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Relevant Training

Communicating Compliance Across the Business

PHARMACEUTICAL AND DEVICE SALES & MARKETING COMPLIANCE
April 30, 2013

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Objectives

1. Understand key adult learning principles and their impact
2. Learn how to develop a training plan
3. Discuss ways to make training more effective
4. Evaluate training lessons from companies under CIA
5. Review possible mechanism to assess training

Course Agenda

1. Adult learning principles
2. Developing a training plan
3. CIA lessons
4. Training Effectiveness
5. Assessments

Adult Learning Principles: Malcolm Knowles (1970)

Learner Preferences:		Recommended Action:
1. Autonomous and self-directed	→	Explain the purpose and encourage participation
2. Life experiences and knowledge	→	Connect learning to the user's experience
3. Goal-oriented	→	Organized/Structured content
4. Relevancy-oriented	→	Set clear objectives and relate material to learner
5. Practical	→	What's in it for me (WIIFM)
6. Respect	→	Treat learners as equals

Sources: http://media.wiley.com/product_data/excerpt/50/07645598/0764559850.pdf , http://honolulu.hawaii.edu/intranet/committees/FacDevCom/guidebk/teachtip/adults-2.htm

Impact of Adult Principles on Developing a Training Strategy

- Adults learn differently
- Customization and relevance help keep the audience's attention
- Repetition helps retention

Adults Learn Differently

➢ Active vs. passive learning

Active	Passive
♦ Wants opportunity to participate ♦ Prefers training in groups	♦ Wants time to process the information ♦ Prefers training by themselves

➢ Visual vs. Auditory vs. Kinesthetic

Visual	Auditory	Kinesthetic
♦ Need to see it ♦ Use pictures/charts/etc ♦ Written directions ♦ Visualize the process	♦ Need to hear it ♦ Use debates/panels ♦ Spoken directions ♦ Group discussions	♦ Need to do it ♦ Allow breaks / movement ♦ Role playing ♦ Use computers

Source: http://media.wiley.com/product_data/excerpt/50/07645598/0764559850.pdf

Customization and Relevancy

- Relate the content to the specific audience / functional area
- Tell them what they need to know
- Use company-specific language and details
- Keep curriculum up to date

Repetition Helps Retention

- Adults aren't that different than children
- Don't believe me: Ask your sales and marketing teams!
- What's the difference between compliance policies and a blood drive?

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Developing a Training Plan

Complications:

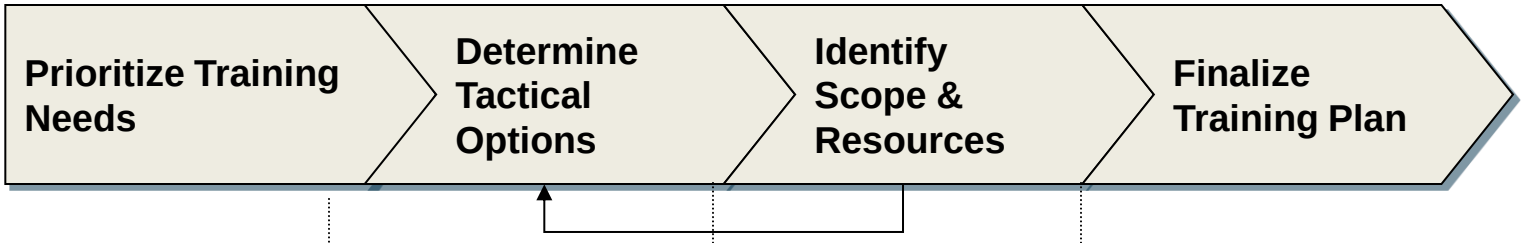
- Access to trainees is limited
- Fully customized, engaging, relevant training is resource-intensive

Actions:

- Create concise presentations that maximize the time of the trainees
- Develop a training strategy that maximizes the available training resources

The Goal: Provide the right content to the right person via the right medium at the right time

