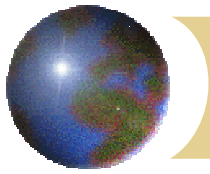




Exploring Business Risk Principles for EHS

**NAEM Workshop
May 10, 2006**

Jim Thomas
Global Head – HSE, NEM & BC
Novartis Consumer Health (Gerber)

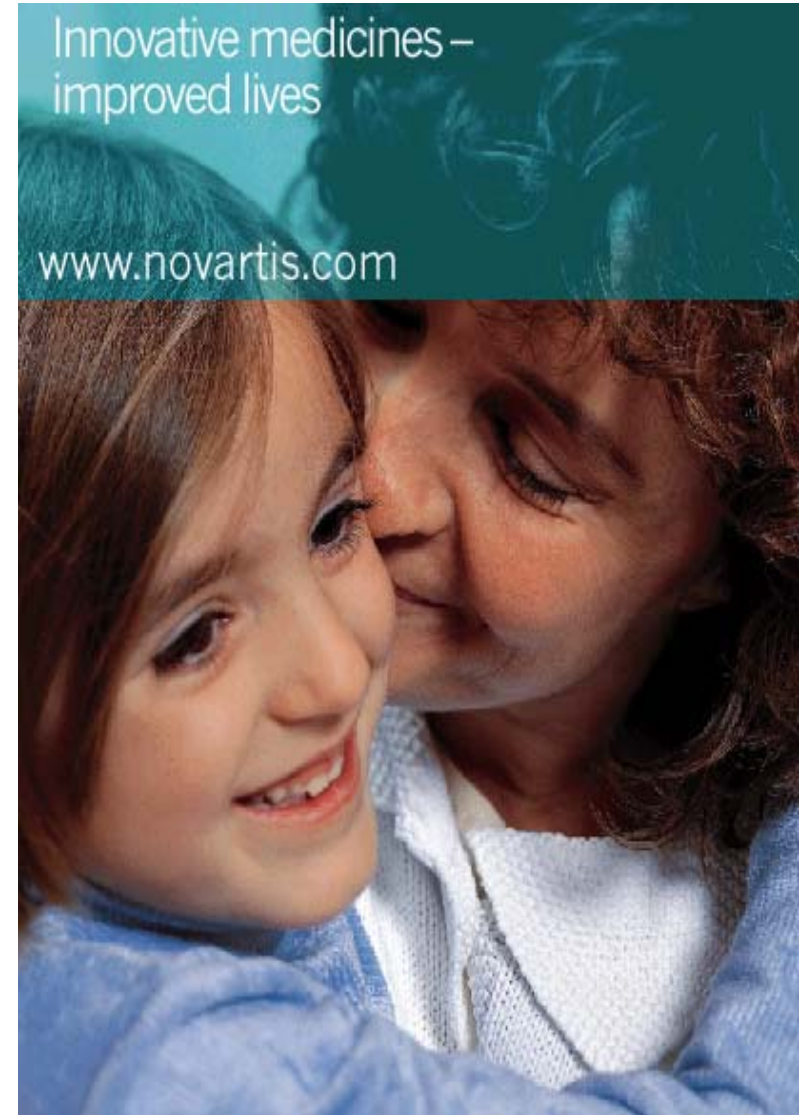


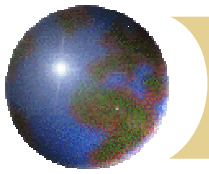
Novartis

A World Leader in Healthcare

Our Purpose

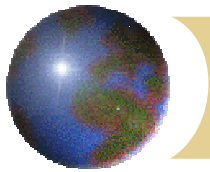
We want to discover, develop and successfully market innovative products to cure diseases, to ease suffering and to enhance the quality of life. We also want to provide a shareholder return that reflects outstanding performance and to adequately reward those who invest ideas and work in our company.





Novartis Facts

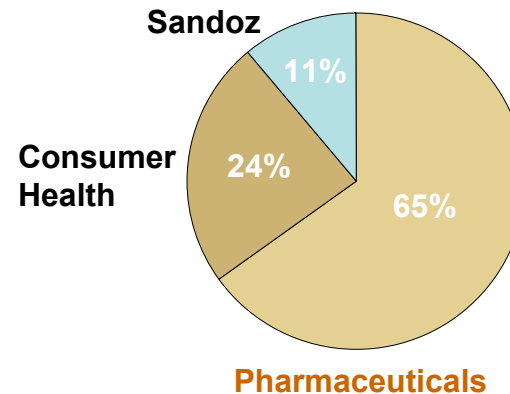
- 20th largest company worldwide (based on market capitalization)
- 2005 – 32.2 B in sales, 6.1 B in net income, 91,000 employees
- 4th largest branded Pharma company & 2nd largest generic Pharma company



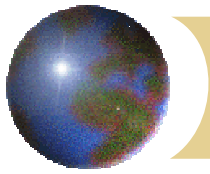
Novartis in the US

- **Novartis Pharmaceuticals Corporation** — branded pharmaceuticals
- **Novartis Consumer Health, Inc.** —
 - (Gerber baby foods and baby care products)
 - OTC: over-the-counter medications
 - Generics: Sandoz, Inc.
 - CIBA Vision: contact lenses, lens care and ophthalmic surgical products
 - Animal Health: companion animal care products
 - Animal Vaccines - vaccines for the farm animal market
- **Novartis Biomedical Research Institute** - worldwide pharmaceutical research headquarters in Cambridge, MA
- **Headquarters in New York City**
- **Approximately 15,000 employees**
- **US accounts for more than 40% of worldwide sales.**

