Deloitte.

Compliance Auditing & Monitoring Boot Camp

Co-Chaired/Co-Moderated by:

- **L. Stephan Vincze, Director, Deloitte & Touche, LLP, Co-Chair/Co-Moderator**

- **Lawrence P. Platkin, Vice President and Compliance Officer, Bayer Healthcare LLP, Co-Chair**

- Michael Hercz, Director, Deloitte & Touche LLP, Co-Moderator

The 13th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, Washington, D.C

November 5, 2012

Welcome!

(We are about to have some fun!)

Agenda

Introduction of Boot Camp panelists

Review of preconference Boot Camp agenda

Review key compliance auditing and monitoring considerations

Panel presentations/discussions

Interactive audience/panel discussions

Introduction of Boot Camp panelists

Boot Camp panelists

Lori Alarimo, Esq.
Vice President and Deputy Compliance Officer, Allergan, Former Assistant General Counsel, Pfizer, Irvine, CA

Diane E. Bieri, Esq.
Partner, Arnold & Porter LLP, Washington, DC

Thomas C. Frongillo, Esq.
Partner, Head of Litigation (Boston Office) and Co-Chair of the White Collar Criminal Practice, Weil Gotshal & Manges, Boston, MA

Michael Hercz, Esq.
Director, Audit and Enterprise Risk Services, Deloitte & Touche LLP; Former Vice President and Chief Compliance Officer, Victory Pharmaceuticals, Inc., Costa Mesa, CA (Co-Moderator)

Vickie L. McCormick
Vice President, Health Care Compliance, DePuy, Inc.; Chief Compliance Officer, DePuy Orthopedics, Inc.; Former Chief Compliance Officer, St. Jude Medical, Warsaw, IN

Jeff Rosenbaum
Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Global Head, Ethics & Compliance, Novartis Oncology, Boston, MA

Lawrence P. Platkin
Vice President and Compliance Officer, Bayer Healthcare LLP, Wayne, NJ (Co-chair)

L. Stephan Vincze, JD, LL M, MBA
Director, Audit and Enterprise Risk Services, Deloitte & Touche LLP; Boston, MA (Co-chair/Co-Moderator)

Review of pre-conference Boot Camp agenda

Boot Camp Agenda

Compliance auditing best practices drivers for renewed focus on compliance auditing — data collection, analysis and reporting, etc.

- Sample compliance auditing cycle/approach
- The use of risk assessments to guide audit planning
- Compliance audit focus areas — where are we seeing the highest risks?
- Legal considerations — when should an audit be privileged, if ever?

Compliance monitoring best practices drivers for increased importance of compliance monitoring — CIA's, commercial, R&D, etc.
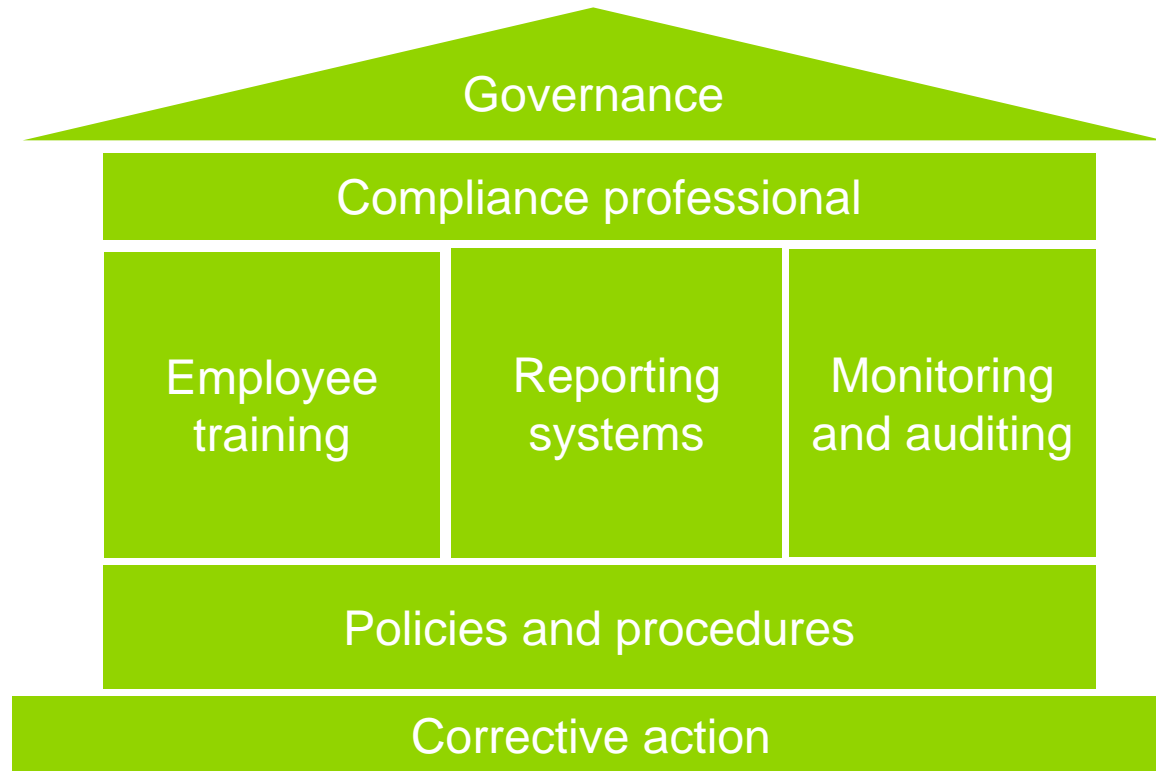
- Types of monitoring — physical, electronic, risk-based targeting and scoring process
- Legal considerations
- Panel/audience discussion on different approaches, perspectives and practices

