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1.06 Integrating Compliance with Business:

Developing and Operating a Business-Facing Compliance Program

A Case of Partnership

Facilitator

Jody Ann Noon
National Practice Leader
Life Sciences & Health Care
Regulatory Practice
Deloitte & Touche LLP

Presenters

Ty Howton
Healthcare Compliance Officer
Genentech

David Davidovic
Senior Director
Business Practices
Genentech

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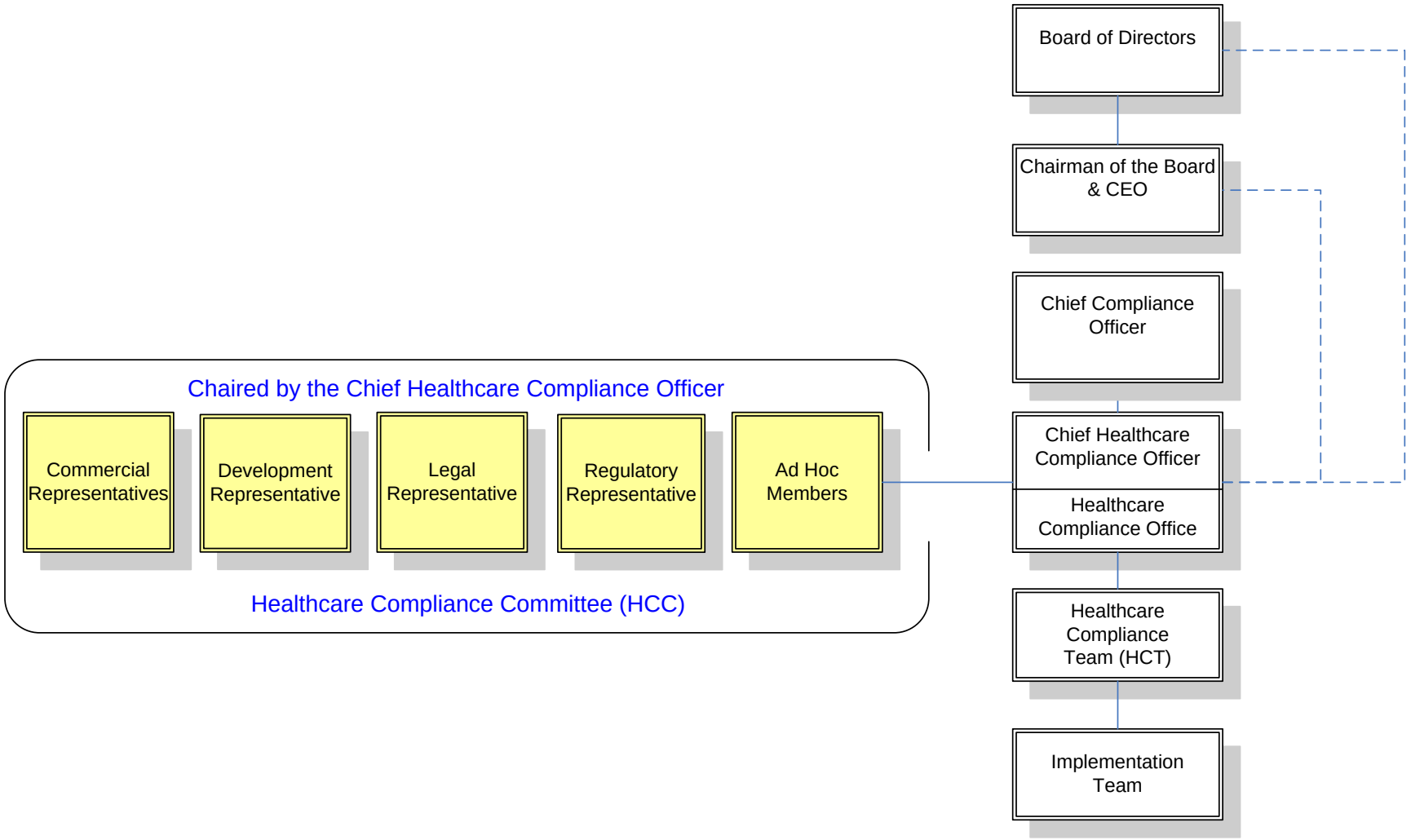
Today's Panel Discussion

- Genentech has always had a strong compliance foundation.
  - Formalized compliance activities in 1995, 8 years before the OIG issued its Guidance for Pharmaceutical Manufacturers in 2003
  - And has been continuously growing and enhancing since then.

