Cross cultural Compliance and Compliance Across Borders

Compliance Across Asia – New Challenges and Chances for Practical Integrity

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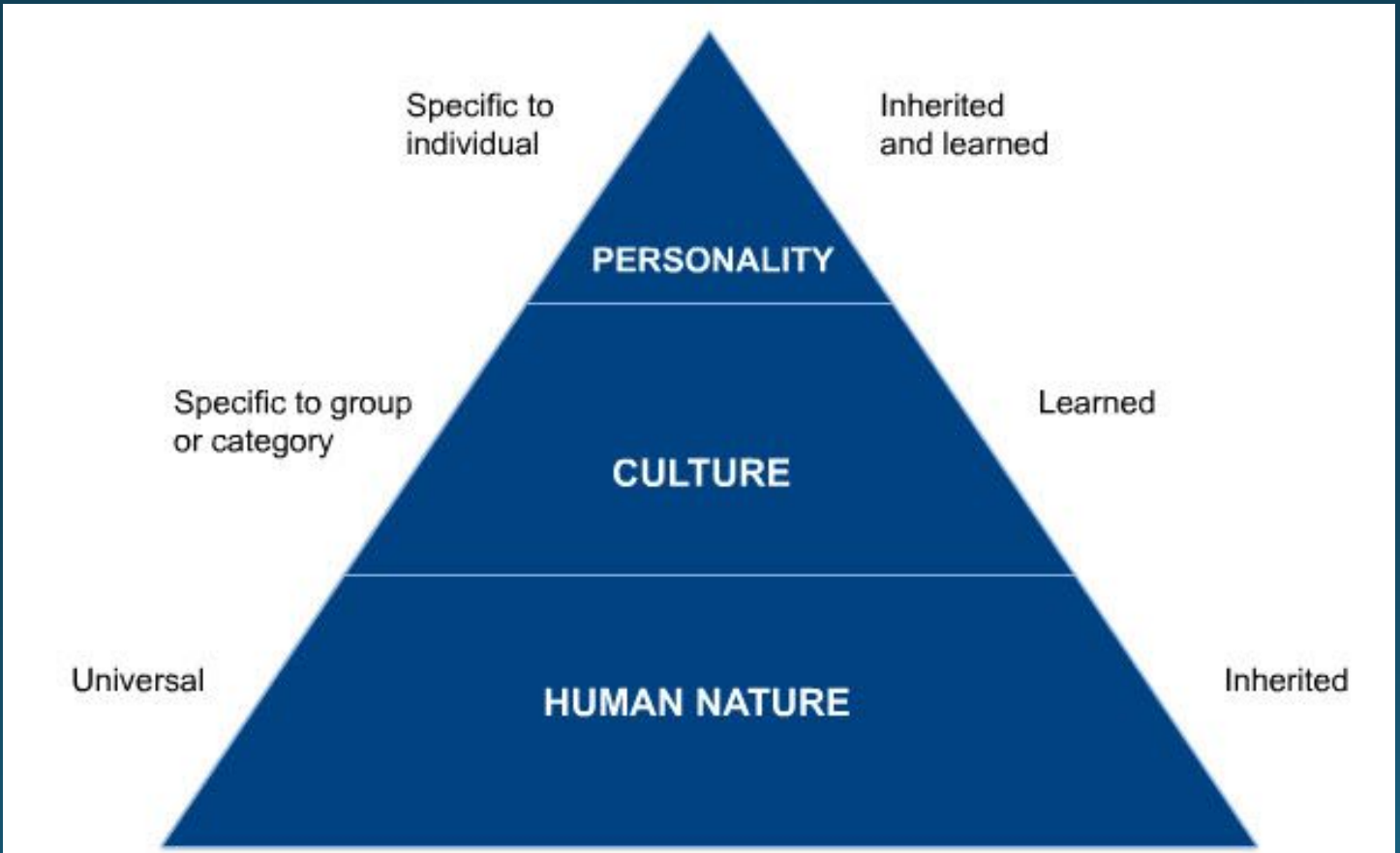
Ronald Goon

