PSCI Virtual Supplier Conference 2020 (India)

Session 1 – PSCI Updates and Management Systems

Disclaimer: Compliance with local requirements is the responsibility of companies and their local business areas. The information in these presentations is not intended to supersede, take the place of, or conflict with, local government requirements.
Practicalities

- Switch to audio feed only for better connection

- Breaks

- We’ll be using Sli.do for Q&As and polls, please follow the link under Q&A on Livestream webpage (Sli.do event code: PSCIIndia)

- Feedback survey
ANTI-TRUST STATEMENT

While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

i. Price fixing;
ii. Product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation;
iii. Standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete);
iv. Codes of ethics administered in a way that could inhibit or restrict competition;
v. Group boycotts;
vi. Validity of patents;
vii. On-going litigation;
viii. Specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information.
THE PHARMACEUTICAL SUPPLY CHAIN INITIATIVE (PSCI)

An Introduction

Caroline O’Brien, PSCI Chair
Global Quality Audit - Regional Hub Director Asia Pacific, AstraZeneca
AGENDA

THE VISION & INTRODUCTION

MEMBERSHIP

THE CHALLENGE

PSCI PRINCIPLES & HOW WE WORK

WHAT WE DO

OUR IMPACT & 2020 HIGHLIGHTS

ADVISORY PANEL & PARTNERS

WE WILL HELP YOUR SUPPLY CHAIN!
Speaker Bio

- Caroline O’Brien, PSCI Chair

- Global Quality Audit Regional Hub Director for Asia Pacific and Japan based in Osaka, Japan. Responsible for managing the Asia Pacific team, as well as conducting audits of AstraZeneca manufacturing sites, contractors, suppliers, due diligence and other audits where specialized expert technical skills and experience are needed.

- Previously she was the Director of Operations Compliance, where her responsibilities included developing and leading the implementation of the Compliance strategy in Global Operations and Supply Chain.

- She is also an experienced Safety, Health and Environment professional undertaking sites audits for both internal and external supply network.
PSCI: THE VISION

Our **VISION** is to establish and **promote responsible practices** that will continuously improve **ethics, human rights & labor, health, safety and environmentally sustainable outcomes** for our supply chains.
45 member companies* already share the **PSCI VISION** and are committed to continuous improvement in the supply chain

*Associate members have the following symbol: The rest are full members.
THE CHALLENGE

Alone we can do so little,
Together we can do so much.
ADDRESSING THE CHALLENGE

INTERNATIONAL STANDARDS / FRAMEWORKS

CAMPAIGNS

Nordea

LEGISLATION

PATIENTS & VALUE BASED HEALTHCARE

PRESSURE FROM BUYERS

MODERN SLAVERY ACT

Redefining Health Care

SPHS

NHS
ADDRESSING THE CHALLENGE

SUPPLY CHAIN ISSUES

FIRE

BONDED LABOUR

POLLUTION

BRIBERY AND CORRUPTION

WORKING HOURS
THE PSCI PRINCIPLES

ETHICS
- Anti-bribery and corruption
- Fair competition
- Animal welfare
- Data privacy and security
- Patient safety and access to information
- Avoidance and management of conflicts of interest

HUMAN RIGHTS AND LABOR
- Freely chosen employment
- No child labor
- Legal treatment of young workers
- Non-discrimination
- Fair treatment
- Wages, benefits and working hours
- Freedom of association

HEALTH AND SAFETY
- Worker protection
- Process safety
- Proper control of hazardous substances
- Emergency preparedness and response
- Communication of hazard information

ENVIRONMENT
- Environmental authorizations and reporting
- Management of waste and emissions
- Spills and releases prevention
- Resource efficiency
- Sustainable sourcing and traceability
- Managing the release of pharmaceuticals into the environment

MANAGEMENT SYSTEMS
- Commitment and accountability
- Legal and customer requirements
- Risk management
- Documentation
- Training and competency
- Continual improvement
- Identification of concerns
- Effective communication
HOW WE WORK

BOARD OF DIRECTORS

SECRETARIAT

WORKING COMMITTEES

MEMBERS

Plus, 15 topic-specific Sub-Teams
WHAT WE DO

- A common voice for our industry.
- Set expectations for ethics, labour, health & safety, environment, management systems (The PSCI Principles & Implementation Guidance).

- Build supplier capability
  - Conferences
  - Resource library
  - Webinars

- Define common supplier assessment tools (audit framework, SAQ, ...).
- Audit and promote audit sharing to reduce burden on the industry and drive continuous improvement.

We hosted seven webinars in 2019 and eight so far in 2020. This year, we reached a total of 450+ viewers.
ACCELERATING OUR DIGITAL OFFERING

The data on the right compares 2019 to the previous year. As you can see, our reach continues to grow.

In 2020, in response to COVID-19, we accelerated the digitalization of our resources, offering our member meetings and supplier conferences virtually and launching our community platform for suppliers (more information on next slide).

As a result, we expect to report even higher engagement in 2020.

**REACH**

<table>
<thead>
<tr>
<th>PSCI IN PERSON</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conference attendees ¹</td>
<td>400+</td>
<td>400+</td>
</tr>
<tr>
<td>Webinar attendees</td>
<td>163</td>
<td>400</td>
</tr>
<tr>
<td>Member meeting attendees ²</td>
<td>125</td>
<td>180+</td>
</tr>
<tr>
<td>Total approved 3rd party audit firms</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>3rd party auditors trained</td>
<td>23</td>
<td>40</td>
</tr>
<tr>
<td>Member companies</td>
<td>34</td>
<td>40</td>
</tr>
</tbody>
</table>

1. In 2019 PSCI had supplier conferences in China and India, each of them has welcomed over 200 attendees.
2. For the first time, we welcomed virtual attendees to the 2019 Fall AGM. Over 40 members attended virtually.
3. Resource downloads have increased substantially compared with 2018. Some of this increase is attributable to more comprehensive tracking of resource downloads. However, with web visitors also increasing, the figures also reflect growing popularity of PSCI resources.

<table>
<thead>
<tr>
<th>PSCI ON THE WEB</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique web visitors</td>
<td>26K+</td>
<td>35K+</td>
</tr>
<tr>
<td>Followers on social media</td>
<td>564</td>
<td>941</td>
</tr>
<tr>
<td>Twitter followers</td>
<td>157</td>
<td>201</td>
</tr>
<tr>
<td>LinkedIn followers</td>
<td>407</td>
<td>731</td>
</tr>
<tr>
<td>Document downloads ³</td>
<td>50K+</td>
<td>125K+</td>
</tr>
<tr>
<td>Industrial Hygiene (IH) Introductions Training slides on fundamentals of IH</td>
<td>4K+</td>
<td>7.3K+</td>
</tr>
<tr>
<td>Basic Information for OEL PBOEL-HHC IPI and API</td>
<td>2.3K+</td>
<td>4.5K+</td>
</tr>
<tr>
<td>Best Management Practices for Leak and Spill Control</td>
<td>1.5K+</td>
<td>4.2K+</td>
</tr>
<tr>
<td>Downloads of PSCI Audit Guidance</td>
<td>1.4K+</td>
<td>3K+</td>
</tr>
<tr>
<td>PSCI Principles</td>
<td>1.1K+</td>
<td>2.2K+</td>
</tr>
<tr>
<td>PSCI Principles guidance</td>
<td>1K+</td>
<td>1.5K+</td>
</tr>
</tbody>
</table>
THE LINK: JOIN THE COMMUNITY

Our online platform for members and suppliers

- Hear and comment on the latest industry news
- View shared supplier audits
- Access tools, training and other resources
- Engage with peers through polls, surveys and sharing ideas
- Register for events and activities
- Sign up for the peer to peer mentoring programme
- Check out the work of our Committees and Sub-Teams

BUILDING A SUPPLIER COMMUNITY
The Link isn’t just for members. The Link for Suppliers provides the following benefits to our supplier community:

- Gain greater visibility and control over shared supplier audits
- Be the first to hear about PSCI developments and updates to audit tools
- Access PSCI tools, trainings and resources, improving their capabilities and knowledge of responsible supply chains

pscinitiative.org/login

Having trouble logging in? Ask your company lead to sign you up or email us at info@PSCInitiative.org
2020 HIGHLIGHTS

- Two regional teams formalized – one in India & one in China
- Our first fully virtual supplier conferences for suppliers based in India and China & our first fully virtual member meeting attracting over 140 attendees from our 44 member companies.
- Launch of The Link, our new state-of-the-art community and audit-sharing platform for members and suppliers, with access to all PSCI resources, news, training, audits – and more!
- A project to support the revitalization of the Musi River area in Hyderabad, India
- A project on pharmaceutical raw materials human rights impact
- Developed topic focussed maturity models and training curricula for suppliers
- More webinars covering a wide range of issues (11 planned for 2020 vs 7 in 2019 vs 3 in 2018, reaching hundreds of members and suppliers around the world).
- Building partnerships and engaging with external stakeholders including through our excellent Advisory Panel
- Roll-out of peer-to-peer mentoring scheme.
- Continuing to build on solid membership growth, particularly welcoming mid-sized pharma companies, and consequently expanding our Board from 5 to 7 Directors
Welcome from India Sub-Team

Manjit Singh, PSCI Vice-Chair and India Sub-Team Lead
Associate Director-Corporate Sustainability, Centrient Pharmaceuticals
AGENDA

India Sub-Team overview

PSCI Partner in India

The Link for Suppliers

Objective and activities
Name: Manjit Singh
Title: Associate Director - Corporate Sustainability
Organization: Centrient Pharmaceuticals India Pvt Ltd.
Organization Profile: Centrient is headquartered in The Netherlands and pioneer and leader in penicillin, penicillin-based antibiotics and statins.