- This session will discuss an approach for converting legal and ethical requirements into business-facing processes through a cross-functional compliance initiative. The presenters will provide insights into –
  - The Program's Structure
    - » A cross-functional compliance team
    - » Defined accountabilities
  - Policy & Process
    - » Turning law into processes
    - » End-to-end business involvement in the compliance program
  - Fostering a Culture of Compliance

Healthcare Compliance Program - Structure

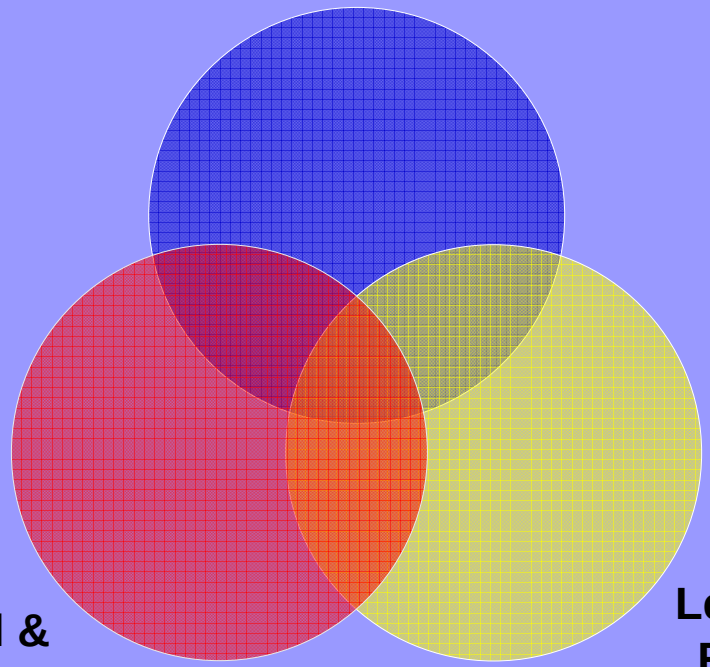


Compliance & Business – The 7 Spaces

Unique and Shared Accountabilities

RACI

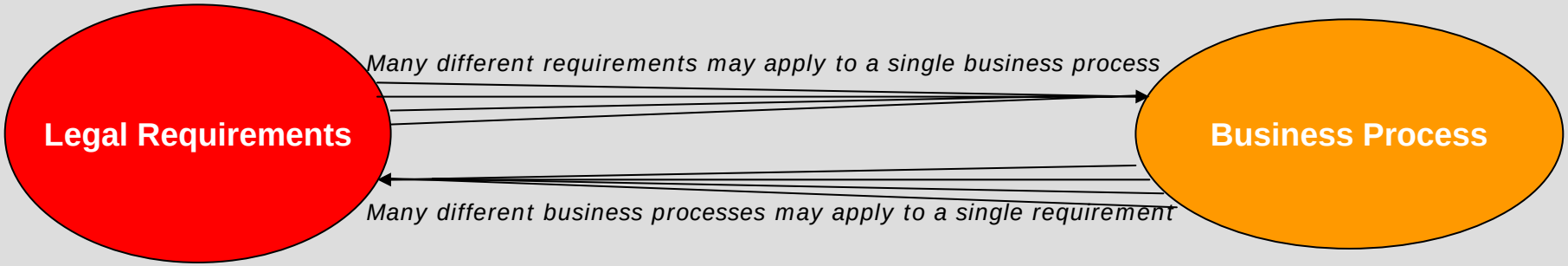
- ***Responsible***
- ***Accountable***
- ***Consult***
- ***Inform***



