

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.

THE MEMBERSHIP

45 member companies* already share the **PSCI VISION** and are committed to continuous improvement in the supply chain

Members as of August 2020

	abbvie						
			Catalent				 <small>Roche A member of the Roche group</small>
							
							
							 
					<p>*Associate members have the following symbol: </p> <p>The rest are full members.</p>		

THE CHALLENGE

Alone we can do so little,
Together we can do so much.

ADDRESSING THE CHALLENGE

INTERNATIONAL STANDARDS / FRAMEWORKS



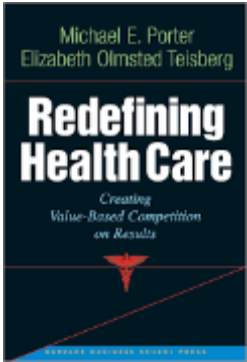
CAMPAIGNS



LEGISLATION



PATIENTS & VALUE BASED HEALTHCARE



PRESSURE FROM BUYERS



ADDRESSING THE CHALLENGE



THE PSCI PRINCIPLES



ETHICS

道德

- 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

人权与劳工

- 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

健康安全

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



ENVIRONMENT

环境

- 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

管理体系

- Commitment and accountability
- Legal and customer requirements
- Risk management
- Documentation
- Training and competency
- Continual improvement
- Identification of concerns
- Effective communication

HOW WE WORK



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



PHARMACEUTICAL SUPPLY CHAIN INITIATIVE (PSCI) WEBINAR:

Hazardous Reactions

Presented by: Process Safety Sub-Team

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

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

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

PSCI IN PERSON	2018	2019
Conference attendees ¹	400+	400+
Webinar attendees	163	400
Member meeting attendees ²	125	180+
Total approved 3rd party audit firms	11	12
3rd party auditors trained	23	40
Member companies	34	40

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.

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

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

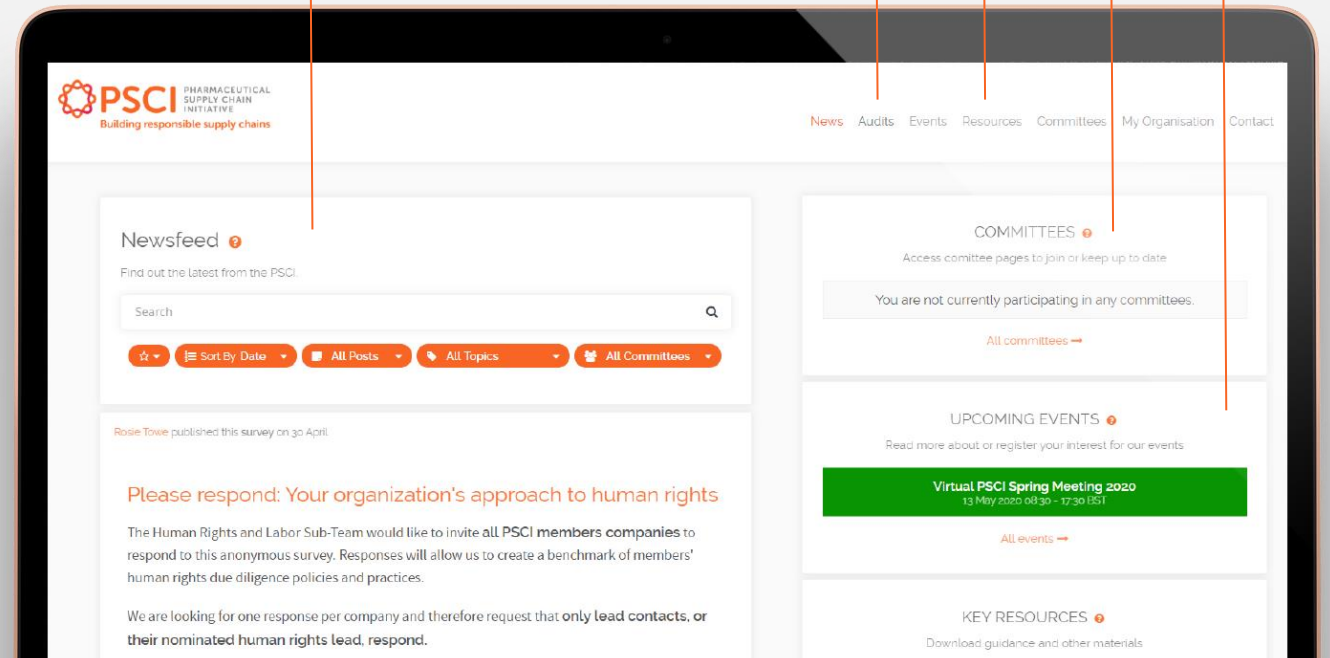
VIEW AND
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COMPANIES

JOIN AND
READ ABOUT
WORKING
COMMITTEES



pscinitiative.org/login

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



Speaker Bio

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

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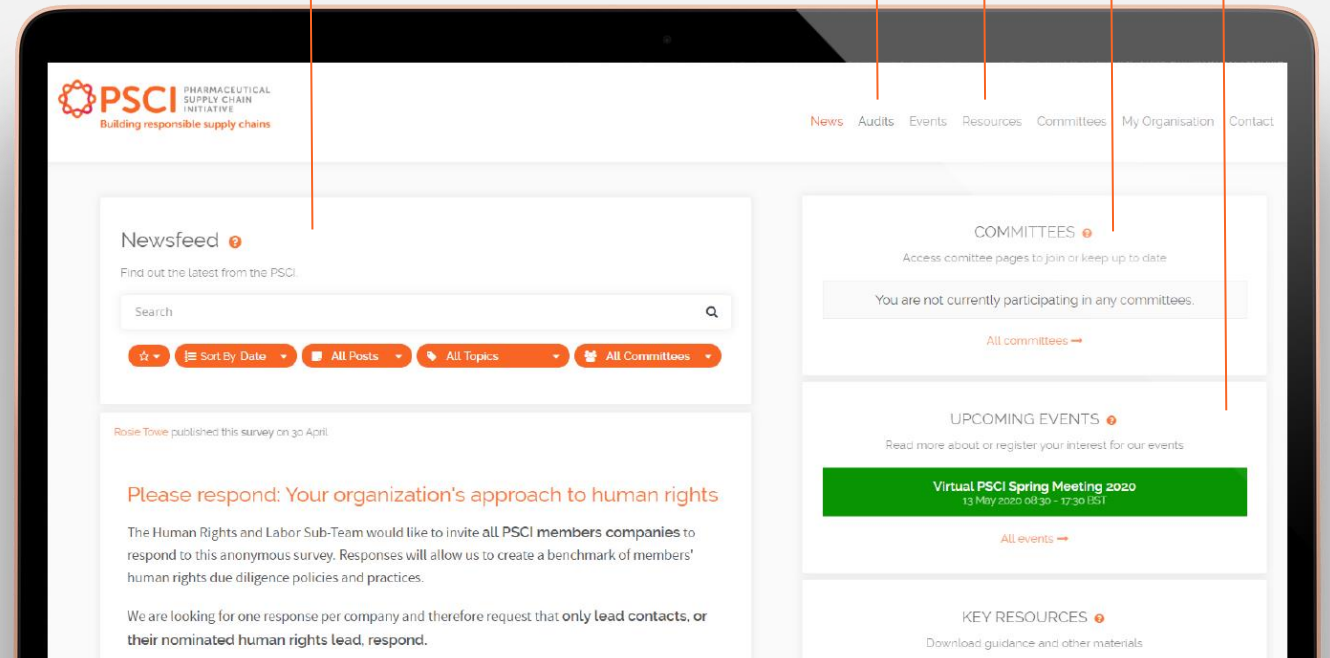
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The PSCI's capability building vision and plans

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:

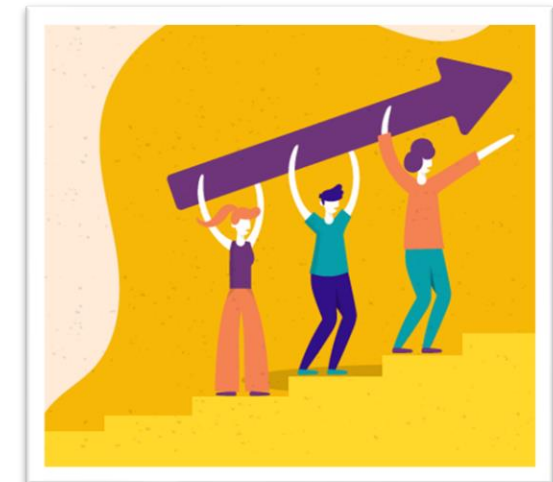
- Started 1997 Janssen Pharmaceutica Belgium (J&J)
- Different EHS&S roles R&D, fill finish and chemical production in J&J
- 2007-2009 Industrial Hygienist Alza - California, US
- 2010-2011 EH&S Expert Asia Pacific - Beijing, China

Contact information: ivdveld1@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



PHARMACEUTICAL SUPPLY CHAIN INITIATIVE (PSCI) WEBINAR:

Anti-Bribery and Corruption & GDPR

Presented by the Ethics Sub-Team

- 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.

Three day supplier conference in Hyderabad, 2019, attended by over 200 supplier delegates



Frank Buijs from Takeda presenting PSCI at the Association of Innovative Medicines in the Netherlands in November 2019

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



PSCI's learning model

	Level 1: Foundational 'primers'	Level 2: Tools & techniques	Level 3: Specialised content	Level 4: Expert access
Description	The first level will be foundational primers on key topics – what all suppliers need to know to have a common level of knowledge.	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.	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.	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.
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.
<i>Example from the Environment sub-team's model: The PSCI Principles on Environment</i>	<ul style="list-style-type: none"> • <i>What are The Principles?</i> • <i>What are the expectations?</i> • <i>Auditing and compliance</i> 	<ul style="list-style-type: none"> • <i>Preparing for audit against The Principles</i> • <i>Case study exemplars</i> 	<ul style="list-style-type: none"> • <i>Customer expectations – beyond The Principles</i> 	<ul style="list-style-type: none"> • <i>TBD</i>
<i>Example from the Environment sub-team's model: Climate change</i>	<ul style="list-style-type: none"> • <i>What is Climate Change?</i> • <i>Sources of Greenhouse Gases (GHG)</i> • <i>The basics of measurement</i> 	<ul style="list-style-type: none"> • <i>Calculating your carbon footprint</i> • <i>What is scope 3?</i> 	<ul style="list-style-type: none"> • <i>Developing a carbon strategy</i> 	<ul style="list-style-type: none"> • <i>TBD</i>