A look to the future: what's needed, what's wanted, and what do we need to get there in the next 2-5 years?

# Review of key compliance auditing and monitoring considerations

Compliance program key elements

Governance

Compliance professional

Employee training | Reporting systems | Monitoring and auditing

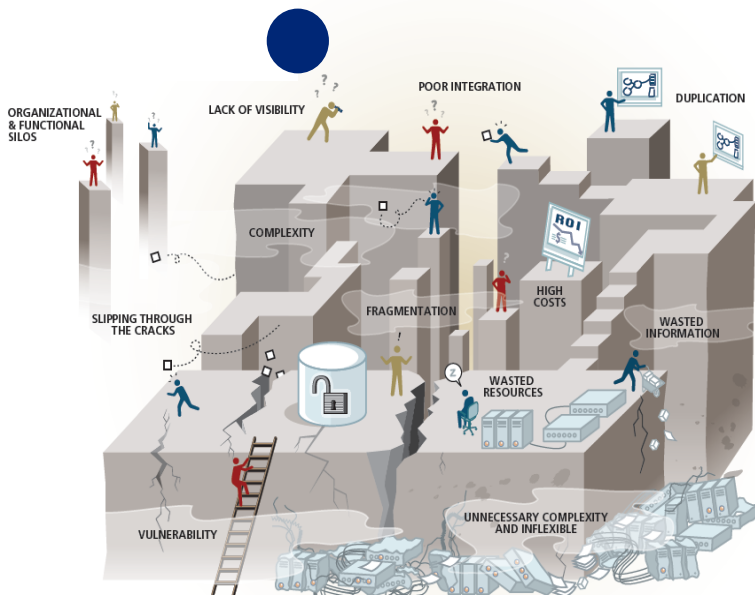Policies and procedures

Corrective action

A structure for managing regulatory risks within the enterprise

Silo-ed operations has lead to silo-ed compliance
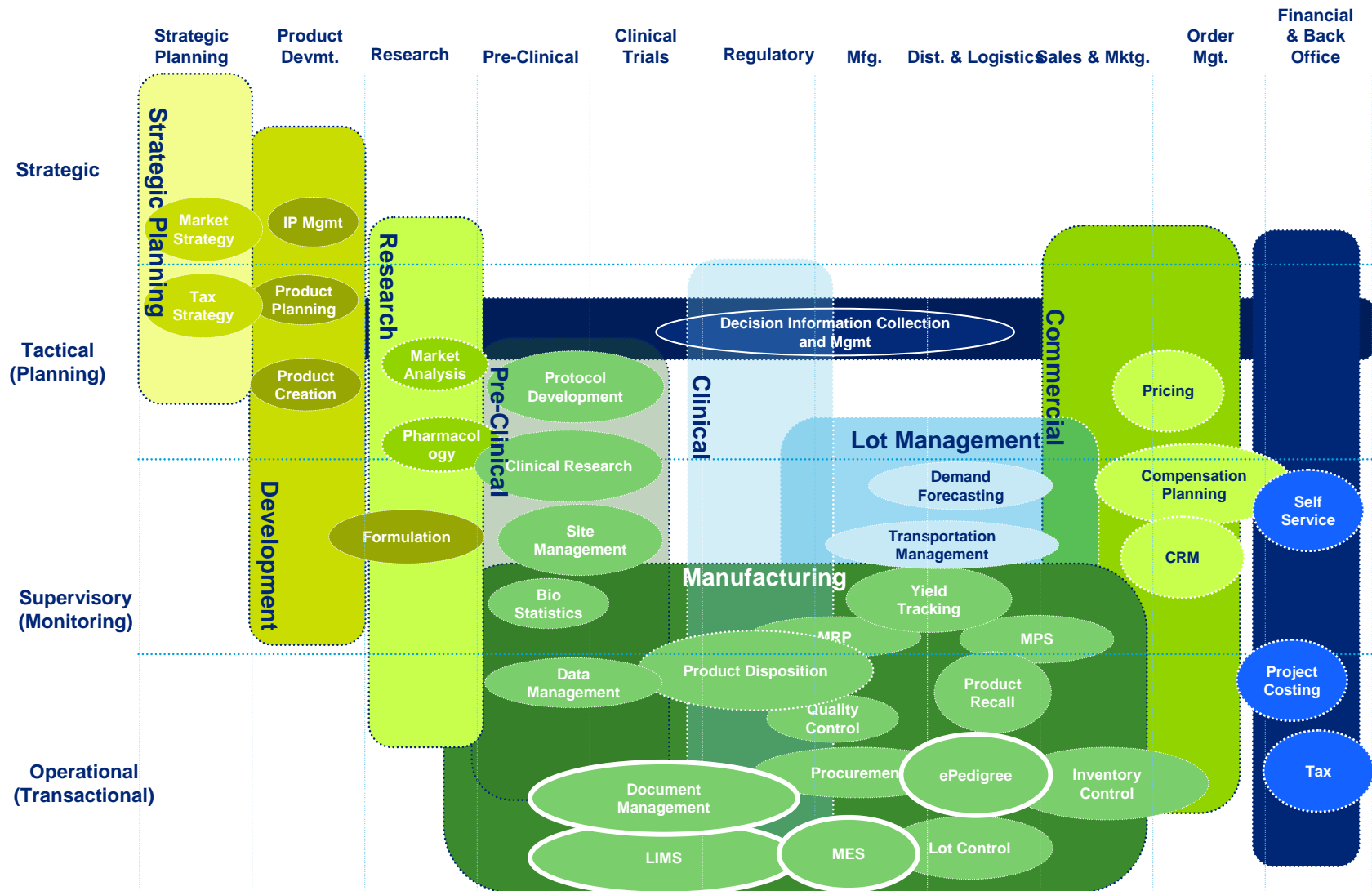
The transformation opportunity

Current state

- Managed in silo's
- Mostly reactionary
- More projects than programs
- Handled separately from mainstream processes and decision-making
- People used as middleware
- Limited and fragmented use of information technology

Future state

- Enterprise approach
- Integrated compliance program
- Program based approach
- Embedded within business processes and decision-making
- Effective use of information technology

Global and domestic compliance programs are moving toward a more centralized oversight model, acting as a hub to coordinate key processes and policies

- Changing regulations that require greater global consistency, speed, integration, coordination and reporting in a more highly regulated global market place with greater risks are driving this evolution toward *"enlightened decentralization."*

- The goal is a *fully integrated global program across business units* that achieves the right mix between global consistency with local customization *to achieve maximum compliance and business effectiveness*.