Manjit has about 33 years’ experience in pharmaceutical manufacturing operations.
He is responsible for global sustainability at Centrient.
Manjit is PSCI Vice Chair and lead for PSCI India Sub Team
He is bachelor in chemistry from Punjabi University, Patiala.
PGDIM - Operations, Indira Gandhi National Open University, Delhi.
Welcome By - PSCI India Sub Team

India Sub Team, warmly welcome you to Virtual India Conference. Hope conference will immensely benefit to strengthen sustainability in operations.
PSCI India Sub-Team Member Companies

Constituted in Nov 2019, 11 member companies and 16 people are part of India Sub team.
PSCI India Sub Team - Objective

- Working with Indian suppliers, Industry associations, media and professional bodies to evaluate the sustainability related needs and work together to build a sustainable supply chain.
- Support to develop the contents for long term training, capacity building workshops, audit committee and communication.
PSCI India Sub Team - Activities

- Meets monthly, concluded brainstorming session identified 14 topics and projects. Developed roadmap till 2022.
- Developed partnership with KDPMA and in discussion with other industry association for partnership.
- Supporting conference, leverage and share Indian experience through local speakers.
- Submitted the response on Indian draft standards.
- Support to Musi River Revitalization initiative.
- Webinar on India labour law regulations planned in Q4, 2020.
PSCI Partner in India

Karnataka Drugs And Pharmaceuticals Manufacturer's Association

Activities:
- Currently in phase of relationship building via leadership meetings
- Exchange of PSCI promotional material
Supplier Self-Initiated Audits

You asked, we delivered:

- Suppliers can now initiate PSCI Audits
- Ensure audit quality by using the PSCI Audit process and PSCI approved audit firms
- Reduce your audit burden by sharing with customers on secure PSCI platform
- Conduct at your convenience and choose your scope – EHS/Mgmt Systems and/or Ethics/Labor
- Be proactive - Identify risks and improvement opportunities
- Improve your performance against PSCI principles
THE LINK: JOIN THE COMMUNITY

Our online platform for members and suppliers

- Hear and comment on the latest industry news
- View shared supplier audits
- Access tools, training and other resources
- Engage with peers through polls, surveys and sharing ideas
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BUILDING A SUPPLIER COMMUNITY

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- Access PSCI tools, trainings and resources, improving their capabilities and knowledge of responsible supply chains

Having trouble logging in? Ask your company lead to sign you up or email us at info@PSCInitiative.org
The PSCI's capability building vision and plans

*Our vision for structured learning*

Ingrid Vande Velde, PSCI Supplier Capability Committee co-lead
Senior Manager EHS&S External Supply EMEA/ASPAC, Johnson & Johnson
Ingrid Vande Velde

Johnson & Johnson
Senior Manager EHS&S External Supply EMEA/ASPAC
PSCI Supplier Capability Committee co-lead

Past experiences:
- Started 1997 Janssen Pharmaceutica Belgium (J&J)
- Different EHS&S roles R&D, fill finish and chemical production in J&J
- 2007-2009 Industrial Hygienist Alza - California, US
- 2010-2011 EH&S Expert Asia Pacific - Beijing, China

Contact information: ivdvel1@its.jnj.com
The position today

- 45 members of PSCI spend $400Bn+ each year with 100,000s of suppliers

- Capability and maturity varies enormously across this supply chain – some are world-leading, some are just starting out

- Knowledge and skills are critical to sustainability improvement

- How can we offer a structured approach to:
  - Growing maturity
  - Skills development
The PSCI vision

Our **VISION** is to establish and **promote responsible practices** that will continuously improve **ethics labor, health, safety and environmentally sustainable outcomes** for our supply chains.
How do we deliver that vision?

- A common voice for our industry.
- **Set expectations** for ethics, labour, health & safety, environment, management systems (The Principles & Implementation Guidance).

**Build supplier capability**
- Conferences
- Resource library
- Webinars

- Define common **supplier assessment tools** (audit framework, SAQ, ...).
- **Audit and promote audit sharing** to reduce burden on the industry and drive continuous improvement.
Where we are today

- Largely face-to-face training: Two supplier conferences, one in India and one in China with 400+ supplier delegates.
- More peer-learning and bigger impact by inviting leading suppliers to present.
- Twelve presentations at external events across Europe and Asia.
- Seven webinars offered live and recorded.
- A growing library of online content with 125,000 downloads last year.
The questions we asked ourselves

- How can we go further and bring better structure to our online content?
- How to blend the in-person and online?
- How can we exponentially grow our scale and impact?
- Organisational versus individual learning? How can we better link together the ideas of ‘maturity’ and ‘skills’?
- How can we accommodate different levels of understanding on different topics?
Capability building vision

ETHICS
- Anti-bribery and corruption
- Fair competition
- Animal welfare
- Data privacy and security
- Patient safety and access to information
- Avoidance and management of conflicts of interest

HUMAN RIGHTS AND LABOR
- Freely chosen employment
- No child labor
- Legal treatment of young workers
- Non-discrimination
- Fair treatment
- Wages, benefits and working hours
- Freedom of association

HEALTH AND SAFETY
- Worker protection
- Process safety
- Proper control of hazardous substances
- Emergency preparedness and response
- Communication of hazard information

ENVIRONMENT
- Environmental authorizations and reporting
- Management of waste and emissions
- Spills and releases prevention
- Resource efficiency
- Sustainable sourcing and traceability
- Managing the release of pharmaceuticals into the environment

MANAGEMENT SYSTEMS
- Commitment and accountability
- Legal and customer requirements
- Risk management
- Documentation
- Training and competency
- Continual improvement
- Identification of concerns
- Effective communication
Capability building vision

1. Primers
   Raising awareness, making the case

2. Tools and techniques
   Getting started, “How to” guides

3. Specialised content
   From content experts, context-specific

4. Expert access
   Mentoring, problem-solving, collaborating

Experts

PSCI
## PSCI’s learning model

### Description

<table>
<thead>
<tr>
<th>Level 1: Foundational ‘primers’</th>
<th>Level 2: Tools &amp; techniques</th>
<th>Level 3: Specialised content</th>
<th>Level 4: Expert access</th>
</tr>
</thead>
<tbody>
<tr>
<td>The first level will be foundational primers on key topics – what all suppliers need to know to have a common level of knowledge.</td>
<td>The second level will offer a more detailed view into each area, describing some of the nuances and challenges in each area, along with recommendations in terms of tools and techniques that might be helpful.</td>
<td>The third level, and probably the most engaging for suppliers aiming to lead in this space, will be a series of specialised content modules. Here, the content will be more sector specific and draw content from thought leaders. For example, CHWMEG for waste management, GCIPR for Green Chemistry, WRI on water. We will also be able to draw on industry expertise and knowledge from PEG – such as the GHG guidance in development.</td>
<td>The fourth level is really intended for those suppliers that are leading and would benefit from access to industry leaders. This might be about specific technical challenges faced by suppliers or an opportunity to think about specific mutually beneficially projects or joint initiatives.</td>
</tr>
</tbody>
</table>

### Delivery method

| Simple but visually engaging and content-rich two-page guides for suppliers to view online or download. | Recorded online videos with links to proprietary or external content. | ‘Live’ webinars, with a Q&A session, recorded and available as online videos. | Agreed on a case by case basis as discussions and content are likely to be very specific. |

### Example from the Environment sub-team’s model: The PSCI Principles on Environment

- What are The Principles?
- What are the expectations?
- Auditing and compliance
- Preparing for audit against The Principles
- Case study exemplars
- Customer expectations – beyond The Principles
- TBD

### Example from the Environment sub-team’s model: Climate change

- What is Climate Change?
- Sources of Greenhouse Gases (GHG)
- The basics of measurement
- Calculating your carbon footprint
- What is scope 3?
- Developing a carbon strategy
- TBD
## Organisational maturity

<table>
<thead>
<tr>
<th>Supplier Maturity</th>
<th>Starting out</th>
<th>Developing</th>
<th>Implementing</th>
<th>Leading</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compliance with law</strong></td>
<td>PLUS</td>
<td>• Audits / baselines / risk assessments complete</td>
<td>PLUS</td>
<td>• Embedded in culture</td>
</tr>
<tr>
<td><strong>Necessary policies in place</strong></td>
<td></td>
<td>• Key risks and highest impacts identified</td>
<td></td>
<td>• External recognition / awards</td>
</tr>
<tr>
<td><strong>Minimum standards are being met</strong></td>
<td></td>
<td>• Measurement and recording systems in place</td>
<td></td>
<td>• Taking an advocacy stance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Management responsibility has been allocated</td>
<td></td>
<td>• Approach includes whole value chain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Targets and objectives set</td>
<td></td>
<td>• External partnerships across industry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Supporting partners / customers to improve.</td>
</tr>
<tr>
<td>PLUS</td>
<td></td>
<td></td>
<td></td>
<td>• Sustainability drives innovation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Sustainability leads to differentiation and commercial advantage</td>
</tr>
</tbody>
</table>

### Level 1: Foundational ‘primers’
- Foundational primers on key topics
- Simple but visually engaging and content-rich two-page guides for suppliers to view online or download.
- Primers will demonstrate the minimum standards, enable suppliers to prepare for their journey and raise awareness of the key topics.

### Level 2: Tools & techniques
- Challenges, tools and techniques
- Recorded online videos with links to proprietary or external content.
- As suppliers develop their programme, they will draw on these tools and techniques, including audit frameworks, risk assessment tools, and ‘how to’ guides.

### Level 3: Specialised content
- Specialised content modules for those aiming to leadership
- ‘Live’ webinars, with a Q&A session, recorded and available as online videos.
- Suppliers have established good systems for key risks and are now aiming for excellence. Case studies inspire them, specialist content fills in their remaining knowledge gaps.

