

# Risk Management in Pharma Industry

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EHS Risk Management

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# Background



**Alexandra Bauloye,**

**EHS Risk Management and  
Governance**

Joined GSK in July 2007

## **Previous experience:**

- EHS Regional Lead, Africa (GSK)
- Quality Assurance Manager (GSK)
- Project Manager for NGO's (Medecins Sans Frontieres, Handicap International)

## **Educational Background:**

- Master in Public Health (University of Nancy)
- Master in Sociology & Anthropology (ULB, Bxl)
- ISO Auditor Certified

Our global scale



# GSK around the world



95,490

employees around the world



>150

countries in which we operate

6.9bn

packs/doses of medicines, vaccines and healthcare products delivered in 2018

85%

of employees are proud to work for GSK





# Pharmaceuticals

Our Pharmaceuticals business has a broad portfolio of innovative and established medicines with leadership positions in respiratory and HIV. We are strengthening our pipeline through a focus on science related to the immune system, human genetics and advanced technologies.

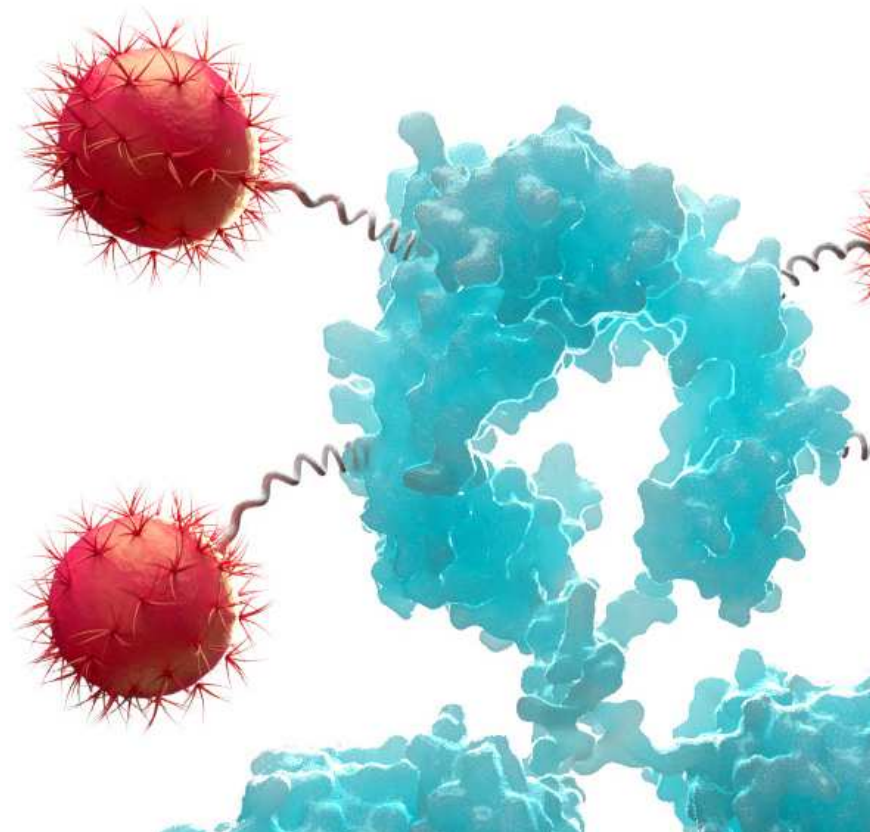
## £17.3bn

Sales turnover 2018

### Top 3 sales drivers 2018

Dolutegravir portfolio	HIV
<i>Ellipta</i> portfolio	Respiratory
<i>Seretide/Advair</i>	Respiratory

Antibody with cytotoxic drug attached





# Vaccines

We are the leading vaccines company in the world, delivering over 2 million vaccine doses every day to people living in over 150 countries. Our portfolio helps protect people throughout their lives. We have recently introduced breakthrough vaccines for shingles and meningitis B.