Organisational maturity

Supplier Maturity	Starting out	Developing	Implementing	Leading
	<ul style="list-style-type: none"> Compliance with law Necessary policies in place Minimum standards are being met 	<p>PLUS</p> <ul style="list-style-type: none"> Audits / baselines / risk assessments complete Key risks and highest impacts identified Measurement and recording systems in place Management responsibility has been allocated Targets and objectives set 	<p>PLUS</p> <ul style="list-style-type: none"> Processes in place with clear responsibilities for key staff Employees are aware and trained as appropriate Targets generally being achieved Improvement projects External verification External partnerships being developed Public reporting or other transparency Risks are adequately managed 	<p>PLUS</p> <ul style="list-style-type: none"> Embedded in culture External recognition / awards Taking an advocacy stance Approach includes whole value chain External partnerships across industry Supporting partners / customers to improve. Sustainability drives innovation Sustainability leads to differentiation and commercial advantage

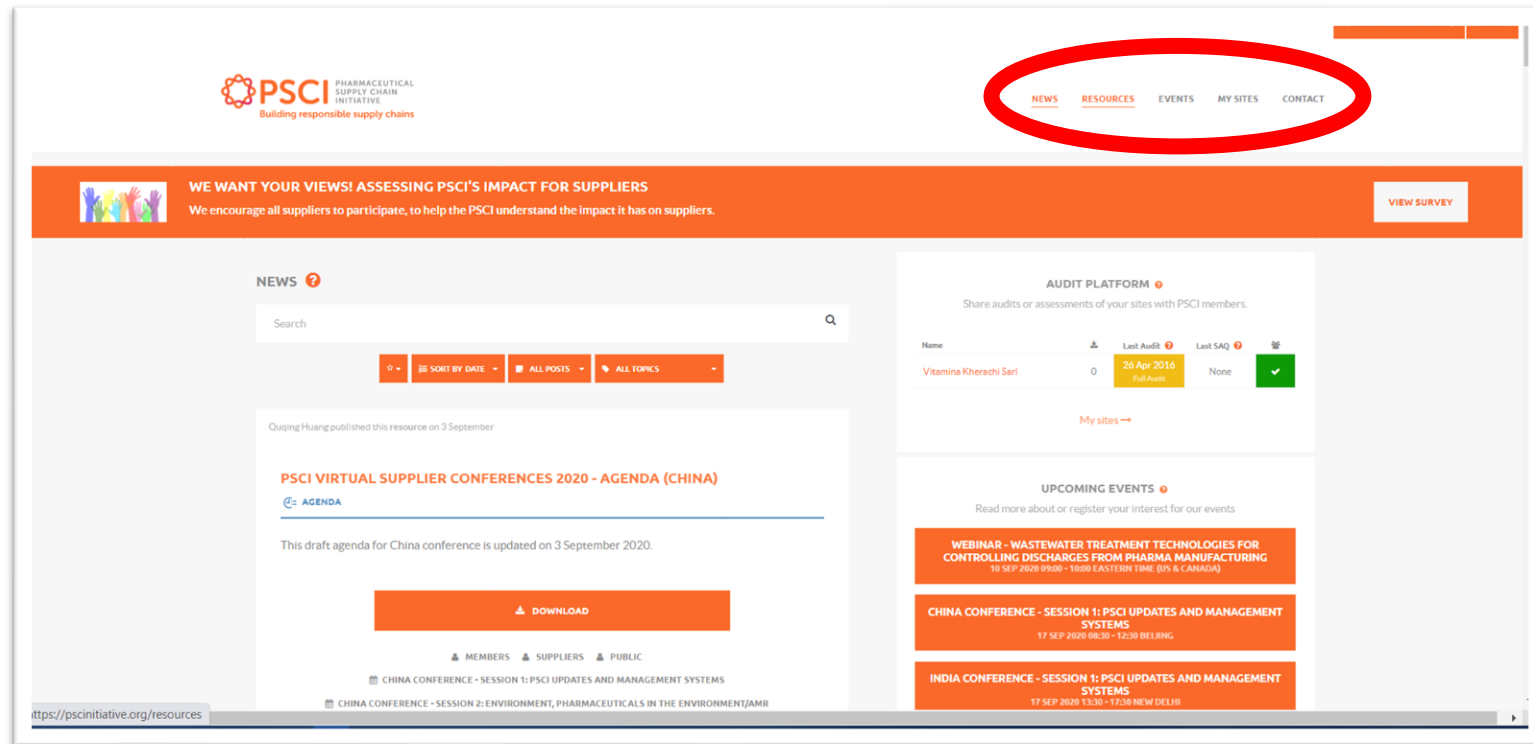
Learning model	Level 1: Foundational 'primers'	Level 2: Tools & techniques	Level 3: Specialised content	Level 4: Expert access
	Foundational primers on key topics	Challenges, tools and techniques	Specialised content modules for those aiming to leadership	Access to industry leaders, mutually beneficially projects or joint initiatives for those established in leadership.
	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.
	<i>Primers will demonstrate the minimum standards, enable suppliers to prepare for their journey and raise awareness of the key topics.</i>	<i>As suppliers develop their programme, they will draw on these tools and techniques, including audit frameworks, risk assessment tools, and 'how to' guides.</i>	<i>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.</i>	<i>Leading suppliers are as likely to be sharing their expertise as they are to be learning; a network of experts, working in partnership.</i>

	Level 1: Foundational 'primers' <i>Downloadable guide for suppliers</i>	Level 2: Tools & techniques <i>Online videos and links</i>	Level 3: Specialised content <i>'Live' webinars with external input</i>
The PSCI Principles on Environment	<ul style="list-style-type: none"> • What are The Principles? • What are the expectations? • Auditing and compliance 	<ul style="list-style-type: none"> • Preparing for audit against The Principles • Case study exemplars 	<ul style="list-style-type: none"> • Customer expectations – beyond The Principles
Environmental Management	<ul style="list-style-type: none"> • Writing Environmental policy • Basic of an EMS • Measuring performance 	<ul style="list-style-type: none"> • Standards and certification • Setting goals and targets 	<ul style="list-style-type: none"> • Developing Science Based Targets
Incidents & accidents	<ul style="list-style-type: none"> • Understanding legislation & responsibilities • Safe operating procedures • Managing a spill or release 	<ul style="list-style-type: none"> • What happens when it goes wrong? • Best practice leak or spill control 	<ul style="list-style-type: none"> • Real time monitoring and citizen science
Climate change	<ul style="list-style-type: none"> • What is Climate Change? • Sources of Greenhouse Gases (GHG) • The basics of measurement 	<ul style="list-style-type: none"> • Calculating your carbon footprint • What is scope 3? 	<ul style="list-style-type: none"> • Developing a carbon strategy
Energy efficiency	<ul style="list-style-type: none"> • Managing energy • Changing behaviour • Areas for efficiency improvement 	<ul style="list-style-type: none"> • Factory improvements • Renewable energy opportunities 	<ul style="list-style-type: none"> • Renewable energy opportunities
Green logistics	<ul style="list-style-type: none"> • What are green logistics • Impacts of distribution • Business travel 	<ul style="list-style-type: none"> • Road vs shipping vs air transport • New technology (i.e., electric vehicles) 	<ul style="list-style-type: none"> • Principles of EV100
Water	<ul style="list-style-type: none"> • Water management • Water quality • Using less water 	<ul style="list-style-type: none"> • Understanding your water risks • Measuring water scarcity 	<ul style="list-style-type: none"> • Green chemistry and ZDHC
Waste	<ul style="list-style-type: none"> • Waste hierarchy • The basics of waste management • Handling hazardous waste 	<ul style="list-style-type: none"> • Writing waste management procedures • Opportunities for reuse or recycling 	<ul style="list-style-type: none"> • Zero waste to landfill
Packaging	<ul style="list-style-type: none"> • Types of packaging • Understanding impacts • Plastics 	<ul style="list-style-type: none"> • Recycling opportunities • Rightsizing and optimisation 	<ul style="list-style-type: none"> • Eliminating plastics
Raw materials	<ul style="list-style-type: none"> • Raw material sourcing • Key issues and materials • Customer expectations 	<ul style="list-style-type: none"> • The important material standards • Understanding raw material traceability 	<ul style="list-style-type: none"> • 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.



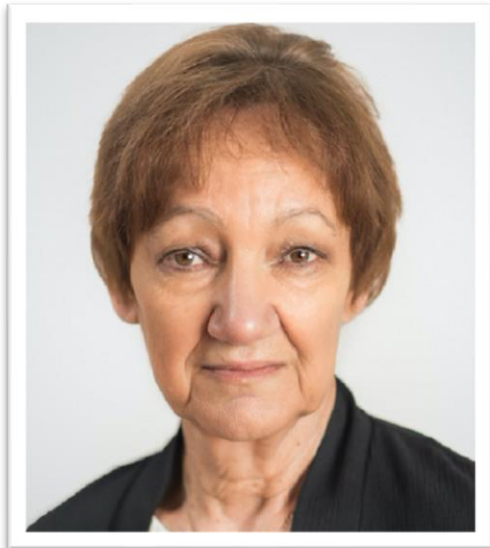
Introducing our next speaker

“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/>



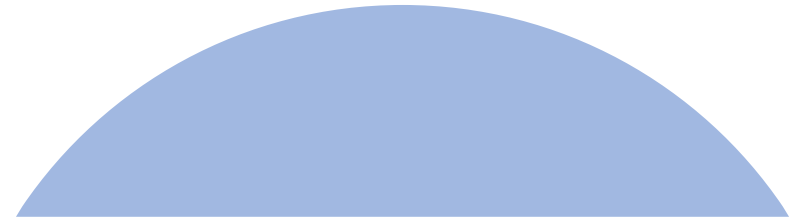
Professor Diana Laurillard
University College, London



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?

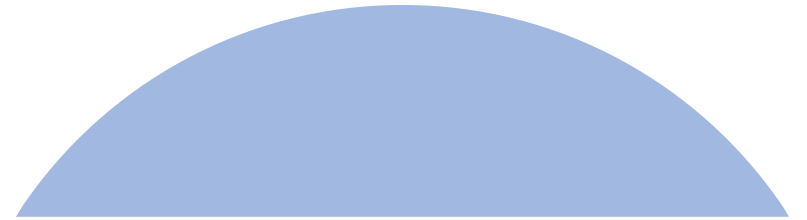
What makes a good online learning design?

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 on line this year

A collaborative global approach to health and wellbeing requires universal education

Sustainability

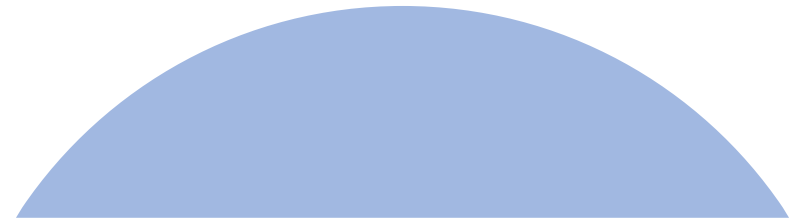
Around 2.4% of global CO2 emissions come from aviation. The industry is responsible for around 5% of global warming.