### Level 4: Expert access
- Access to industry leaders, mutually beneficially projects or joint initiatives for those established in leadership.
- Agreed on a case by case basis as discussions and content are likely to be very specific.
- Leading suppliers are as likely to be sharing their expertise as they are to be learning; a network of experts, working in partnership.
<table>
<thead>
<tr>
<th>Level 1: Foundational 'primers'</th>
<th>Level 2: Tools &amp; techniques</th>
<th>Level 3: Specialised content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Downloadable guide for suppliers</td>
<td>Online videos and links</td>
<td>'Live' webinars with external input</td>
</tr>
</tbody>
</table>

**The PSCI Principles on Environment**
- What are The Principles?
- What are the expectations?
- Auditing and compliance
- Preparing for audit against The Principles
- Case study exemplars
- Customer expectations – beyond The Principles

**Environmental Management**
- Writing Environmental policy
- Basic of an EMS
- Measuring performance
- Standards and certification
- Setting goals and targets
- Developing Science Based Targets

**Incidents & accidents**
- Understanding legislation & responsibilities
- Safe operating procedures
- Managing a spill or release
- What happens when it goes wrong?
- Best practice leak or spill control
- Real time monitoring and citizen science

**Climate change**
- What is Climate Change?
- Sources of Greenhouse Gases (GHG)
- The basics of measurement
- Calculating your carbon footprint
- What is scope 3?
- Developing a carbon strategy

**Energy efficiency**
- Managing energy
- Changing behaviour
- Areas for efficiency improvement
- Factory improvements
- Renewable energy opportunities
- Renewable energy opportunities

**Green logistics**
- What are green logistics
- Impacts of distribution
- Business travel
- Road vs shipping vs air transport
- New technology (i.e., electric vehicles)
- Principles of EV100

**Water**
- Water management
- Water quality
- Using less water
- Understanding your water risks
- Measuring water scarcity
- Green chemistry and ZDHC

**Waste**
- Waste hierarchy
- The basics of waste management
- Handling hazardous waste
- Writing waste management procedures
- Opportunities for reuse or recycling
- Zero waste to landfill

**Packaging**
- Types of packaging
- Understanding impacts
- Plastics
- Recycling opportunities
- Rightsizing and optimisation
- Eliminating plastics

**Raw materials**
- Raw material sourcing
- Key issues and materials
- Customer expectations
- The important material standards
- Understanding raw material traceability
- Conflict minerals

Level 4 (Expert access) will be agreed on a case by case basis as discussions and content are likely to be very specific.
ACCESSING OUR CONTENT

- Launch of The Link, our new state-of-the-art community and audit-sharing platform for members and suppliers, with access to all PSCI resources, news, training, audits – and more!
What’s in it for me?

The PSCI Principles are the standards we ask you to reach.

To help you get there we will offer you huge amounts of free resource…

- … from the most foundational content to world-leading expertise …
- … including practical tools …
- … all structured around our important topics …
- … available to you online 24-7 …
- … and linked with our supplier maturity models and our assessment tools.
Introducing our next speaker

“The hottest trend in higher education right now is... MOOC learning.

MOOCs — short for Massive Open Online Courses — were supposed to democratize education.

Quarantiners can’t get enough. MOOC companies like Coursera have signed up 10m new users since mid-March, and edX and Udacity have seen similar upticks.”

https://thehustle.co/05272020-moocs-are-back/

Professor Diana Laurillard
University College, London
The Future of Online Learning

Diana Laurillard
UCL Knowledge Lab
Why do we need high quality online learning?

What counts as high quality online learning?
Outline

Why do we need high quality online learning?

What counts as high quality online learning?

What makes a good online learning design?

Building knowledge about high quality online learning
Why do we need high quality online learning?
The UN Sustainable Development Goals

Quality education for all underpins all the SDGs
Why do we need high quality online learning?

**Pandemics**

Globally, over 1.2 billion children are out of the classroom

All university students will be studying at least partly online this year

A collaborative global approach to health and wellbeing requires universal education

**Sustainability**

Around 2.4% of global CO2 emissions come from aviation. The industry is responsible for around 5% of global warming.

Globally, only 20% of the population have ever taken a flight. We frequent flyers contribute a very disproportionate share of emissions.

Reducing air travel is one of the most effective things individuals can do to shrink their carbon footprints.
What counts as high quality online learning?
What counts as high quality learning?

The Conversational Framework

Derived from theories and research on learning and teaching (Laurillard, 2002, 2012)

To represent the teaching-learning process as

• a series of iterative exchanges
• between the learner and a ‘teacher’ and
• between a learner and their peers
• at two levels of concepts and practices
What does it take to learn in formal education?
What does it take to learn in formal education?

Teacher concepts

Teacher communication cycle

Learner concepts

Peer communication cycle

Peer concepts

Mock election

Teacher modelling cycle

Learner practice

Peer modelling cycle

Peer practice
Types of learning mapped to the framework

Learning through ‘acquisition’
Types of learning mapped to the framework

Learning through ‘inquiry’
Types of learning mapped to the framework

Learning through ‘practice’
Types of learning mapped to the framework

Learning through ‘discussion’
Types of learning mapped to the framework

Learning through ‘collaboration’
Types of learning mapped to the framework

Learning through ‘production’
How does technology help? *Conventional methods*

These learning types are encouraged through a variety of conventional methods.
How does technology help? *Conventional methods*

Teacher concepts

- Lectures
- The library
- Write a report

Peer concepts

- Discussion groups
- Peer concepts

Learning environment

- Learning environment
- Labs
- Peer practice

Learner concepts

- Learner concepts

Learner practice

- Group projects
- Peer practice

*These learning types are encouraged through a variety of conventional methods*
How does technology help CPD? Digital methods

- Acquiring
- Inquiring
- Producing

Learner concepts
- Discussion
- Peer concepts

Teacher concepts
- Learner concepts
- Practising

Learning environment
- Collaborating
- Peer practice

The same learning types are encouraged also through a variety of digital methods
How does technology help CPD? Digital methods

The same learning types are encouraged also through a variety of digital methods
What makes a good online learning design?
What makes a good online learning design?

The Learning Designer

A free open online design tool to help with moving your teaching online.

Based on the six learning types from the Conversational Framework – a model of what it takes to learn.

Supports teachers and educators to
• design a sequence of blended and online teaching and learning activities
• analyse their pedagogic design
• share their learning designs with each other

https://www.ucl.ac.uk/learning-designer
Adapting a learning design

Express the details of your pedagogy
Use research-based pedagogic properties to express your learning design.
Learn more

Adapt/Create
The Browser screen categorises existing designs according to pedagogic approach, education sector, topic area, and project needs. You can also search by keyword. When you select a design and turn editing on it becomes yours to edit and adapt, stored in 'My designs'. Or you go to the Designer screen to design from scratch.
View details »

Analyse/Review
As you design each step of the session you can specify the type of learning activity, duration, group size, teacher presence/or not, online/or not, synchronous/or not, and any resources to be attached. The 'designed time' is tracked, along with pie charts and bar charts showing the nature of the learning experience you're designing, in the Analysis tab. This helps you review and revise your design.
View details »

Share/Publish
Once drafted, you can share your design by sending its url to a colleague, or publish it by placing it in 'My designs' public space, or you can export the code for someone else to upload it, or export it to Word to share it with colleagues and students.
View details »
Adapting a learning design

Vocational Education and Training

Using video to showcase a skill  last modified on Wed 23 August 2017 at 18:08:55
Edited by EileenKennedy

Searching for information online  last modified on Thu 31 August 2017 at 18:26:56
Edited by Administrator, derived from Searching for information online by diana

Collaborative learning: Drafting a good assignment  last modified on Sat 30 January 2016 at 19:21:43
Edited by you

Developing your own ideas on a topic (conventional) v2  last modified on Sat 30 January 2016 at 19:32:27
Edited by you

Developing your own ideas on a topic (blended)  last modified on Sat 30 January 2016 at 14:56:33
Edited by you

Inquiry-based learning project (online)  last modified on Sat 30 January 2016 at 19:44:53
Edited by you

Understanding the workplace (Conventional)  last modified on Fri 15 January 2016 at 22:21:54
Edited by you

Understanding the workplace (Blended)  last modified on Fri 15 January 2016 at 18:55:35
Edited by you

Using progress monitoring and metrics to assess work against schedule  last modified on Thu 15 March 2018 at 19:01:29
Edited by you

BTE activity design session for WCC  last modified on Sun 30 July 2017 at 17:14:59
Edited by Administrator

Apprenticeship Induction session  last modified on Fri 16 March 2018 at 15:54:04
Edited by you

Analyze/Review

As you design each step of the session you can specify the type of learning activity, duration, group size, teacher presence/or not, online/or not, synchronous/or not, and any resources to be attached. The ‘designed time’ is tracked, along with pie charts and bar charts showing the nature of the learning experience you’re designing, in the Analysis tab. This helps you review and revise your design.

Share/Publish

Once drafted, you can share your design by sending its url to a colleague, or publish it by placing it in ‘My designs’ public space, or you can export the code for someone else to upload it, or export it to Word to share it with colleagues and students.

View details »
Adapting a learning design
Adapting a learning design

Learning Designer   Home   Browser   Designer

Timeline   Analysis

Vocatio

Using video to showcase   Edited by Ellen Kennedy
Searching for information   Edited by Administrator
Collaborative learning   Edited by you
Developing your own ide   Edited by you
Inquiry-based learning p   Edited by you
Understanding the workq   Edited by you
Understanding the workq   Edited by you
Using progress monitori   Edited by you
BVE activity design sessi   Edited by Administrator
Apprenticeship Inductor   Edited by you

Name: Understanding Risk Assessment Onli
Topic: Risk Assessment
Learning time: 1 hours 10 minutes
Size of class: 25
Description: This is a design for a class using wholly online methods.

Mode of delivery: Wholly online
Aims:
- This session introduces Risk Assessment, and invites students to apply it in a context they are familiar
Outcomes:
- Knowledge: Be able to explain Risk Assessment.
- Application: Be able to apply Risk Assessment to a
- Analysis: Be able to analyse a specific context in

Add TLA   Expand notes

- New design   Import design   Export design   Share   Save

Introduction to Risk Assessment

Read Watch Listen

Watch the presentation about Risk Assessment.
It explains why... how... what...
Does Risk Assessment make sense to you? Please pause the video to note any questions you have.

Discuss

Post your questions to the [Discussion site] at [date, time].
Click 'Like' for any other questions you would like to know the answers to.
Check the site on [date, time] when the trainer will show the answers to your questions.