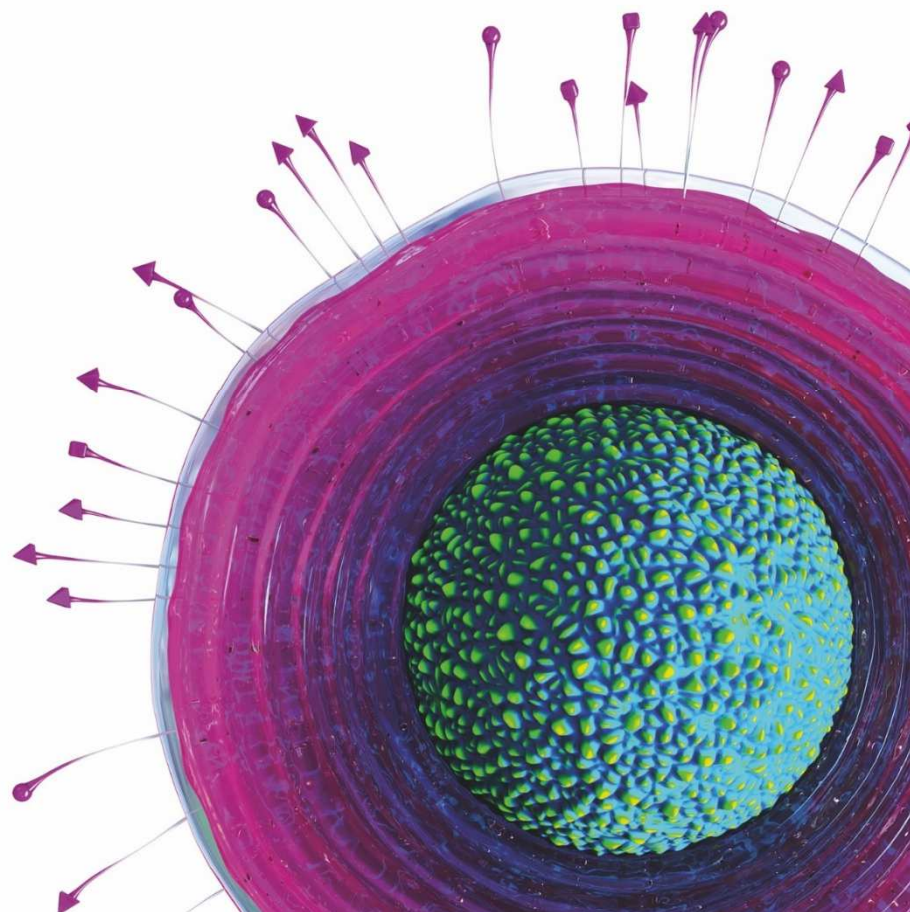
## £5.9bn

Sales turnover 2018

### Top 3 sales drivers 2018

Menigitis	Paediatric and adult
Hepatitis	Paediatric and adult
Shingles	Adult

Herpes zoster virus of shingles





# Consumer Healthcare

We are the world's largest Consumer Healthcare company following our new joint venture with Pfizer. We develop and market a portfolio of consumer-preferred and expert-recommended brands including *Sensodyne*, *parodontax*, *Poligrip*, *Advil*, *Voltaren*, *Panadol*, *Centrum*, *Otrivin* and *Theraflu*.

## £7.7bn

Sales turnover 2018

### Top 3 selling GSK brands 2018

<i>Sensodyne</i>	Oral health
<i>Voltaren</i>	Pain relief
<i>Panadol</i>	Pain relief

Nociceptors, the sensors of the pain pathway



# My role in Corporate EHS

	Risk Management	Governance	Performance	Incident Investigation
Mission	<ul style="list-style-type: none"> <li>Establish, develop and maintain the enterprise EHS&amp; 'management system', to facilitate the delivery of GSK's EHS&amp;S Plan, Risk Reduction programs and to drive EHS continuous improvement.</li> <li>Define GSK's expectations for EHS&amp;S Risk Management and Governance through robust Global Standards and supporting materials, consistent with internal and external stakeholder expectations.</li> <li>Provide oversight of EHS&amp;S risks mitigation to senior leadership.</li> <li>With assistance from data reporters around the GSK world, collect robust EHS&amp;S performance data in order to identify trends and risk and share it with Senior Management</li> </ul>			
My Activities	<ul style="list-style-type: none"> <li>Consolidate and Report EHS Risk Profile to Senior Management</li> <li>Ensure standardization and alignment of processes, terminology, ways of working across the Business Unit</li> <li>Create guidance, materials, training packages, update written Standards</li> <li>Provide support and training to key stakeholders</li> <li>Facilitate Community of Practice</li> <li>Measure Business Unit Performance against objectives</li> <li>Review compliance through Audit and Management Monitoring</li> </ul>			

# Agenda

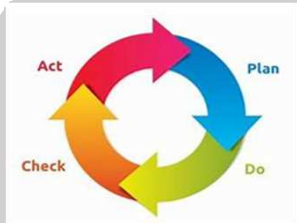
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- Regulations
- Key Principles for success
- Standardisation
- Scoping
- Tools examples



