PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSM Maturity Model

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AGENDA

Introduction

PSM Maturity Model

PSM Primers

PSM Team

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- Vijay Bendi (J&J)
- Germano D`Arasmo (Gilead)
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- Andreas Ludwig (Boehringer Ingelheim)
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Speaker Bio

- Daniel is Lead HSE Advisor in the Elanco External Manufacturing EMEA &API Hub Basel, Switzerland
- PhD in Chemistry from Humboldt University in Berlin, Germany with 16 years of experience in Chemical Industry, Insurance and Pharmaceutical Industry. Functional experience in R&D, HSE, Engineering and Manufacturing
- Working in Elanco for 5 year.
- Additional work as Loss Prevention Manager and Tech Transfer Project Lead
- Team lead of the PSM sub-team of the PSCI Capability Committee

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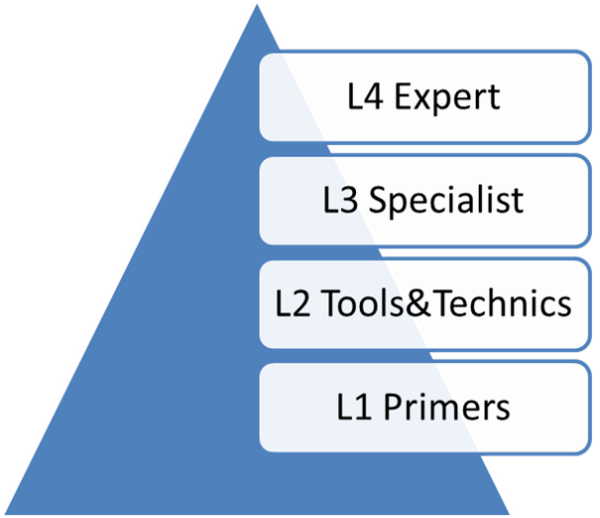
Introduction

- Maturity models for different topics are been created
- Each maturity model has 4 levels from **Starting** out to **Leading**

	Starting out Level 1: Primers	Developing Level 2: Tools & techniques	Implementing Level 3: Specialised content	Leading Level 4: Expert access

- The maturity models shall help the suppliers to identify there current standing and where are areas of improvement



PSM Maturity model: Managment

	Starting out Level 1: Primers	Developing Level 2: Tools & techniques	Implementing Level 3: Specialised content	Leading Level 4: Expert access
Management	• Assign an appropriately qualified PSM person with defined responsibility (Process Safety) and necessary resource to fulfil the role.	• Risk evaluation and prioritization (safety systems, emergency equipment)	• Develop substitution program for most dangerous chemicals (Inherent safety practices) • Contractor programs in place with respect to PSM • Implement an internal audit system	• Investigate PSM incidents, implementation of corrective actions + sharing learning • information on PSM studies, provided to all employees • Benchmark PSM program, best practices + implement • External PSM program Audit

PSM Maturity model: Risk Assessment

	Starting out Level 1: Primers	Developing Level 2: Tools & techniques	Implementing Level 3: Specialised content	Leading Level 4: Expert access

Risk Assessment	• Basic PSM training for EHS, Engineers and Management:
	  ○ Understanding of chemical reaction and fire/explosion hazards
		• Train PHA (HAZOP / What-if) techniques by example
		• Conduct PHA in suitable team
		• PHA available for most hazardous processes
			• Include critical safety parameters in Operational instructions +communicate with affected employees
			• PHA available for all processes
				• Fully integrate PSM in every business decision:
				  ○ periodically update PSPI information, PSPI database
				  ○ periodic update all PSM related trainings
				  ○ periodic inspection, review and improvement of all process safety (program & field)
				  ○ periodically update PHA studies
				  ○ implement a document retention policy
				  ○ participate in national and international PSM congresses, training events
				  ○ membership of PSM organizations (CCPS, etc.), literature, ...

PSM Maturity Model

	Starting out Level 1: Primers	Developing Level 2: Tools & techniques	Implementing Level 3: Specialised content	Leading Level 4: Expert access
PSI	• Understand the need for process safety information to support decisions	• Gather appropriate Process Safety Information required to assist PHA	• Appropriate Process Safety Information for all processes available	• Proactive (forward) safety studies and in house PSI monitoring capabilities
MoC	• Management of Change (MoC) procedure	• MoC procedure & practice	• MoC process fully implemented with involvement of PSM expert	• MoC included in external PSM program Audit
Training	• Basic PSM training for EHS, Engineers and Management: ○ Fundamentals of PSM ○ PSM elements ○ ATEX or NFPA ○ Flammable & explosive materials ○ Static electricity ○ Understanding of dust explosion hazards	• Basic PSM training for shift supervisor and operator	• Full PSM training for EHS, Engineers, shift supervisor and operator Competency Management System –Safety Critical Task assessment and documentation of competence for operators	• Continuous monitoring and update of training program (track record) and competency assessments on Safety Critical Tasks (reviewed on a suitable timeline (e.g. every 3 years or when a change is made)

PSM Maturity model: fire Protection

	Starting out Level 1: Primers	Developing Level 2: Tools & techniques	Implementing Level 3: Specialised content	Leading Level 4: Expert access
Fire Protection	• *Fire water supply/ hydrant system* • Fire detection in all areas - *Automatic smoke detection & fire alarm in high risk areas* • Hot work permit in place • Maintenance/inspection program for equipment (spare back-up pump, jockey pump, valves locked open) • Passive fire protection (fire doors, walls etc.)	• Trained people on site for first response • Fire protection program started • Adequate fire water, fire pump(s), hydrants and enough foam generating liquid provided (based on calculation) • Fire extinguishers are available at strategic locations and inspected periodically (ensure employees know how to use extinguisher)	• Fire protection program started with continuous improvement • audits for fire protection • Automated extinguishing systems in all high risk areas	• Automated extinguishing systems in all high risk areas and warehouses >> *(in all the buildings)* • *The facility is equipped with an on-site fire station and fire truck (for larger facilities)*

Process Safety Primers

- Already available

Title
Dust explosion protection
PHA
GHS
Static Electricity
Not Described Situations

in Preparation

Title
Fire detection
MoC
Tank farm safety
Boiler safety
Basic PSI
ATEX

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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