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?



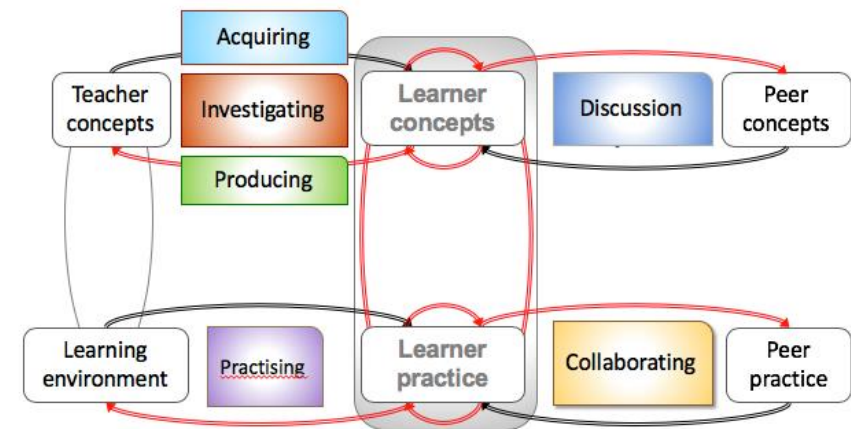
What counts as high quality learning?

The Conversational Framework

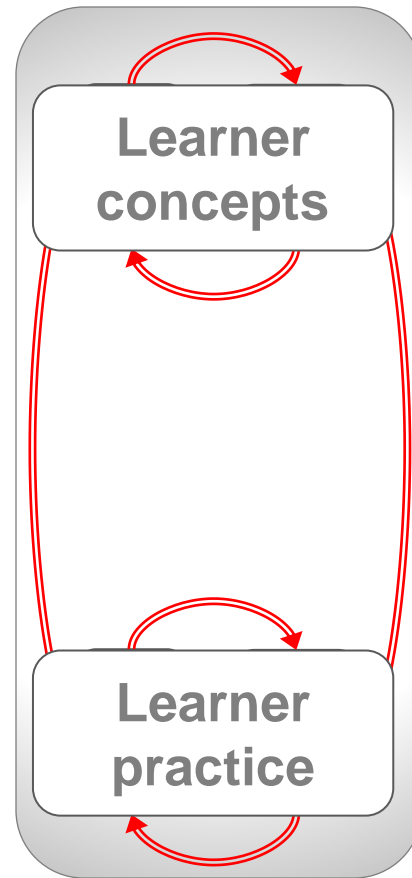
Derived from theories and research on learning and teaching (Laurillard, 2002, 2012)

To represent the teaching-learning process as

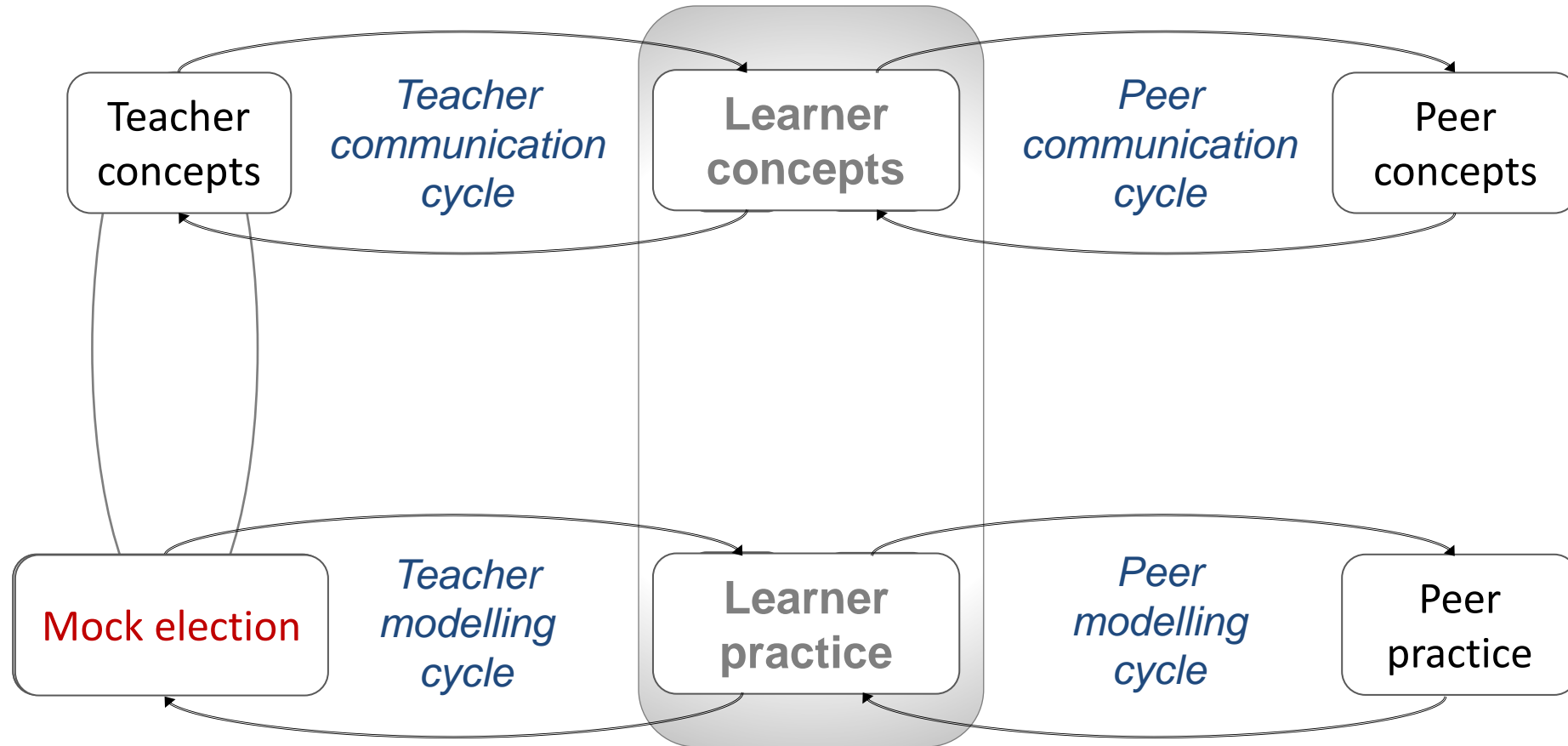
- a series of iterative exchanges
- between the learner and a 'teacher' and
- between a learner and their peers
- at two levels of concepts and practices



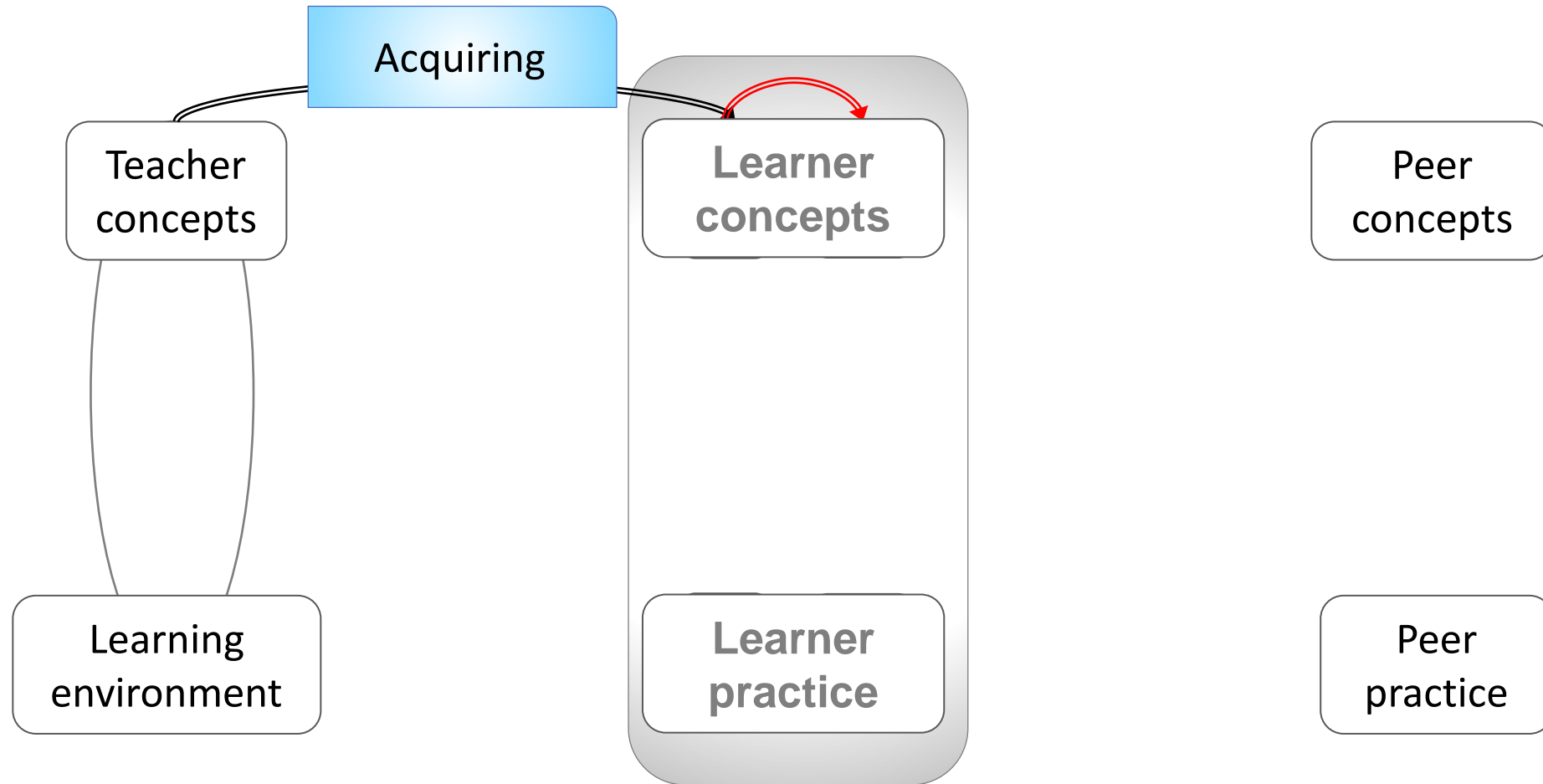
What does it take to learn in formal education?



What does it take to learn in formal education?

