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## 3.06. Integrating Compliance with Business:

# Integrating Compliance Auditing & Monitoring with Internal Audit

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### Facilitator

Sheryl Vacca  
West Coast Practice Leader  
Life Science and Health Care  
Regulatory Practice  
Deloitte & Touche LLP

### Presenters

David Chandler  
Director  
Corporate Compliance  
Amgen

Wayne Davey  
Director  
Corporate Audit  
Amgen



## Disclaimer

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**The information presented and discussed represents the opinions of the authors/presenters and, although descriptive of general activities, they do not necessarily reflect the views of either Amgen or Deloitte & Touche LLP**

# Outline

- Overview of Corporate Compliance and Corporate Audit at Amgen
- This Session will discuss how Amgen's Corporate Compliance and Corporate Audit have worked together
- The presenters will provide insights into
  - The Corporate Compliance Program Structure
  - The Approach that Corporate Compliance and Corporate Audit have taken in defining Role and Responsibilities

# Wayne Davey

**As Executive Director of Corporate Audit for Amgen, Wayne Davey works with the General Auditor, senior company management, and the audit function staff to provide independent, objective assurance and consulting services designed to add value and improve the operations of Amgen. Upon joining Amgen in June 2004, he became the Project Leader for Amgen's successful Sarbanes-Oxley compliance and certification efforts. He is currently assigned to lead all worldwide operational and compliance audits.**

**Prior to his current position at Amgen, Wayne was the CFO and VP of Business Operations at the Rockwell Scientific Company (RSC), a privately-held technology company with approximately \$110 million in annual sales. Prior to his position at RSC, he served as Director of Corporate Accounting for Rockwell International and then later in a similar position at Hughes Electronics.**

**Wayne received a BS degree from the University of Arizona and an MBA degree from UCLA.**

# David Chandler

**David Chandler is a Director of Corporate Compliance over the Outcomes and Analysis program at Amgen Inc. His responsibilities include the selection and deployment of a unified audit management system, analysis of audit data within and across audit organizations, and reporting on critical audit findings to executive management.**

**Prior to his current position he was the Manager of the Compliance and Regulatory program at 3M Pharmaceuticals where his responsibilities included monitoring and developing compliance programs for cGMP, GCP, GLP, HIPAA, Pharmacovigilance, PDMA, WLF, PhRMA Code of Conduct, OIG Guidance, Medical Education, State reporting requirements, and grant and consultant activities. Previous position included Manager of Toxicology at 3M Corporation, Director of the Hazardous Materials Program for the State of Oregon and Principle/Director of the Chemical and Risk Information System and Associate Professor at Oregon Health Sciences University.**

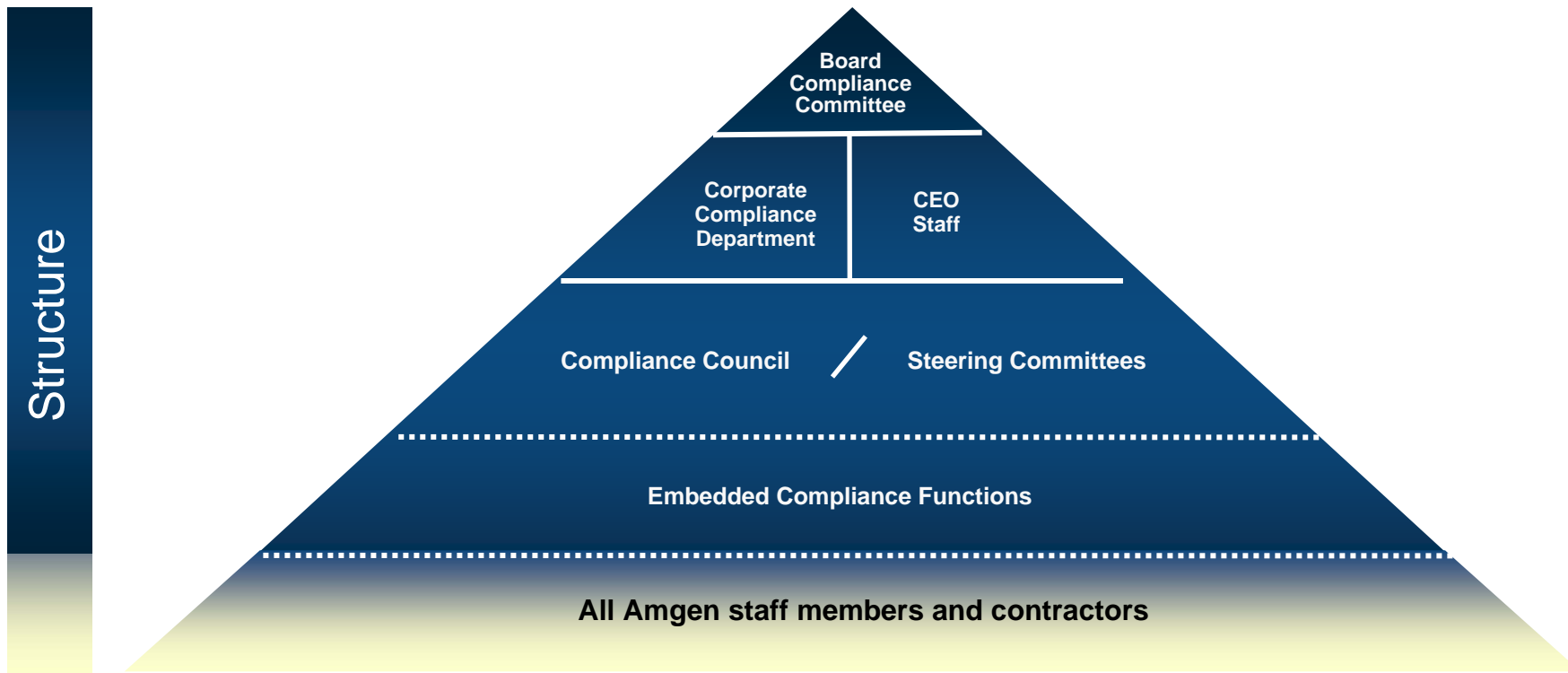
**David holds a Ph.D. in Pharmacology/Toxicology from the University of California, Davis, and an MBA from the University of St. Thomas.**