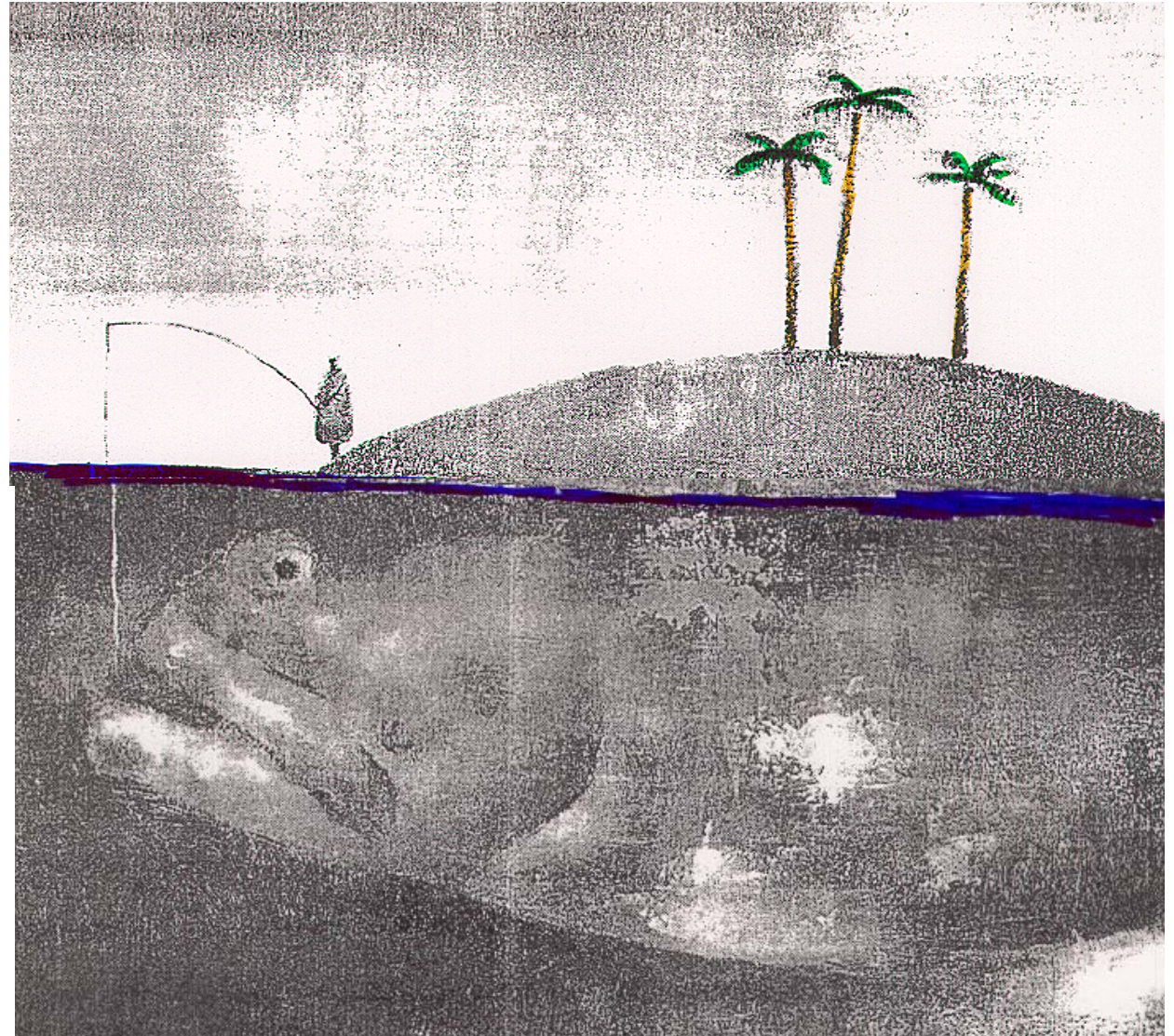
Sales by division 2004*

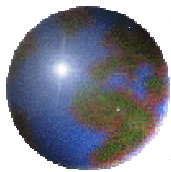


● **Novartis Total: 28.2 bn (USD)**



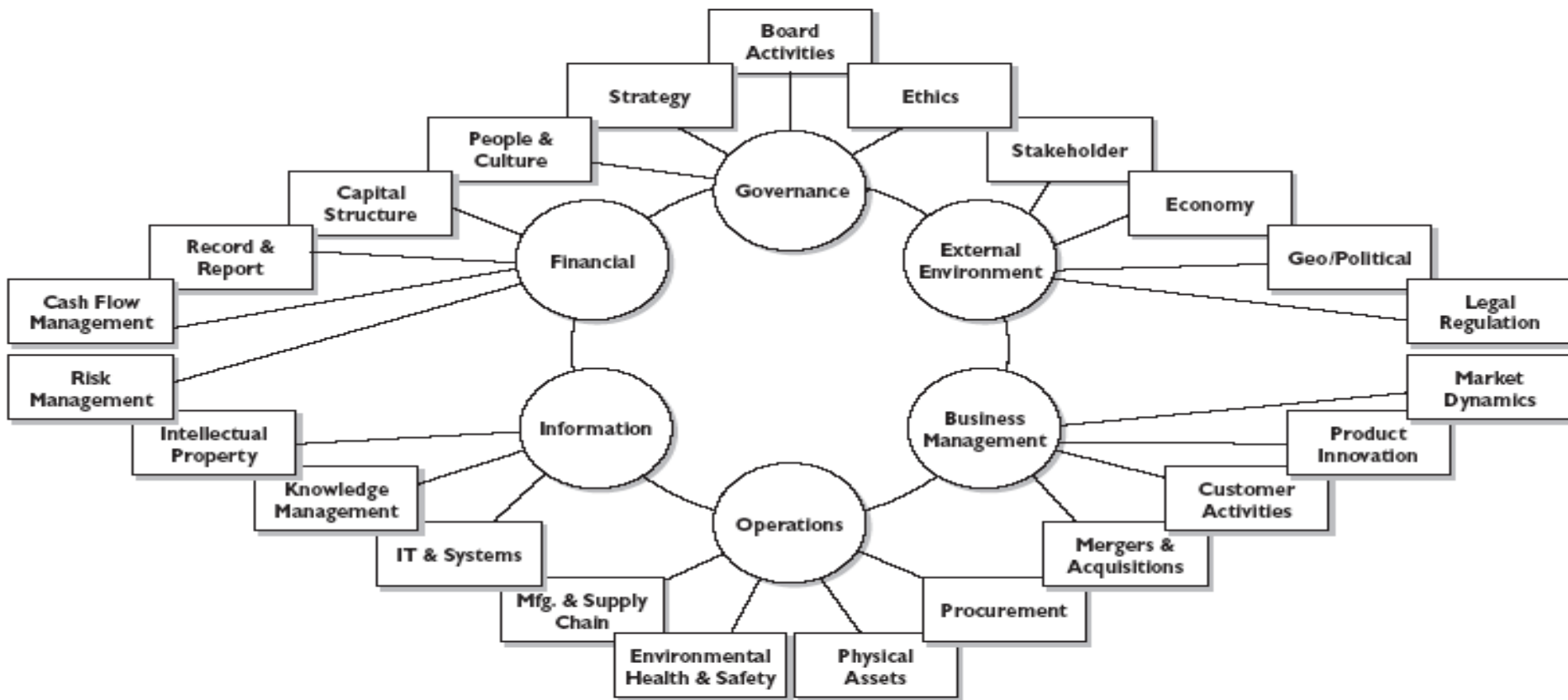
**Risk - it
isn't always
where you
think it is**



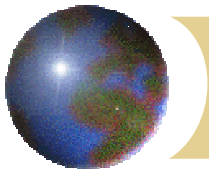


RISK TAXONOMIES

RISK UNIVERSE



Source: The Dow Chemical Company (based on E&Y Risk Universe, used with permission); Working Council for Chief Financial Officers research.