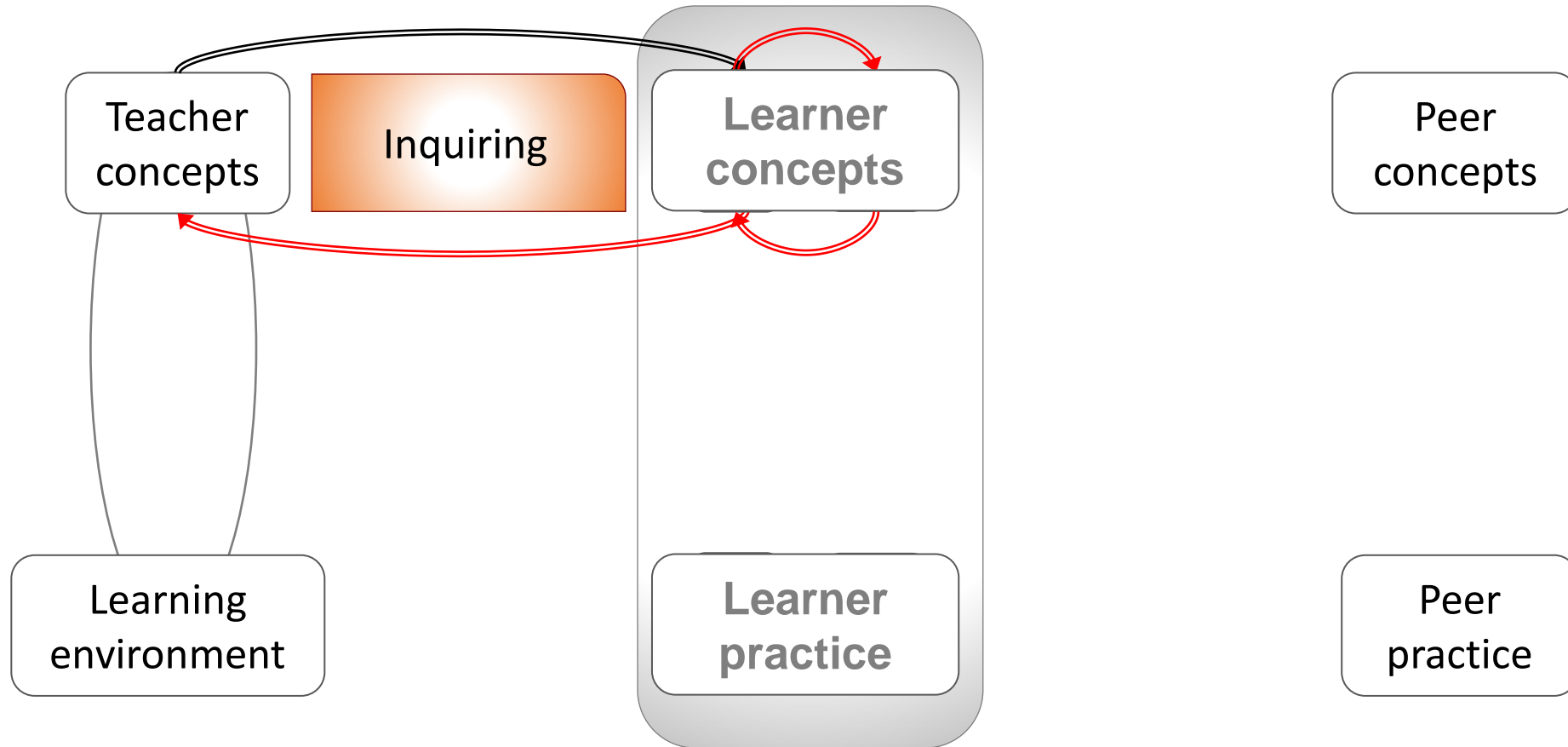


Types of learning mapped to the framework



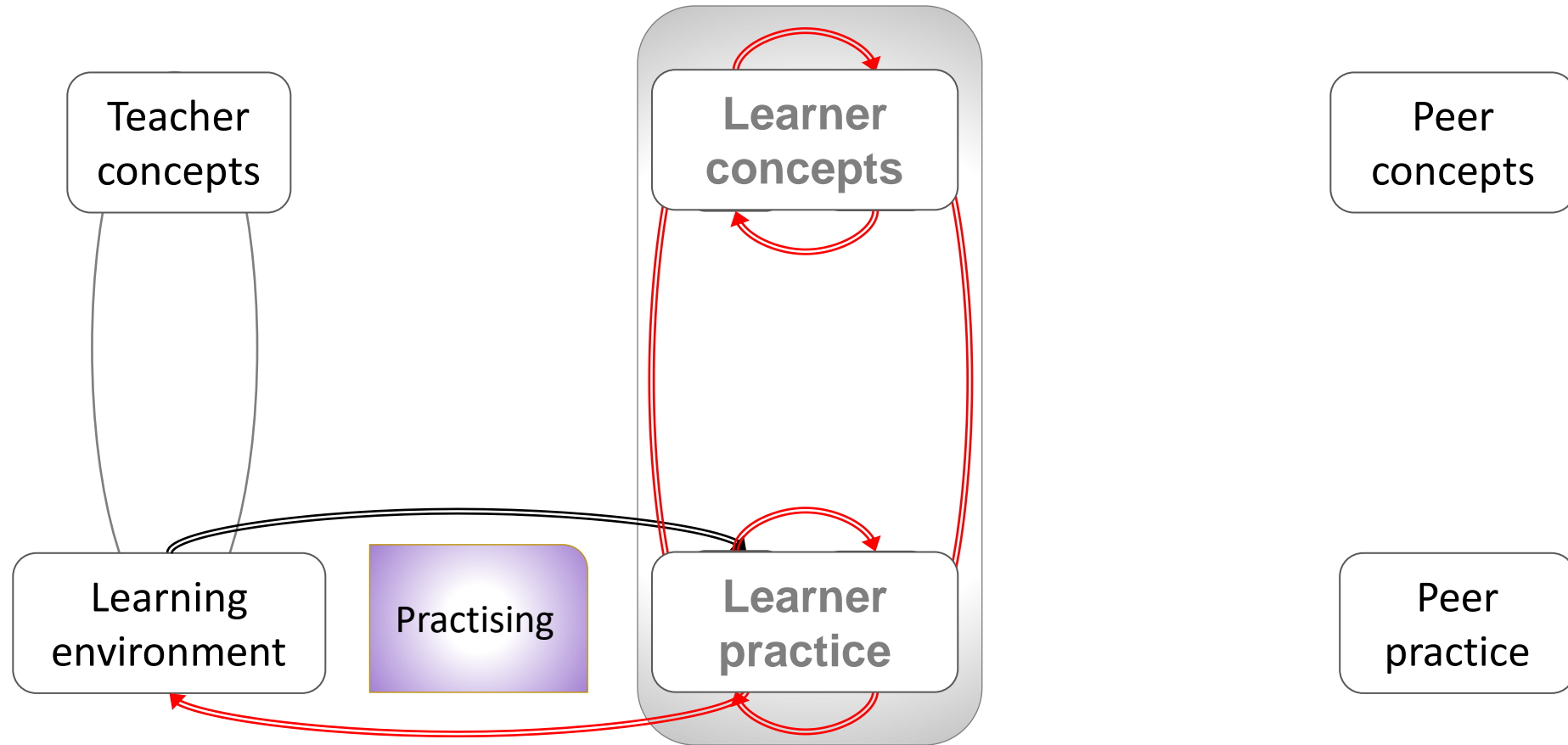
Learning through 'acquisition'

Types of learning mapped to the framework



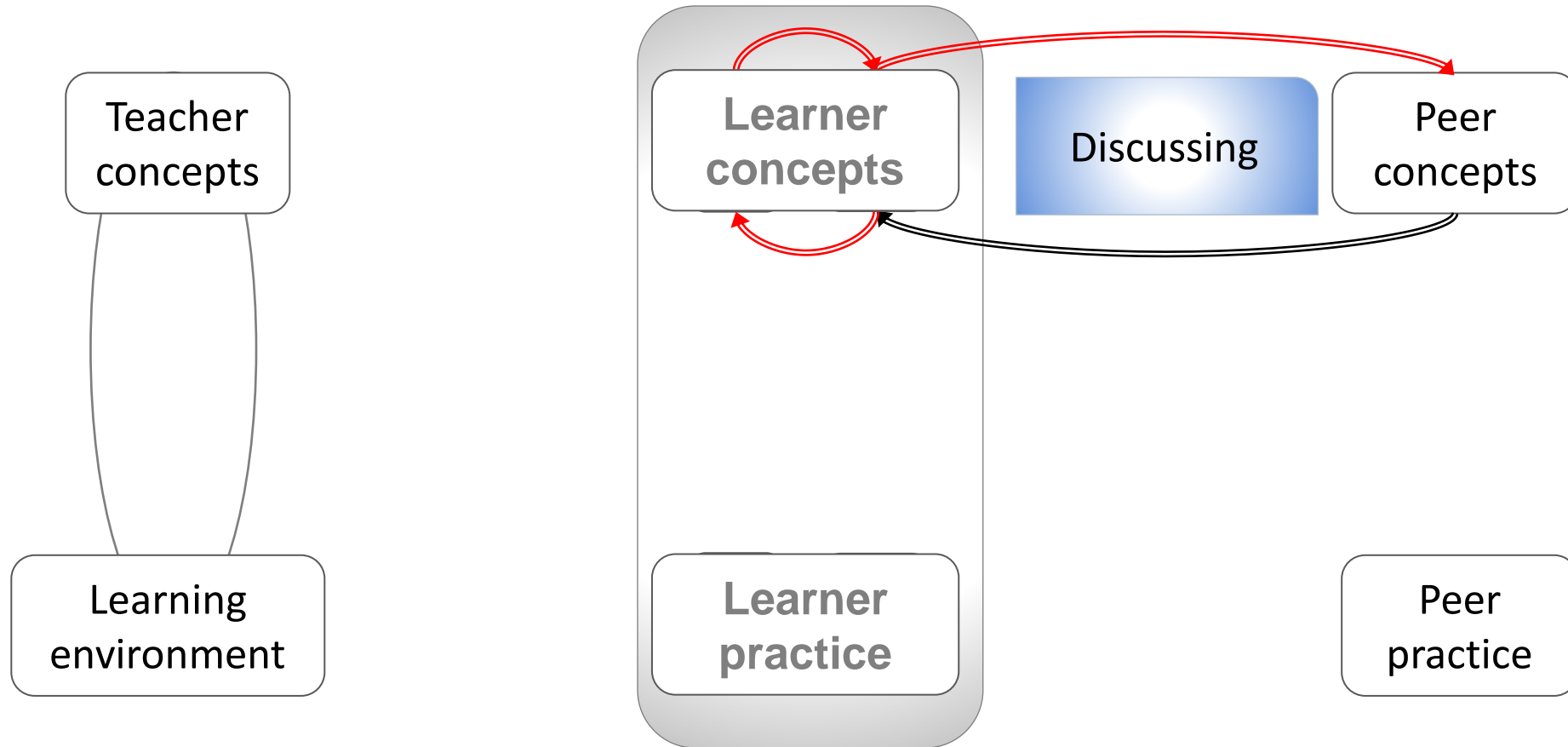
Learning through 'inquiry'

