



ENVIRONMENT,  
HEALTH, SAFETY  
& SUSTAINABILITY

# Containment of Polioviruses -Moving Barriers

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# Introduction



- Janssen Vaccines
  - Formerly known as Crucell (a Dutch vaccine company)
  - 2011: Crucell was acquired by J&J
  - 2016: Crucell is named Janssen Vaccines & Prevention

# Introduction





- Janssen's challenge



**“Our enemy is disease. We fight it with everything we’ve got, whatever it takes, wherever it takes us. Join our fight against disease.”**

**Johnson & Johnson** INNOVATION

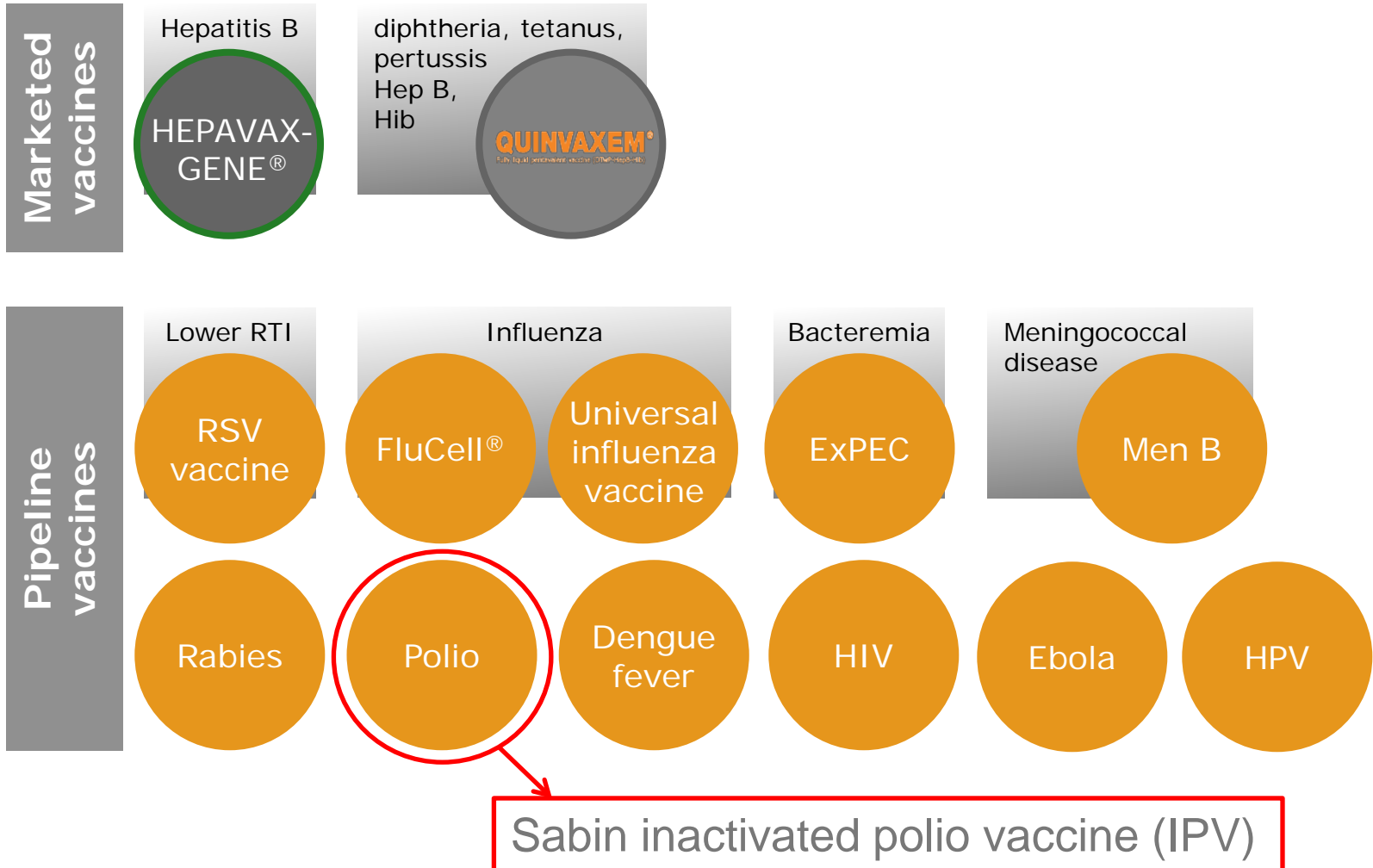
#### WE ARE SEEKING INNOVATIONS THAT:

-  Address a particular cohort with a critical unmet medical need in Johnson & Johnson's strategic areas of interest, such as lung cancer and metabolic diseases
-  Integrate a novel approach that combines pharmaceutical, devices and/or consumer health solutions
-  Address part or all of the spectrum of prevention, interception and cure
-  Outline how the award would help them reach a critical milestone within the timeframe of a single year and provide a full "time-to-market" plan for their solution

**janssen**

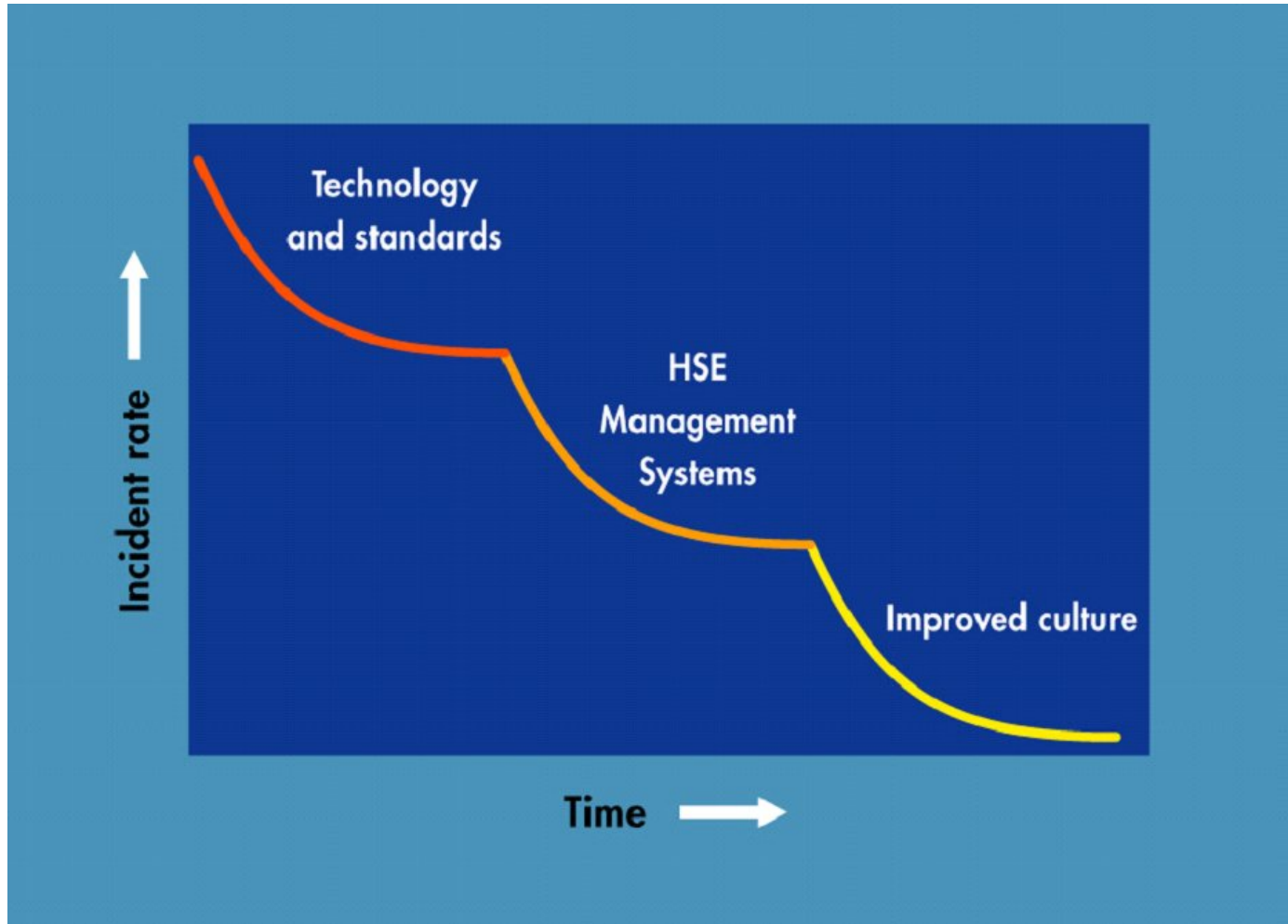
# Introduction

- Janssen Portfolio



# Containment of Polio and Safety Culture

- How does Janssen Vaccines perform?



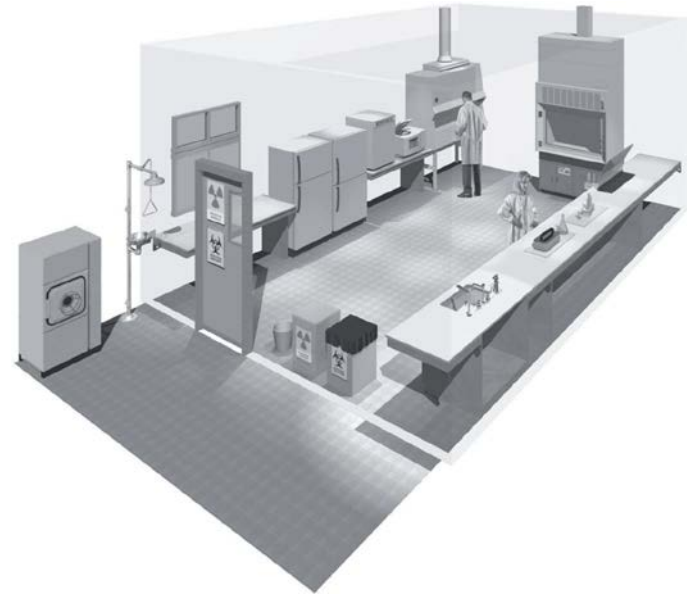
# Containment of Polio

- Containment of wild type polio (Salk)

- WHO: BSL-polio
  - BSL-2
  - vaccinated operators (pos. titer)
- Janssen Vaccines: BSL-2<sup>+</sup>
  - BSL-2
  - vaccinated operators (pos. titer)

*Additional BSL-3 practices:*

- BSL-3 like gowning
- exhaust via biosafety cabinets (HEPA filtered)
- biowaste: double disinfection (chemical + heat)
- storage vials on lab



# Containment of Polio

- Containment of attenuated type polio (Sabin)
  - BSL-1
- Janssen Vaccines:
  - BSL-2
  - vaccinated operators (pos. titer)

Higher containment levels for polio:

-“Safety is a top priority at Janssen R&D”

-The Netherlands is polio-free

-“Bible belt” region nearby (non-vaccinated group)