Global Risks

Economic

- Oil prices/energy supply
- Asset prices/Indebtedness
- US Current Account deficit and US dollar
- Coming fiscal crises
- China
- Critical infrastructures

Societal

- Regulation
- Corporate governance
- Intellectual Property rights
- Organized crime
- Global pandemics
- Slow & Chronic Diseases (Industrialized world)
- Epidemic disease (Developing world)
- Liability Regimes

Environmental

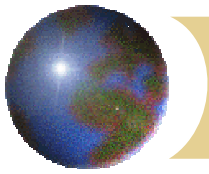
- Tropical cyclones
- Earthquakes
- Climate change
- Loss of ecosystem services

Technological

- Convergence of technologies
- Nanotechnology
- Electromagnetic fields
- Pervasive computing

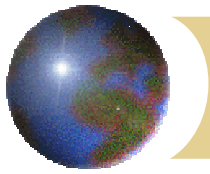
Geopolitical

- Terrorism
- European dislocation
- Current and future hotspots

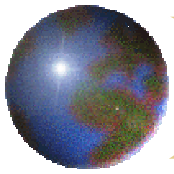


Novartis Risk Tools

- **HSE Risk Portfolio** – a matrix used to convey information on risk to management for decision-making
- **Business Continuity Management** – is the act of anticipating incidents which will affect mission critical functions and processes for the organisation and ensuring that it responds to any incident in a planned and rehearsed manner.
- **Product Stewardship** - seeks to continuously ensure the active management of benefits and risks of our products by providing measures to protect and benefit consumers in line with our Corporate Citizenship commitment, and to manage the product-related risks of Novartis as a whole.
- **Enterprise Risk Management** - essential part of Novartis strategic management which aims to ensure that business, financial, legal, and reputation risks are appropriately managed to reasonable assure the attainment of Novartis objectives and long-term business success



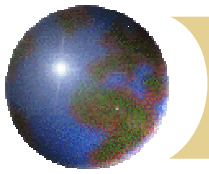
Novartis Risk Portfolio



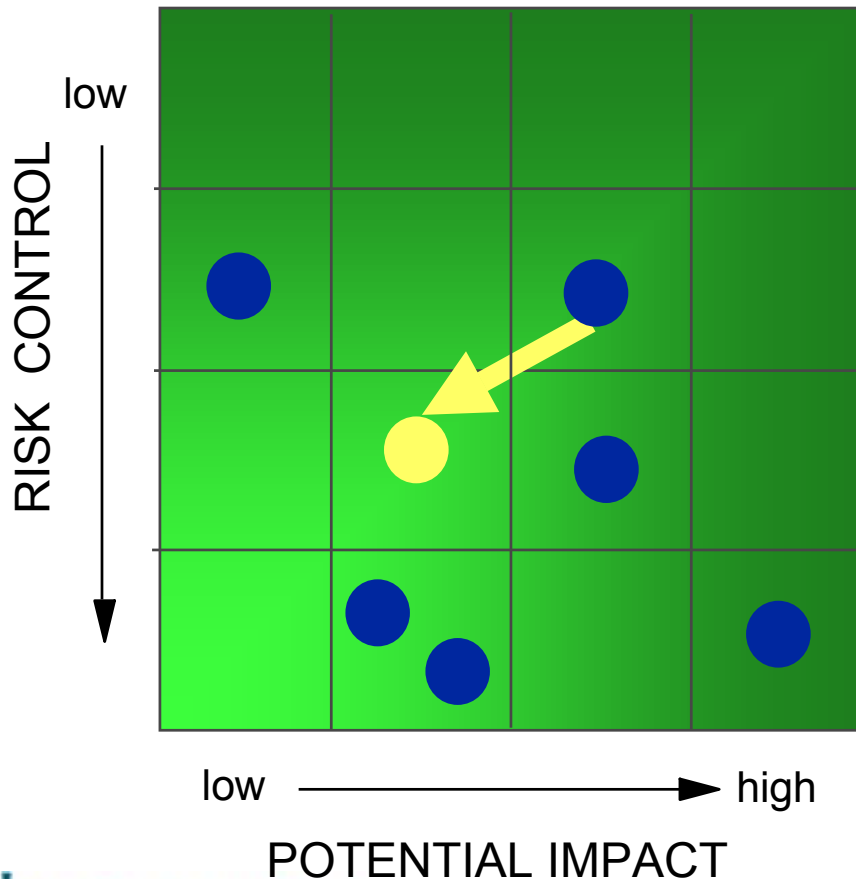
Columbia Shuttle Accident



This view was taken from Dallas. (Robert McCullough/© 2003 The Dallas Morning News)

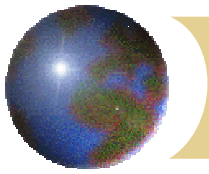


Novartis Risk Portfolio



Objectives

- ▶ Overview of major risks at site, sector, country, group level
- ▶ management awareness, involvement and support
- ▶ basis for planning and setting goals
- ▶ record of improvements