Types of learning mapped to the framework



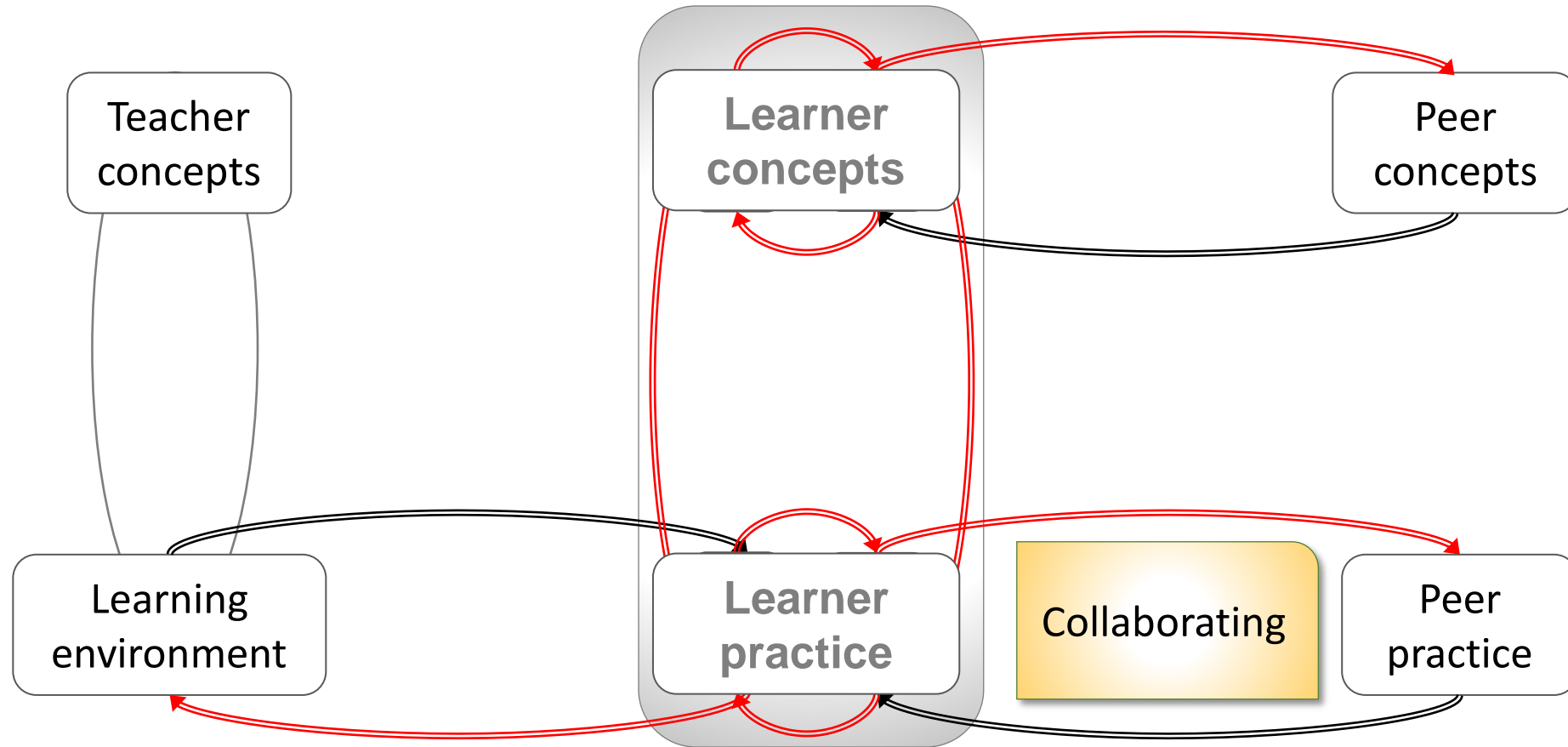
Learning through 'practice'

Types of learning mapped to the framework



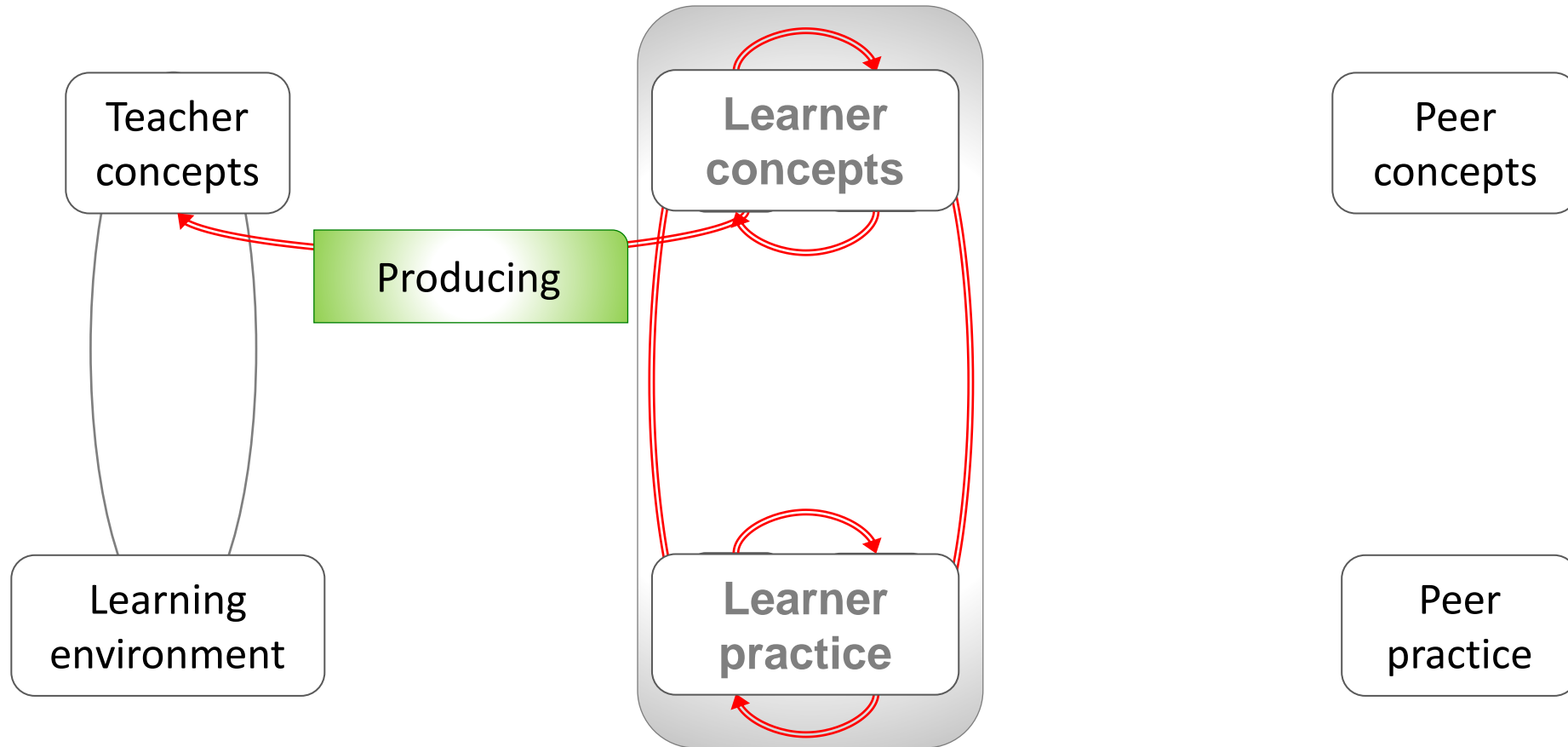
Learning through 'discussion'

Types of learning mapped to the framework



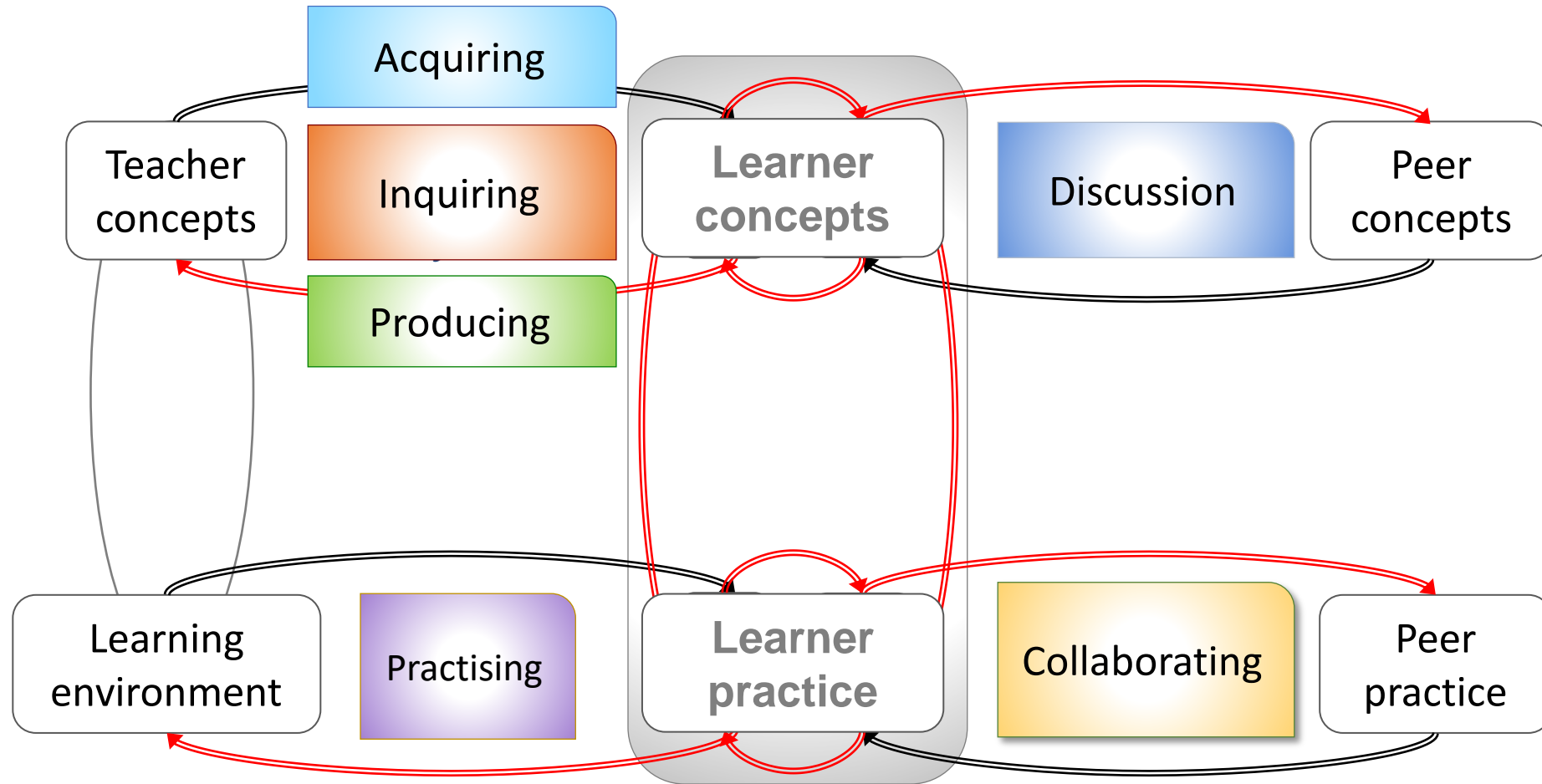
Learning through 'collaboration'