Compliance and Culture

- Compliance
  - The act of following the rules (government legislation and regulations, industry codes, established guidelines or specifications, company policies and procedures)
  - Ever increasing list of legislation, regulations and requirements
    - Anti-corruption/Anti-bribery
- **Culture**
  - The behaviours, beliefs, values, and symbols of a group of people - their way of life - that they accept, generally without thinking about them, and that are passed along by communication and imitation from one generation to the next
  - Symbolic **communication**

Hofstede's Pyramid of Culture



Source: Hofstede, *Cultures and Organizations: Software of the Mind*, 2005

Global Environment

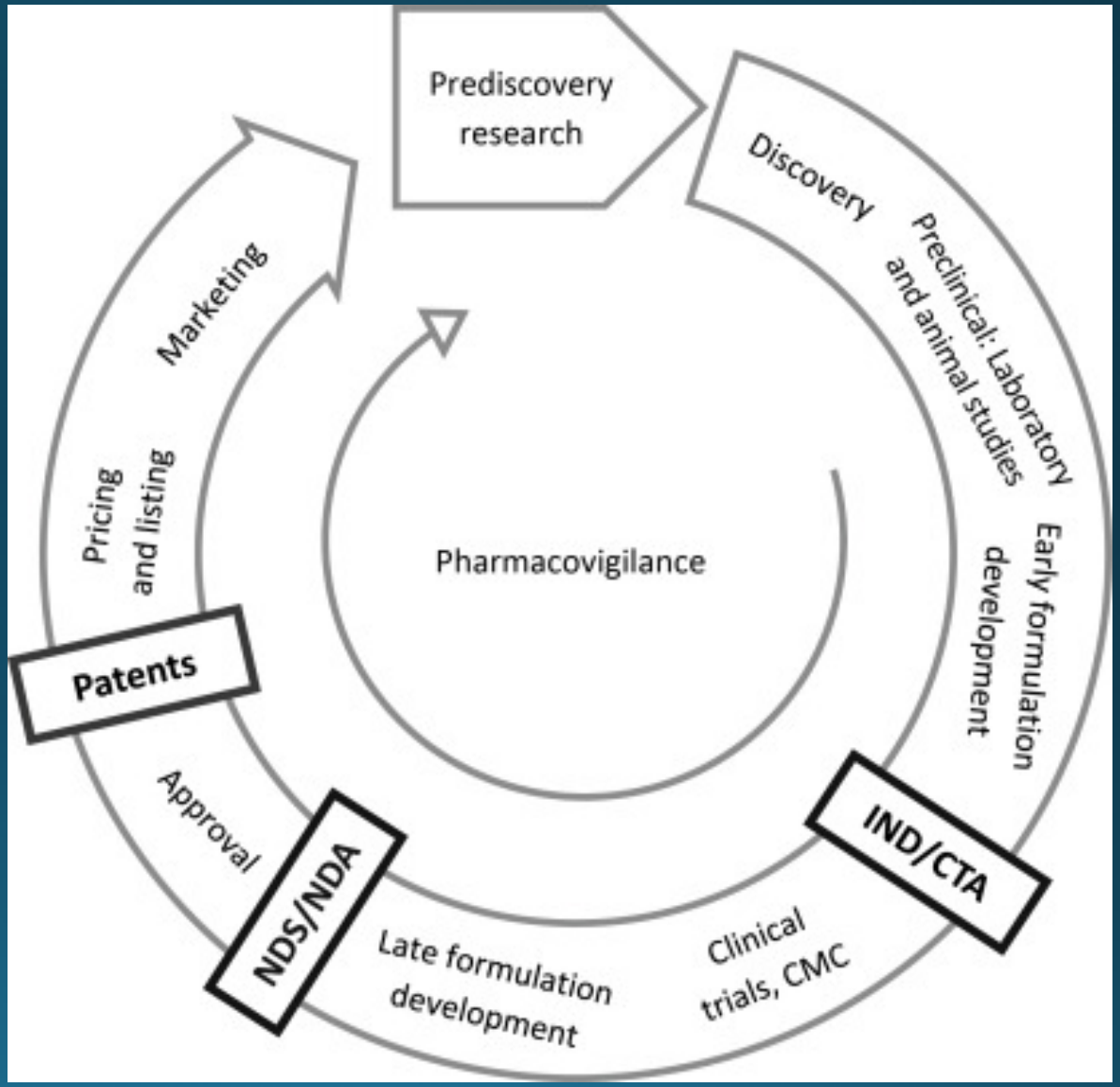
Healthcare Company Environment

- Internal Environment
  - Company Values
  - Company Policies and Procedures
  - Tone of the management
  - Organization Structures and Changes
  - Compensation
  - Employee Treatment
  - Different local cultures in the markets the company operates

Healthcare Company Environment

- External Factors
  - Legislation and regulations in the jurisdictions the company operates
  - Industry codes of practice and ethics
  - Different local cultures in the markets the company operates
  - Customer expectations
  - Competitor behaviour and practices
  - Special interest groups

Pharmaceutical Product Lifecycle



Pharmaceutical Product Lifecycle

Healthcare Company Environment

- Business Partners and Third Party Intermediaries
  - R&D Collaborators
  - Clinical Research Organizations
  - Site Management Organizations
  - Regulatory Consultants
  - External Manufacturers
  - Logistics Agents
  - Custom Clearance Agents
  - Distributors/Sales Agents
  - Market Survey Agencies
  - Travel Agents

Creating a Culture of Compliance

- **Communication and Tone of the Management**
  - Clear and transparent messages on the expected behavior from the very top and every level of management
- **Training and Awareness**
  - Continual training on laws, regulations and codes of practice - updates on the latest requirements
  - Understanding the regulations and expectations
- **Business Operations and Product Lifecycle**
  - Considered in all aspects and stages of business (R&D, production, sales , distribution)