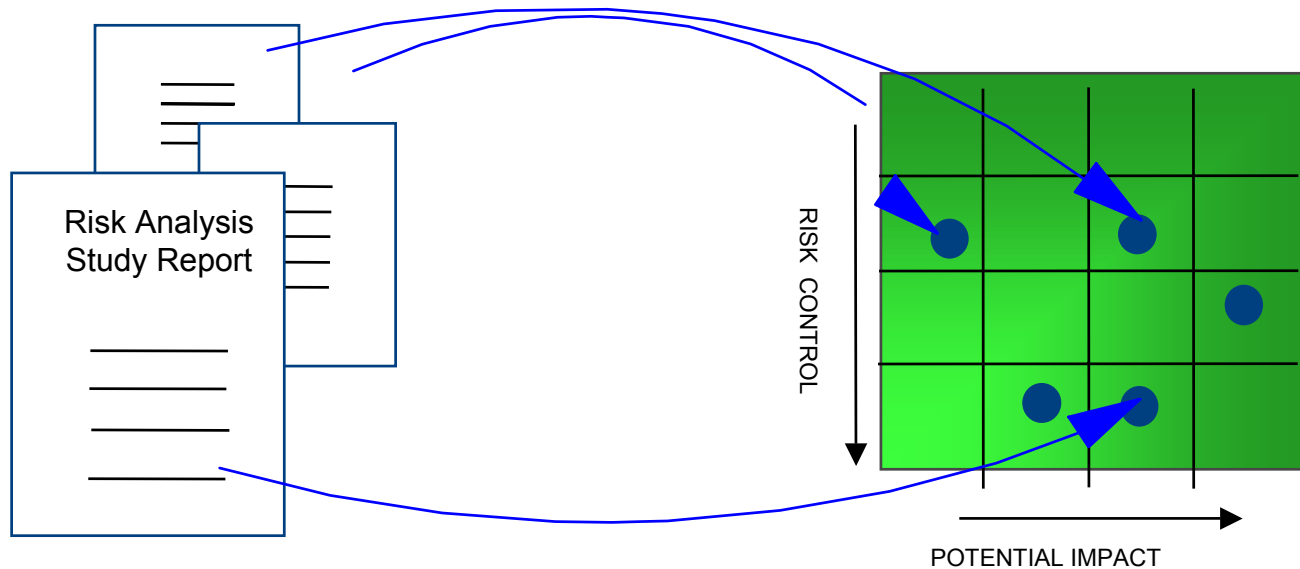


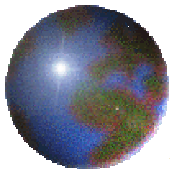
Risk Analysis

Analysis of **individual** projects, activities, or facilities
basis for project decisions

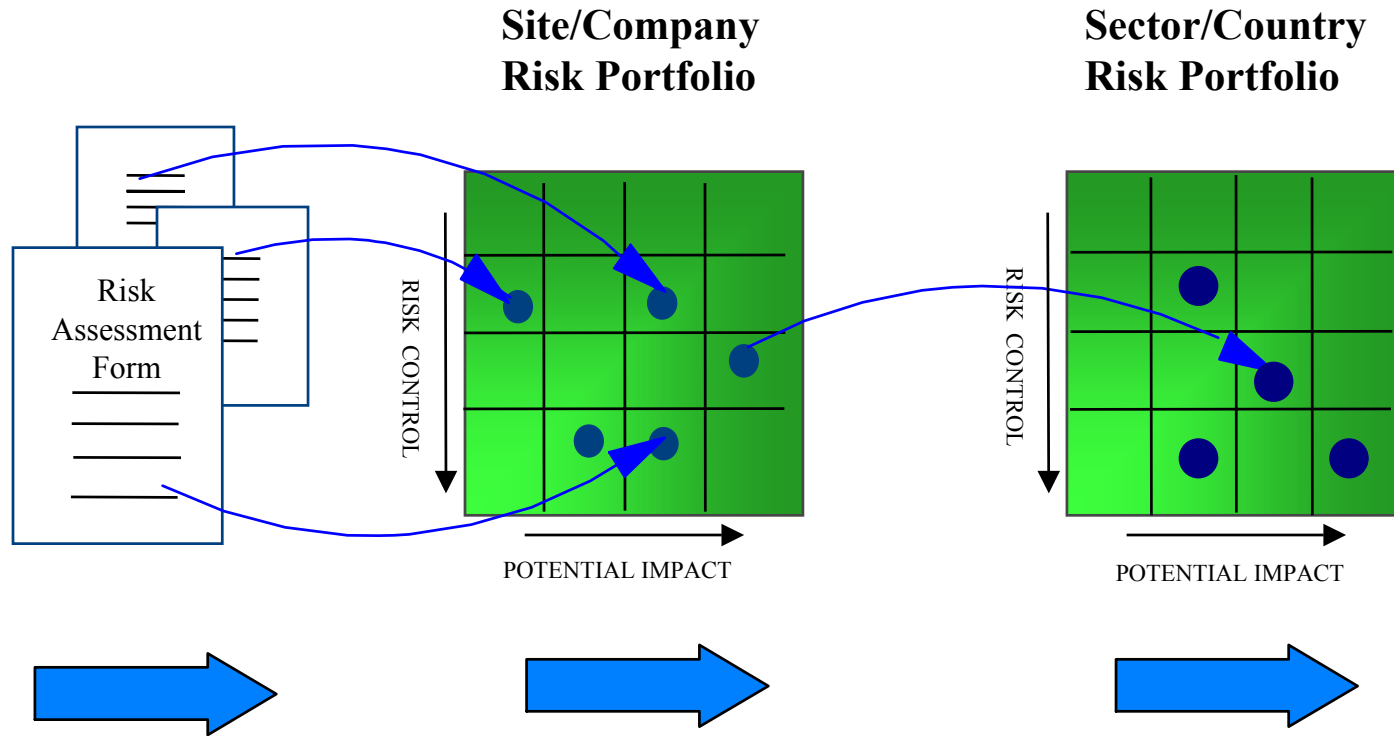
Risk Portfolio

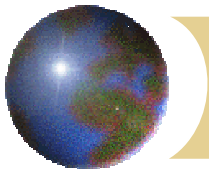
Overview of **major** risks of a site, company, Sector, country
basis for **strategic planning**