Compliance road map
Monitoring and auditing

- Develop auditing and monitoring plan

- Develop auditing and monitoring tools

- Prepare for each audit

  – Define scope

  – Define sample

  – Test tool — inter-rater reliability

  – Conduct review

  – Document findings and observations

  – Obtain management corrective action plan

  – Confirm correction
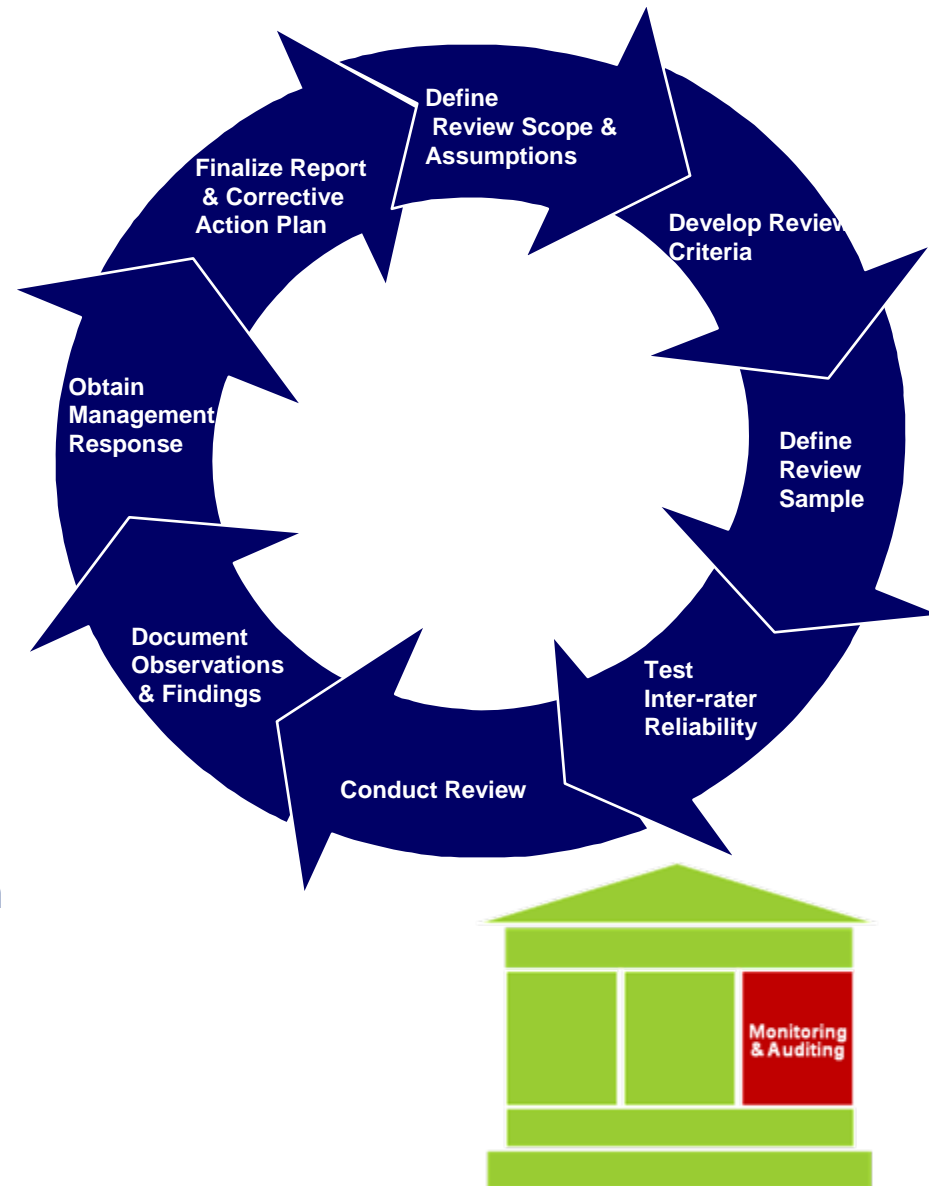
How to determine appropriate auditing and monitoring focus