Applying Risk Assessment

Produce

Think of an example of a situation that is relevant to Risk Assessment in your context, and how you could make use of it.
Make notes to share with your group.
Arrange a time when you will meet with your group online.

Discuss

In your group, take turns to share your ideas of how you would use Risk Assessment in each of the 1 situations.

Collaborate

In your group, decide on your best example, and what you will post to the class site.
Give a brief description of how you would use Risk Assessment in

Read through the other groups' posts to the class site, notes on what you will contribute to the discussion.
Discuss with the trainer, using the audio and the chat, the groups have posted to the class site, and how you actions in future by applying Risk Assessment.

The class discussion of Risk Assessment is on Jira, ti
The discussion is on Jira, ti
Adapting a learning design

Applying Risk Assessment

Produce

Think of an example of a situation that is relevant to Risk Assessment in your context, and how you could make use of it. Make notes to share with your group. Arrange a time when you will meet with your group online.

Discuss

In your group, take turns to share your ideas of how you would use Risk Assessment in each of the 3 situations.

Collaborate

In your group, decide on your best example, and what you will post to the class site. Post a brief description of how you would use Risk Assessment in which situation.
Analysing a learning design

The pie-chart analyses the distribution of types of learning in the design, in this case, acquisition, collaboration and production, but mostly discussion. There are no rules about what it should be, but now you have the opportunity to consider if that looks appropriate.

It is entirely online (pale blue), no f2f
There is some trainer presence (dark brown) to respond to questions, and conduct the plenary discussion
More than half is synchronous (dark pink) - with a group and with the trainer

There is mostly individual work (pale green), then groups, then whole class
Sharing a learning design

On the Designer screen you can Export your design to Moodle (upcoming version)

Or Export to Word, to send to learners, or discuss with others

You can also Share it by creating a url to send to colleagues

https://www.ucl.ac.uk/learning-designer
How can we build knowledge about high quality online learning?
A community of practice: innovating, testing, and sharing new ideas for effective design

Building knowledge for science and scholarship
A community of practice: innovating, testing, and sharing new ideas for effective online learning design

What is the pedagogic equivalent of the scholarly journal?

An online collaborative community using digital tools to share testable co-designed peer-reviewed adaptable learning designs

Building knowledge of online learning design
Large-scale online courses to orchestrate collaborative knowledge development by education professionals

How To Teach Online: Providing Continuity for Students

Explore online teaching with this practical course for educators designed in response to the COVID-19 pandemic.

Go to course - started 27 Apr

Duration: 3 weeks
Weekly study: 2 hours
Learn: Free
Digital upgrade: Free
Large-scale online courses to orchestrate collaborative knowledge development by education professionals

FutureLearn course ‘How to Teach Online’
Running since 23 March, >80,000 teachers from all sectors
Thousands of comments in discussions of every step
  Sharing ideas and problem solutions
  Professionals collaborating to build knowledge
Edraak course (Arabic) on ‘Teaching Online’
Running since 26 April, >22,000 teachers across the MENA region
  Sharing ideas and problem solutions on Padlet
Large-scale online courses to orchestrate collaborative knowledge development by education professionals

FutureLearn course ‘How to Teach Online’
Running since 23 March,
80,000 teachers from all sectors
Thousands of comments in discussions of every step
Sharing ideas and problem solutions

Edraak course (Arabic) on ‘Teaching Online’
Running since 26 April,
22,000 teachers across the MENA region
Sharing ideas and problem solutions on Padlet

Strategies for large-scale online courses to orchestrate collaborative knowledge development by education professionals

- Utilizing chatbots to enhance engagement and foster collaboration
- Implementing gamification to increase motivation and participation
- Integrating social media platforms to facilitate sharing and networking
- Employing peer assessment to promote self-reflection and improvement
- Utilizing mobile applications to provide personalized learning experiences
- Encouraging collaboration through virtual workshops and webinars
- Leveraging virtual reality to create immersive learning environments
- Implementing adaptive learning technologies to adjust to individual needs
- Promoting interdisciplinary approaches to foster innovation and creativity
- Using learning analytics to track progress and adapt instruction
- Implementing cross-border partnerships to share resources and expertise
Large-scale online courses to orchestrate collaborative knowledge development by education professionals

Participants applied their observation skills to collect data in their local environments, adding a photo and a note to explain their analysis.

As we share the challenges of people from a comprehensive design perspective. I will share some pictures from my surroundings, where you can see how to exploit magazine encroach on sidewalks specifically designed for pedestrians, as well as some related ideas.
The UN Sustainable Development Goals
We need high quality online learning to reach all who need it, and for sustainability.

High quality online learning will focus on making the learner an active participant in learning.

A good learning design will sequence a range of types of learning.

We now have the technologies to build community knowledge about high quality online learning.
BREAK 1

Conference resumes at 14:55. Please come back in 10 minutes.
PSCI Shared Audits

What have we learned about our suppliers and how it impacts our Capability Building efforts

Shelly Shope
Elanco Animal Health
Capability Committee Co-Lead
Speaker Bio

- Shelly Shope

- HSE Sr Advisor, Elanco Animal Health
- PSCI Capability Committee Co-Lead
**PSCI audit sharing program**

- **Audit sharing program** allows suppliers to be assessed against the standards agreed by PSCI members and enables suppliers to share audits with multiple members via a web-based platform. This means fewer audits for each supplier and efficiency gains for our members.


- It is **applicable to ALL suppliers** in the Pharma supply chain.

- It works in tandem with our **capability building program** to support continual improvement of our suppliers.

- To take part in a PSCI audit, please visit: [https://pscinitiative.org/sharedAudits](https://pscinitiative.org/sharedAudits)
## PSCI audit platform overview

<table>
<thead>
<tr>
<th>Until July 2020</th>
<th>644 Registered suppliers</th>
<th>442 Uploaded audits</th>
<th>67% Audited within 3 years</th>
<th>66% Shared audits</th>
<th>2200+ Audit downloads</th>
</tr>
</thead>
</table>

- Steady growth of audit uploads in the past three years (2017-65, 2018-122, 2019-122). With the presence of pandemic, suppliers are encouraged to take virtual audits and close corrective actions in 2020.
- Over 65% audits are from core suppliers, such as, API, finished formulations and chemical suppliers.
- Around half of the audits are from suppliers in China (21%), India (15%), and the US (11%).

![Audits distribution](https://via.placeholder.com/150)
Audit Findings Analysis (2017-2019)

- Average number of findings per audit tends to decrease over the years.
- H&S has always been the area with most findings, which occupies over 50% of the findings in 2019, followed by Management System and Environment.
- The presence of Environment findings has been growing over the past three years.
- Percentage of Labor and Ethics findings are going down annually, together consist of 8% of findings in 2019 - reasons behind this could include increased number of HSE audits, qualifications of auditors etc, or the emphasis on HSE focused audits vs Comprehensive audits (HSE + Ethics/Labor).
Audit Findings Analysis (2018-2019)

- Over 70% of the findings are found in API, Chemical and Finished Formulations suppliers, half of them are from China and India (2018-2019).

- Topics/subclauses with most findings:
  - #1 - H&S:
  - #2 - Environment:
  - #3 - Management System:
  - #4 - Labor:
  - #5 - Ethics:

- Around 1% of total findings are critical findings every year.
  - Many suppliers & members opt not to share audits while they are closing critical findings – which may explain why it is low

- 2018 Audit process expanded to add formal “Major/Minor” categories

- Critical findings are found in H&S, Environment and Labor in the past two years, but not in Ethics and Management System.

Finding classification

<table>
<thead>
<tr>
<th>Finding classification</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical*</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Major</td>
<td>4%</td>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td>Minor</td>
<td>2%</td>
<td>22%</td>
<td>44%</td>
</tr>
<tr>
<td>Other</td>
<td>92%</td>
<td>61%</td>
<td>42%</td>
</tr>
</tbody>
</table>
Top Critical & Major Findings...if you have these issues also please proactively focus on them

- **Health & Safety:**
  - **#1: Exposure & PPE:**
    - Risk to employees not acceptable and/or No risk assessment to pharmaceutical dust
    - PPE is inadequate, insufficient or employee/contractors not trained
  - **#2: Safe to Work programs** have significant gaps:
    - Significant gaps in grounding/bonding/electrical classification; no Arc flash assessment
    - Confined space permit not evident or exists but not completed based on permit review
    - No Lockout/tagout program and no Contractor Safety approval process or training
    - Machinery on walkthrough are missing guards with no SOP to work on them
    - Hot work permits show evidence of not following policy on check-backs etc
    - Pallet racks show visible danger to personnel from falling hazards
  - **#3: Process Safety**
    - HAZOP not done or recommendations not implemented with no plan
    - Significantly missing process safety information on basis for safety of reaction
    - No combustible dust hazard assessment with high energy unit ops and dust collectors
    - Inerting practices & procedures inadequate on inerting (charging tanks, drums, vessels and milling)
  - **#4: Emergency Response**
    - Emergency equipment and alarms not functional/not maintained
    - Missing emergency equipment in high hazard areas, no smoke detectors or other fire protection alarm
    - Drills don’t cover all employees and not learning recorded or acted on

For major learning - call into the free India/China Safety, PSM, and IH webinar series on 19 October 2020
Top Critical & Major Findings...if you have these issues also please proactively focus on them

- **Environmental:**
  - #1: **Spill Control / Leaks**
    - No secondary containment for hazardous chemicals or haz waste or overfill on underground tanks
    - Spill kits not available or no spill procedure
    - Visible evidence of past or current leaks on ground
    - Release valves not connected to a collection system for treatment before discharge
  - #2: **Wastewater**
    - Site has not measured its compliance parameters or exceeds a parameter or has missed required frequency of monitoring
    - Site has not assessed its API discharge impact to the environment
    - Site has sludge which is not properly stored to protect spill, exposure, or discharge
  - #3: **Hazardous Waste**
    - Lack hazardous waste disposal record;
    - Empty solvent drums disposed without cleaning
    - Quantity of hazardous waste generation is higher than consent quantities by agency
    - Full chemical barrels stored on soft soil in scrap yard without weather or spill protection
    - Waste burned on site without license and/or Non-authorized vendors used to handle hazardous waste
  - #4: **Permits**
    - Missing permit for a plant within the site
    - Permit applied for but not received and operation started

For major learning - call into the free India/China Environmental webinar series on 24 September 2020
Top Critical & Major Findings...if you have these issues also please proactively focus on them

- **Human Rights/Labor:**
  - overtime working for excessive hours without sufficient pay as per law
  - taking deposit for workers
  - records related to wages, benefits and working hours were not available
  - no policy regarding labor practice; no written form
  - no child labor policy or not keeping employee age proof records

- **Ethics:**
  - No refresher training for ethics training
  - No formal grievance process

For major learning - call into the free India/China Ethics and Human Rights/Labor webinar series on 15 October 2020
Top Critical & Major Findings…if you have these issues also please proactively focus on them

- **Management System:**
  - No BCP program or BCP not tested and outdated
  - No oversight of CAPAs including investigation of incidents
  - No Management of Change for HSE
  - No process to evaluate your own Suppliers for HSE
  - Ineffective self-auditing to ensure practice matches policy for HSE programs (based on other findings)

Why do we find the Critical and Major issues?