Developing a Training Plan



- List out topics for training
- Gather data and process for inputs
- Assess priorities

- List out prioritized courses
- List out access points (e.g. national meetings, newsletters)
- Identify medium and duration for content delivery
- Develop preliminary methodology plan

- Identify FTE / budget considerations
- Assess internal or external resources
- Evaluate type of training and duration; consider modifying scope
- Develop draft training plans (1 and 5 year)

- Document one year plan by quarter
- Document 5 year plan by year
- Gain approval of overall plan

Developing a Training Plan

Step 1A: List out courses

Brainstorm training needs by course type:

- New content
- Refresher training
- Updates to existing courses
- Communications (emails, newsletters, etc.)

Brainstorm training needs by functional area:

- Sales
- Marketing Teams
- Managed Markets
- Medical Affairs (e.g. MSLs, Other HQ)
- R&D
- Senior Leadership and/or Board of Directors

Brainstorm list can be both high-level and granular

Developing a Training Plan
Step 1B: Gather Data on Relevant Risk and Mitigating Factors

Identify Risk and Mitigating Factors

Sample Risk Factors:

- Regulatory requirements
- Seriousness of non-compliance
- Pervasiveness of activity
- Frequency of inquiries

Sample Mitigating Factors:

- Effectiveness of prior training
- Frequency of communications
- Existing process documentation/controls
- Prior auditing and monitoring activities

Collect Data Against Factors

Evaluate Internal Factors:

- Policies and procedures
- Internal investigations
- Hotlines
- Corrective actions
- Survey results

Evaluate External Regulations:

- Federal Laws
- State Laws
- PhRMA
- AdvaMed
- Recent Settlements / CIAs
- FDA Warning Letters
- Code of Federal Regulations

Developing a Training Plan
Step 1C: Determine Priorities

- Evaluate list of training courses against risk and mitigating factors
- Assign priority level (e.g. High, Medium, Low) for completion of course
- Assign criticality for High Priority Items (Urgent, Moderate, Eventual)
- Assess likely ease of implementation
- Develop prioritized list of topics to cover

Training priorities can be coordinated with overall risk assessment

Developing a Training Plan
Step 2: Determine Tactical Options

1. List Courses to Create

Example

- PhRMA Code Refresher
- Code of Conduct Refresher
- Update to New Hire Training - Sales
- What is "Fair Balance?" - Brand
- New policy on Social Media – Sales
- New policy on Social Media – Brand
- Running a Compliant Ad Board
- Sunshine Act Overview
- Sunshine Act Vendor Training

2. Identify / Prioritize Methodology

Illustrative

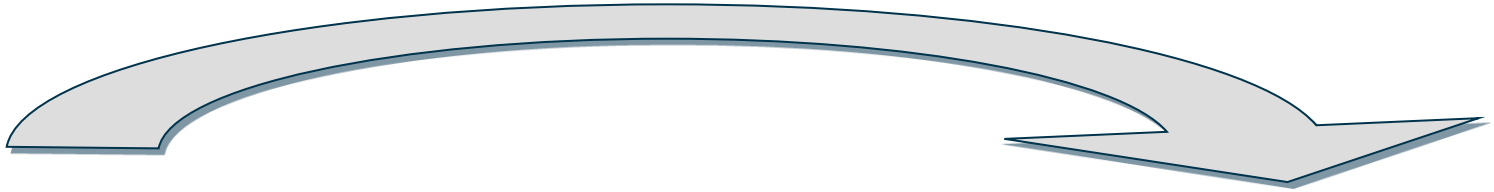
Course Name	Live Training	CBT	Communication
PhRMA Code Refresher	X		
Code of Conduct Refresher		X	
Update to New Hire Training - Sales		X	
What is "Fair Balance?" - Brand			X
New policy on Social Media – Sales			X
New policy on Social Media – Brand			X
Running a Compliant Ad Board			X
Sunshine Act Overview	X		X
Sunshine Act Vendor Training		X	