# Safety Culture

- Safety Culture at Janssen

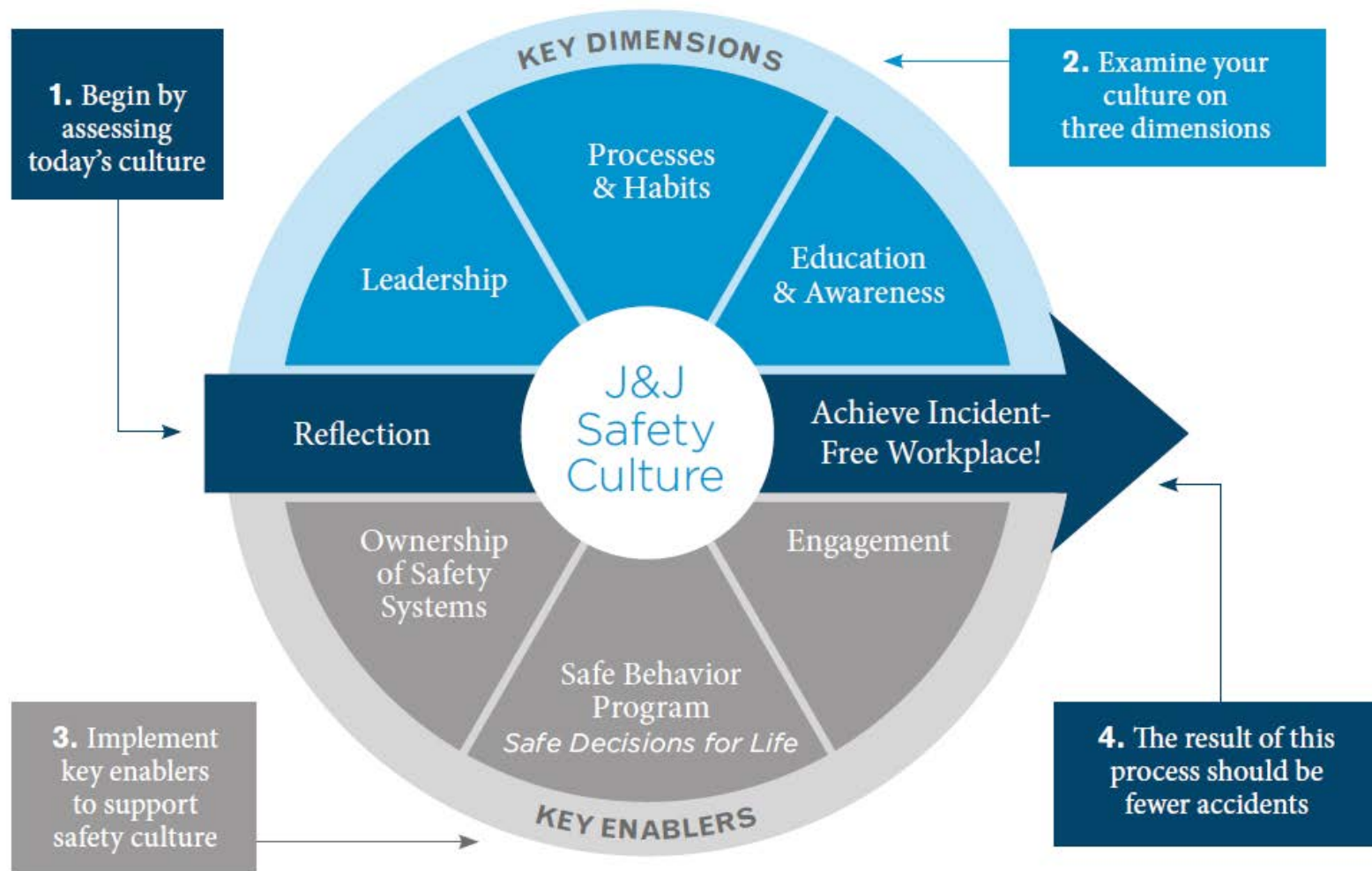
*Johnson & Johnson*

# SAFETY CULTURE ROADMAP

A Standard Approach for Janssen Research & Development



# Safety Culture



# Safety Culture

- Leadership/Ownership of Safety Systems
  - *Integrated OSS*
  - Example:
    - EHS&S Standard: Biosafety Chapter
    - Standard Owner: Biosafety Officer
    - Key Stakeholders: employees from different departments involved in biosafety (scientists, operators,...)

# Safety Culture

- Processes and Habits/Safe Decisions for Life
  - *SD4L*
  - Safe behavior program
  - Set expectations how to work safely
  - Observe people at work, providing feedback and coaching
  - Measuring and analyzing trends
  - Reinforcing safe behavior

# Safety Culture

- Safety Education and Awareness/Employee Engagement
  - Examples:
    - For every task, consider how to do it more safely
    - Know how and when to use PPE and control mechanism/tools (eg biosafety cabinets)
    - Being alert to workplace changes which may impact safety
    - Freely coach one another on safe behavior

# Safety Culture

- Gemba Walk (“the real place” 現場 )
  - Visit by manager
  - Encourage leadership
  - Behavior-based: attention on good practices
  - Learn where and how improvements need to be made, consistently and frequently spend time on the work floor

