

# Approaches to Operating a Compliance Program with a Small Compliance Department

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## Implementing Compliance Programs in Smaller Companies

- There are many advantages—utilize them to the fullest
- Establish an effective process to develop policies
- Culture of the company has significant impact on implementation
- May be rules-based, values-based, or both
- Getting the message out is key—for all employees

# Policy Development Process

- One Model – “The Tablets are Handed Down”
  - Advantages
    - Speed
    - Control
  - Disadvantages
    - Lack of Buy-in by stakeholders
    - Policy out in advance of practices

## Policy Development Process (cont'd)

- Another Model: Substantial Stakeholder Involvement
  - Advantages
    - Implementation alongside policy development
    - Judgment calls are made “together” – increasing chance of successful implementation
    - Greater credibility if business involved
  - Disadvantages
    - Process can spin out for too long
    - Opportunities for “filibuster”
    - “Too many cooks in the kitchen”

## Policy Development Process (Long Form)

- ID stakeholders
  - Legal, Regulatory, Medical, Marketing/Sales, Operations (this is key), HR
  - Don't just focus on top level – the devil is in the details – and top level folks may not have them
  - Role for Compliance?
    - The “engine”
    - Convener, creator of first drafts, arbitrator

## Policy Development Process (cont'd)

- Use the senior-most level only when necessary, e.g.
  - Excessive filibustering
  - Lack of focus
- This is about implementation and practicality, not just theory
- Tremendous learning opportunity for Compliance function

## Policy Development Process—Training

- Training Plan should be developed along with the policies
  - Employees (sales/marketing/“reviewing functions”/audit)
  - Vendors (great opportunities here)
- Role for Compliance
  - Presenters/explainers

## Policy Development Process—Training (cont'd)

- Live presentation with discussion and questions
  - Tremendous advantage for smaller companies
- “Top Ten lists”
- Summaries
- E-learning/video
- Distribute policy

## Potential Challenges for Small Companies

- Strong need to focus on meeting near-term business objectives – may be critical to survival in some cases
- Company may not be seen as likely target for enforcement action due to low profile - perceived compliance risk in near term may be low
- Culture – likely to present some challenges as well as benefits – may be averse to perceived “bureaucracy”
- Resources – need to implement program without major expense or distraction (see “Integration”, below)
- All of these require different approaches than might be taken in a large, established pharma company

## Values vs. Rules Orientation

- Not an “either-or” question – we clearly need both – it’s a question of balance and emphasis
- Training regarding specific rules should be grounded in the underlying principles whenever possible – helps with understanding as well as compliance
- Degree of emphasis on values/principles vs. rules may vary depending on level in the organization
- May be easier in a small company to generate discussion of values and their application in relatively small groups (e.g., dept meetings)

## Focus on Culture

- Culture is critical to the long-term success of your program – to meeting the program objectives
- Identify the existing culture and tailor your approach – whether you need to build, tweak, or maintain
- Core Values and Code of Conduct are the foundation of your communications efforts – should be closely aligned
- Build alliances with HR and other groups doing similar work – extend your reach and ensure integration
- Validate your observations about culture with data if possible, and measure progress over time

# Integration

- Consider and seek to align messages coming from various parts of the company – build a “virtual” compliance department
- Communications should consistently demonstrate the importance of the company’s core values
- Examples of critical initiatives for ensuring integration:
  - New employee orientation
  - Leadership development
  - All compliance-related training (GxP, EH&S, employment law)
  - Company awards programs

## Communication in a Small(er) Company

- Allows for the “best of both worlds”
  - Face-to-face training for key risks and key risk areas
  - E-Learning for more general, easier-to-understand concepts

# Face-to-Face Training

- Face-to-face training for key groups (e.g., sales, marketing)
  - Compliance staff can really make an impression
  - Individual questions can be addressed
  - Message is not lost or diluted through “train the trainer” or e-training
  - Training can be specifically tailored to the individual group being addressed
  - Difficult to do when you have several thousand reps
  - More than just PowerPoint!
    - ARS
    - Videos
    - Contests

## Special Training Techniques



“You do not want to sell off-label”

## Use E-Learning to Communicate to Broader Groups

- Efficient way to deliver consistent message
- Useful for easy-to-understand concepts
- Less resource intensive
- Easy to track
- Many “learning management systems” are available today

## Start 'em Young



Sales Representative in Training

## Challenges in a Small(er) Company

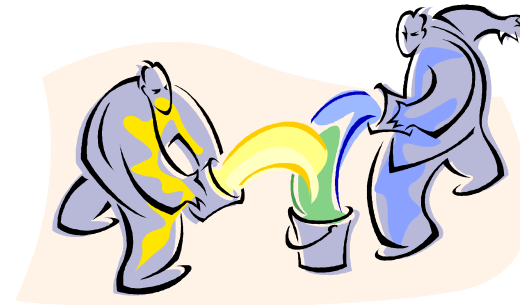
- Companies are often more “entrepreneurial”
- Employees may be less receptive to compliance messages
- Compliance is “newer” to senior management
- Putting systems and processes in place can be costly

# Special Considerations

- Training the Board of Directors
- Training Executive Officers
- What makes this training successful?
  - Remember that they are a different audience
  - Regularly distribute relevant materials to illustrate important points—this is training
  - Try to make it more of a discussion, rather than a lecture—engage them
  - Keep the time to a minimum—schedule additional sessions if necessary
  - Consider an outside lawyer to help if you feel they are not receptive to your message

## Conclusion

- Training may be the single most important key to the success of your program
- Having fewer compliance resources does not mean your training can't be engaging, fun and successful
- Be creative both in content and in delivery



## Disclaimer

The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the presenters' employers. Any examples provided are hypotheticals and should not be attributed to any individual company.