Types of learning mapped to the framework



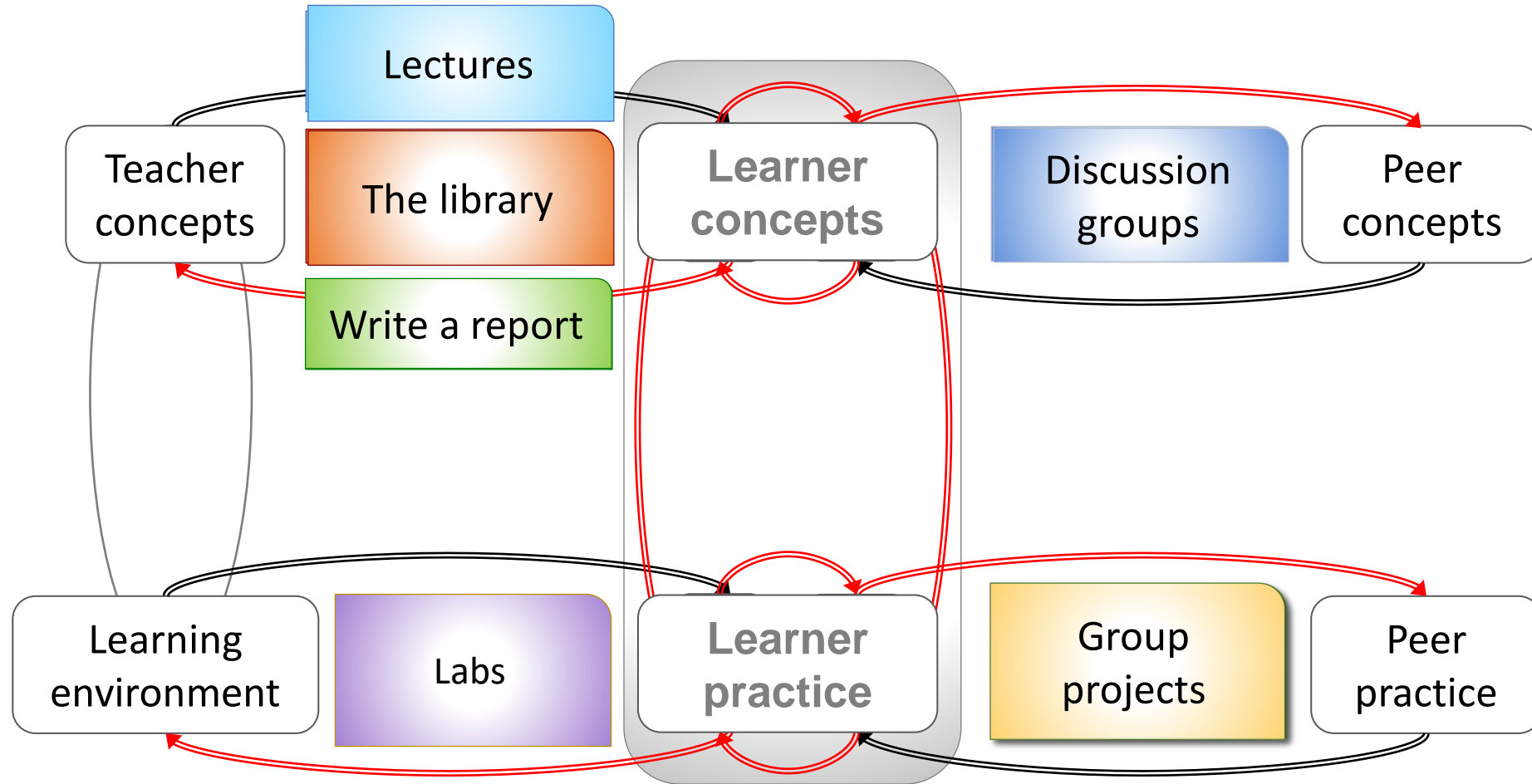
Learning through 'production'

How does technology help? *Conventional methods*



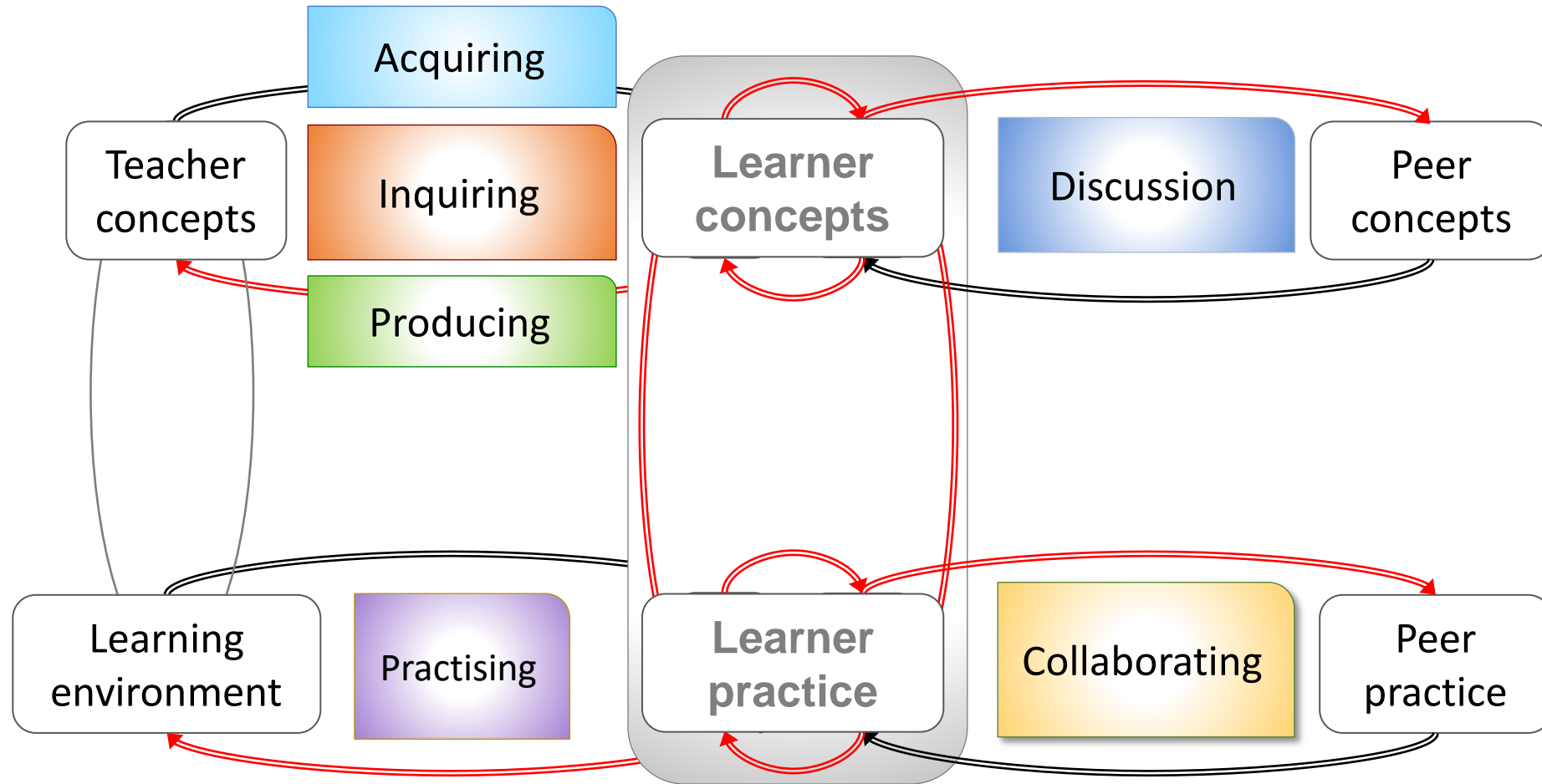
These learning types are encouraged through a variety of conventional methods

How does technology help? *Conventional methods*



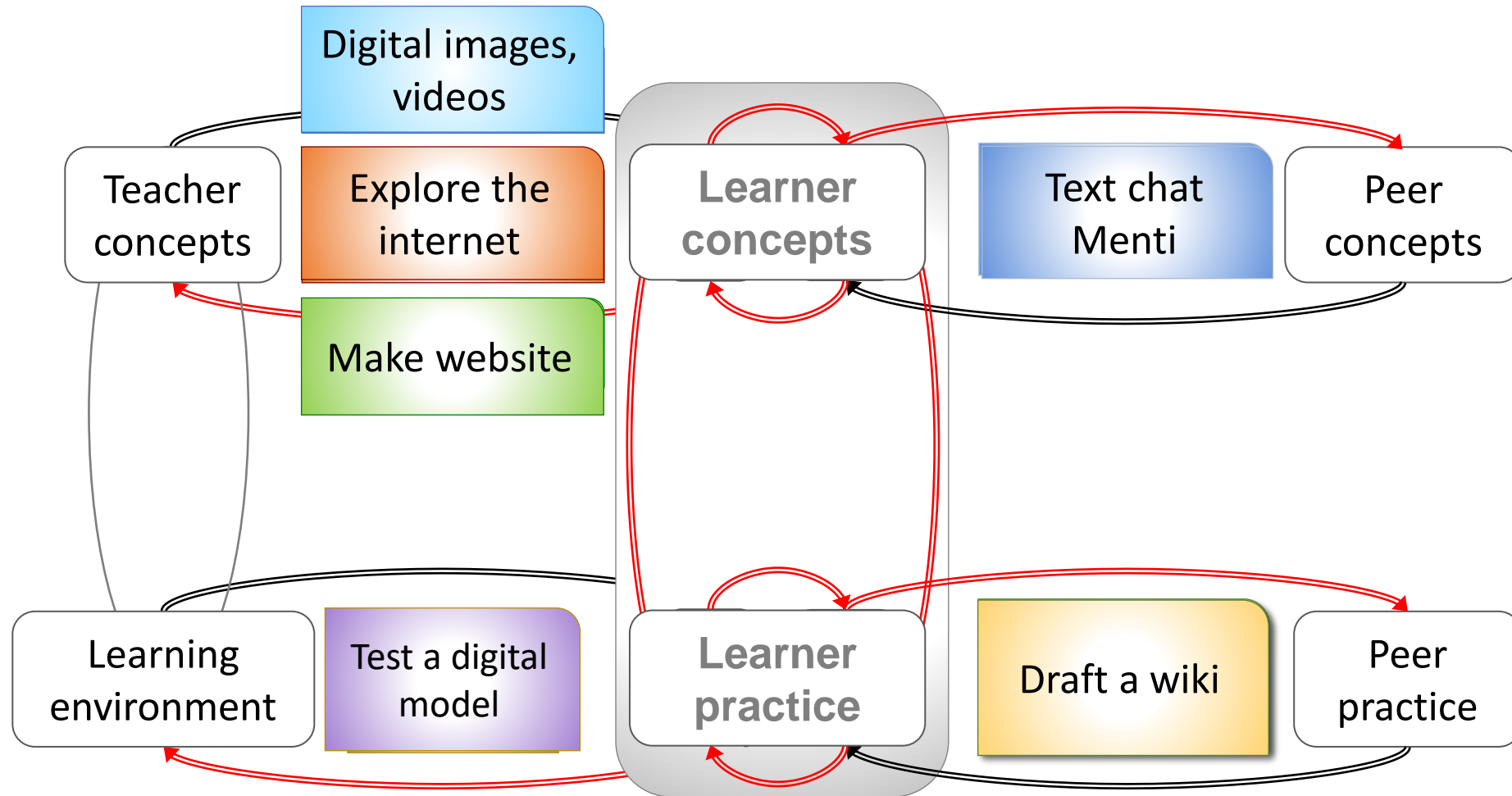
These learning types are encouraged through a variety of conventional methods