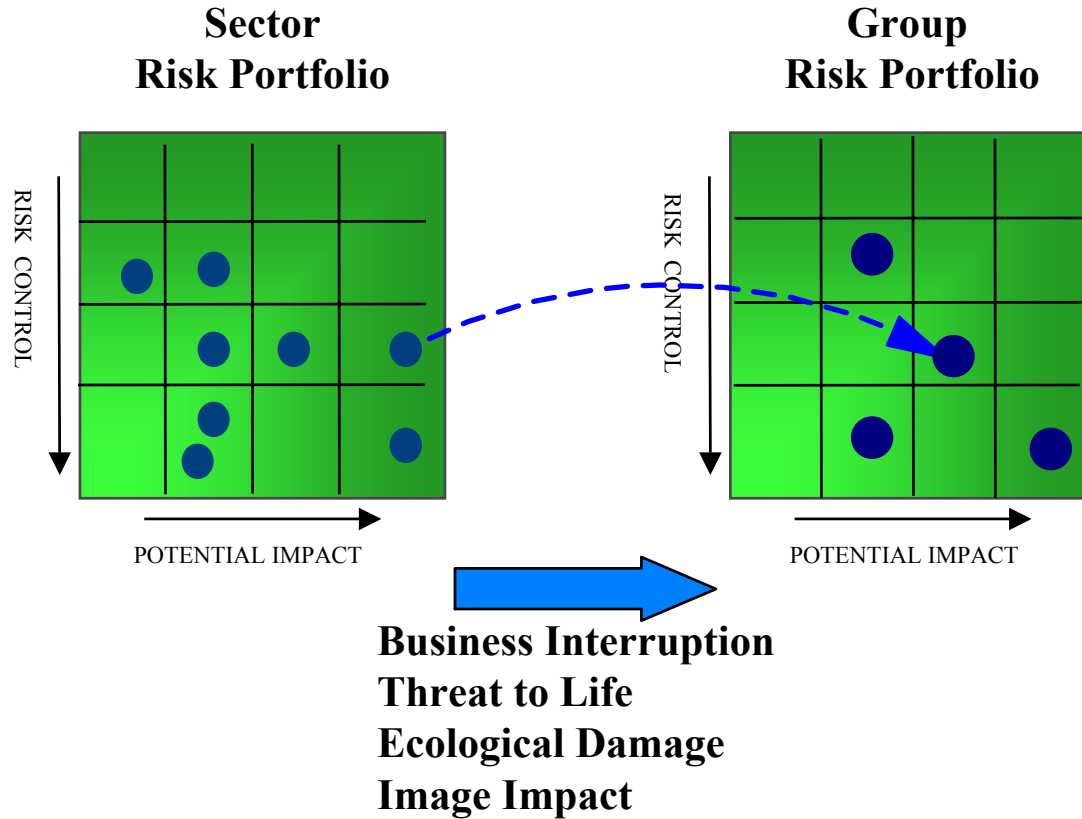


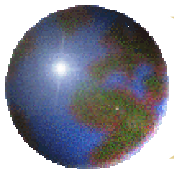
Risk Portfolio Preparation and Application





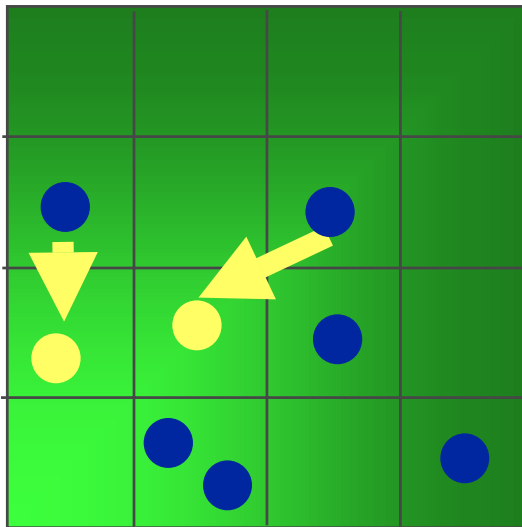
Consolidation on Group Level



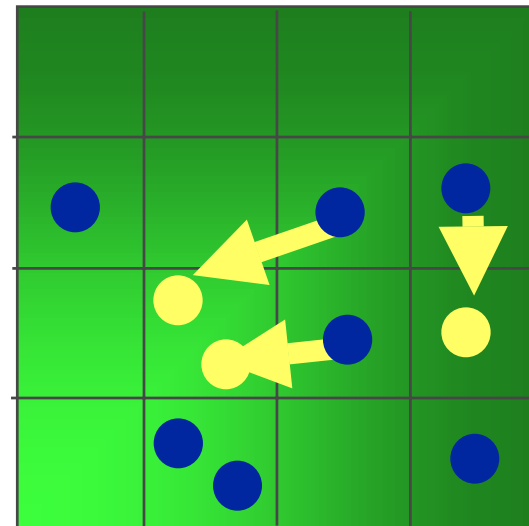


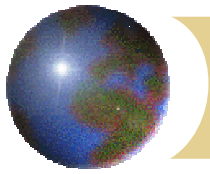
Action Programs

Site Portfolio

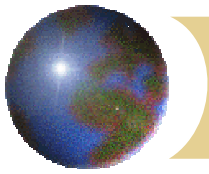


Sector Portfolio





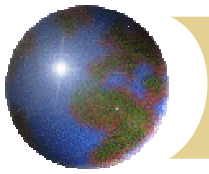
Novartis
Business Continuity Management



NYC Blackout



- -- 2 p.m. FirstEnergy Corp.'s Eastlake Unit 5, a 680-megawatt coal generation plant in Eastlake, Ohio, trips off.
- -- 3:06 p.m. FirstEnergy's Chamberlin-Harding power transmission line, a 345-kilovolt power line in northeastern Ohio, trips.
- -- 3:41 p.m. An overload on First Energy's Star-South Canton 345-kilovolt line trips a breaker at the Star switching station, where FirstEnergy's grid interconnects with a neighboring grid owned by the American Electric Power Co.
- -- 3:46 p.m. AEP's 345-kilovolt Tidd-Canton Control transmission line also trips where it interconnects with FirstEnergy's grid, at AEP's connection station in Canton, Ohio.
- -- 4:08 p.m. Utilities in Canada and the eastern United States see wild power swings.
- -- 4:09 p.m. The already lowered voltage coursing to customers of Cleveland Public Power, inside the city of Cleveland, plummets to zero.
- Ultimately, fifty million people lost power in eight states and parts of Canada.

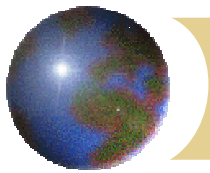


What is the common understanding of Business Continuity Management ?