Assess risk and prioritize

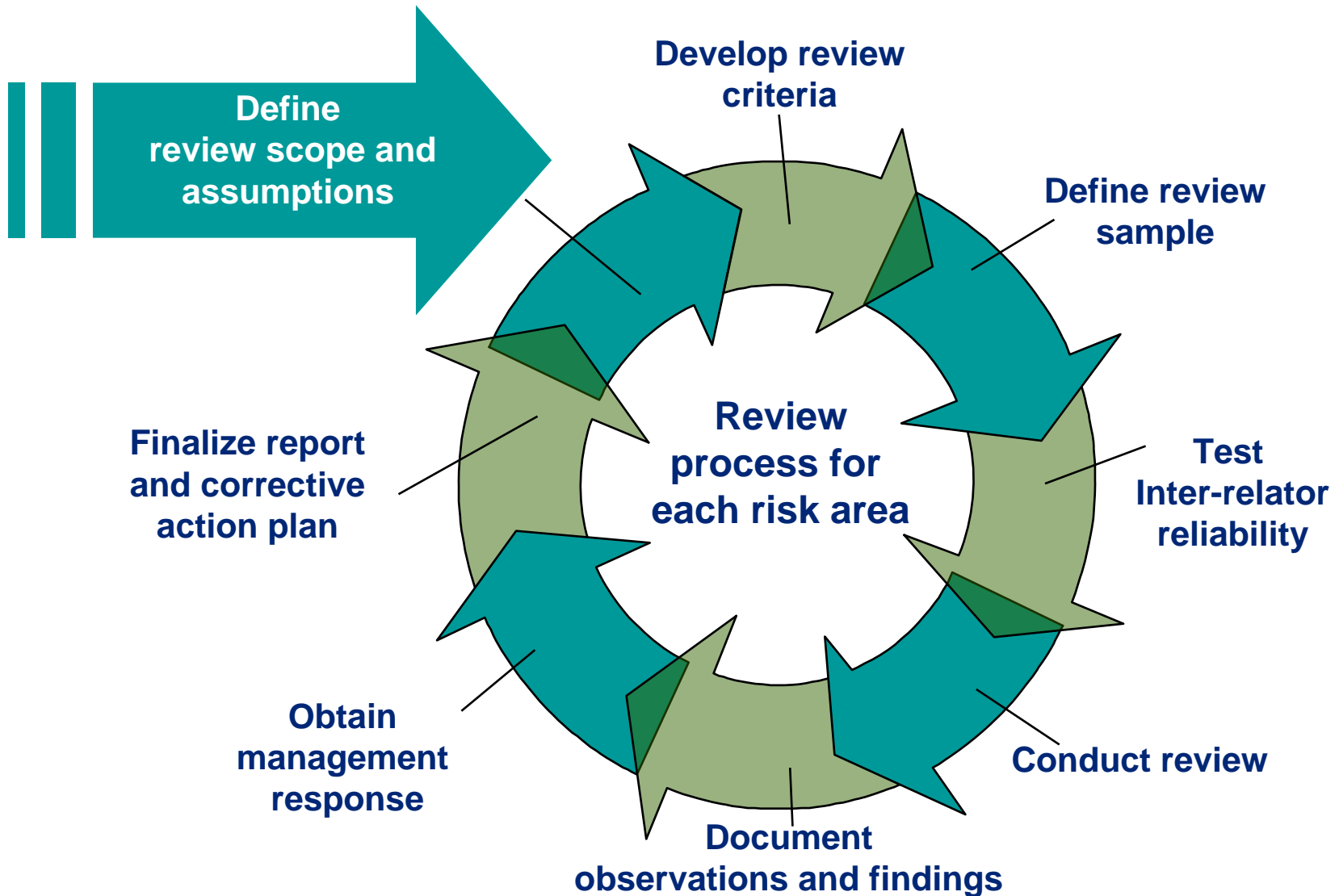Follow the Office of Inspector General (OIG) example in 2013 WorkPlan:

• Assess top challenges

• These challenges then become priorities for focus

• Issue workplan every year

• Constantly assess relative risks and potential impacts

• Before starting audits, ask:

– How many dollars are at risk?

– How many individuals are affected ?

– Is anyone's life, health, safety at risk?

– Any concerns from previous past issues?

