

Management Systems

Introduction to the Maturity Model

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Speaker Bio

2015 – present	HSE Advisor, Elanco Asia- Pacific, Japan, ANZ
2012 – 2015	Legal work and practice
Prior to 2012	Variety of positions in HSE and HR senior management at global pharmaceutical company, university, hospital
2011:	Variety of consulting work
2011:	Admitted to practice law, graduated JD from UTS
2007	MLLR – Sydney Uni
Prior to 2007	MSc – UNSW
	BSc – Sydney Uni



Management Systems Maturity Model

Overview of Management Systems

Maturity Model

Details of Maturity Model

Areas of Concern from PSCI Assessments – Management Systems

Common Gaps from PSCI Assessments – Management Systems



What is a Management System?

- A **management system** is the framework of policies, processes and procedures used by an organization to ensure that it can fulfill all the tasks required to achieve its objectives.
- **Management system** is the way in which an organization manages the inter-related parts of its business in order to achieve its objectives. These objectives can relate to a number of different topics, including product or service quality, operational efficiency, environmental performance, health and safety in the workplace and many more.
- In its most basic sense, a **management system** is how organizations ensure things get done.
- Your workplace probably already has the basic elements of a management system;
- Includes principles, framework, accountabilities, procedures, training, record keeping....etc;

Examples of Management Systems

- ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 161 [national standards bodies](#).
- Examples of ISO Standards include:
 - ISO 50001 - Energy management
 - ISO 9001 - Quality management
 - ISO 14000 family - Environmental management
 - ISO 45001 - Occupational health and safety
 - ISO 37001 – Anti-bribery management systems
- SAI certification:
 - SA 8000 – Social Accountability
- International Standards **make things work**. They give world-class specifications for products, services and systems, to ensure quality, safety and efficiency.

External Certification – some thoughts....

- External certification can be beneficial for the business – e.g.:
 - Some govt. or other supply contracts may require or give preference to companies with external certifications;
 - Public reporting.
- However:
 - External certification needs to reflect **what is actually happening at the site**;
 - We've seen major deficiencies at some external certified sites;
 - In some cases, external certification is more document driven than actual practice driven;
 - We've seen examples of expired external certification;

Points to Consider in Management Systems

- Tailored and suitable for your business;
- It works – makes your workplace more efficient;
- It's sustainable;
- It's integrated with other key components of your business – e.g. Quality, productivity; Customer Service;
- It's able to provide evidence for monitoring, review, continual improvements and compliance.

PSCI Questionnaire – Management Systems

- Q1 – Commitment and Accountability;
- Q2 - Q4 – Legal and Customer Requirements;
- Q5 - Q8 – Risk Management;
- Q9 – Documentation;
- Q10 – Training and Competency;
- Q11 – Continual Improvement.

Management System Maturity

- Maturity based on issues such as:
 - Established processes;
 - Governance;
 - Systems/tools;
 - Metrics, KPIs
- Starting Programs - the basics may be there, minimal processes that are not well established;
- Developing Programs - basic internal processes; developing site-wide awareness;
- Implementing Programs - processes are in place; clear responsibilities for key staff;
- Leading programs - established and robust processes; embedded into the business culture.

Management Systems Maturity Model

- Bridget Ferrari, Takeda
- Marisol Clark, AbbVie
- Sulaiman Hamidi, Allergan
- Roberta Haski, Elanco
- Carlos Herrero, Centrient Pharmaceuticals
- Bob Holman, Merck
- Cheryl O'Hara, GSK
- Doug Yunaska, Merck