What can PSCI do to promote a stronger HSE culture and HSE Management System?

Post a PSCI audit – do you seek to understand the root cause of the gap? Or just fix that one issue found?
PSCI Audit Resources: Under What we do...

**PSCI E-LEARNING TOOL**

We have created the e-learning tool to help member companies and suppliers to understand the Principles. The tool is available freely to all.

[VISIT SITE]

**APPROVED AUDITORS**

In order to ensure quality and integrity, PSCI Audits are carried out either by qualified internal auditors working at PSCI member companies or by professional and independent third party audit firms.

PSCI has approved twelve professional, independent third party audit firms to perform PSCI Audits:

Audit resources can be found on PSCI website: [https://pscinitiative.org/sharedAudits](https://pscinitiative.org/sharedAudits)
Learnings from responding to Covid-19, an experience sharing from Pfizer, India

Ranjana Ganguly
Global EHS Leader – India and Pakistan Operations
Pfizer Healthcare India Private Limited
Speaker Bio

- Name: **Ranjana Ganguly**

- Title: Global EHS Leader – India and Pakistan operations

- Company: Pfizer Healthcare India Private Limited

- Location: Bangalore, India

- Contact details: ranjana_ganguly@pfizer.com

Biosketch: Ranjana is a chemical engineer by training and an EHS professional since 1995. She is a Fellow of the prestigious program Leadership for Environment & Development (LEAD). She started her career as a Regulator in Central Pollution Control Board (CPCB), Delhi followed by Confederation of Indian Industries (CII), international consulting and General Electric (GE) prior to joining Pfizer in 2018. She has been working with the Healthcare Industry for over 13 years. Ranjana has a deep background in EHS management systems, is passionate about Sustainability and is one of the early practitioners from India working on global issues like Climate Change. She has been an editor of a quarterly magazine “Green Business Opportunities” published by CII and has worked on some other publications on topics like Indian Environmental Legislation, Life Cycle Engineering and International Multilateral Agreements. Throughout her career in Industry Ranjana has been exploring ways to enhance operational ownership of EHS and work on risk-based approach for resolution of EHS issues. In her current role as a part of Global EHS team in Pfizer, Ranjana works closely with the company’s operations in India and Pakistan. Outside of work Ranjana enjoys travelling to be in the midst of nature and learn about different cultures, loves to spend time with family and is an absolute foodie.
AGENDA

Introduction

Objective of this session

Experience sharing from our ongoing Covid-19 response

Q&A
Objective of this session

Experience sharing based on our ongoing pandemic response to:

- Enable holistic approach to manage the current crisis
- Provide insights for Business Resilience
Key focus areas to ensure a holistic approach to our pandemic response...

- Develop a comprehensive Pandemic Preparedness Plan (PPP)
- Allocate required resources including budget, setting up teams with clearly defined roles and responsibilities across all levels, deploying ‘Actively Caring’ initiatives to support employees
- Risk assessment and site readiness plan to ensure no onsite transmission through no/low primary contacts, social distancing, PPE availability, sanitization, screening, isolation, OHC readiness
- Deploy tools for uniform and timely reporting, tracking, communication
- Plan operations with on-site essential colleagues (reduced footfall) support work-from-home and return to site or field as applicable
- Issue updated PPP based on reviews and feedback
- Keep all information current based on changing needs
- Incorporate learnings into aspects like facility design, operation planning, digital needs, Preventive Maintenance, business continuity
- Integrate Covid-19 related activities into regular goal setting process
- Allocate resources for future needs based on pandemic response experience
- Consistent and continuous awareness creation, training and communication
- Employees to meet expectations like contact recording, PPE use, hygiene practices, social distancing, wellness check, isolation needs as applicable, proactively engage to drive improvement and follow applicable travel restrictions
- Regular sharing of good practices, challenges, learnings
- Ensure timely reporting of expected data such as positive cases, absenteeism, potential impact to operations, government reporting as applicable
- Maintain onsite condition as per PPP expectations such as sanitization and disinfection, engineering controls to enable social distancing, availability of PPEs and working screening tools
- Periodic review of government updates, PPP, tools and templates
- Mock drill to check robustness of onsite procedures
- Regular CMT meetings to review aspects like current status, progress on planned improvements, employee feedback, contact recording forms
- Periodic leadership reviews to assess status of pandemic preparedness, potential impact on regular activities/projects and help needed
- Check-ins with those working from home, in quarantine or isolation

...for keeping colleagues safe, ensuring continued operations and supply for our patients
Glimpses on how we are addressing these needs
Example 1 - Meeting regional challenges in India

- **Employee transportation** – organizing for additional buses to ensure reduced occupancy in each vehicle, working with transporters to provide partitions in seats (see photo), maintaining sanitization after each use, last mile connectivity from home to bus pickup point, use of PPEs like face mask and face shields during commute.

- During **complete lockdowns** - keeping up to date with the government directives, getting required number of service passes for safe commute of employees, arranging stay arrangements for required teams, supporting essential services such as food supply through Corporate Social Responsibility (CSR) initiatives.

- Providing **alternate lodging** for colleagues staying in shared accommodation for quarantine purpose (as applicable)

- Ensuring **colleague safety as nationwide unlock led to steep rise in cases** – Continuous awareness creation, supporting quarantine needs for primary contacts, introduction of self declaration process to discourage participation in public events, use of public transport, travel out of town and so on.

- **Supporting medical infrastructure** – Supporting colleagues through Occupational Health Center helpline, testing support, proactive assessment of hospital availability and so on.

Enabled through onsite Crisis Management Teams (CMT) and regular connect across India teams.

Photo – partitions provided in buses
Example 2 – Phases of response

1. Monitoring and Pre-Impact Phase
   No known case, or isolated cases in the country / state

2. Screening/Protection Phase
   Multiple confirmed case(s) in country or localized outbreak in the local community in the vicinity of the site

3. Active Case Phase
   Active Case(s) on site and/or significant outbreak affecting site operations

4. Phased Resumption Post Pandemic Peak
   Focuses on the planning for phased resumption of business operations and easing of restrictions limiting personnel at sites

Closely linked with local community transmission status
Example 3 – Risk Assessment to minimize onsite primary contacts

COVID-19: Site Operations - Primary Contact Assessment & Mitigation

<table>
<thead>
<tr>
<th>SL.No</th>
<th>Department</th>
<th>Activities</th>
<th>No. of persons working/involving</th>
<th>Zero Primary contacts (Yes/ No)</th>
<th>If No What additional controls required</th>
<th>Mitigation/Remarks</th>
<th>Pre implementation</th>
<th>Post implementation</th>
</tr>
</thead>
</table>

Hierarchy of controls

- **Elimination**: Critical ops assessment to plans onsite accommodation (to eliminate external exposures), Restricting visitors/ vendors, single person operation, meeting rooms closed, only hot food served
- **Substitution**: Remote working, using personal mode of commute, remote shift handover
- **Engineering controls**: Physical barriers, additional washing facilities/ sanitizing stations, isolation rooms, decontamination kit, facility HVAC assessment
- **Administrative controls**: Stagger schedules, social distancing, hand hygiene, enhanced cleaning/ disinfection, awareness sessions, signages, screening colleagues (example temperature)
- **PPE**: Protection by using personal protective equipment like face masks, face shields, gloves etc.

Activities Assessed

- 246 Activities Assessed
- 193 No Primary Contact
- 11 -2 -20 -11 -9

No Primary Contact Activities Assessed
Example 4 – Controls to increase social distancing

- Team working on a project with digital support
- Queuing at entry
- Cafeteria – seating spread out, timing staggered
- 2-screens setup for simultaneous calibration
- Partitions in inspection areas
- Partitions in manufacturing area
- Cafeteria - partition on dining tables
- Plexiglass seat partitions in buses
Example 5 – Training and communication

Training

Quick Check
Which of the following shows correct face mask use?
Select the correct answer, and then click submit.