• Then:

– Get input from credible sources to inform prioritizations

– Use data analysis, input from field, etc., to determine emerging trends

Excerpt from OIG 2013 workplan

Guidance from Principal Deputy IG, Larry Goldberg:

The review process

Define review scope and assumptions

Develop review criteria

Define review sample

Test Inter-relator reliability

Conduct review

Document observations and findings

Obtain management response

Finalize report and corrective action plan

Review process for each risk area
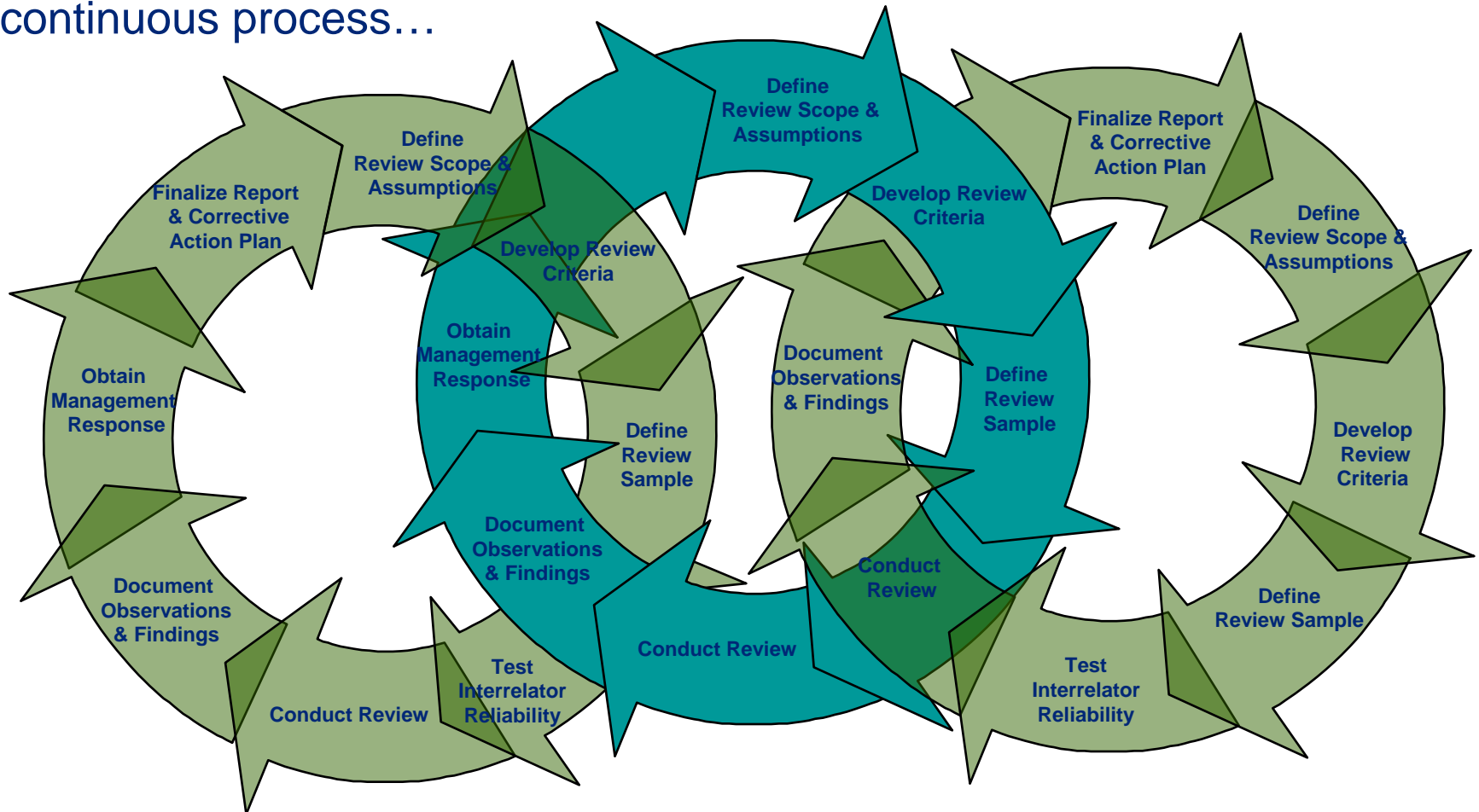
The monitoring plan

Monitoring never ends…each review leads to the next, and the monitoring plan and unplanned issues drive additional monitoring activities. It is a continuous process…