How does technology help CPD? Digital methods



The same learning types are encouraged also through a variety of digital methods

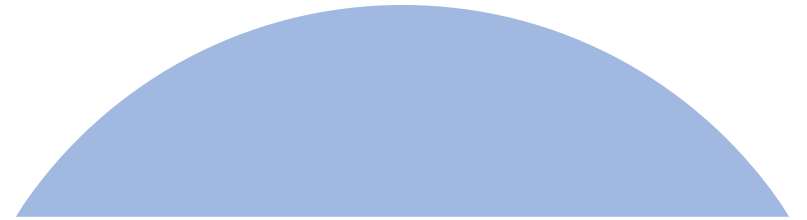
How does technology help CPD? Digital methods



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

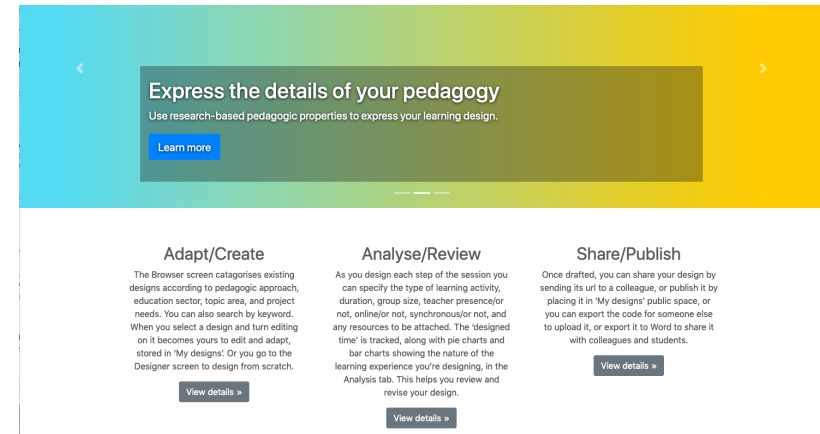
A free open online design tool to help with moving your teaching online.

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>



The screenshot displays the Learning Designer interface. At the top, there is a navigation bar with "Learning Designer", "Home", "Browser", "Designer", and "Administrator". The main area shows a design process for a "wiki activity".

Name: Which ICT tool? wiki activity
Topic: Teacher education
Learning time: 60 minutes
Designed learning time: 60 minutes
Number of students: 50
Description: This activity is based on a learning design used by Tim Neumann at the IOE to introduce trainee teachers to

Aims: To practice using a wiki for learning
To discuss a range of learning technologies and their uses for

Outcomes:

- Construct a around wiki.
- Compile a list of learning technologies and
- Apply peers' ideas to your own practice
- Give feedback

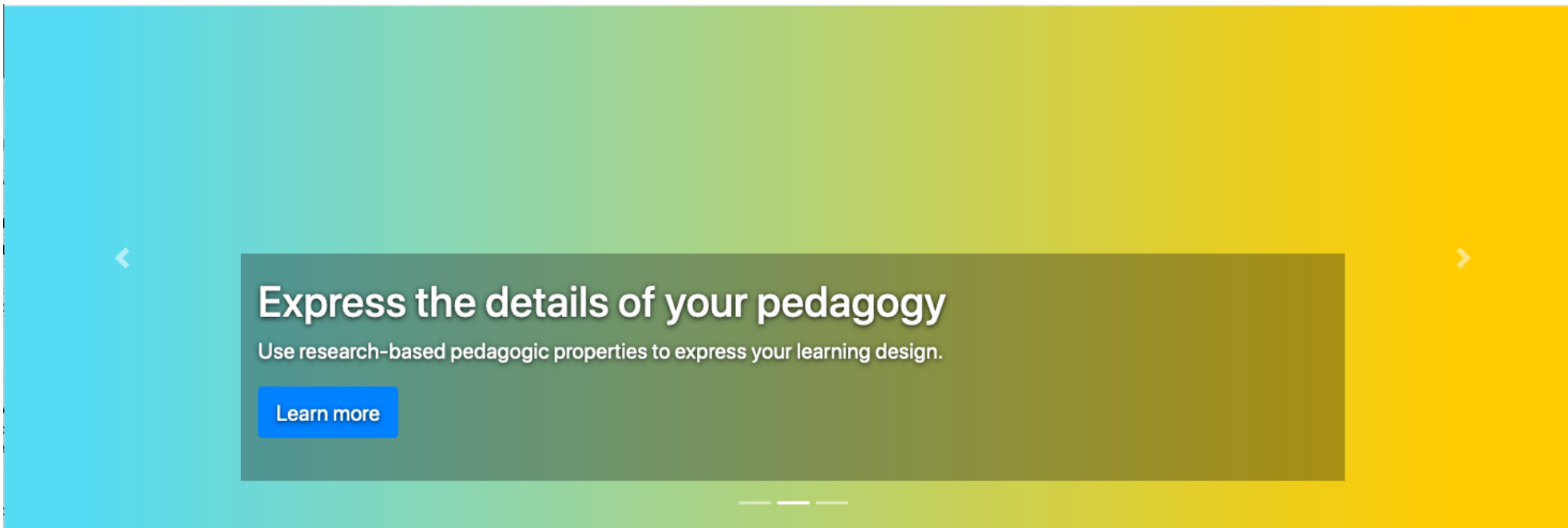
Progress Chart: A pie chart showing the progress of the design process. The chart is divided into three segments: "Production" (33.33%), "Dis", and "Pro".

Buttons: + Add TLA, New design, Import design, Export design, Share, Save

Design Steps:

- Produce:** Create a shared resource of learning technologies for education. Respond to the question: Which ICT tool (software, function, website, social media) might be useful for education? Go to the wiki and add a new page, then
- Discuss:** Comment on others' contributions. From the list of pages (click on the Page button):
 - select a tool that you have used or plan to use,
 - read its description, and
- Collaborate:** Create a folksonomy for the wiki contents. Categorise the various pages using tags to create a folksonomy: Go to one of the wiki pages and edit the page tags 'Edit' link

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.

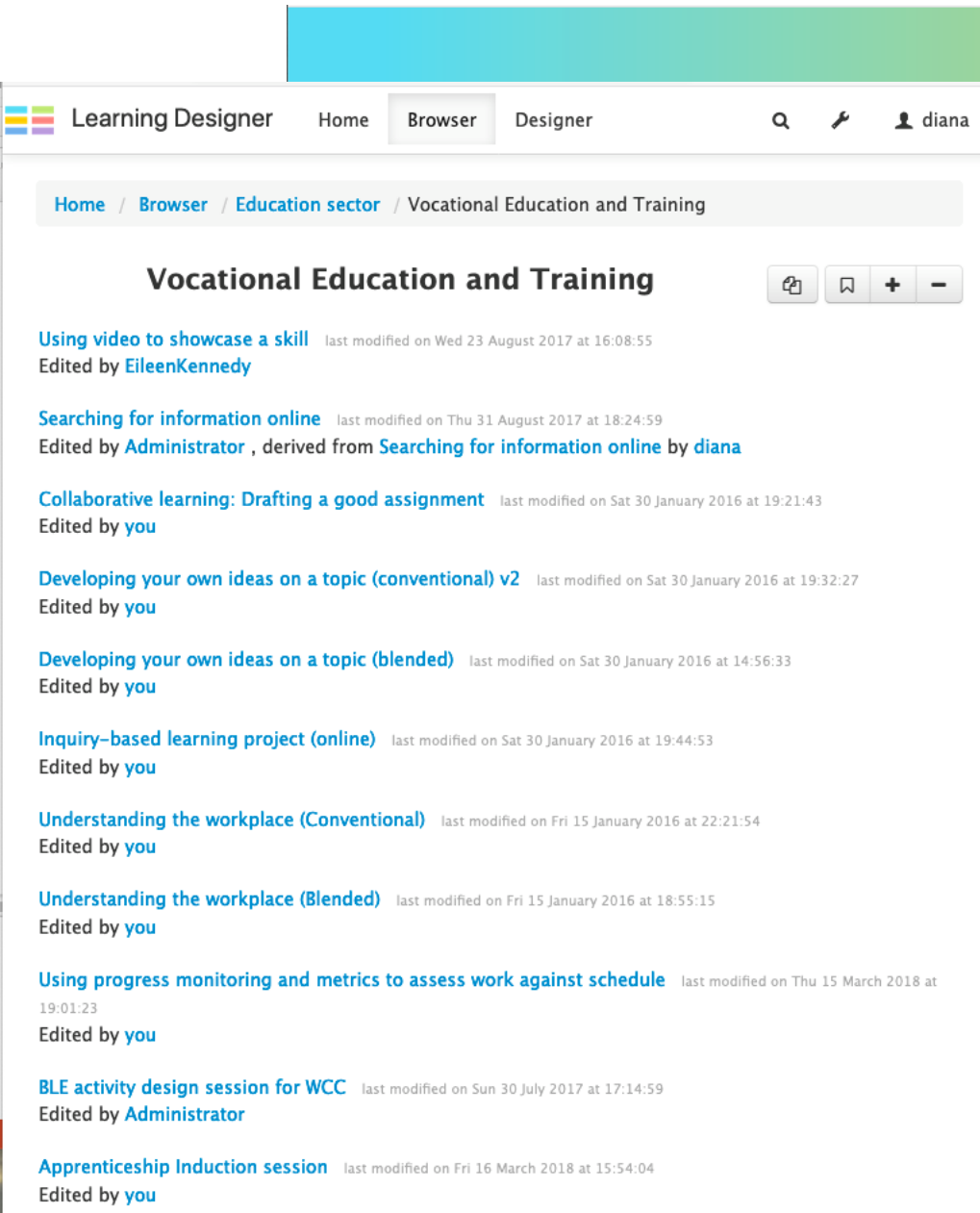
[View details »](#)

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



Learning Designer Home **Browser** Designer 🔍 ✎ 👤 diana

Home / Browser / Education sector / Vocational Education and Training

Vocational Education and Training

Using video to showcase a skill last modified on Wed 23 August 2017 at 16:08:55
Edited by EileenKennedy

Searching for information online last modified on Thu 31 August 2017 at 18:24:59
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 18:55:15
Edited by you

Using progress monitoring and metrics to assess work against schedule last modified on Thu 15 March 2018 at 19:01:23
Edited by you

BLE 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



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.