# Regulations and Guidances



## Risk Management

ISO 45001

**BS ISO 45001:2018**  
Occupational health and safety  
management systems  
Requirements with guidance for use

ISO 31000

INTERNATIONAL  
STANDARD **ISO**  
**31000**  
Second edition  
2018-02

Risk management — Guidelines

ICF Q9

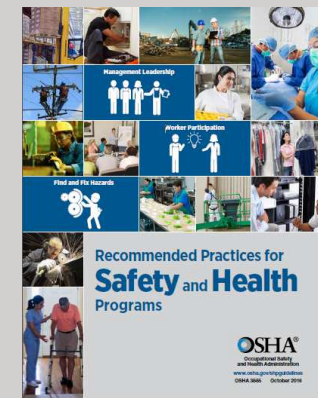
ICH HARMONISED TRIPARTITE GUIDELINE  
**QUALITY RISK MANAGEMENT**  
Q9



## Risk Control

HSG48

OSHA



# Risk Management



## Framework..

ISO 31000

- 5.2 Leadership and commitment
- 5.3 Integration
- 5.4 Design
  - 5.4.1 Understanding the organization and its context
  - 5.4.2 Articulating risk management commitment
  - 5.4.3 Assigning organizational roles, responsibilities
  - 5.4.4 Allocating resources
  - 5.4.5 Establishing communication and consultation (governance)
- 5.5 Implementation
- 5.6 Evaluation
- 5.7 Continuous Improvement.

## Process

- 6.3.2 Defining the scope
- 6.3.3 External and internal context
- 6.3.4 Defining risk criteria (scoring matrix)
- 6.4 Risk assessment.
  - 6.4.2 Risk identification.
  - 6.4.3 Risk analysis
  - 6.4.4 Risk evaluation.
- 6.5 Risk treatment
  - 6.5.2 Selection of risk treatment options
  - 6.5.3 Preparing and implementing risk treatment plans.
- 6.6 Monitoring and review
- 6.7 Recording and reporting

## Planning.

ISO 45001

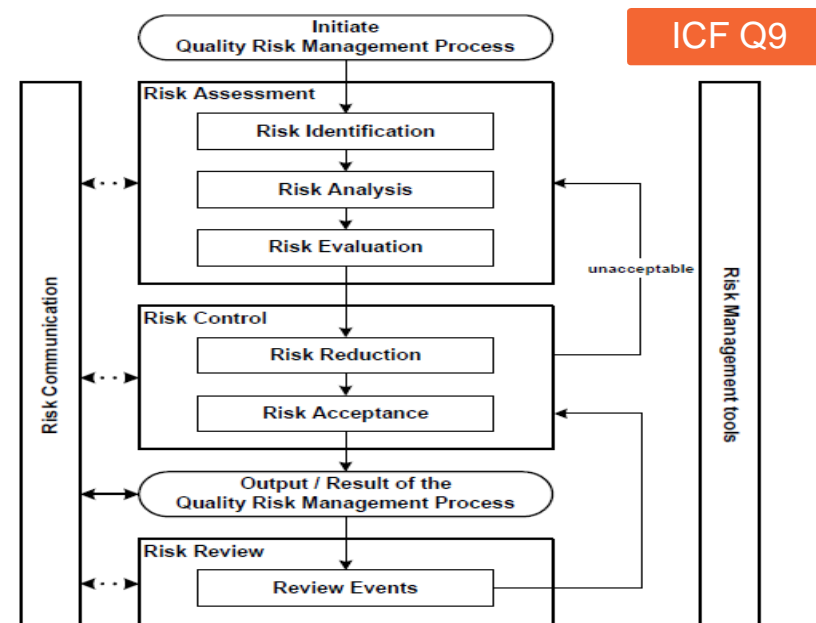
- 6.1.2 Hazard identification and assessment of risks
- 6.1.3 Determination of legal requirements and other requirements