# **Sheryl Vacca**

**Sheryl Vacca is the West Coast Practice Leader in the Life Sciences Regulatory Practice at Deloitte & Touche LLP. Sheryl is also the National Lead for Health Care Internal Audit for Deloitte. Sheryl has been in life science for 28 years and has a significant amount of experience in regulatory compliance, auditing and monitoring and dispute areas in life sciences. She has been involved with the development of compliance and operational controls, internal audit and has expertise in providing advice on regulatory compliance issues for life science focusing on internal control process, key risk areas in regulatory compliance, financial and compliance due diligence, operational design and litigation support including voluntary disclosures to enforcement agencies.**

**Sheryl is a nationally recognized speaker and has published on compliance related topics, including auditing and monitoring concepts, quality of care, compliance program elements and compliance program effectiveness. Ms. Vacca is a Past President and current Board Member of the Health Care Compliance Association. Ms. Vacca has her BSN and also holds a master's degree in administration. She is also a member of the Editorial Board for the Journal of Health Care Compliance, published by Aspen Publishers.**

# Amgen's Corporate Compliance Model is Based on Embedded Compliance Functions with Centralized Oversight



## Manufacturing & Distribution

- Good Manufacturing Practices (GMP)
- Import/Export Controls

## Research & Development

- Good Clinical Practices (GCP)
- Good Laboratory Practices (GLP)
- DEA Licensure
- Animal Research (USDA)