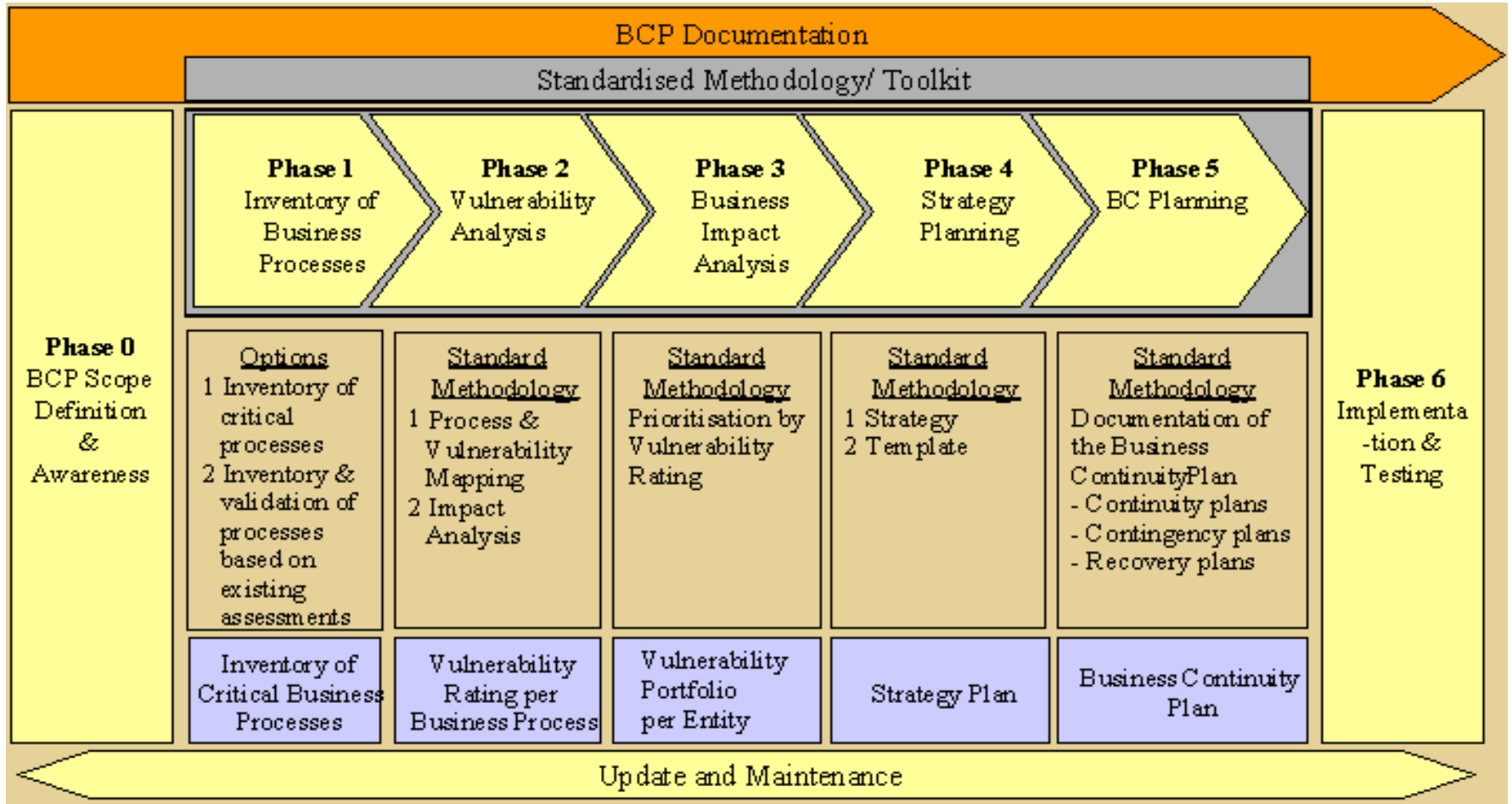
Business Continuity Management is the act of anticipating incidents which will affect mission critical functions and processes for the organisation and ensuring that it responds to any incident in a planned and rehearsed manner.

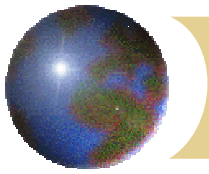
Its objective is to ensure the uninterrupted availability of all key business functions, processes, and resources required to support essential business activities

Business Continuity Management is an integral part of the risk management framework within an organisation.

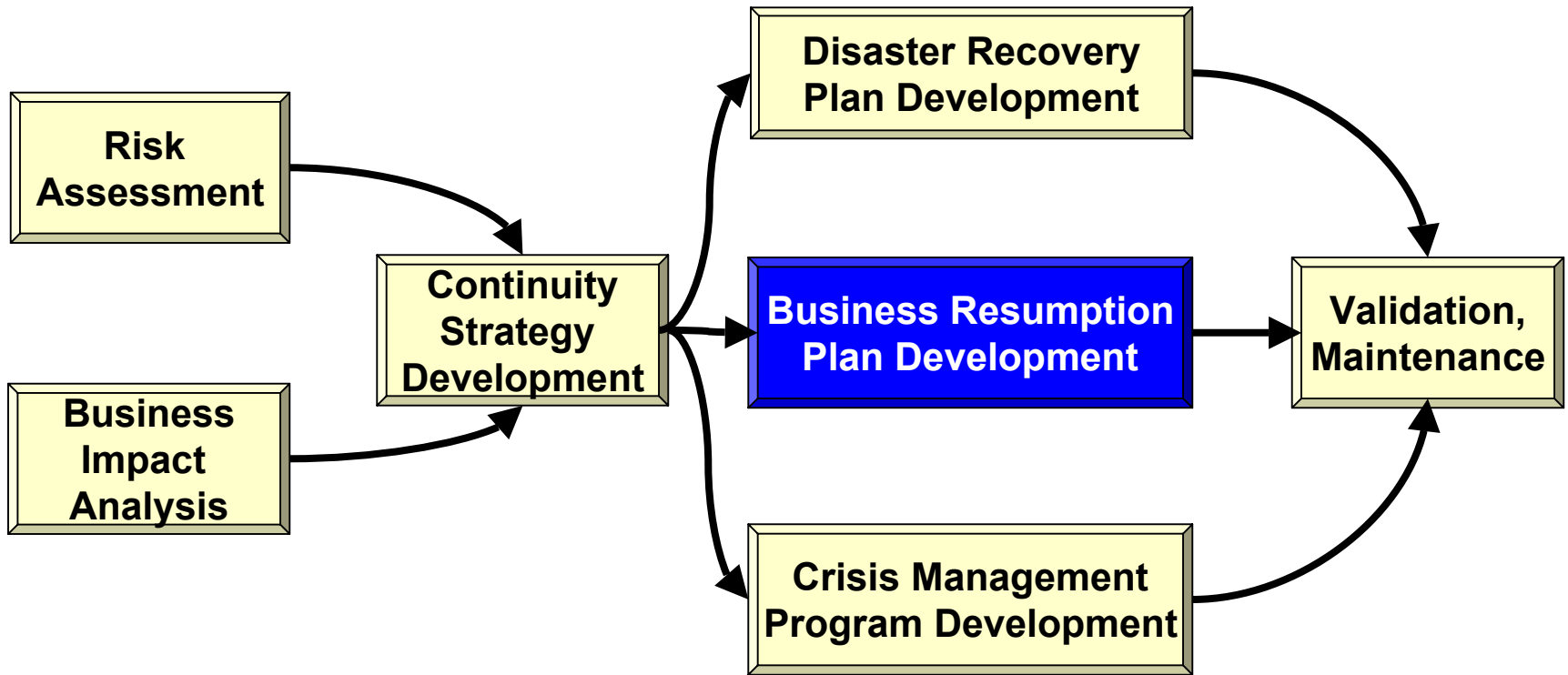


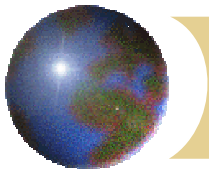
BCP Structure and Methodology





The Business Continuity Management Life Cycle

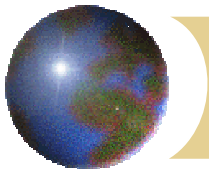




Strategies for Reducing Risk

Examples of typical strategies for reducing risk include:

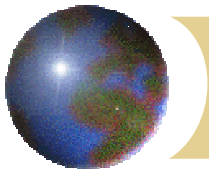
- physical building and perimeter security
- fire detection and suppression systems
- UPS systems (uninterruptable power supply)
- computer security systems (e.g. passwords, firewalls)
- regular backup of electronic data
- secure storage of critical paper documents
- minimising ‘single points of failure’
- regular maintenance of equipment
- employee screening procedures
- executive travel policies, etc.