## Operation

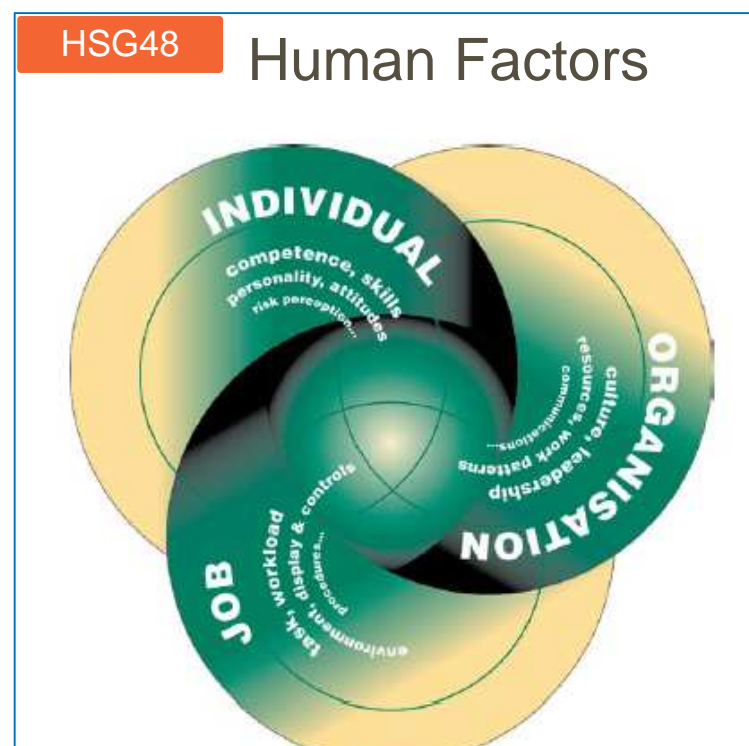
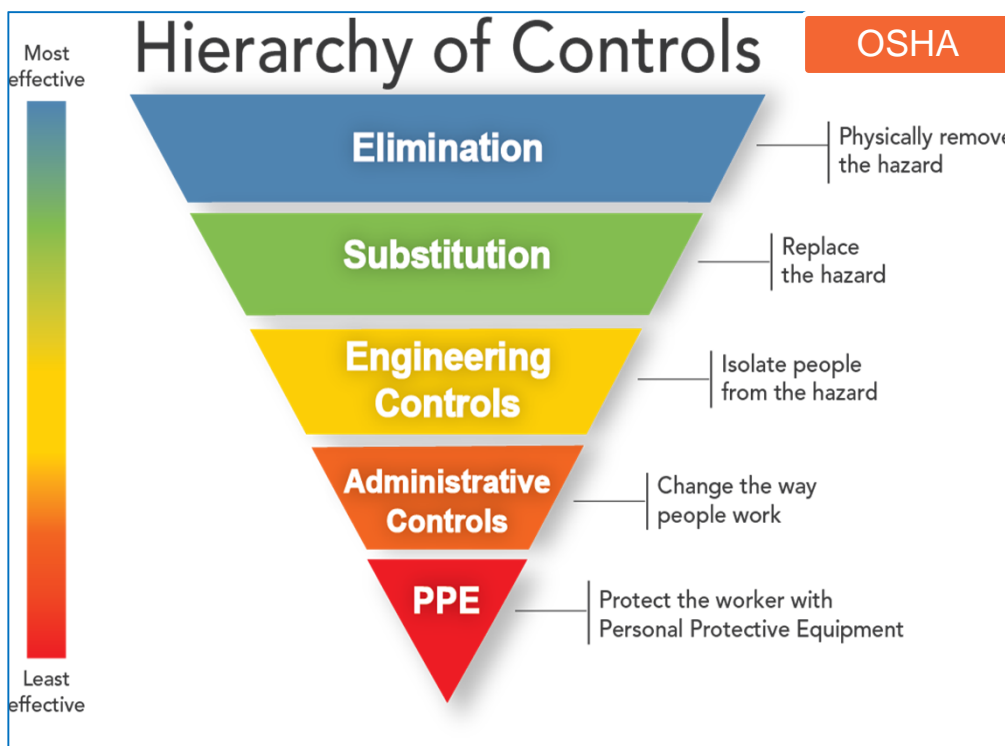
- 8.1.2 Control: Eliminating hazards and reducing OH&S risks