3. Develop Preliminary Topic and Type Plan

Illustrative

- PhRMA Code Refresher: Live for Sales Reps (Nat'l Sales Mtg); CBT for Marketing
- Code of Conduct Refresher: CBT
- Running Compliant Ad Boards: Newsletter Communication
- Update to New Hire Training: CBT

Developing a Training Plan
Step 3: Identifying Scope and Required Resources



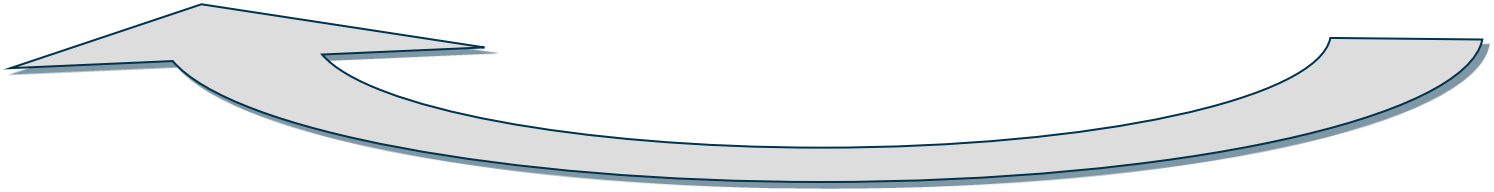
Identify Available Resources

- Available internal resources to develop courses
- Define support and involvement of functional areas being trained
- Determine impacted audiences and access/availability for training
- Available budget for external resources
- Submit and receive RFPs for external assessment estimates

Final Training Plan

Determine Scope of Assessments

- Identify desired type (live/CBT/Communication/etc.)
- Determine length of course
- Determine impacted audiences
- Calculate required resources
- Develop draft Training Plan
- Consider revising methodology and duration or allocating additional resources



Developing a Training Plan
Step 4A: Develop a One Year Plan For Course Development

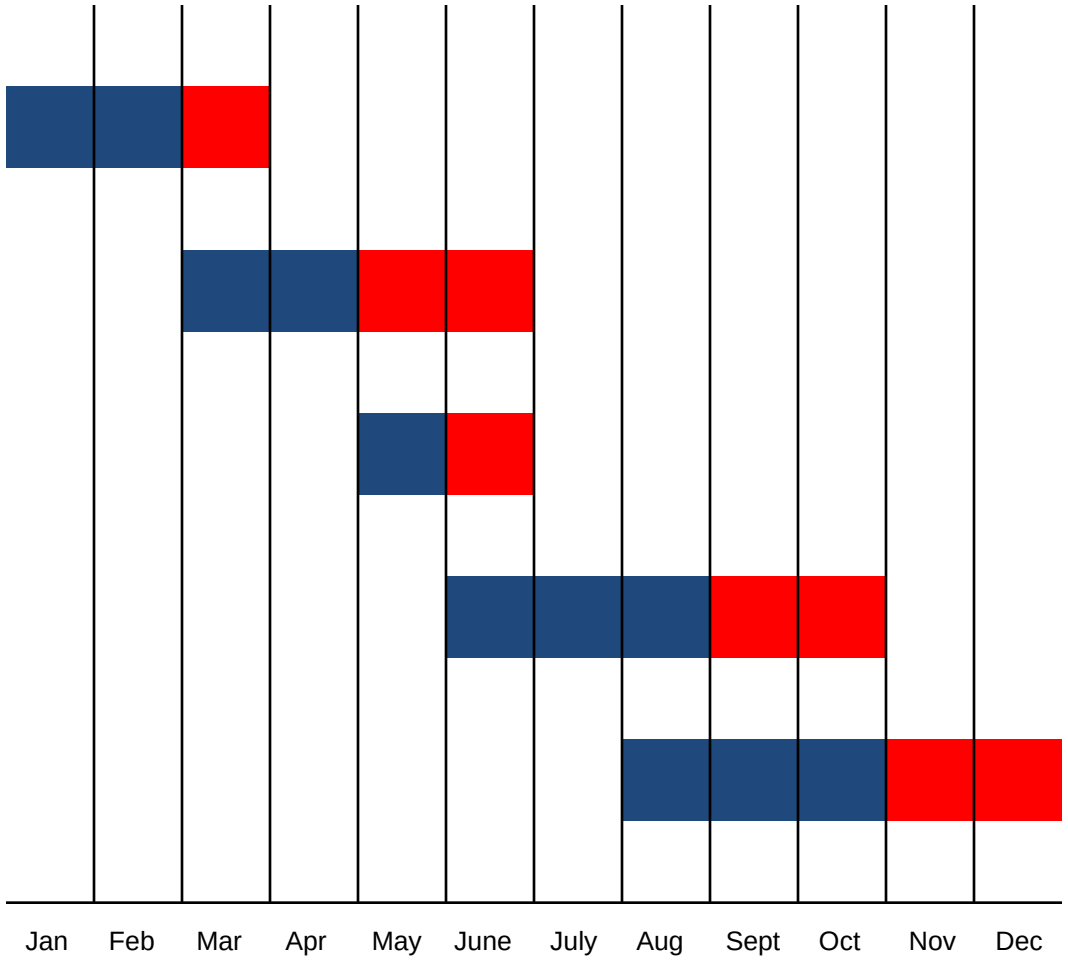
Course 1: Compliant Ad Boards (Newsletter – 2 Mo)