# Safety Culture

- Self-Inspections
  - Inspection of the laboratories/production areas
  - Performed by lab head to check and improve EHS on the workflow

## EHS Inspection Form

Date of EHS inspection			
Department			
Inspection done by			
Inspected area(s)			
<b>Item</b>	<b>OK</b>	<b>Not OK</b>	<b>N/A</b>
Area is clean and tidy			
No storage of materials in halls, etc			
No cardboard boxes in lab			
Spill kit is in place			
Evacuation routes are not blocked			
(eye) showers are not blocked, eye showers are flushed			
fire extinguishers and first aid kit are not blocked			
Safety equipment is clearly indicated			
Chemicals are stored adequately (leaktray, separated, fire cabinet)			
All chemicals, solutions are labeled			
Amount of chemicals on benches/hood/BSC is minimal			
Use of electrical leads is minimized and max 1 lead is used			
Internal gas storage is minimized and are stored safely			
Waste is segregated and disposed of according to procedures			
PPE in lab: long trousers, closed shoes, labcoat, glasses, gloves, etc)			
PPE in operational areas: safety shoes, long trousers, glasses, hearing protection, etc.			
Spills are prevented			
<b>Improvements/Actions</b>			

Signature: \_\_\_\_\_ Signature EHS: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_

After the inspection, send a copy to EHS

# Safety Culture

- Safety Culture Survey
  - Survey performed every other year
  - Questions on leadership, safe behavior, awareness, trust, respect,....

## SAFETY CULTURE LEVEL

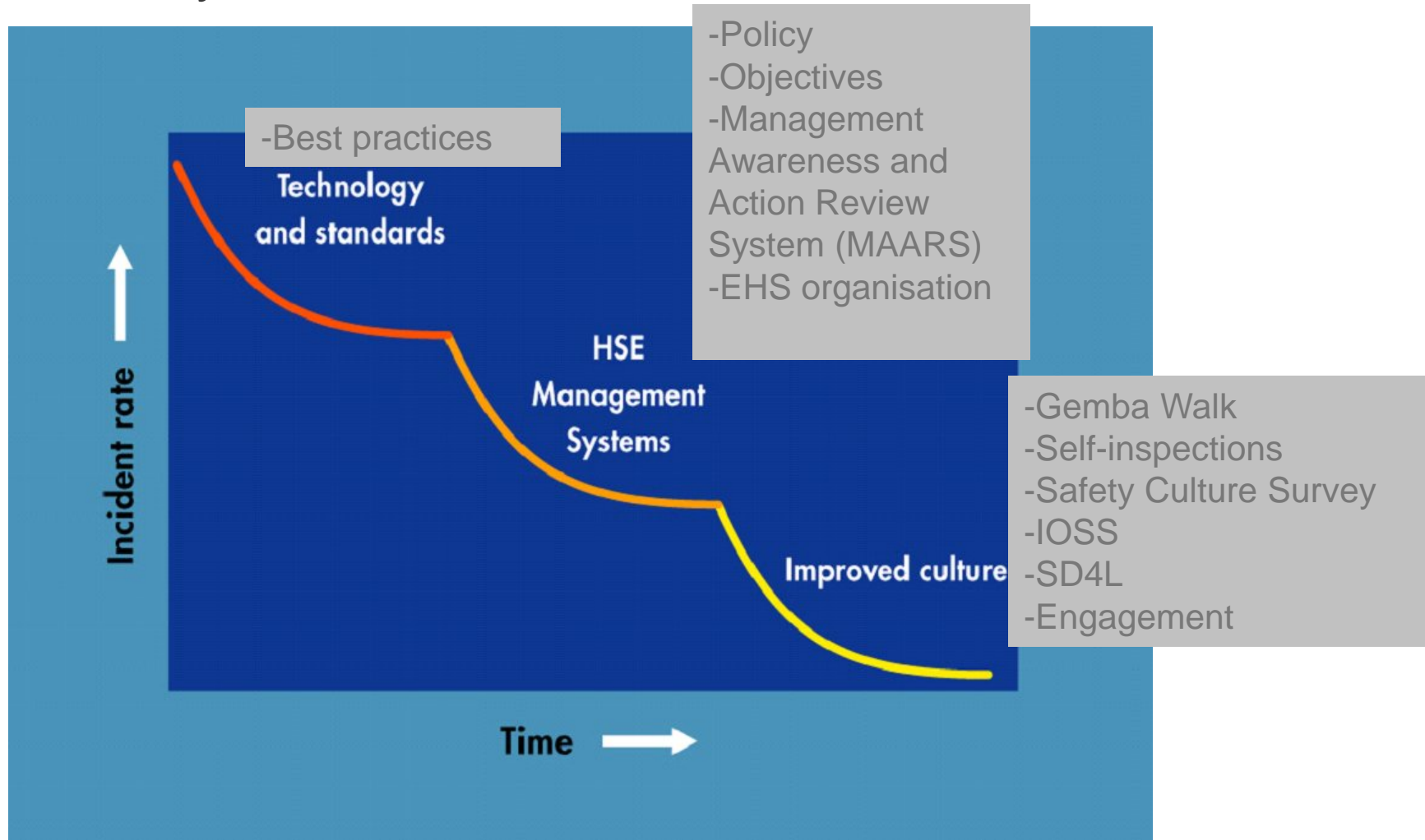
	Level	For each dimension (3)
<b>LEADING</b>	4	> 90% [Mostly + Always] AND < 2% [Not at all + Sometimes]
<b>SUCCEEDING</b>	3	> 80% [Mostly + Always] AND < 10% [Not at all + Sometimes]
<b>IMPROVING</b>	2	> 65% [Mostly + Always]
<b>BEGINNING</b>	1	> 35% [Mostly + Always]
<b>BROKEN</b>	0	≤ 35% [Mostly + Always]