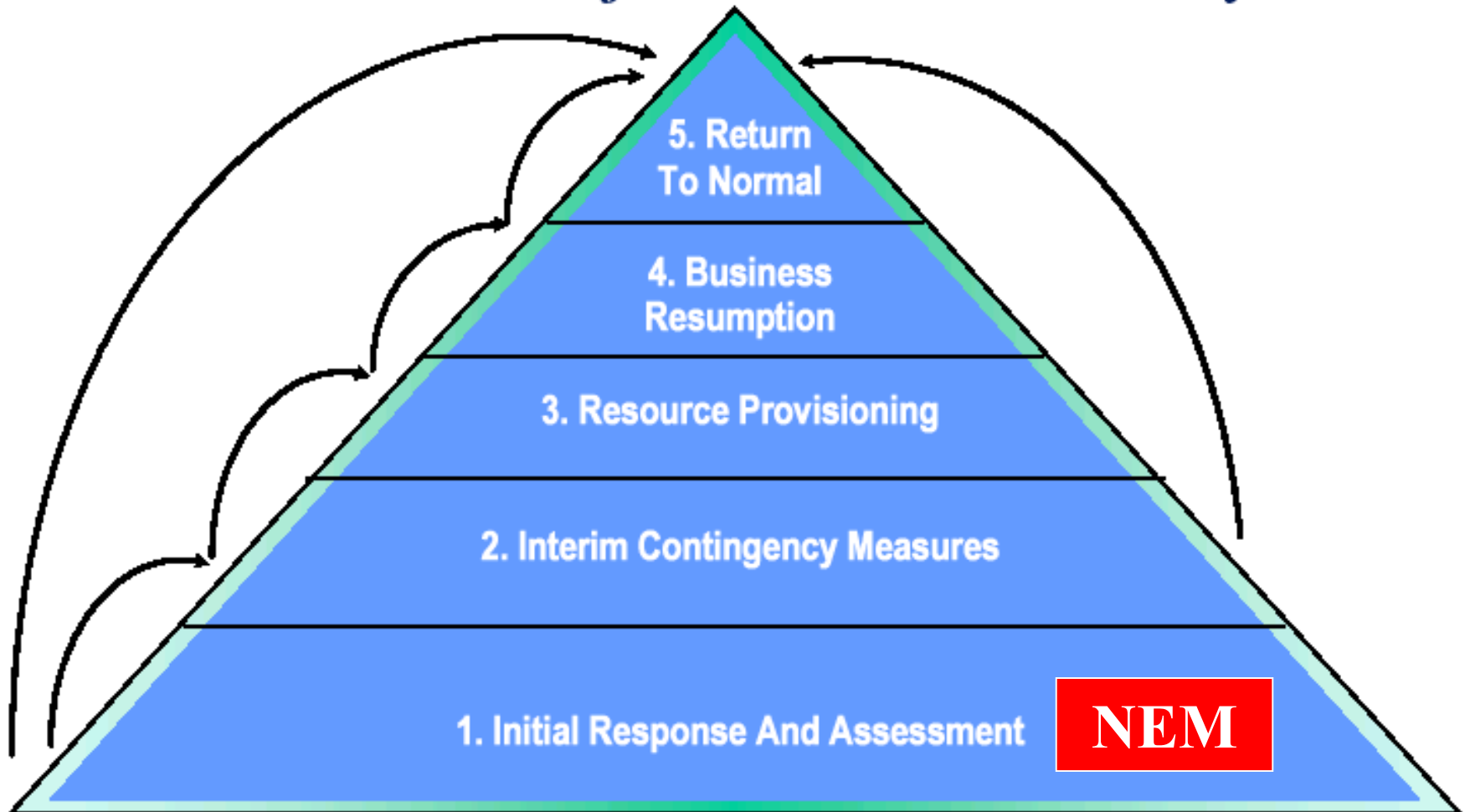
Strategies for Reducing Impact

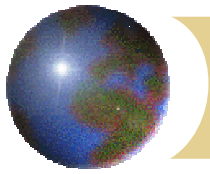
Examples of typical strategies for reducing impact include:

- developing ‘workaround’ procedures for loss of computer systems
- developing contingency procedures for specific events (e.g. postal strike, transportation problems)
- splitting business operations between two or more locations
- maintaining safety stock of raw materials at an alternate location
- keeping finished inventory in more than one location
- establishing alternate means of voice or data communication
- pre-establishing outsourcing arrangements
- cross-training employees
- developing executive succession plans, etc.

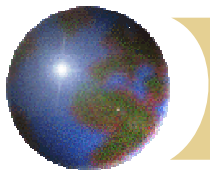


What are the Phases of a Business Continuity Plan?





Novartis
Product Stewardship



..i LOOKED BOTH WAYS
BEFORE CROSSING THE
STREET.. AND THEN i
STEPPED INTO A
MANHOLE!

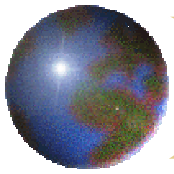


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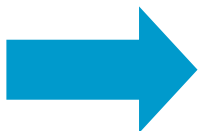
Tom Wagon & TEMIE

U/P

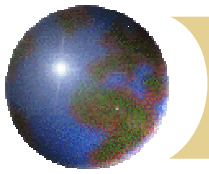


Product Stewardship: Scope

- Product Stewardship stands for systematic review and assessment of product related benefits and risks, and implementation of processes and measures
 - to maintain risks in a justifiable relation to the benefits and opportunities of the product,
 - to respect the Corporate Citizenship commitments of Novartis, and
 - to enhance our competitive advantage



“Anticipatory Management”



Product Stewardship: Scope

The objectives of Product Stewardship are to:

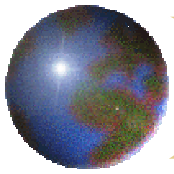
- Provide consumers of our products with effective and safe products,
- Reduce product-related risks to the extent that is possible.

Therefore, the underlying approach of Product Stewardship is built on:

- Systematic assessment and review of product-related benefits and risks;
- Anticipatory product portfolio management;
- Integrated decision making and management processes to maintain the product-related risks to the extent that is possible.