MANAGEMENT SYSTEMS MATURITY MODEL		PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE Building responsible supply chains	
This maturity model has been developed: (1) as a tool to help you assess the current state of your organization's Management Systems relative to PSCI's Supplier Audit Questionnaire and (2) to understand what PSCI Member Companies look for in their suppliers.			
	STARTING	DEVELOPING	LEADING
Management Commitment & Accountability	<ul style="list-style-type: none"> Written Management Commitment regarding EHS, Labor/Human Rights and Ethics related processes Occasional followup on EHS, Labor/Human Rights and Ethics topics at Management Team (MT) Meetings Processes documented through SOPs or other means 	<ul style="list-style-type: none"> EHS, Labor/Human Rights and Ethics as standard agenda topics for Management Team Meetings EHS, Labor/Human Rights and Ethics topics handled in line with relevant certifications (ISO or equivalent) Process applied (SOPs, KPIs or measurements for processes) 	<ul style="list-style-type: none"> Proactive leaders effectively make a difference, demonstrate commitment Continuous Improvement cycle in place and monitored by Management Team Employees empowered to approach management with suggestions, questions
Legal & Customer Requirements	<ul style="list-style-type: none"> Identify and comply with minimum regulations, standards and relevant customer requirements 	<ul style="list-style-type: none"> Compliant with regulations and has a program to address noncompliance or under performance, including 	<ul style="list-style-type: none"> Compliant culture among general workforce, with strong KPI focus on legal and customer expectations from EHS, Labor and Ethics
Risk Management	<ul style="list-style-type: none"> Limited risk assessment; and program in place Risk assessments are high and are not task specific Reactive risk prioritization; minimal consideration for continuity 		<ul style="list-style-type: none"> Proactive culture that proactively addresses regulatory changes; conduct due diligence to identify and comply with regulation and customer needs
Training and Competency	<ul style="list-style-type: none"> Training is ad-hoc and reactive Formal discipline is used to enforce rules Supervisory Control of day to day tasks 		<ul style="list-style-type: none"> Management becomes integral part of business, including a formal control program Consistently demonstrates risk management and awareness Routinely reviews risks and business by and implements improvements to risk scores
Continuous Improvement and KPIs/Metrics	<ul style="list-style-type: none"> Limited or reactive KPIs in place to measure progress toward achieving goals and objectives Limited management/employee awareness on how to measure progress toward achieving goals/targets Metrics/KPIs have minimal management sponsorship 	<ul style="list-style-type: none"> KPI/Metrics available for some of the goals/targets and measure leading indicators Management is aware of metrics/KPIs and are reviewed periodically; KPIs only visible to management Opportunities for improvement are identified and managed 	<ul style="list-style-type: none"> Leading/predictive and Lagging indicators are used to measure performance against goals/objectives Proper investigation programs to prevent further incidents Culture of Continuous Improvement throughout organization with metrics highly visible and transparent Employees empowered to make recommendations and changes
Established Processes	<ul style="list-style-type: none"> Simple EHS, Ethics and Labor/ Human Rights standards and processes are in place Variable evidence of processes to facilitate/demonstrate commitment to SAQ concepts Continual Improvement efforts are minimal 	<ul style="list-style-type: none"> Processes align to requirements of generally recognized 3rd party certification systems Demonstrated awareness of processes supporting SAQ concepts Continual Improvement opportunities lead to optimization of current practices 	<ul style="list-style-type: none"> Workers clearly understand established processes supporting SAQ concepts Continual Improvement is encouraged at all levels of facility Workers are empowered to implement and continually improve processes supporting SAQ concepts
Systems, Tools and Documentation	<ul style="list-style-type: none"> Minimal records/data/Documents available to support program Limited governance to review/revise/update documents Minimal control of access to records/data/Documents 	<ul style="list-style-type: none"> Governance program in place to manage records/data/Documents Oversight of procedures limited and may not include reviews by Subject Matter Experts (SMEs) Systems standalone and not integrated/limited availability for parts of operations/business 	<ul style="list-style-type: none"> The organization has established a governance system with set policies to define documentation requirements across the enterprise Tools in place to manage activities, roles and responsibilities integrated with business processes Formal process to manage access control and data privacy

Now aligned with the four-tier PSCI common framework

Maturity Model...

- This maturity model has been developed:
 - (1) as a tool to help you assess the current state of your organization's Management Systems relative to PSCI's Supplier Audit Questionnaire and
 - (2) to understand what PSCI Member Companies look for in their suppliers.
- Please use this in conjunction with your contact at the Member Company to identify where your organization would like to make improvements.