- **Enabling Technology**
  - Use of technology for implementation and governance (e.g., training programme support, process control, compliance monitoring)
- **Audit and Monitoring**
  - Establish processes for measuring performance, incident reporting of improper behaviour
- **Remediation**
  - Identify root causes of problems and implement corrective actions
- **Recognition**
  - Reward right behaviour and penalize wrong behavior

- Coors Beer in Mexico
  - Actual → Turn It Loose
  - Spanish → Suffer From Diarrhea

- KFC in China
  - Actual → Finger lickin' good!
  - Translated → Eat your fingers off!

- Coca Cola in China
  - Pronounced Ke-kou-ke-la → Bite the wax tadpole
  - Changed later to ko-kou-ko-le → Happiness in the mouth

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Cultural Compliance Challenges

- Personal Gifts
  - Special Occasions/Festive Celebrations
    - Mooncakes

  - Significant Life Events
    - Weddings
      - Red Packets
    - Deaths
      - White Gifts

Cultural Compliance Challenges

- Inappropriate Venues
  - Luxury or resort locations
  - MICE venues with casinos

- Contract Provisions
  - Anti-corruption and anti-bribery compliance
  - Audit rights

Compliance and Ethics

- Ethics and compliance are essentially different sides of the same coin. Compliance is following the law, while **ethics** is doing what is right regardless of what the law says. Compliance is something that the government requires you to do. Ethics, on the other hand, is something you choose to consider when taking action.

- "Compliance is a framework for ensuring an organization and its people comply with laws and regulations that are applicable to it and minimizing the risk of noncompliance," notes Gerry Zack, CEO of both the Society for Corporate Compliance and Ethics (SCCE) and the Health Care Compliance Association (HCAA). "One of the many facets of a compliance program is ethics."

- "Ethics goes beyond what the law requires. It involves doing the right thing and following both the spirit and not just the letter of the law."
  -Carol Tate, Intel

ကျေးဇူးတင်ပါတယ်

Salamat

Terima Kasih

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谢谢

Dankeschön

Thank You

감사합니다

cảm ơn ban

Gracias

धन्यवाद

ありがとうございました

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