Minimum requirement across the company as well as site specific needs – primarily offered online and virtually

Communication

Through displays, posters, townhalls, dashboards, alerts, emails
Example 6 – Enabling hygiene practices

- Foot pedal based hand wash stations at entry
- Shoe decontamination - dip in 1% sodium hypochlorite solution followed by soaking mats
- Hand tool used to reduce touchpoint
- Providing care kits including masks, face shields, sanitizers
Example 7 – Sanitization

- Increased cleaning of common areas
- Vehicle cleaning before entry
- Disinfection of documents, couriers
Example 8 – Mock drill
Some insights from Covid-19 response to help build a robust Business Resilience (BR) program

Examples from ongoing pandemic response

- The global governance framework established – Global Task Force – Divisional Task Force – Site Leaders Forum – EHS / BR Leaders Forum, focused on a response that aligned with contemporary scientific knowledge and has served well in tackling the pace of change warranted (noting evolving external guidance from organizations such as World Health Organization (WHO), Center for Disease Control (CDC) etc.)
- A comprehensive process established within Pfizer to capture learnings this far and establish plans to integrate to business processes for ongoing response
- Outreach to suppliers undertaken to support them in plan development
- Pfizer has established a process to evaluate requests for ‘RTS’ (Return to Site) when the external triggers indicate that resumption could be feasible

Longer term insights

- A proactive approach helps – the Pfizer approach to the pandemic is to focus on planning and preparedness rather than alarm or panic
- We need to think out-of-the-box while planning – who would have imagined in 2019 that a business resilience program could require 50% employees working from home
- Stating the focus area(s) is very important – One of the key factors that helped us greatly was the work on primary contact minimization
- Identifying the required expertise is key – for the pandemic response we have been leveraging internal expertise to support planning initiatives for each area of focus by utilizing functional subject matter experts throughout the corporation
- Recognizing that crisis is not always short-term – As with this pandemic, we need to prepare holistically including aspects like succession planning
- One-size-fits-all does not work – Standardization and alignment at all levels is important. At the same time the program needs to be flexible and enable customization based on local needs.
Thank you for listening...

A lot has changed in 2020, not just our vocabulary. Let us all collaborate to meet the current challenge and emerge stronger from this experience.
Draft Indian Chemical Management and Safety Rules (CMSR), 20xx (India-REACH)

Dr. Jayachandran Nair
CEO – GPC India
Global Product Compliance (GPC) Group, Sweden
Dr. Jayachandran Nair

Title: CEO – GPC India
Organization: Global Product Compliance (GPC) Group, Sweden

Email: jmnair@gpcregulatory.com; compliance@in.gpcregulatory.com
Contact: +91 901 109 5112
Website: gpcgateway.com

About GPC
Global Product Compliance (GPC) specializes in Global Regulatory Compliance Solutions across sectors globally. SSS Europe, a familiar name in chemical regulatory and compliance services now formally belongs under the umbrella of GPC Holding Sweden.

Since 2008, we have emerged as one of the leading names among Global Regulatory Compliance Service Providers with Representation services in Europe, Asia and Middle East for respective chemical regulations.

Our over 1000 Happy Clients are a testimony to the great rapport we share with them and the fine quality that we offer in our services. This is also reflected in the fact that we have about 99% customer retention.
AGENDA

India CMSR – India REACH (5th Draft - 24 Aug 2020)

- GPC in brief and GPC’s engagement in Indian CMSR
- ICMSR – Key words, Objective, Scope, and Authorities
- Chapters & Related Schedules
- Timeline and Obligations under ICMSR
- Fees: Notification, Registration
- Actionable for PSCI members (Overseas and Indian) & Importers
- GPC: Your Knowledge Partner toward ICMSR compliance
- Interaction (Q&A)
Global Product Compliance (GPC)

- Indian Chemical (Management and Safety) Rules (ICMSR)
- EU-REACH
- Korea-REACH
- Eurasia REACH
- Turkey REACH (KKDIK)
- UK-REACH
- Taiwan Regulation (TCSCA)
- Chemical Regulations in USA, Canada, Australia, Thailand, China, Japan & Brazil.
- Cosmetics Regulation (EU, India, USA).

1000+ Happy Clients.
99% Customer retention
172+ companies opted to switch over to GPC
Global Product Compliance (GPC)

Services
- Registrations & Notifications
- Global Regulatory Compliance & Status Assessment
- Substance & Dossier Evaluation Process Management
- Lead Registration activity & Technical dossier preparation
- Toxicological assessment & Dossier updates
- Contract Study Management & Monitoring
- Compliance Verification & Certificates
- REACH & CLP compliant SDS & Extended e-SDS
- SDS translations in over 30 languages

Services – Key facts
- Managed portfolio of 9000+ substances.
- Registered 1200+ substances.
- Lead Registration & consortia management of 400+ substances.
- 9000+ pre-registrations and notifications within chemical and cosmetic regulations, globally.
- Authored 4200+ REACH & CLP compliant SDSs and 320+ e-SDSs.
- Extensive network of OECD-GLP certified CROs.
- ‘Supply Chain Communication Portal’ for seamless regulatory communication and due diligence – between supplier, buyer, and OR. The portal is used by 4000+ users.

GPC provide regulatory intelligence to industry and prepare industry for the compliance requirements & related challenges!

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GPC Engagement with Indian CMSR

2010
Ministry of Commerce / CHEMEXCIL engaged GPC for report on regulatory status of EU REACH regulation and its impact on Indian Industry Proposed Road-map for Indian Chemical Regulation

2011-2018
GPC was actively engaged with Ministry of Commerce and Dept. of Chemicals and Petrochemicals on the development of Draft National Chemical Policy

July 2018
GPC as a member of CII’s National Chemical Committee, was engaged in drafting a proposal for chemical rules and – submitted it to the government

Jan 2019
GPC was asked to present the draft Chemicals Rules in National Standard’s Conclave organized by CII and Ministry of Commerce

May 2019
Ministry of Commerce later formed a technical committee to review the regulation, wherein GPC and CII were the only non-governmental representative. The technical committee adapted GPC’s draft of the proposed chemicals rules as an official draft

2020
Since Mid 2019, draft is being updated and has been circulated for the comments by the industry bodies, on 4th draft in March 2020. After stakeholder’s consultation meeting on 11th May 2020, an updated draft was released on 7th Sept 2020 (5th Draft)
### ICMSR – Key words, Objective, Scope, Authorities

<table>
<thead>
<tr>
<th>Key Words</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance; Substance in Mixture; Mixture; Articles; New Substance, Existing Substance; Priority Substance; Hazardous Substance; Chemical Accident; Intermediates; Isolated Storage; Industrial Activity; Occupier; Manufacturer; Importer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective &amp; Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification, Registration and Restrictions, or prohibitions, as well as labelling and packaging requirements related to the Use of Substances..... Placed or intended to be Placed in Indian Territory</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authorites</th>
</tr>
</thead>
<tbody>
<tr>
<td>The National Chemical Authority with 4 key organs to implement the Rules:</td>
</tr>
<tr>
<td>• Steering Committee</td>
</tr>
<tr>
<td>• Scientific Committee</td>
</tr>
<tr>
<td>• Risk Assessment Committee</td>
</tr>
<tr>
<td>• Chemical Regulatory Division</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemistry Unit</th>
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</thead>
<tbody>
<tr>
<td>Toxicology Unit</td>
</tr>
<tr>
<td>Chemical Accident Unit</td>
</tr>
<tr>
<td>Packaging &amp; Labeling Unit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Techno-legal Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priority Substance Unit</td>
</tr>
<tr>
<td>Information Technology Unit</td>
</tr>
<tr>
<td>Socio-Economic Unit</td>
</tr>
</tbody>
</table>
## India Chemicals (Management & Safety) Rules

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Definitions, Objective &amp; Scope</td>
</tr>
<tr>
<td>II</td>
<td>National Chemical Authority</td>
</tr>
<tr>
<td>III</td>
<td>Notification Registration &amp; Restrictions on Use</td>
</tr>
<tr>
<td>IV</td>
<td>Safety &amp; Accident Preparedness</td>
</tr>
<tr>
<td>V</td>
<td>Labelling &amp; Packaging</td>
</tr>
<tr>
<td>VI</td>
<td>Miscellaneous (Penalties and Enforcement)</td>
</tr>
</tbody>
</table>
# India Chemicals (Management & Safety) Rules

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>PBT &amp; vPvB Assessment Criteria</td>
</tr>
<tr>
<td>II</td>
<td>List of Priority Substances required to be Registered (750 Subs.)</td>
</tr>
<tr>
<td>III</td>
<td>Concerned Authorities</td>
</tr>
<tr>
<td>IV</td>
<td>Substances Exempted for the purpose of Chapter III and V</td>
</tr>
<tr>
<td>V</td>
<td>Information to be provided for Notification</td>
</tr>
<tr>
<td>VI</td>
<td>Restricted or Prohibited Substances (Phosgene as on date, will be added later...)</td>
</tr>
<tr>
<td>VII</td>
<td>Contents of Technical Dossier</td>
</tr>
<tr>
<td>VIII</td>
<td>Format for Chemical Safety Report</td>
</tr>
<tr>
<td>IX</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>X</td>
<td>Hazardous Chemicals (669 Substances, will be added latter...)</td>
</tr>
<tr>
<td>XI</td>
<td>Isolated Storage At Installations Other Than Those Covered By Schedule XIII (30 Subs.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>XII</td>
<td>List of Hazardous Chemicals for Application of Chapter IV (Safety &amp; Accident Preparedness) (179 Subs. + Flammable Gas &amp; Liquids)</td>
</tr>
<tr>
<td>XIII</td>
<td>Industrial Installations (Alkylation, Condensation, Hydrolysis, Sulphonation &amp; so on ...) 20 identified</td>
</tr>
<tr>
<td>XIV</td>
<td>Information to be Furnished by the Occupier</td>
</tr>
<tr>
<td>XV</td>
<td>Details to be Furnished in the Off Site Emergency Plan</td>
</tr>
<tr>
<td>XVI</td>
<td>Information to be Furnished Regarding Notification of a Chemical Accident</td>
</tr>
<tr>
<td>XVII</td>
<td>Information in Labelling</td>
</tr>
<tr>
<td>XVIII</td>
<td>Format Of Certificates</td>
</tr>
<tr>
<td>XIX</td>
<td>Fees and Fines Payable</td>
</tr>
</tbody>
</table>
Timeline & Obligation under ICMSR

- **Notification of Substances** ≥ 1 ton/year
- **Evaluation of files and substances**
- **Authorization of Substances of concern by Committee**
- **Registration of Schedule II Chemical Substance** (750) ≥ 1 ton/year
- **Restriction & Prohibition of Unacceptable Substances**
- **Annual Reporting** - No later than 60 days after the end of each calendar year

Information in the supply chain

Chemical Properties & Uses: Up & down - Supply chain
Timeline & Obligation under ICMSR