	Starting Program	Developing Program	Implementing Program	Leading Program
Commitment & Accountability	<ol style="list-style-type: none"> 1. Written management commitment regarding EHS, Labor/Human Rights and Ethics 2. Occasional follow-up on EHS, Labor/Human Rights and Ethics topics at management team meetings 	<ol style="list-style-type: none"> 1. EHS, Labor/Human Rights and Ethics are standard agenda topics for management team meetings 2. Commitment and accountability are documented through SOPs or other mean 	<ol style="list-style-type: none"> 1. Specific senior managers are responsible and held accountable for implementing the commitments 2. Senior managers are actively involved in EHS, Labor/Human Rights and Ethics topics 3. Appropriate resources are allocated to ensure delivery of the commitments 4. EHS, Labor/Human Rights and Ethics topics are handled in line with relevant 3rd party certifications (ISO 14001, OHSAS 18000 or equivalent) 	<ol style="list-style-type: none"> 1. Proactive leaders effectively make a difference, demonstrate commitment and leadership on EHS, Labor/Human Rights and Ethics topics 2. The management team monitors continuous improvement 3. Employees are empowered to approach management with suggestions and questions
Legal & Customer Requirements	<ol style="list-style-type: none"> 1. Identify and comply with minimum regulations, standards and relevant customer requirements 	<ol style="list-style-type: none"> 1. EHS, Labor/Human Rights and Ethics are included in Legal Register 2. Actively conduct due diligence to identify and comply with regulation and customer requirements 	<ol style="list-style-type: none"> 1. Program to address noncompliance or under performance, including customer requirements 2. Ongoing consultations and reviews of forthcoming legislation to identify potential changes in regulations 	<ol style="list-style-type: none"> 1. Compliant culture among general workforce, with strong KPI focus on legal and customer expectations on EHS, Labor/Human Rights and Ethics topics 2. Empowered culture that proactively anticipates regulatory changes 3. Beyond legal compliance culture

	Starting Program	Developing Program	Implementing Program	Leading Program
Risk Management	<ol style="list-style-type: none"> Limited risk assessment process and program in place Risk assessments are high level and not task specific Reactive risk prioritization with minimal consideration for business continuity 	<ol style="list-style-type: none"> All tasks are assessed, including permit to work used to control high risk activities Incidents are investigated and analysed 	<ol style="list-style-type: none"> Well defined process for risk assessment and business continuity in place, including scoring matrix Adherence to risk management plans and procedures Everyone gets involved in risk assessment, including workers Proactive formal risk assessment process; potential problems are eliminated before they occur Incident learnings shared with all management and staff levels 	<ol style="list-style-type: none"> Risk Management becomes integral part of everyday business, including a formal change control program Everyone consistently demonstrates risk management and awareness Business routinely reviews risks and business continuity and implements improvements to reduce risk scores
Documentation	<ol style="list-style-type: none"> Minimal records/data/documents available Limited governance to review/revise/update documents Minimal control of access to records/data/documents 	<ol style="list-style-type: none"> Oversight of documentation/procedures limited and may not include reviews by Subject Matter Experts (SMEs) Systems standalone and not integrated/limited availability for parts of operations/business 	<ol style="list-style-type: none"> Governance program in place to manage records/data/documents Formal process to manage access control and data privacy Documents, policies, procedures and processes aligned across functional areas and result in one system for the entire enterprise 	<ol style="list-style-type: none"> Established governance system with set policies to define documentation requirements across the enterprise, making sure that all documentation necessary to demonstrate conformance with the PSCI Principles and compliance with applicable regulations is available Tools in place to manage activities, roles and responsibilities integrated with business processes