Course 2: PhRMA Code HQ (CBT– 2 Mo.)

Course 3: PhRMA Code Sales (Live – 1 Mo.)

Course 4: Update to New Hire Compliance (CBT- 3 Mo.)

Course 5: Code of Conduct Refresher (CBT – 3 Mo)



= Development Time

= Training Period

Developing a Training Plan
Step 4B: Document 5 Year Plan With Future Needs

Training Plan

Year 1

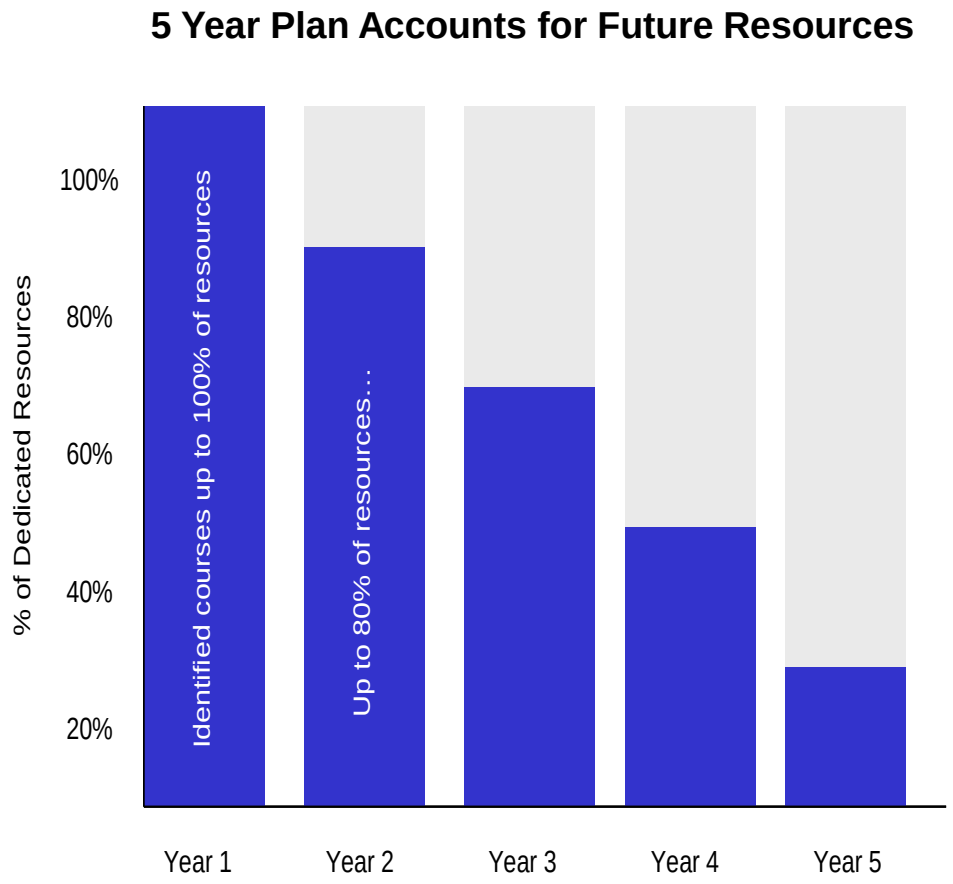
- Compliant Ad Boards
- PhRMA Code HQ/Sales
- Update to New Hire Compliance
- Code of Conduct Refresher