Initial Notification Period

- **Start date**: Say April 2021
- **End date**:
  - *Qty > 1 T/year*
  - **6 months**
  - **1 year**
  - **18 months**

**Rule into force 20xx**

**Timing + Schedule + Volume**

- **New substances**: Notify **60 days prior to placing in market**
- **Annual Reporting**: No later than **60 days after the end of each calendar year**
- **Registration of substance in Schedule II**: (750 as on date)
- **For Qty <1 T/year**: Reg. requirements based on Scientific committee & Divisions recommendations
- **Qty > 1 Ton / year**

**Missed Notification period – Substance existing: 60 days prior to placing**

- **Substance in Schedule II includes**: Carcinogenic, Toxic for reproduction, Endocrine Disturbors

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## Fees: Notification & Registration

### Approx.: Fees for Notifiers and Registrants (Rs. ‘000)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Rule</th>
<th>Payable entity (MSMEs)</th>
<th>Payable by all other entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8 (5)</td>
<td>Notification by tonnage band</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-10 TPA</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 TPA</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100-1000 TPA</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 TPA</td>
<td>250</td>
</tr>
<tr>
<td>2</td>
<td>10 (10)</td>
<td>Registration by tonnage band</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-10 TPA</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 TPA</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100-1000 TPA</td>
<td>120</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 TPA</td>
<td>375</td>
</tr>
<tr>
<td>3</td>
<td>16 (5)</td>
<td>Request for authorization for use of a restricted substance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>4</td>
<td>17 (3)</td>
<td>Request for confidentiality</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>19 (4)</td>
<td>Filing an appeal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>100</td>
</tr>
</tbody>
</table>
## Fees: Update Notification & Registration

Approx.: Fees for Updating tonnage band in notification and registrations (Rs. '000)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Rule</th>
<th>Payable entity (MSMEs)</th>
<th>Payable by all other entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Updating tonnage band</td>
<td>From 1- 10 TPA To 10 - 100 TPA</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 1- 10 TPA To 100 - 1000 TPA</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 1- 10 TPA To &gt; 1000 TPA</td>
<td>240</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 10- 100 TPA To 100-1000 TPA</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 10- 100 TPA To &gt;1000 TPA</td>
<td>220</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 100- 1000 TPA &gt; 1000 TPA</td>
<td>170</td>
</tr>
</tbody>
</table>
## Fees : Joint Registration

### Approx.: Fees for Joint Registration per Registrant ( RS. '000)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Rule</th>
<th>Tonnage band</th>
<th>Payable entity (MSMEs)</th>
<th>Payable by all other Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 (10)</td>
<td>1-10 TPA</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 TPA</td>
<td>30</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 - 1000 TPA</td>
<td>80</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 TPA</td>
<td>250</td>
<td>600</td>
</tr>
</tbody>
</table>

Joint Registration is valid for the same substance !!!
Actionable for PSCI members

- Indian Manufacturer / Importer / DU: Follow guideline and be a Notifier

- Overseas Manufacturer:

  - Authorized Representative has similar function as “Only Representative” in EU-REACH & K-REACH.

  - Foreign Traders may not appoint an Authorized Representative

Foreign Manufacturer of

- Substance
- Substance in Mixture
- Priority Substance in Article

Shall appoint an Indian Legal entity to comply with ICMS Rules on its behalf
## Actionable for PSCI members - Notification

<table>
<thead>
<tr>
<th>Action</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notify all substances that are placed in Qty &gt; 1 TPA</td>
<td></td>
</tr>
<tr>
<td>Notification is <strong>not Free</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Key data required:</strong> Spectra, Hazard Classification, Uses, DU if any, Tonnage Band, Storage Capacity, SDS (Rule 9(2))</td>
<td></td>
</tr>
<tr>
<td><strong>Annual update by 1(^{st}) March each year</strong> – tonnage (actual); new/change information; if tonnage change (fee difference)</td>
<td></td>
</tr>
<tr>
<td>Registration within other regulations / Acts – are also required to Notify with ICMS Rules</td>
<td></td>
</tr>
<tr>
<td>Late Notification</td>
<td></td>
</tr>
<tr>
<td><strong>New Substance</strong> (60 days prior to placing)</td>
<td></td>
</tr>
<tr>
<td><strong>Existing Substance:</strong> if missed notification window – 60 days prior to placing it in market.</td>
<td></td>
</tr>
</tbody>
</table>
Notification Process:

1. Substance Notifier
2. Submit Notification
3. Chemistry unit (Authorities)
4. Submit Requested Additional Information
5. Preliminary check
6. CBI Check If Any
7. Information satisfactory
8. No CBI Check Request
10. Techno Legal Unit Cleared CBI Application
11. Substance entered into Notified Substance Register
12. Notification Number Assigned & Certificate Released
13. Continue placing substance in Market
14. Submit in 30 days
15. 60 days Prior to placing in Market
16. New Chemical
17. Request for information
Substances that are notified within the “Initial Notification Period” are considered as Existing Substances

All substances that are not notified in the Initial Notification Period are considered as New Substances.
Evaluation Process: Post Notification

1. Substance Data Availability Check
2. Evaluation of collected Data
3. Check Potential Risk on Substance Use
4. Priority Substance Unit (Authorities)
   - Taken for Evaluation
   - Recommends Steering Committee
5. For Addition / Deletion of substance to Schedule II
   - Final Recommendation to Central Government
   - Schedule II Updated
6. Goes for Public Consultation
   - Inputs Public Consultation
   - In 90 days
   - Steering Committee
Actionable for PSCI members - Registration

- Registration - Substances listed in Schedule II
  Priority Substances

- Registration within 18 months after inclusion in Schedule II

- Currently Schedule II contains 750 substances.

- Technical Dossier needs to be prepared.

- Chemical Safety Assessment (report) for > 10 TPA.

- Exposure Scenario Assessment (report) for < 10 TPA.

- Registration fee is applicable – Company Size & Tonnage

- Option to jointly submitting the registration,

- Update Technical Dossiers - within 60 days of any change or revision in information

Joint Registration is valid for the same substance!
**Actionable for PSCI members: Registration process**

- **Substance for Registration > 1 Ton/Year**
  - Update Tech. dossier within **60 days** for new information or changes if any
  - Submit Requested Additional Information (60 days)

- **Schedule II Chemical**
  - Submit Tech. Dossier

- **Toxicology Unit**
  - Preliminary Checks
  - Evaluates submitted Data
  - Registration Number & Certificate Released

- **CBI Check if any**
  - No CBI Check Request
  - More Information Required

- **Techno Legal Unit**
  - Cleared CBI Application

- **Information Satisfactory**
  - Data Satisfactory

- **Virtual Supplier Conference SEP-OCT 2020**
Currently 750 substances are listed as Priority Substances in Schedule II. – Notify & Register

Schedule II will be updated from time to time

Labeling and packaging requirements (Rules 33 & 34)

Import of Priority substances: Inform Authority 15 days before importation. (Rule 27)

Certain Priority Substances may qualify as – Hazardous Substances (Rule 16(3))
Actionable for PSCI members – Restriction (VI)

Substances that are Listed in Schedule VI: Restricted or Prohibited Substances

As on today only one substance restricted: Phosgene (carbonyl chloride)
**Actionable for PSCI members: Evaluation & Restriction Process**

**All Registered Substances**
- Evaluation Based on Available Data
  - Risk Assessment including hazard identification, hazard characterization, exposure assessment, and risk characterization.

**Priority Substances Unit**
- Evaluated by
- Recommends
- Risk Assessment Committee & Steering committee
- Substance Identified for Restriction
  - Submit Request for Authorization for Restricted Use
  - If Deemed Fit; Authorization Granted for 4 Years
  - Upon Re-application: Extension of Authorization granted for additional 4 years.

**Inclusion or Deletion to Schedule X, XI and XII**
- Restriction on a Priority Substance has been notified
- Prohibit use of substance

**Public Consultation within in 90 day by Steering Committee**
- prior to recommending the Central Government!

---

**VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020**

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Intermediate substance not included in Schedule II are exempted from Registration:

But to be Notified!
## Actionable for PSCI members – Hazardous substance

- **Currently 669 substances are listed as Hazardous Chemical List in Schedule X. -- Notify**
- **Schedule X will be updated from time to time**
- **labeling and packaging requirements (Rules 33 & 34)**
- **Provide Evidence to Authorities that they have identified the Chemical Accident hazards**
  - Adequate Steps taken to prevent accidents & to limits its impact
- **Evidence shall be provided within 30 days of commencement of the activity or within 30 days of coming into force of these Rules, which ever is later.**
- **Obtain an Acknowledgement from Authority with 60 days**
| **Transport** – Tracking & Communication System; Labeling, give prior intimation the State Pollution Control Boards |
| **Safety Audit of installation** – within 6 month; every 2 years |
| **Site Safety Report (New industrial activity - 90 days before)** – Steps in accident prevention; Provide information, training, equipment and antidotes – to Employees; and Get Approval from Authorities |
| **Isolated storage and quantity Thresholds** (Schedule XI & XIII - industrial installations) |
| **Onsite / off-site Emergency Preparedness Plan** within 3 months; (on-site - mock drill every 6 month) |
| **Notification of Accident** within 24 hrs.; report within 72 hrs. Report on preventive action with 6 months of accident |
GPC : Your Knowledge Partner - ICMSR compliance

**Existing Substance**

**New Substance**

**Substance**

**Notification Certificate**

**Registration Certificate**

**Continue Business**

**Do not place substance in market till Suspension Revoked / withdrawn**

**Penalties on per days basis of violation of Rule**

**Should not / Cannot Buy substances**

**Still Continuing placing substance in market**

**Registration suspended**

**Notification Certificate**

**Rule 8**

**Rule 10**

Do not Miss Notification & Registration Deadline once The Rule is into Force!
Safety Culture- J&J Perspective

Dr. Raju Ingale
Senior Director – EHS&S Asia Pacific
Johnson & Johnson Pte Ltd
Dr. Raju Ingale

- Johnson & Johnson Pte Ltd
  Senior Director EHS&S Asia Pacific

- Past Experiences:
  - Worked with world’s Top 5 Brands in their respective categories.
  - Experienced End-to-End Supply Chain Leader
  - United States Patent Holder
  - Setup many Green field sites
  - I’m influenced by Learn-Unlearn-Relearn process.
  - I believe in doing the “Right” thing, even if it means going back to basics.
  - Attitude to me is “What you do when no one is watching you”

- Contact information ringale@its.jnj.com
AGENDA

How habits are formed
Life Saving rules
Tool-box talks
How Habits are formed

Synergy between Knowledge, Skills & Attitude

**Knowledge**
- Know what

**Skills**
- Know how

**Ability**
- Know why

**Attitude**

**Head - What**

**Heart - Why**

**Hands - How**

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Life Saving Rules

Report ALL incidents and SIF-Ps immediately.