Three Dimensions of Safety Culture

Leadership  
Process/Habits  
Education/  
Awareness

# Containment of Polio and Safety Culture

- Safety Culture at Janssen





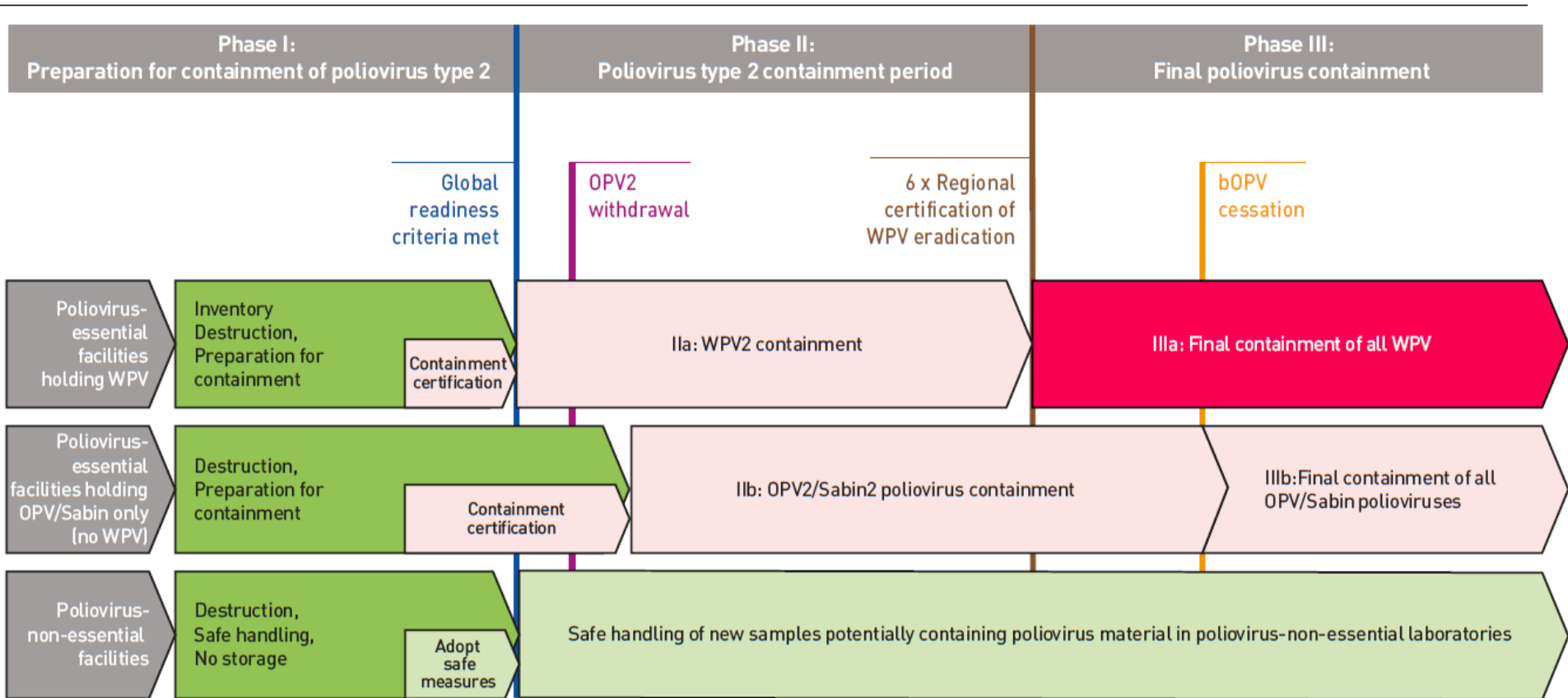
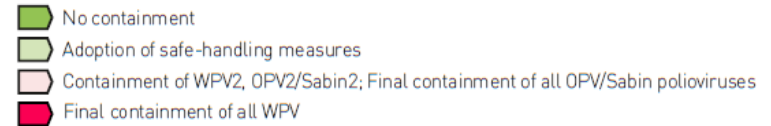
# Global Action Plan III (GAPIII)

