentation of attendees at programs can lead to issues including misreporting names and meal amounts for transparency initiatives (i.e., Open Payments requirements) • Misreporting HCP expenditures can potentially hurt Company's relationships with HCPs • Misreporting can lead to fines from state and federal governments
Remediation	• Consider imposing more stringent rules around documentation and close out for speaker program activities • Consider requiring DM and/or Speaker Vendor review of speaker program documentation..

Records Review Results

PROMOTIONAL PROGRAMS – HCP MEALS

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Records Review Findings

- Sales Representatives missing itemized receipts
- Meals exceeding the cost-per-person meal limitation
- Inappropriate alcohol consumption at company-sponsored programs
- Meals exceeding what would be considered modest and infrequent

Potential Impact

- Missing documentation and details of actual purchases and number of meals on itemized receipts could allow for potential policy violations going undetected
- Excessive alcohol provided by a company could be interpreted as "entertainment". This can lead to potential violations of PhRMA/AdvaMed Code as well as prohibitions of certain state laws (Vermont and Massachusetts).
- Meals exceeding the per person limit violates internal company policy regarding modest meals which could lead to PhRMA/AdvaMed Code and/or Anti-Kickback Statue violations

Remediation

- Speaker Program Management, Expense Reporting, and/or Aggregate Spend systems should create flags that identify any meal amounts that are over the per person meal limit or frequency and send a notification directly to Compliance and to appropriate sales management
- Required review by Sales Management of individual sales representative T&E reports could include review for itemized receipts

Planning for Records Reviews

Planning for Records Reviews

COMMON CHALLENGES

- Business pushback
- Inadequate systems
- Lack of responsiveness with system owner
- Lack of available data to audit
  - No speaker programs completed during review period
  - No expense reports submitted during review period

Planning for Records Reviews

PROACTIVE ACTIVITIES

- Schedule calls/meetings with each system owner to better understand the type of data that is available for audit
- Complete a "Mock Document Request" with all system owners to identify gaps in the process. Select a random sales representative and complete a test Records Review.
  - Record relevant information such as:
    - Time it takes to receive information after a request is made
    - What the information looks like (Excel spreadsheets, PDFs, Screenshots, etc.)
    - Data fields available for review
    - Resource impact or other considerations
- Plan ahead—create an Annual Auditing and Monitoring Plan to schedule and plan for all A&M activities, including Records Reviews

Planning for Records Reviews

MOCK DOCUMENT REQUEST PARTIAL SCREENSHOT

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A Mock Document Request exercise provides valuable insight into the overall Records Review process.

Records Review Scope Area	Document Requested	Document Format	Minimum Required Data Fields	Source System	Business / IT Contact	Date Requested	Date Received	Resource Impact / Considerations
Speaker Program Activities	Speaker Program Detail Screen Shots	PDF	Program Details, Venue, Speakers, Attendees, Tasks, Financials, Sales Representative Evaluation Form	SpeakerPro				
	Completed Attendance Sheet	PDF	N/A	SpeakerPro				
	Speaker Program Vendor Invoice	PDF	Itemized Receipts from programs	SpeakerPro				
Call / Sample Records	Export of all Call Records	Excel	Sales Representative Name, Call Date and Time, HCP Name, HCP Specialty, State License #, Address, Products Detailed	SFA				
	Export of all Sample Distribution Records	Excel	Sample Drop Date and Time Samples Dropped, Sample Quantity, Signature	SFA				
	Sample Inventory Records	Excel	N/A	SFA				
Expense Reports / Exhibits & Displays	Export of all Expense Data	Excel	Expense Type, Transaction Date, Vendor, Purpose, City, Approved Amount	Concur				
	Full expense report including receipt information and any applicable Attendance Sheets	PDF	N/A	Concur				

Final Thoughts

- Work to gain business buy-in—this will ensure that data requests are taken seriously and are provided in a timely manner
- Create a thorough plan at the beginning of each monitoring period
  - Who will be your primary auditors?
  - How will you ensure accuracy in your review?
  - How will you document findings to allow for trending and analysis of findings?
  - Do you require external support outside of your department and/or company?

Questions?

Speakers

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Tracy is a Senior Director with Huron Life Sciences and has over 25 years of experience in the life sciences and health care industries. She assists pharmaceutical and medical device manufacturers with their regulatory compliance and risk mitigation matters, especially in the areas of sales, marketing, medical affairs and clinical operations. She has led numerous CIA Implementation and IRO projects and, as a result, she is frequently called upon to help clients with their written controls, processes, systems and monitoring and auditing activities so that they meet CIA and IRO requirements. Tracy regularly works with clients' in-house and outside legal counsel, compliance officers and their teams, and other senior operations professionals.

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Elaina is an Associate in Huron Consulting Group's Life Sciences practice. She is experienced in assisting pharmaceutical and medical device manufacturers manage complex regulatory environments in areas of sales and marketing compliance, Corporate Integrity Agreement adherence, and state and federal reporting requirements, among others. In particular, Elaina is experienced in conducting compliance program gap assessments, participating on Independent Review Organizations, developing promotional and non-promotional monitoring programs, and acting as a live field force monitor for speaker programs and ride-alongs. Prior to consulting, her past experience includes positions in both sales and compliance for two separate pharmaceutical manufacturers.


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