	Starting Program	Developing Program	Implementing Program	Leading Program
Training and Competency	<ol style="list-style-type: none"> 1. Training is minimal, ad-hoc and reactive 2. Formal discipline is used to enforce rules 3. Supervisory Control of day to day tasks 	<ol style="list-style-type: none"> 1. Training curriculum in place and regularly reviewed 2. Cross-organisation training on different areas and tasks set to further develop workers 	<ol style="list-style-type: none"> 1. Automated system for monitoring of training compliance 2. Development of workers is a priority and investment is made in learning 3. Competency in critical training programs is assessed 4. Competency requirements are established 	<ol style="list-style-type: none"> 1. Workers are highly skilled and demonstrate a high level of training awareness 2. Business encourages professional development, membership of professional groups and further education
Continual Improvement	<ol style="list-style-type: none"> 1. Minimal continual improvement efforts 2. Limited or reactive KPIs in place to measure progress toward achieving goals and objectives 3. Limited management/employee awareness on how to measure progress toward achieving goals/targets 4. Metrics/KPIs have minimal management sponsorship 	<ol style="list-style-type: none"> 1. KPI/Metrics available for some of the goals/targets and measure lagging indicators 2. Management is aware of metrics/KPI and are reviewed periodically; KPIs only visible to management 	<ol style="list-style-type: none"> 1. Improvement opportunities are identified and managed and lead to optimization of current practices 2. Incidents are properly investigated, and corrective action plans adopted (with regular follow-up to ensure implementation) 	<ol style="list-style-type: none"> 1. Leading/predictive and Lagging indicators are used to measure performance against goals/objects 2. Culture of Continuous Improvement throughout organization with metrics highly visible and transparent 3. Employees empowered to make recommendations and changes 4. Continual Improvement is encouraged at all levels of facility 5. Workers are empowered to implement and continually improve processes

	Starting Program	Developing Program	Implementing Program	Leading Program
Identification of Concerns	<ol style="list-style-type: none"> 1. Limited identification of concerns 2. Role restricted to management 	<ol style="list-style-type: none"> 1. Processes in place to allow and encourage workers to report concerns, illegal activities or breaches of the PSCI Principles without threat of or actual reprisal, intimidation and reprisal 2. Concerns are investigated and corrective action taken if needed 	<ol style="list-style-type: none"> 1. Culture of reporting concerns embedded throughout all levels of the organisation 	<ol style="list-style-type: none"> 1. Employees are empowered and proactively encouraged to identify concerns 2. Incidents and serious near misses are investigated, root causes and action plans are identified and shared to embed a proactive approach
Communication	<ol style="list-style-type: none"> 1. Communication is ad hoc and reactive; communication takes place on a need-to-know basis 	<ol style="list-style-type: none"> 1. Communication regular; the process is well defined and documented 	<ol style="list-style-type: none"> 1. Communication takes place using plural established audience appropriate communication channels 	<ol style="list-style-type: none"> 1. Communications processes, plans and channels are regularly reviewed to ensure their effectiveness. Workers, contractors and suppliers are fully informed and demonstrate good understanding of The PSCI Principles and other relevant content

Areas of Concern from PSCI Assessments

- Who signs off and approves the components of the Management System?
- Is what is seen across the site match the written programs and the regulatory requirements?
- Does the site know their risks and regulatory obligations?
- Is the site generally compliant to regulatory requirements?
- Is the site sufficiently resourced for its Safety, Environment, Labour and Ethics programs?
- Is the site technically capable to address Safety, Environment, Labour and Ethics programs?
- Does training exist for the above?
- Does the site have a self-inspection/auditing program to show their programs are actually being followed?
- Who is responsible and accountable for Safety, Environment, Labour and Ethics programs?
- What are the gaps and why are there gaps?
- Is the site willing to improve?
- Are there major **system** failures, gaps?

Common Gaps in Management Systems from PSCI assessments

- Regulatory compliance – gaps in knowledge of requirements, incomplete and/or expired permits, licenses, no system to keep current with changes in reg. requirements;
- Risk assessments – site does not understand or use risk assessment;
- BCP – lack of BCP, major risks not analysed, no recovery strategy, has not been practised;
- Change Management – usually in place for Quality, but minimal HSE, Labour, Ethics considerations;
- Documentation – minimal developed, implemented and documented processes, SOPs not reviewed, SOPs **NOT FOLLOWED**, gaps in training programs

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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.