- In short
  - Inventory of (essential) polio facilities
  - Destruction of unneeded poliovirus materials
  - Certification of essential facilities
    - Enhanced containment levels (also for attenuated strains)
    - Biorisk Management
  - Legal framework



# GAPIII

- 3x phases



# GAPIII

- Containment

**Table 1: GAPIII containment safeguards at a glance**

	Poliovirus type 2 containment period	Final poliovirus containment period	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
1° safeguards: Prevent infection & release of contaminated materials			
Operator protection <sup>2</sup>	Yes	Yes	Yes
Decontamination of materials/equipment	Yes	Yes	Yes
Dedicated effluent treatment plant	No <sup>3</sup>	No <sup>3</sup>	Yes <sup>4</sup>
Air/exhaust treatment	No	No	Yes <sup>5</sup>

# GAPIII

- Containment

**Table 1: GAPIII containment safeguards at a glance**

	Poliovirus type 2 containment period	Final poliovirus containment period	
	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
2° safeguards: Population immunity in country hosting the facility			
IPV doses	≥ 1	≥ 1	≥ 3
IPV coverage	= DTP3 coverage <sup>6</sup>	= DTP3 coverage	>90% <sup>7</sup>
3° safeguards: Environment & location			
Siting of facilities in areas with low transmission potential ( $R_0$ ) for wild polioviruses	No	No	Yes

DTP3: Diphtheria–tetanus–pertussis vaccine third dose.

# GAPIII

- Challenges

Containment	GAPIII			
	Phase II		Phase III	
	OPV2	WPV2	all OPV	all WPV
Entrance: double door, interlock, alarm	+	+	+	+
Air exhaust treatment	- (1)	- (1)	- (1)	+ (2)
Exit airlock with use of shower (3)	+	+	+	+ (4)
Autoclave (HEPA exhaust, pass through)	+	+	+	+ (4)
Effluent (treatment with heat or chemicals)	+	+	+	+ (5)
Fumigation possible	+	+	+	+

Footnotes:

(1) with proper prim/sec containment

(2) HEPA, dedicated HVAC, sealed, fumigation possible, no back flow

(3) no showering upon use of class III BSC

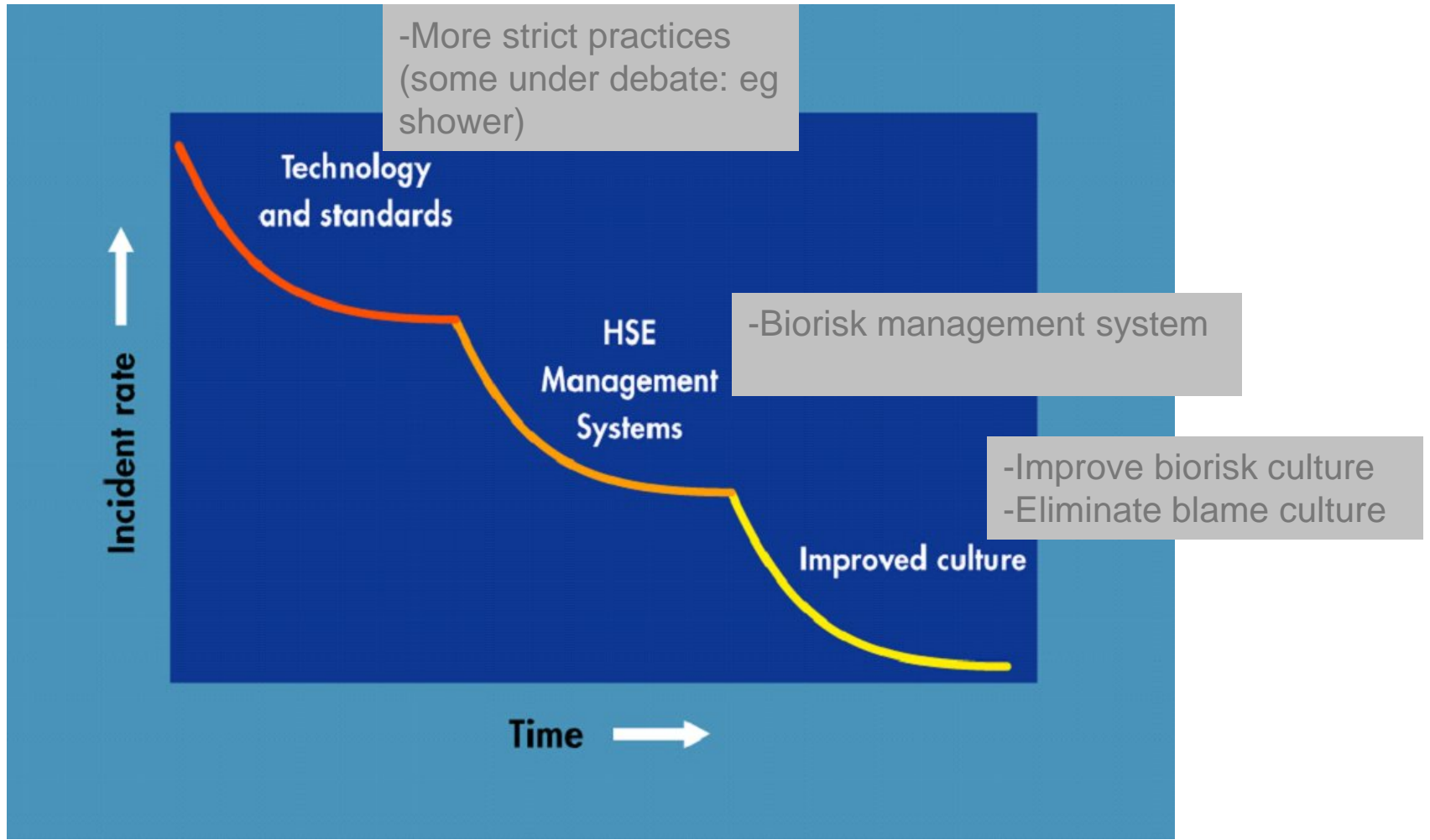
(4) drain to kill tank

(5) dedicated effluent system

Our current facilities do not meet the GAPIII guidelines, but are safe based on risk assessments

# GAPIII

- Containment and Safety Culture



# Final remark

- Implementation of GAP III guidelines will force companies, institutes to upgrade their facilities or even invest in newly build laboratories and production areas.
- Having legislation running behind, players in the field of polio should take their responsibility for containment of polioviruses along moving barriers.