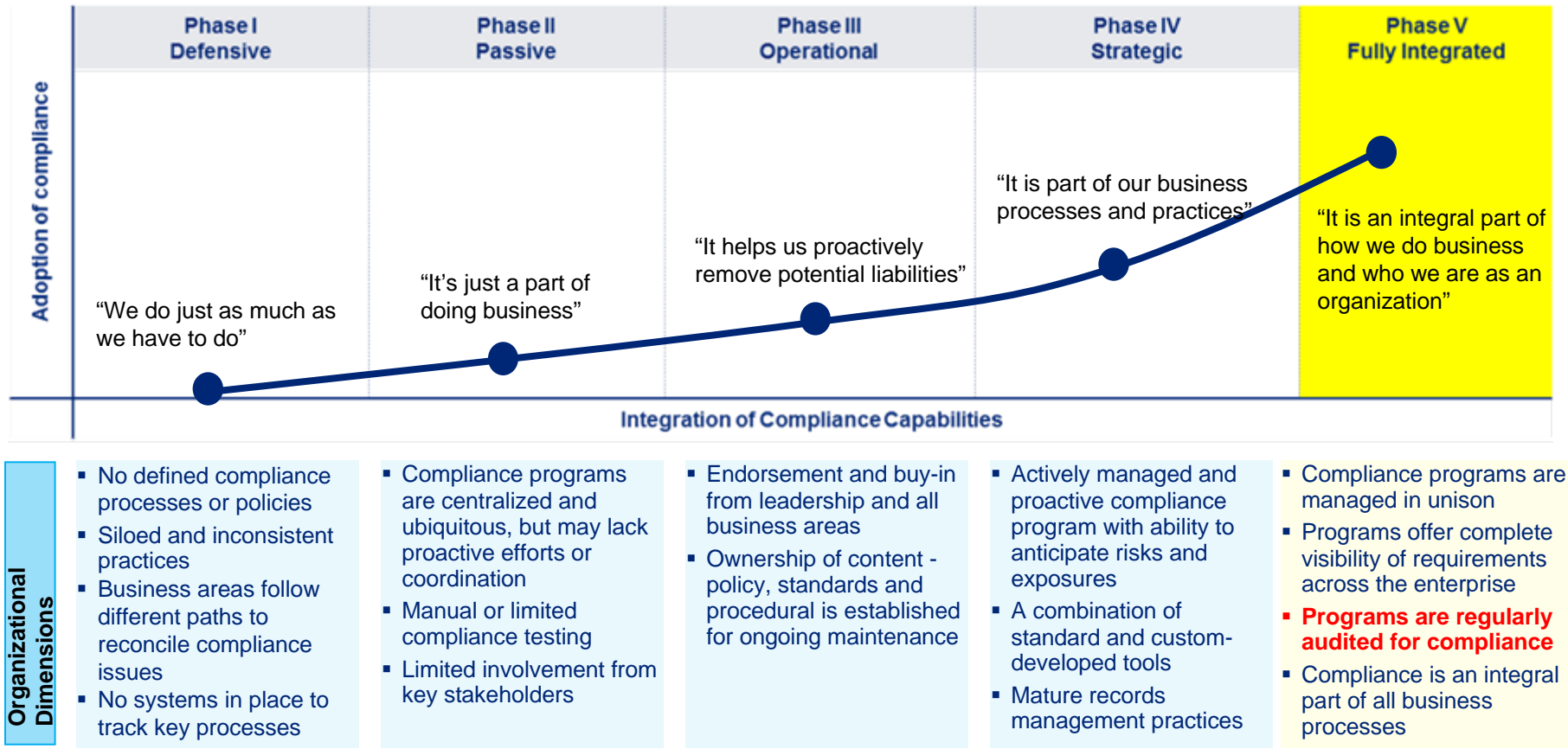# Annual audit plan development: a risk-based approach

- Risk assessment data

- Interviews with senior leadership

- Input from compliance organizations and legal

- Linked to Enterprise Risk Management activities

Sample risk drivers

– Sales growth

– Staff inexperience factor

– External ethical environment

– Prior audit

– Management team turnover

– Self assessment questionnaire
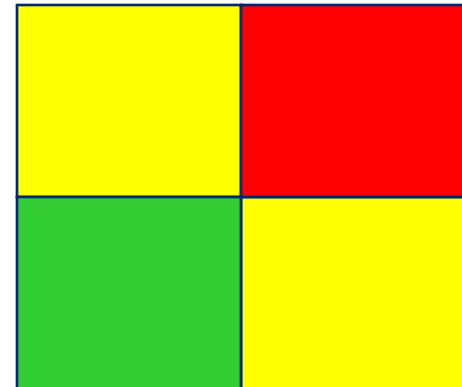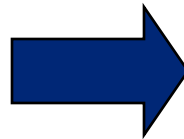
Organizational dimensions drive increased maturity of the organization's compliance programs and overall culture of compliance