Year 2

- Course A
- Course B
- Communication C
- Communication D…

Year 3-5…

Course A…



Assess Effectiveness of Training and Adjust Plan Accordingly

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CIA Lessons: Identifying Training Opportunities

What training is required?

U.S. Department of Health & Human Services
Office of Inspector General

- General Training
  - CIA requirements
  - Compliance Program (including the Code of Conduct)

- Specific Training (relating to Covered Functions)
  - Applicable Federal health care program requirements
  - Applicable FDA requirements
  - Company Policies and Procedures
  - Personal obligation of each individual involved to comply
  - Legal sanctions for violations of the applicable Federal health care program and FDA requirements
  - Examples of proper and improper practices

Source: https://oig.hhs.gov/fraud/cia/agreements/Par_Pharmaceutical_03042013.pdf

CIA Lessons: Identifying Training Opportunities

Company	Date	New Hire – General	New Hire - Specific	Refresher General	Refresher Specific
Par Pharmaceutical	Mar-13	1 hour	3 hours	1 hour	3 hours
Amgen	Dec-12	1 hour	3 hours	1 hour	3 hours
Boehringer-Ingelheim	Oct-12	1 hour	3 hours	1 hour	3 hours
GSK	Jun-12	1 hour	3 hours	1 hour	3 hours
Abbott	May-12	1 hour	3 hours	1 hour	3 hours
Merck	Nov-11	2 hours	2 hours	2 hours	2 hours
Novo Nordisk	May-11	1 hour	3 hours	1 hour	3 hours
UCB	May-11	1 hour	3 hours	1 hour	3 hours

Note: All of the above require that new hires must be trained within 30 days

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Ensuring Effectiveness

- Variety of formats
- Involve senior management
- Customize content
- Engage the audience

Training Effectiveness

Training formats

- Live training
- Train the trainer
- Computer based training
- Read and acknowledge
- Web-ex/Remote conferencing
- Podcasts

Involve Senior Management

- A message from the CEO…
- Email communication

"We are dedicated to excellence in all that we do. By working to ensure compliance with…"

Richard Wright
President and CEO, XYZ Company

Customize the content

- What's in it for me?
- Ensure courses are relevant to the trainees
- Keep in mind….