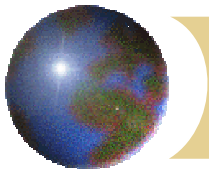


“Anticipatory Management”



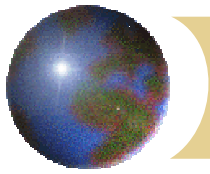
Product Stewardship: Motivation

- Reasons for this initiative
 - Corporate Citizenship Commitments
 - Corporate Governance
 - Integral part of strategic risk reduction
 - Insurance protection for an increasing number of products is no more available
 - Prevention of punitive damage claims



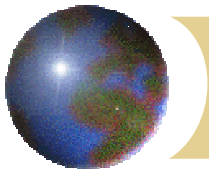
Product Stewardship: Objectives & Issues

- Establish an early awareness system
 - define scientific/technical, ethical, business/financial, legal/regulatory indicators
- Establish cross-functional methodology to assess products & portfolios - high transparency
 - define factors and scale for “impact” and “degree of control”
 - adapt methodology for physical risk management (ZHA) to product stewardship
- Integrated decision making process
 - integrate product stewardship into strategy, priority and target setting & decision making processes
 - define roles & responsibilities



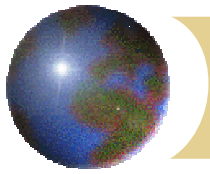
Product Stewardship: Objectives & Issues

- Foster Communication & Networking
 - regular cross communication processes (BU's, BU's & Corporate)
 - sounding board/expert panel (internal/external/scientific/medical)
- Investigate and consider regulatory & legal implications
 - awareness regarding consequences of documentation
 - use of attorney/client privilege

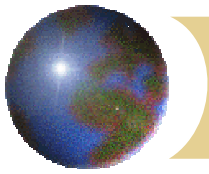


Product Stewardship: HSE Role

- Knowledge transfer: Expertise from physical risk management as a blue print for Product Stewardship
- Key part of “early warning system” – contact with NGOs, other companies, industry organizations, etc.



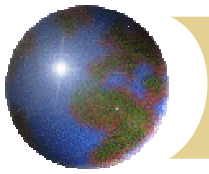
Novartis
Enterprise Risk Management



*“Continually prepare for the unexpected.
Even when the unexpected happens, you are prepared.”*

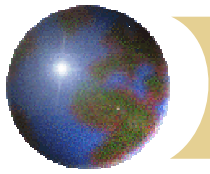


Former NYC Mayor Rudi Giuliani

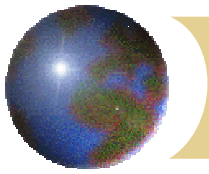


Novartis ERM

- ERM is the process of assessment, treatment, and monitoring of business risks to assure, to the extent possible, the attainment of Novartis objectives and long-term business success.
- It likely covers but is not limited to the risks associated to the activities of research, development, manufacturing, marketing, and sales of products; risks related to finance, regulatory compliance, intellectual property, site security, products, as well as health, safety and environmental protection.

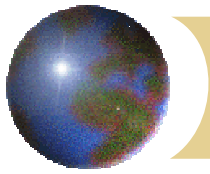


Novartis
Pandemic Flu Planning



Setting the Stage - Pandemic of 1918

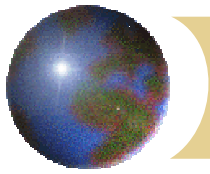
- More people died in a twenty-four week period (mid-September – early December) than have died from AIDs in 24 years or that died from the Black Death in a century.
- Normally flu chiefly kills the elderly and infants, but half of the deaths were of young men & women.
- Total deaths have been estimated as high as 80-100 million (1/16th of the world's population at that time).
- Was also caused by a bird virus.
- Finally faded out in 1920.



Possible Insurance Industry Scenario

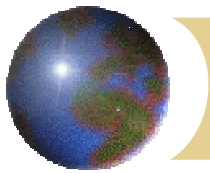
The following is a brief sketch of the possible conflationary impacts of a major human outbreak.

- Several cities in East Asia suffer major outbreaks of human-to-human transmission.
- International travel is severely affected,
- Pandemic-specific vaccine supplies are secured and security authorities prepare for external contingencies and domestic insurgency.
- Emergency supply chain management is instituted, based on the possibility that 50% of those infected die. Commodities and services needed to survive for one to three years are identified.
- Non-critical industries reduce output or close.
- Even with full-scale vaccine production in nine countries with 12% of the global population, fewer than 500 million people (14% of the world's population) can be vaccinated in a year.
- May include disruption of supply chains and trade flows
- An exacerbation of financial imbalances and the transformation of intellectual property regimes for pharmaceutical products; rioting to gain access to scarce supplies of antivirals and vaccines
- A possible collapse of public order
- Possible partial de-urbanization as people flee population centers
- The extinction of trust in governments; decimation of specific human skill sets;
- Possible forced, large-scale migration, associated with the further collapse of already weak states.



US Congressional Budget Office Projections

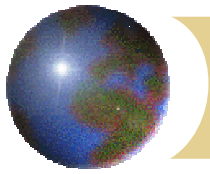
- Severe Pandemic (US impacts)
 - 90 million will fall ill (30% of population)
 - 2 million die (2.5% of those who fall ill)
 - Economic growth will stop, GDP to fall by 5%
 - Workforce effects
 - 30% of workforce affected
 - For surviving ill, average time away from work: 3 weeks
 - 1 million workers will die (0.75% permanent reduction in workforce)



H5N1 (Avian Flu) - Spread and Mortality

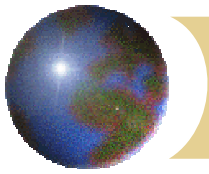


Total 191 human cases, 108 fatalities = 57%



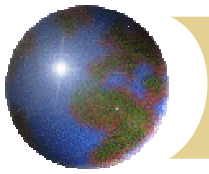
Novartis Pandemic Flu Planning

- In every Business Unit, an Executive Committee member responsible for planning activity
- Goal to have plans developed and in place by this Fall.



Opportunities for HSE – Novartis Example

- Business Continuity assigned to HSE to coordinate
- Head of Corporate Risk Management (responsible for ERM) was formerly the Global Head of HSE for Pharma BU
- Leadership of Pandemic Flu planning teams often BU HSEOs



Conclusions

Current

- If your focus is just on compliance, then you may be viewed as overhead, a cost of doing business and a candidate for out-sourcing.

Future

- Focusing on risk management allows you to be pro-active, to be viewed as being strategic and to get involved in new areas with expanded responsibilities.