## Performance evaluation..

- 9.1 Monitoring, analysis and performance evaluation
- 9.3 Management review



# Risk Control



# Key principles for success

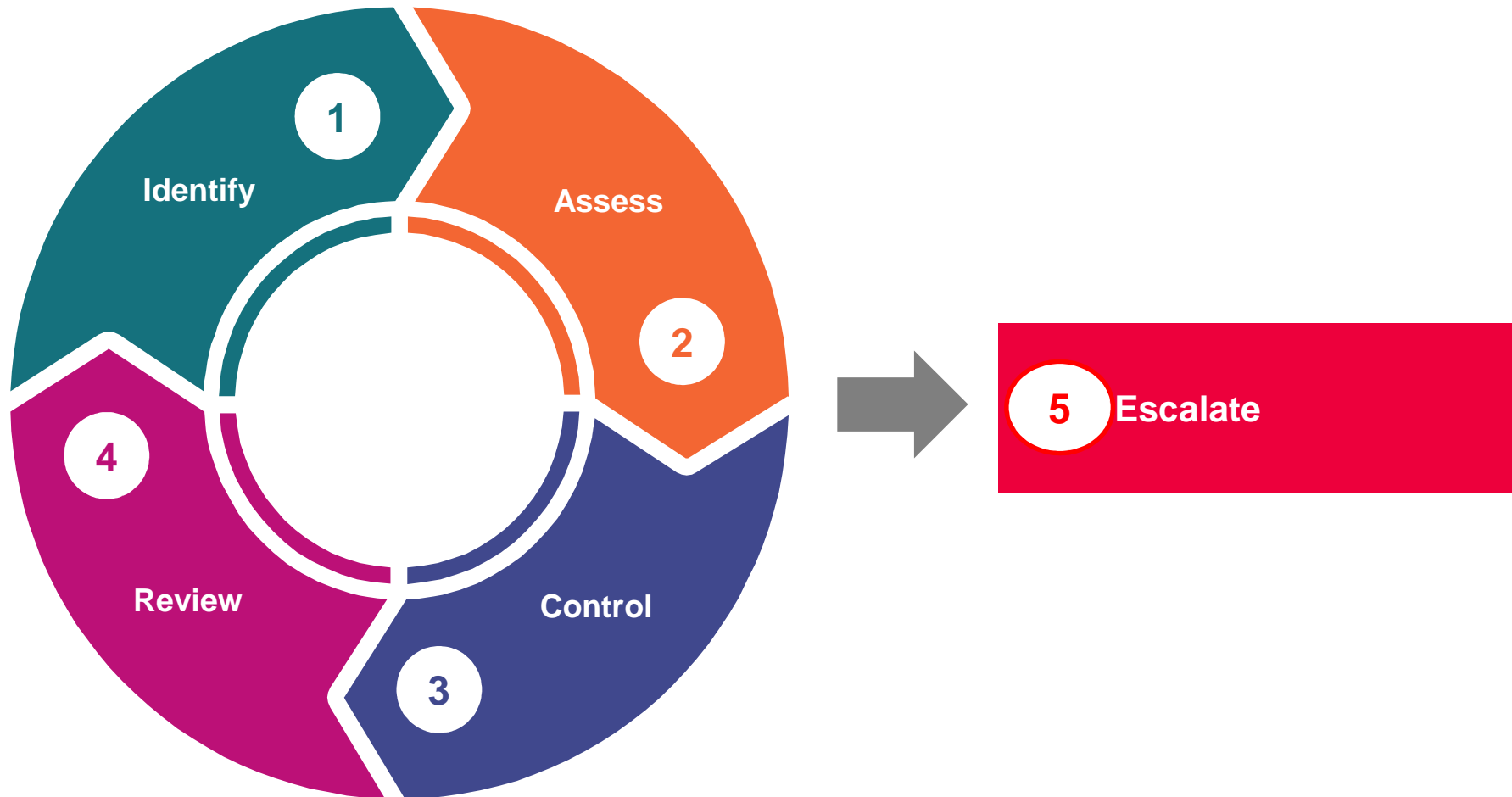
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- Leadersip Commitment, Risk Management Culture
- Integrated Risk Management
- Governance (Tier meeting) and escalation rules
- ★ Standardisation of process, scoring grid, terminology
  - Roles and Responsibilities ( RM Process Owner and Risk Facilitators)
  - Community of Practices to ensure alignement in ways of working
  - Alignement with budget and resources forecast (prioritisation)
- ★ Scoping of Risk Assessment
- ★ Keep tools as simple as possible ( easy to understand and to use)






# Standardisation

# Process



# Terminology



	<b>Hazard</b>	Potential source of harm or damage
	<b>Cause of event</b>	<b>Circumstances and conditions</b> that enable an event to occur <b>from hazards</b>
	<b>Risk Event</b>	adverse event that might occur if the hazard is not well controlled. It is the answer to the question: "What might go wrong?".
	<b>Who or What</b>	<b>who or what</b> may be harmed and why
	<b>Consequence/Effect/ Impact (Severity)</b>	<b>Outcome</b> from an event that has occurred

# Terminology



The risk description should apply the sentence structure below:

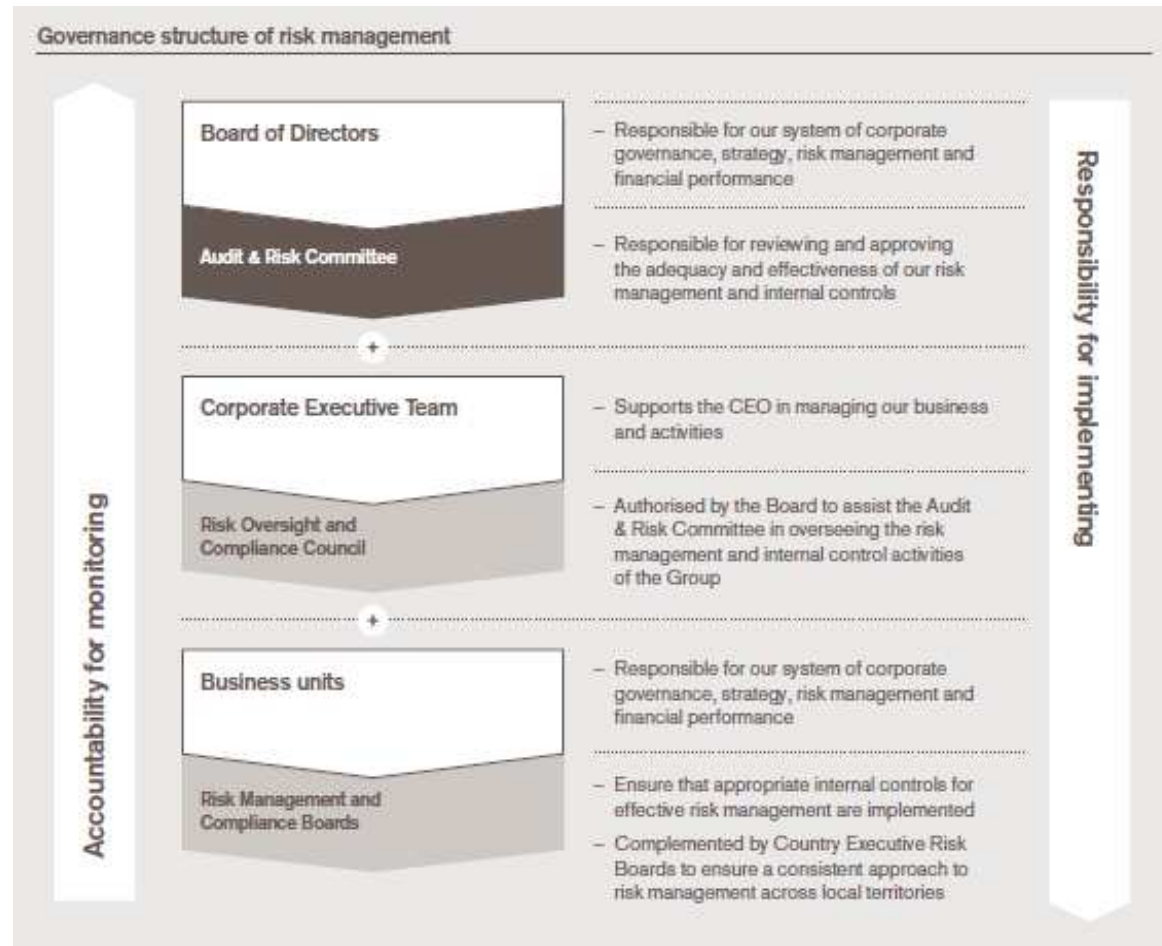
Cause	Risk Event	Consequence
Because of...	There may be a risk of...	With the potential consequence of...

A single *risk* could have multiple causes and consequences as shown in the diagram below.





# Governance



- ❑ Risk Management and Compliance Board (RMCB) exist all all levels of the organisation. It is aligned with the leadership structure.
- ❑ RMCB review all type of Risks and use same
  - attendance
  - agenda
  - escalation rules
- ❑ Allows risk review, decision making, prioritisation, communication and cascade

# Scoping Risk Assessment

# Scoping



Where to Start?



# Scoping:

4 Types of Risk Assessment



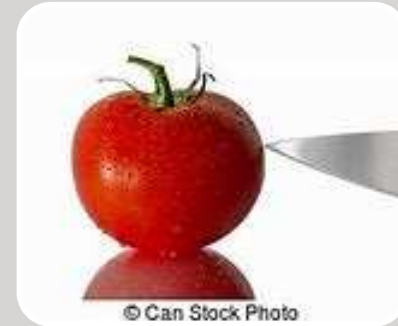
Site  
Overview  
(Level 1)



Workplace  
(zones)  
(Level 2)