Standards

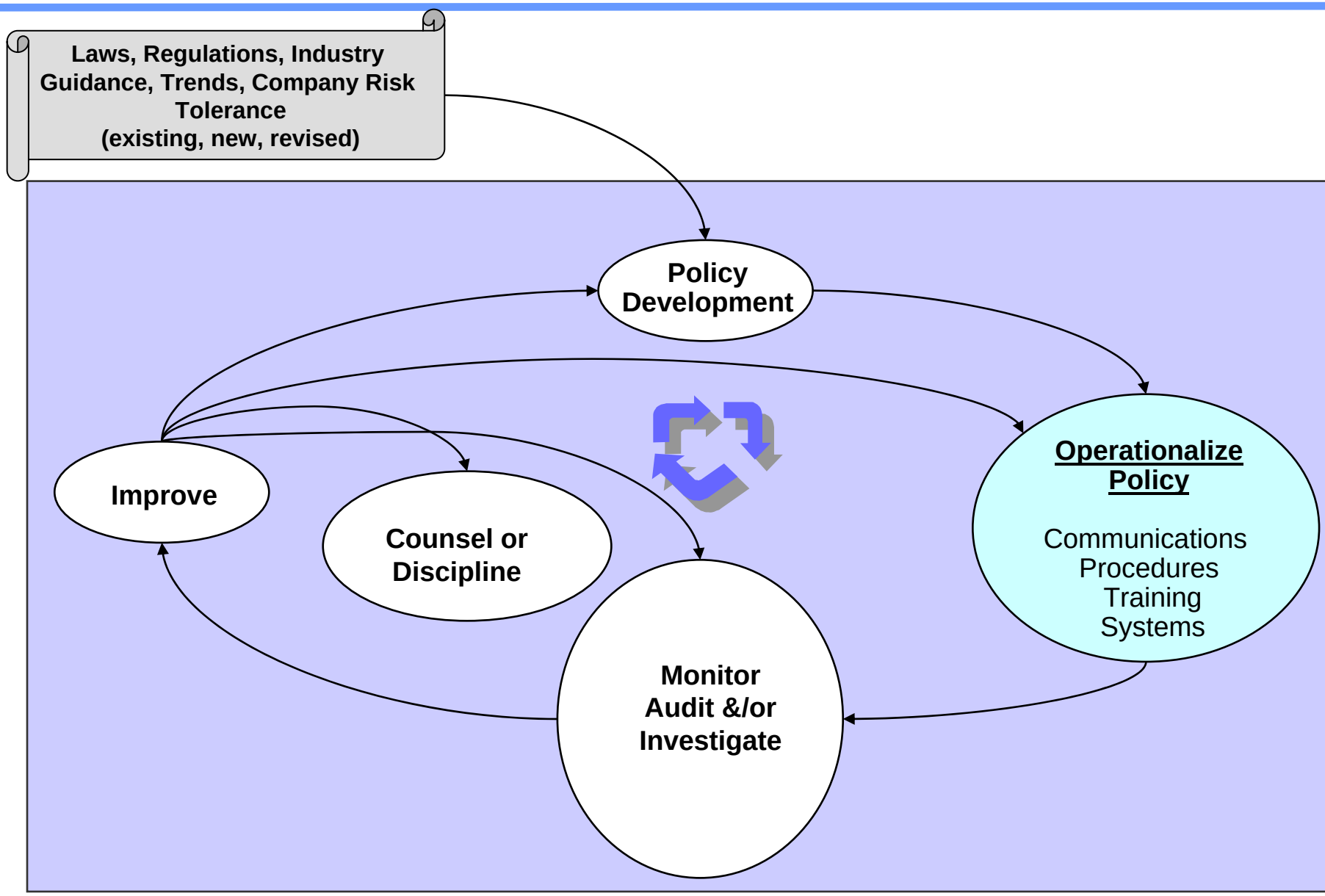
- Organizations are challenged with the translation of legal requirements into business facing standards. It is important to ensure that context not be lost in the translation.
- Program success depends on effective ***change management,*** possible only through clarity and relevance of implementation efforts.