- Always work with a valid work permit when required.
- Always lock & tag out hazardous energies before work begins.
- Always protect yourself against a fall when working at height above 4 feet.
- Never work in confined space without authorization or gas test conducted.
- Never by-pass a machine guard without a permit.
- Never work on live electrical equipment without a permit.
- Never walk under a suspended load.
- Never use powered industrial vehicles unless authorized and only in an authorized way.
Often in many situations

We don't rise to the level of our expectations, we fall to the level of our training.

~ Archilochus
Need for Tool-Box Talks

Challenges of Conventional Training:

1. After some point of time becomes monotonous
2. It becomes a monologue and prevents two way communication
3. It doesn’t make a very interactive and intuitive training method
4. Barriers in language and understanding do creep in
5. 5 min everyday training is much better than 1 full day in a Quarter
6. Classroom environment Vs Shopfloor environment
Why NAPO?

- Doesn’t need a qualified personnel
- Not language dependent
- NAPO videos depicts hazards and risks very intuitively
- Small duration of 2-4 minutes of daily coaching
- Facilitator guides for each video
Sample Video – Bad Vibrations
Advantages of NAPO Video based Training

- **Napo Videos are ‘expertise agnostic’** and doesn’t need a qualified personnel
- NAPO Training Methods are not language dependent
- NAPO videos depicts hazards and risks very intuitively
- Small duration of 2-4 minutes of daily coaching
- Live examples and day to day happenings on Safety depicted
- 5 min connect every shift is much better than one day in a quarter
Napo is co-produced by a European Consortium:

- AUVA
- CIOP
- PIB
- TNO innovation for life
- DGUV
- INRS
- INAIL
- suva

European Agency for Safety and Health at Work

produced by VIA STORIA TV and WEB
“The standard you walk past is the standard you accept”

Lt. David Morrison
BREAK 2

Conference resumes at 17:05. Please come back in 10 minutes.
Management Systems

*Introduction to the Maturity Model*

Roberta Haski
HSE, External Manufacturing, Asia Pacific
Elanco
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

Now aligned with the four-tier PSCI common framework
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.
<table>
<thead>
<tr>
<th>Commitment &amp; Accountability</th>
<th>Starting Program</th>
<th>Developing Program</th>
<th>Implementing Program</th>
<th>Leading Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Written management commitment regarding EHS, Labor/Human Rights and Ethics</td>
<td>1. EHS, Labor/Human Rights and Ethics are standard agenda topics for management team meetings</td>
<td>1. Specific senior managers are responsible and held accountable for implementing the commitments</td>
<td>1. Proactive leaders effectively make a difference, demonstrate commitment and leadership on EHS, Labor/Human Rights and Ethics topics</td>
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<tr>
<td>2. Occasional follow-up on EHS, Labor/Human Rights and Ethics topics at management team meetings</td>
<td>2. Commitment and accountability are documented through SOPs or other mean</td>
<td>2. Senior managers are actively involved in EHS, Labor/Human Rights and Ethics topics</td>
<td>2. The management team monitors continuous improvement</td>
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<td></td>
<td>3. Appropriate resources are allocated to ensure delivery of the commitments</td>
<td>3. Appropriate resources are allocated to ensure delivery of the commitments</td>
<td>3. Employees are empowered to approach management with suggestions and questions</td>
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<td></td>
<td>4. EHS, Labor/Human Rights and Ethics topics are handled in line with relevant 3rd party certifications (ISO 14001, OHSAS 18000 or equivalent)</td>
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<tr>
<td>Legal &amp; Customer Requirements</td>
<td>1. Identify and comply with minimum regulations, standards and relevant customer requirements</td>
<td>1. EHS, Labor/Human Rights and Ethics are included in Legal Register</td>
<td>1. Program to address noncompliance or under performance, including customer requirements</td>
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<td></td>
<td>2. Actively conduct due diligence to identify and comply with regulation and customer requirements</td>
<td>2. Ongoing consultations and reviews of forthcoming legislation to identify potential changes in regulations</td>
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<tr>
<td></td>
<td></td>
<td>2. Ongoing consultations and reviews of forthcoming legislation to identify potential changes in regulations</td>
<td>2. Empowered culture that proactively anticipates regulatory changes</td>
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<tr>
<td></td>
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<td>3. Beyond legal compliance culture</td>
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<tr>
<td></td>
<td>Starting Program</td>
<td>Developing Program</td>
<td>Implementing Program</td>
<td>Leading Program</td>
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</tbody>
</table>
| Risk Management | 1. Limited risk assessment process and program in place  
2. Risk assessments are high level and not task specific  
3. Reactive risk prioritization with minimal consideration for business continuity | 1. All tasks are assessed, including permit to work used to control high risk activities  
2. Incidents are investigated and analysed | 1. Well defined process for risk assessment and business continuity in place, including scoring matrix  
2. Adherence to risk management plans and procedures  
3. Everyone gets involved in risk assessment, including workers  
4. Proactive formal risk assessment process; potential problems are eliminated before they occur  
5. Incident learnings shared with all management and staff levels | 1. Risk Management becomes integral part of everyday business, including a formal change control program  
2. Everyone consistently demonstrates risk management and awareness  
3. Business routinely reviews risks and business continuity and implements improvements to reduce risk scores |
| Documentation  | 1. Minimal records/data/documents available  
2. Limited governance to review/revise/update documents  
3. Minimal control of access to records/data/documents | 1. Oversight of documentation/procedures limited and may not include reviews by Subject Matter Experts (SMEs)  
2. Systems standalone and not integrated/limited availability for parts of operations/business | 1. Governance program in place to manage records/data/documents  
2. Formal process to manage access control and data privacy  
3. Documents, policies, procedures and processes aligned across functional areas and result in one system for the entire enterprise | 1. 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  
2. Tools in place to manage activities, roles and responsibilities integrated with business processes |
<table>
<thead>
<tr>
<th>Training and Competency</th>
<th>Starting Program</th>
<th>Developing Program</th>
<th>Implementing Program</th>
<th>Leading Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Training is minimal, ad-hoc and reactive</td>
<td>1. Training curriculum in place and regularly reviewed</td>
<td>1. Automated system for monitoring of training compliance</td>
<td>1. Workers are highly skilled and demonstrate a high level of training awareness</td>
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<tr>
<td>2. Formal discipline is used to enforce rules</td>
<td>2. Cross-organisation training on different areas and tasks set to further develop workers</td>
<td>2. Development of workers is a priority and investment is made in learning</td>
<td>2. Business encourages professional development, membership of professional groups and further education</td>
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<tr>
<td>3. Supervisory Control of day to day tasks</td>
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<td>3. Competency in critical training programs is assessed</td>
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<td></td>
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<td>4. Competency requirements are established</td>
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<thead>
<tr>
<th>Continual Improvement</th>
<th>Starting Program</th>
<th>Developing Program</th>
<th>Implementing Program</th>
<th>Leading Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Minimal continual improvement efforts</td>
<td>1. KPI/Metrics available for some of the goals/targets and measure lagging indicators</td>
<td>1. Improvement opportunities are identified and managed and lead to optimization of current practices</td>
<td>1. Leading/predictive and Lagging indicators are used to measure performance against goals/objects</td>
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<tr>
<td>2. Limited or reactive KPIs in place to measure progress toward achieving goals and objectives</td>
<td>2. Management is aware of metrics/KPI and are reviewed periodically; KPIs only visible to management</td>
<td>2. Incidents are properly investigated, and corrective action plans adopted (with regular follow-up to ensure implementation)</td>
<td>2. Culture of Continuous Improvement throughout organization with metrics highly visible and transparent</td>
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<tr>
<td>3. Limited management/employee awareness on how to measure progress toward achieving goals/targets</td>
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<td>3. Employees empowered to make recommendations and changes</td>
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<tr>
<td>4. Metrics/KPIs have minimal management sponsorship</td>
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<td>4. Continual Improvement is encouraged at all levels of facility</td>
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<td>5. Workers are empowered to implement and continually improve processes</td>
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<tr>
<td>Identification of Concerns</td>
<td>Starting Program</td>
<td>Developing Program</td>
<td>Implementing Program</td>
<td>Leading Program</td>
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<tr>
<td>1. Limited identification of concerns</td>
<td>2. Role restricted to management</td>
<td>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</td>
<td>1. Culture of reporting concerns embedded throughout all levels of the organisation</td>
<td>1. Employees are empowered and proactively encouraged to identify concerns</td>
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<tr>
<td>2. Concerns are investigated and corrective action taken if needed</td>
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<td></td>
<td>2. Incidents and serious near misses are investigated, root causes and action plans are identified and shared to embed a proactive approach</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Communication</th>
<th>Starting Program</th>
<th>Developing Program</th>
<th>Implementing Program</th>
<th>Leading Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Communication is ad hoc and reactive; communication takes place on a need-to-know basis</td>
<td>1. Communication regular; the process is well defined and documented</td>
<td>1. Communication takes place using plural established audience appropriate communication channels</td>
<td>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</td>
<td></td>
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</tbody>
</table>
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
Thank you for working with the PSCI

To help the PSCI capability building work better for you, please follow the link under Survey tab on the livestream webpage to provide your feedback. Thank you!
For more information about the PSCI please contact:

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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.