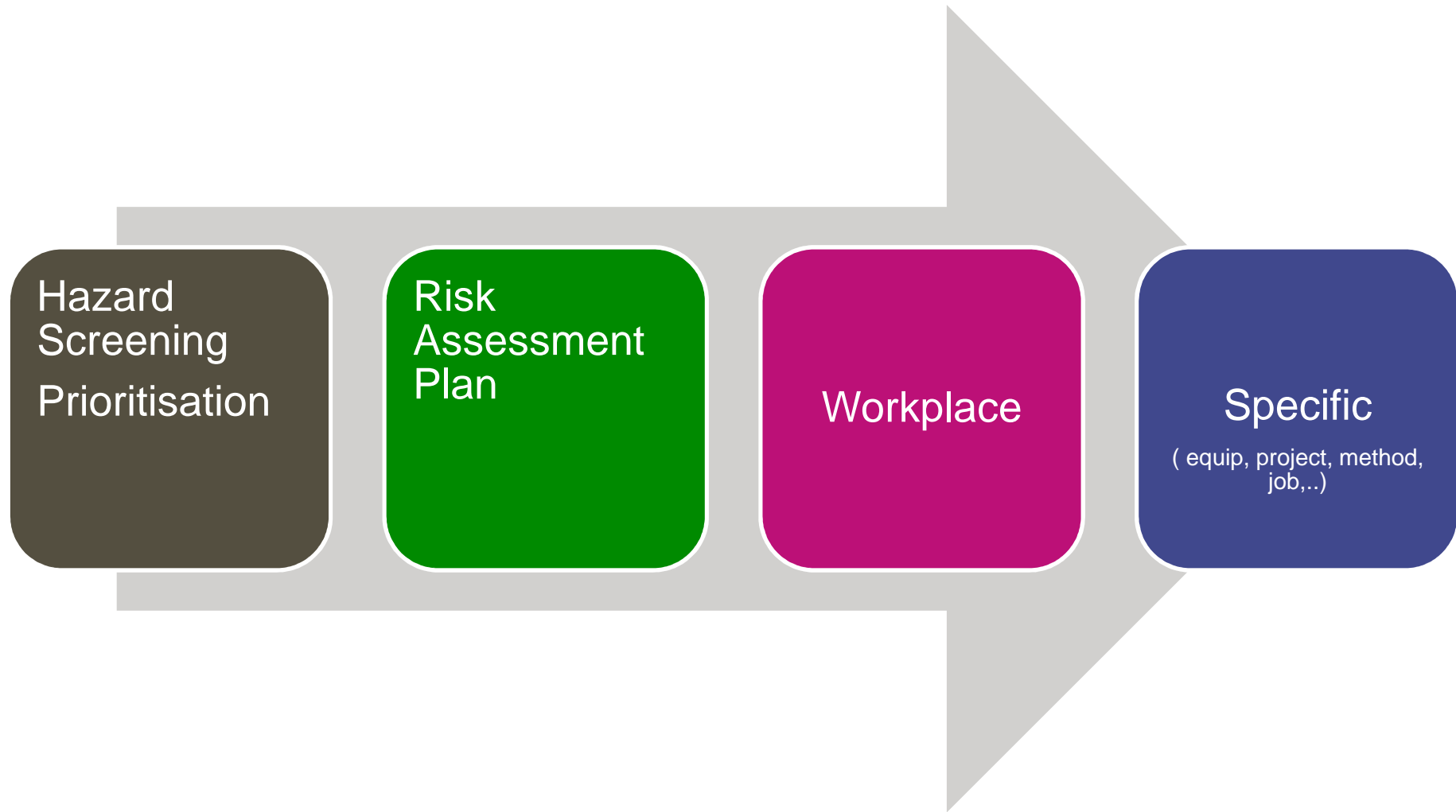
Specific  
(Level 3)



External  
(PESTEL)  
(Level 0)

# Plan

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# Tools examples

# Risk Assessment Tools

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Depending on the type of Risk Assessment, the organization can use a range of techniques for identifying and assessing hazards

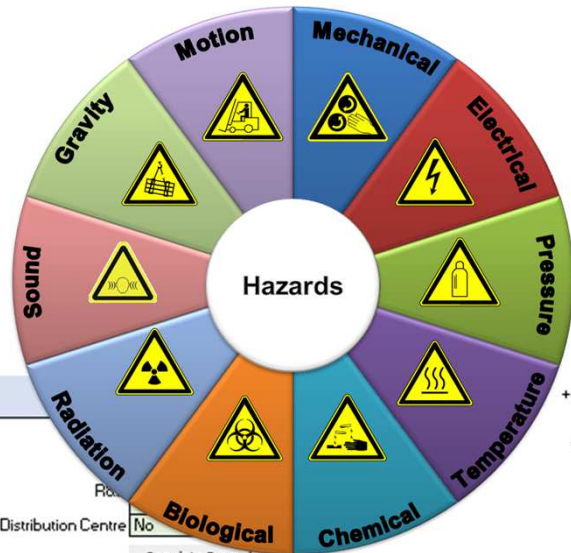
FMEA HAZOP,HAZID,HACCP,DEPARIS, BOW TIE, WHAT IF, EVARIST, SIL, GEMBA, SCENARIO ANALYSIS,...

1) mapping of hazards classified by processes and operations in the zone. It is called a **workplace Risk assessment.**

2) More complex methods are used to assess high severity risks or to perform **specific Risk Assessments.**

**Several factors** need to be considered such as how work is organized, routine and non-routine activities, human factors, potential emergency situations, external activities that might have impact on persons in the workplace.