## Healthcare & Competition

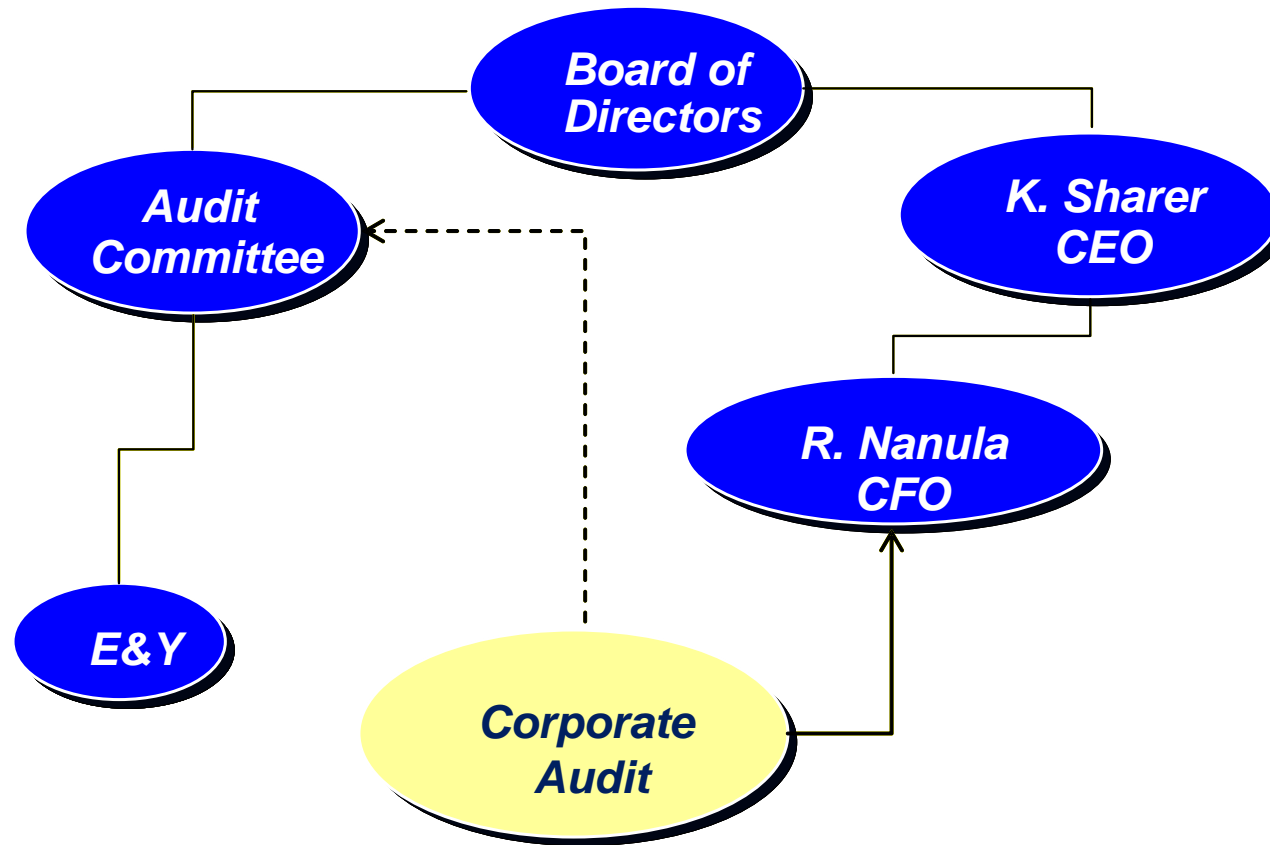
- Anti-kickback/ Sponsorship Laws
- Anti-trust/ Competition
- Drug Safety / Pharmacovigilance
- Pricing & Reimbursement
- Promotional Activities

## Corporate

- Affirmative Action / EEO
- Anti-corruption
- Environmental, Health & Safety
- Good Records Practices
- Privacy
- Validation

### Key Compliance Obligations

# Corporate Audit has Responsibility for General and Financial Audits



**Direct link to Audit Committee provides**

- Independence for Financial Reviews

**Direct link To Senior Management provides**

- Strategic Direction for Operational Reviews
- Exposure & Development Opportunities

# Corporate Audit has Responsibility for General and Financial Audits, Consulting and Investigations

## *Audits*

- *Audit Plan developed from an assessment or management request*
- *Broad scope designed to provide assurance as to the internal control environment*
- *Results shared with Sr. management, Audit Committee and E&Y*
- *Examples:*
  - *Financial reporting / Sarbanes Oxley*
  - *Information Systems*
  - *3rd Party Vendors*

## *Consulting*

- *Management requests*
- *Controls designed and new system/processes*
- *Memo's issued; no ratings given*
- *Examples:*
  - *Push-to-Purchase*
  - *SOX*
  - *ERP*

## *Investigations*

- *Narrowly focused*
- *Conducted in response to specific allegations*
- *Results may be shared with management*

## For Selected Compliance Audits Where Corporate Audit Will Be Conducting the Audit the Following Roles and Responsibilities Have Been Determined

<b>Audit Policy Step</b>	<b>Process Step</b>	<b>Corporate Compliance/Law</b>	<b>Corporate Audit</b>
n/a	Develop catalog of key legal obligations	Lead	n/a
n/a	Develop risk survey	Lead	Participate
n/a	Conduct risk assessment of controls for all significant compliance risks	Lead	Participate
n/a	Prioritize risk area/gaps	Co-Lead (with Embedded Compliance Officer)	Participate
Annual Compliance Risk Assessment (Planning)	Pre-audit process analysis (alignment of risk assessment and test plan)	Co-Lead (with Embedded Compliance Officer)	Co-Lead
Audit Execution	Audit execution	Participate	Lead
Audit Report/Communication	Analyze findings	Co-Lead	Co-Lead
Audit Report/Communication	Issue Report to CCO	Participate/Review	Lead
Audit Report/Communication	Issue Report to Auditee	Lead	Participate
Follow-up Plan and Closure	Corrective Action Proposed by Auditee and Accepted	Co-Lead	Co-Lead
Follow-up	Conduct Compliance or Financial Investigations	Lead Compliance Investigation	Lead Financial Investigations
Follow-up	Conduct Non-Investigation Follow-up Compliance Audits	Co-Lead	Co-Lead
Follow-up	Monitor Corrective Action	Participate	Participate



**QUESTIONS?**