Genentech's Reciprocal Approach to Compliance Standards

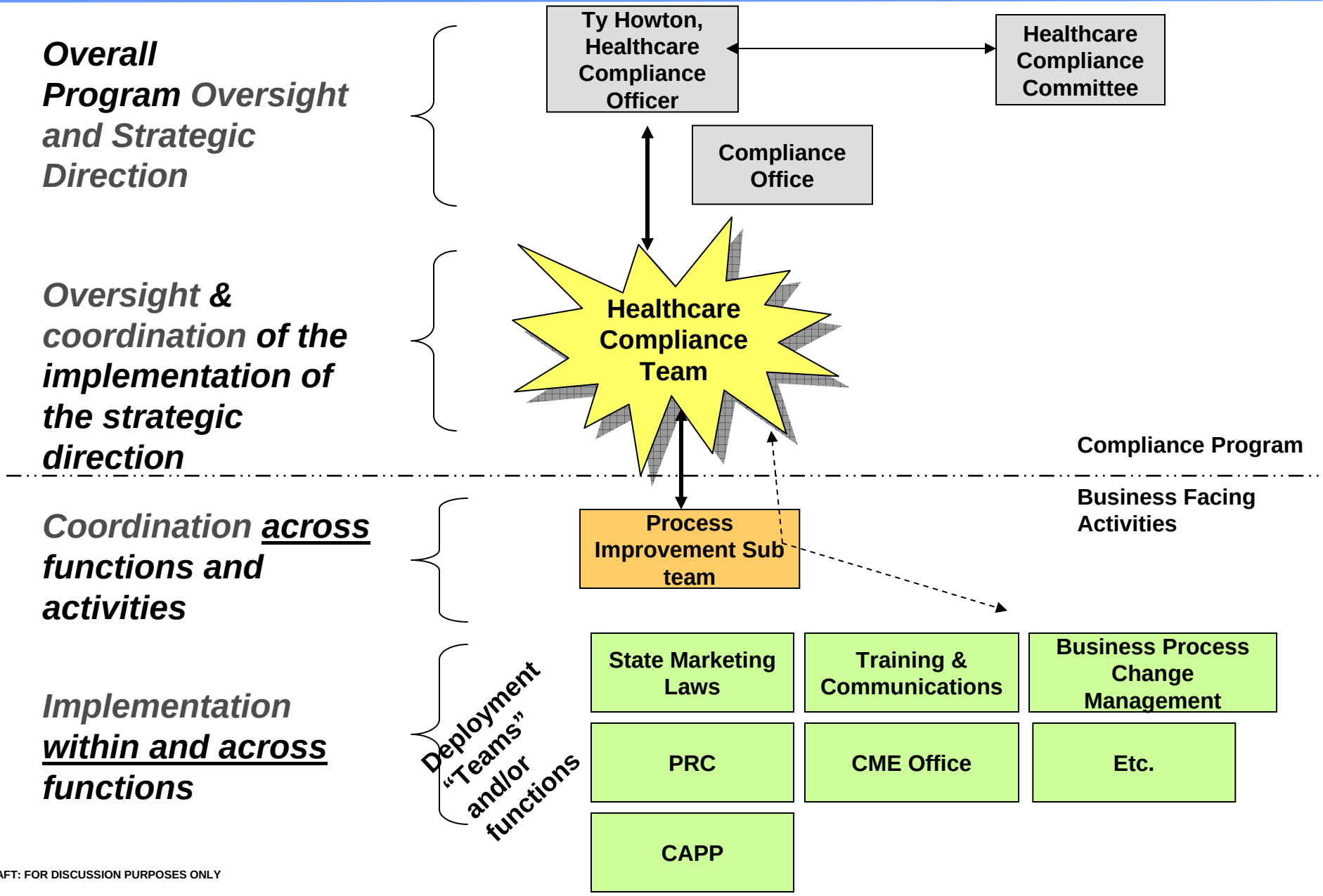


Code of Conduct	High level statements that include compliance with laws, regulations & Genentech's policies
Healthcare Compliance Policies	Statements that set forth Genentech's policies for compliance with specific laws, regulations & industry standards
Healthcare Policy Guidelines	More specific guidance with respect to clearly defined and outlined activities that fall within a policy. A policy may have multiple guidelines associated with it.
Healthcare Practices/Processes & Procedures	Business facing job-specific procedures, templates and tools that assist employees to implement or operate in adherence with a Healthcare Policy Guideline & related policy

The Seven Elements in Action



Healthcare Compliance Program – Business Process Improvement



David Davidovic

- David Davidovic is Senior Director, Commercial Business Practices. He joined Genentech in March 2005 bringing over 26 years' experience in the pharmaceutical industry, most of it with Merck & Co. There he served in many different capacities, most as recently as Executive Director of Marketing.

- His career has included leadership positions in marketing, sales, business development and commercial operations in Canada, in the US and globally, and has covered multiple therapeutic areas and a variety of strategic and operational functions. Among other roles at Genentech, he is responsible for assessing, guiding and implementing Commercial business practices and processes, that include healthcare compliance.

- David holds a BS in physiology and an MBA in marketing/information systems, both from McGill University in Montreal, Canada. He was born and raised in Ecuador.

Ty Howton

- **Ty Howton is Genentech's Chief Healthcare Compliance Officer responsible for overseeing Genentech's Healthcare Compliance Office and Healthcare Compliance Team. Ty joined Genentech's legal department in 2003 and was most recently the Practice Group Leader, Managed Care, Customer Operations and Government Affairs in Genentech's Commercial Law Group .**
- **Prior to joining Genentech Ty was in the Healthcare group at Sidley & Austin. In that capacity he provided counsel to companies on reimbursement, regulatory compliance, fraud and abuse, and Anti-kickback issues. Ty participated in the defense of pharmaceutical companies under government investigations.**
- **Ty holds a BA from Yale University and JD from Northwestern University.**

Jody Noon, RN, JD

- **Jody Noon is the National Practice Leader of Deloitte &Touche, LLP Life Science and Health Care Regulatory Practice. She has over twenty-seven years of clinical, administrative and legal experience in health policy surrounding quality assurance, risk management and compliance. She also has over 15 years' experience as a prior practicing health care regulatory lawyer assisting organizations to comply with Federal Fraud and Abuse, Stark, Medicare, Medicaid and Privacy requirements.**
- **Prior to joining Deloitte & Touche, she assisted health care providers to develop business processes to comply with complex and often conflicting regulations. In doing so, she drafted legislation, negotiated corrective action plans; defended clients in administrative court proceedings initiated by state and federal governmental entities and developed compliance programs.**
- **Jody has published numerous articles and lectures nationally on the subject of compliance.**

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