# Site Screening



Assessment lead:			+++	5	Hazard is present in a form that could lead to fatality(ies) and/or env disaster resulting in adverse health effects amongst local community (10)
Key characteristics:			++	3	Hazard is present in a form that could lead to injuries or illness causing lost time or job restriction; temporary or short-term environmental damage (<1 year) (5)
Primary Manufacturing	Yes		+	1	Hazard is present in a form that could lead to minor injuries requiring first-aid / negligible impact on environment (1)
Secondary Manufacturing	No	Distribution Centre	?	-	Uncertain of level of hazard (8)
Administration	Yes		0	-	Hazard is not present (0)

Mechanical	Chemical	Electrical	Pressure	Temperature	Biological	Radiation	Sound	Well-being	Gravity	Vibration
- Machinery (including powered by electrical, hydraulic, pneumatic, combustion etc) - Work equipment	- Bulk chemical storage - Chemical storage/handling - Toxic, flammable, explosive and/or corrosive gases or liquids - APIs - Sensitizers - Building materials (e.g. asbestos, PCBs) - Combustible dusts - Dusts harmful to health - Ozone depleting substances	- Fixed electrical systems - Static electricity - Portable electrical equipment - Overhead power lines - Buried services	- Pressurized systems - Pressurized gas cylinders - Vacuum	- Hot/cold surfaces - Hot/cold working environments - Flames - Steam - Cryogenic liquids - Exothermic reaction - Hot work (welding, soldering, grinding, cutting, etc.)	- Legionella sources - Pathogens - Animal bites or stings - GMOs	- Ionizing radiation sources - Non-ionizing radiation sources - Electromagnetic frequencies - Lasers - UV/Infrared (covers sunlight or do we need separately?) - Intense visible light	- High noise (equipment/areas)	- Repetitive Motion - Awkward Posture - Physical Effort (push, pull, lift, carry) - Sustained Posture (Maintaining static Position) - Contact/Compression stress - Working away from family - Fatigue - Irregular working hours	- Work at height - Elevated walking/working surfaces - Pits/voids - Lifting operations - Racking / stacking of material (collapse/falling objects) - Slip/trip hazards (obstructions, condition of walking surfaces / transport routes)	- Hand-arm vibration - Whole body vibration

Hazard Screening Rating											Concluding Priority	Add to the RA
++	0	++	?	+++	++	+	+	+	+	++	Highest	
+	0	0	0	0	0	0	0	0	0	0	Lowest	
+++	+++	++	+	+	++	0	0	0	0	0	Mid	
?	+++	++	+	+	++	0	0	0	0	0	Mid	
++	+	+	+++	++	+	+	++	++	++	0	Highest	
0	++	?	0	0	0	0	0	0	0	0	Lowest	
+++	?	+	+	++	++	+	+	+	+	++	Highest	
0	0	0	0	0	?	0	0	0	0	0	Lowest	



# Risk Assessment Plan



The RA plan should be created as an outcome of the Site Overview screening (cf prioritization)

Objectives of the Risk Assessment plan is to:

- Centralize the list of all Risk Assessment performed in a Site ( sort of index)
- Track completion
- Report progress to management

EHS RISK ASSESSEMENT PLAN									
Facility/ Dept	Principal Duty Holder								
Intro Date	Risk Assessment Type	Description	Owner	Due Date	Status	Completion Date	High Risk	Next Review Date	location of doc
	<b>SITE OVERVIEW</b>								
	<b>WORKPLACE</b>								
	Area/zone 1								
	Area/zone 2								
	Area/zone 3,....								
	<b>SPECIFIC</b>								
	Topics ( e.g from EHS Standards)								
	Process/ Method								
	Equipement								
	Project								
	Non-routine Activity								
	Organisational and human Factors								
	Internal Change								
	<b>EXTERNAL FACTORS/CONTEXT ( PESTEL)</b>								
	Legal & Regulatory								
	Social, cultural, political, financial, technological, economic and environmental factors								

# Workplace Risk Assessment



## Level 2 Risk Assessment

Location

Select Controls to prevent causes      Select Controls to prevent / mitigate consequences

Section on Control Selection/ Enhancement

Hazards			Scenarios				Existing controls			Risks				Actions (think about hierarchy/ strength/ indepe			
Hazard Category	Hazard sub-category	Description (of the hazard)	Because of (cause)...	There is a risk of (event)...	With the potential consequence	Consequence type	To prevent the cause	To prevent or mitigate the consequence	Indicative control strength	LI Rating (for ref)	Likelihood	Severity	Risk	Controls to add/ enhance/ strengthen	New Level 3 RA	Rationale for not taking an action	Duty holder/ responsible person
Mechanical	Belts, chains & sprockets	substance, volume, where, ...				Occupational Safety				++	5 Almost Certain	4 Major	VH				
Motion	Powered Industrial Vehicles									+++	3 Possible	1 Insignificant	L				
Chemicals	Sensitisers										4 Likely	3 Moderate	H				
Temperature	Work in high temperature environments									+++	4 Likely	2 Minor	M				



**Thank you for your  
attention!**

**Q&A**