"Tell me why this is important"
and
"Tell me what I need to know"

KISS – "Keep it simple, silly"

Engage the audience

- Keep it entertaining – Humor is a great hook
  - Animation
  - Games
  - Videos
- Scenarios– Provide realistic situations
- Breakouts – Helps the audience learn from each other
- Interactives – Apply practical application of lessons
- Quizzes / Knowledge Check – Provide thought provoking questions

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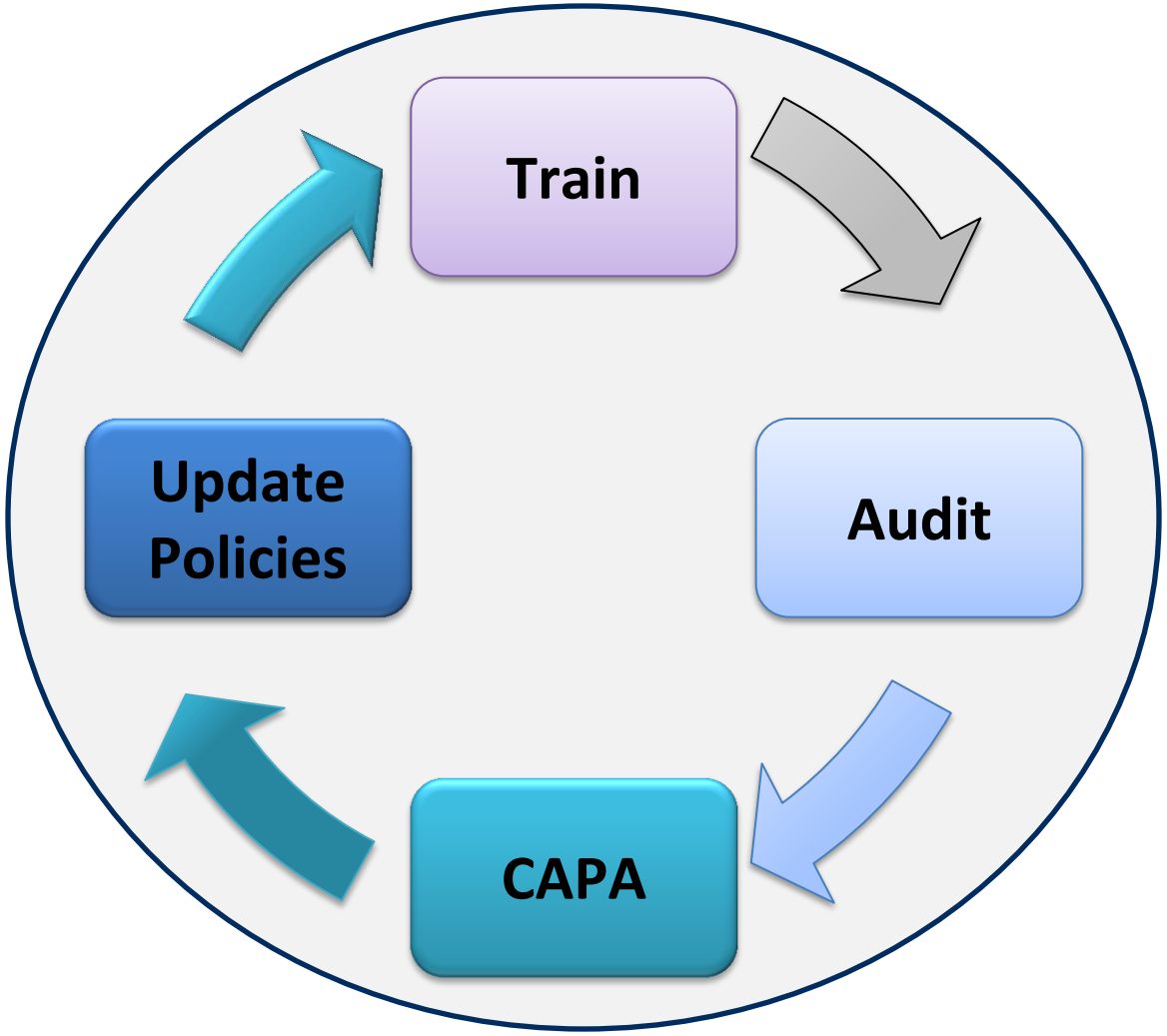
Assessments

How effective was the training?

- Assessments or knowledge checks
- Surveys
- Informal feedback

Measure training based on the results

Training and Audit Cycle



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