	Phase I Defensive	Phase II Passive	Phase III Operational	Phase IV Strategic	Phase V Fully Integrated

Adoption of compliance (vertical axis)

"It is part of our business processes and practices"

"It is an integral part of how we do business and who we are as an organization"

"It helps us proactively remove potential liabilities"

"It's just a part of doing business"

"We do just as much as we have to do"

Integration of Compliance Capabilities (horizontal axis)

Organizational Dimensions

Phase I Defensive	Phase II Passive	Phase III Operational	Phase IV Strategic	Phase V Fully Integrated
▪ No defined compliance processes or policies ▪ Siloed and inconsistent practices ▪ Business areas follow different paths to reconcile compliance issues ▪ No systems in place to track key processes	▪ Compliance programs are centralized and ubiquitous, but may lack proactive efforts or coordination ▪ Manual or limited compliance testing ▪ Limited involvement from key stakeholders	▪ Endorsement and buy-in from leadership and all business areas ▪ Ownership of content - policy, standards and procedural is established for ongoing maintenance	▪ Actively managed and proactive compliance program with ability to anticipate risks and exposures ▪ A combination of standard and custom-developed tools ▪ Mature records management practices	▪ Compliance programs are managed in unison ▪ Programs offer complete visibility of requirements across the enterprise ▪ **Programs are regularly audited for compliance** ▪ Compliance is an integral part of all business processes

Panel presentations/ discussions

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Interactive audience/ panel discussions

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Break -- Do 15 Pushups and Take 15 Minutes !

(Pushups optional) ☺

Interactive audience/ panel discussions

(continued)

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DISMISSED!

Thank you! ☺

Appendix — back-up slides

Auditing and monitoring strategy

There are many issues to consider when determining the organization's auditing and monitoring strategy including:

- Consider integration with Internal Audit Plan

- Determine resources available to execute the plan

- Identify timeframes for audits

- Prioritize risk areas

- Communication of audit to stakeholders

Some key elements of HCC auditing

- Transparency on audit process and ratings

- Clarity on expected role of local team

- Preparation, fieldwork, closing

- Agreement on corrective actions and timelines

- Follow up and validation

- Planned audit vs. surprise

Auditing technique

Sampling:

Determine the risk

Example:

- High risk = pay more attention-use a standard sample size

- Low risk = less monitoring-consider using a probe sample

Sampling methodologies

Things to consider:

•The purpose of the sample or the review objective

•The universe/population/sources of data

•The size of the sample

•What you are going to do with the results

Purpose of the sample

Is the review for:

•Self-disclosure?

•Education?

•Part of an on-going monitoring plan?

•Response to the government, subpoena, etc.?

•Known risk area?

Sampling size

How much is enough?

- What is the purpose of your sample?
- If you are not sure you may want to start with a 30 probe sample

Do you need to test every commercial funding event?

- If you have an employee new to the funding processing role you might want to test to see if this employee is processing the requests as required.

Sampling techniques

- There are many ways to make samples statistically significant.

- Probe/discovery samples are used mainly to determine the size of the full sample in order to meet the required precision and confidence levels.

- Use a statistical sampling when it is impossible or prohibitively expensive to audit all claims in an overall population using a census covering 100% of these claims.

- The alternative is to audit a statistical sample of these claims that is representative of the population using randomly selected and statistically significant number of claims in the sample where every member of the population has an equal positive probability of being selected.

Sampling summary

- Random or judgmental sample selection

- Things to consider:
  - Size of the population/universe
  - Time and expense to review

- There are many ways and reasons to sample or test

- Remember to:
  - Determine why you are testing
  - Who or what you want to test
  - What you are going to do with the results

Information and communication

- The right amount of the right information

- At the right time

- To the right people

Audit reporting — Board and Senior Management oversight

- Aggregate results reported to Audit Committee and Senior Management

- Senior Management receives final report

- Management action plan completed for critical issues are tracked by Audit Services

- Past due action plans for critical issues are reported to the Audit Committee

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