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[View details »](#)

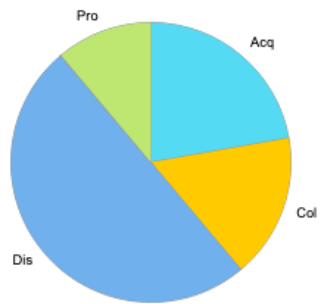
Adapting a learning design

Learning Designer Home Browser Designer 🔧 👤 diana

Home / Browser / Moving Online / Understanding [the Topic] Online

Timeline Analysis

Name	Understanding [the Topic] Online	Mode of delivery	Wholly online
Topic	The Topic	Aims	This session introduces [the Topic] and invites students to ...
Learning time	1 hour and 30 minutes	Outcomes	<input checked="" type="checkbox"/> Knowledge, Application, Analysis
Designed learning ti...	1 hour and 30 minutes	Editor	diana
Size of class	25		
Description	This is a design for a class using wholly online methods. It... <input checked="" type="checkbox"/>		



Turn editing on

Activity	Duration	Icon 1	Icon 2	Icon 3	Icon 4	Icon 5
Introduction to [the Topic]						
Read Watch Listen	10	👤 1	🚫	🗑️	🔒	1
Watch the presentation about [the Topic]. It explains why... how... what... Does [the Topic] make sense to you? Please pause the video to note any questions you have.						
Discuss	10	👤 1	🚫	🗑️	🔒	1
Please post your questions to [the Discussion site] by [date, time]. Click 'Like' for any other questions you would like to know the answers to. Check the site on [date, time] when the teacher will show the answers to your questions.						
Applying [the Topic]						
Produce	10	👤 1	🚫	🗑️	🔒	0
Think of an example of a situation that is relevant to [the Topic] 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	15	👤 3	🚫	🗑️	🔒	1
In your group, take turns to share your ideas of how you would use [the Topic] in each of the 3 situations.						
Collaborate	15	👤 3	🚫	🗑️	🔒	1
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 [the Topic] in which situation.						
Analysing how [the Topic] could guide futu						
Read Watch Listen	10	👤 1	🚫	🗑️	🔒	1
Read through the other groups' posts to and make notes on what you will contribute to discussion.						
Discuss	20	👤 25	🚫	🗑️	🔒	1
The class discussion of [the Topic] is or Discuss with the teacher, using the audio examples the groups have posted to and how you might change your actions applying [the Topic].						

Adapting a learning design

Learning Designer Home Browser Designer diana

Learning Design

Home / Browser / Ed

Vocatio

Using video to showcase Edited by EileenKennedy

Searching for information Edited by Administrator ,

Collaborative learning: D Edited by you

Developing your own ide Edited by you

Developing your own ide Edited by you

Inquiry-based learning p Edited by you

Understanding the work Edited by you

Understanding the work Edited by you

Using progress monitor Edited by you

BLE activity design sessio Edited by Administrator

Apprenticeship Induction Edited by you

Timeline Analysis

Name Understanding Risk Assessment Onlir

Topic Risk Assessment

Learning time 1 hours 30 minutes

Designed learning ti... 1 hours 30 minutes

Size of class 25

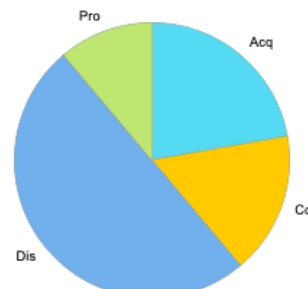
Description This is a design for a class using wholly online methods.

Mode of delivery Wholly online

Aims This session introduces Risk Assessment, and invites students to apply it to 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 10 1

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 10 1

Post your questions to [the Discussion site] by [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 10 1

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 15 3

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

Collaborate 15 3

In your group, decide on your best example, and what you will post to the class site.

Analysing how Risk Assessment could guide your future

Read Watch Listen 10 1

Read through the other groups' posts to the class site, notes on what you will contribute to the discussion.

Discuss 20 25

The class discussion of Risk Assessment is on [date, ti Discuss with the trainer, using the audio and the chat, the groups have posted to the class site, and how you your actions in future by applying Risk Assessment.

Adapting a learning design

Learning Designer Home Browser Designer diana

Timeline Analysis

Applying Risk Assessment

Produce 10 1

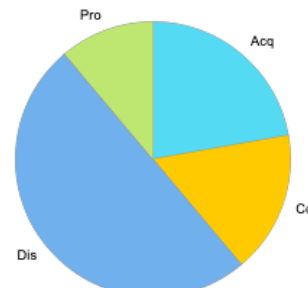
Think of an example of a situation that is relevant to Risk Assessment in your context, and how you could make use of it. Make notes to share with your group. Arrange a time when you will meet with your group online.

Discuss 15 3

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

Collaborate 15 3

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.



Export design Share Save

Analysing how Risk Assessment could guide your future

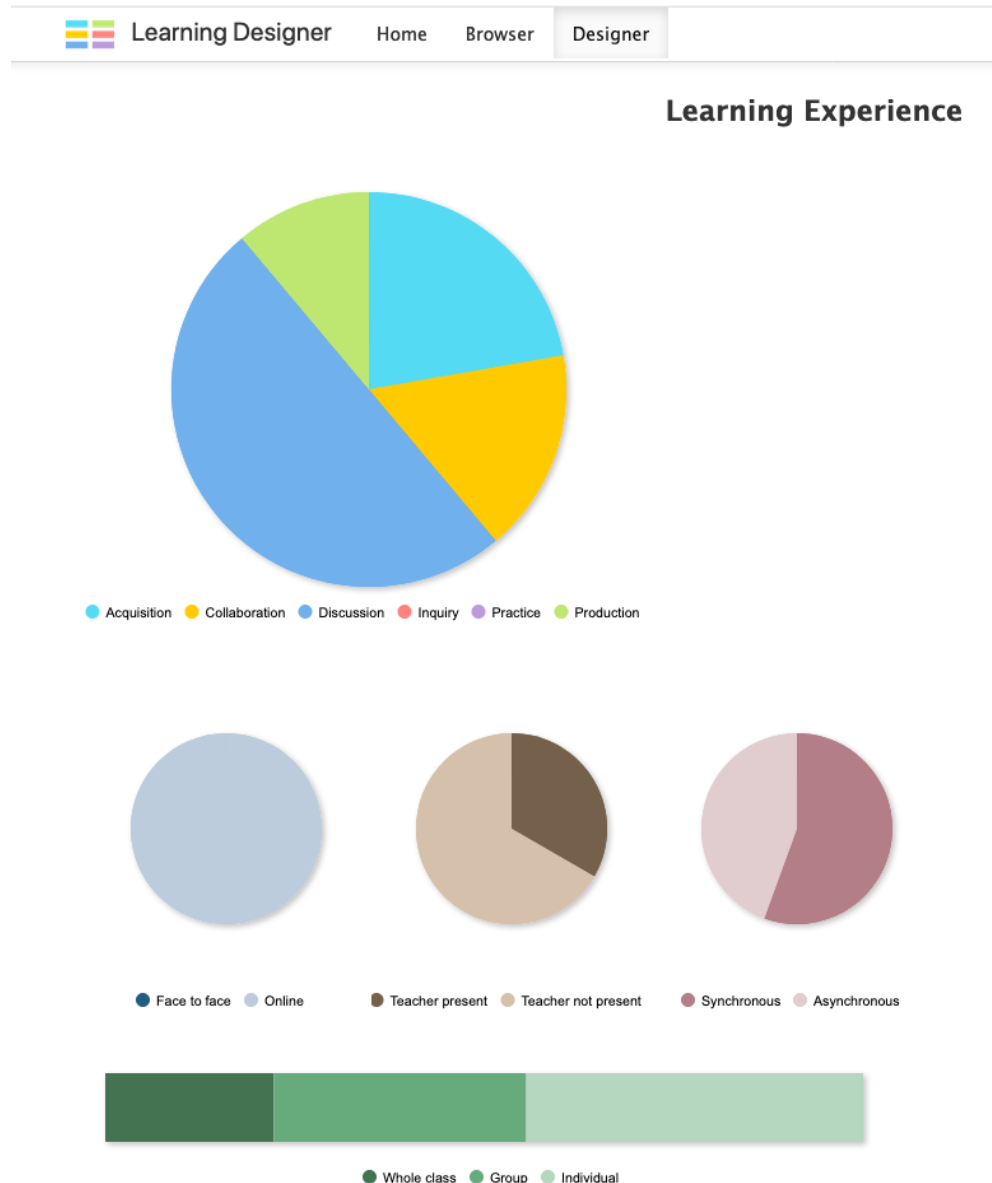
Read Watch Listen 10 1

Read through the other groups' posts to the class site, notes on what you will contribute to the discussion.

Discuss 20 25

The class discussion of Risk Assessment is on [date, ti Discuss with the trainer, using the audio and the chat, the groups have posted to the class site, and how you your actions in future by applying Risk Assessment.

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

Learning Design for: Understanding Risk Assessment Online

Context

Topic: Risk Assessment

Total learning time: 1 hour and 30 minutes

Designed learning time: 1 hour and 30 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 to a context they are familiar with.

Outcomes

Knowledge: Be able to explain Risk Assessment,

Application: Be able to apply Risk Assessment to a specific context

Analysis: Be able to analyse a specific context in the light of [the Topic] and identify how it might change future actions

Teaching-Learning activities

+ Introduction to Risk Assessment				
Read Watch Listen	10 minutes	1 student	Tutor is not available	Online
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.				
<i>Linked resources</i> Screencast or video				
Discuss	10 minutes	1 student	Tutor is available	Online
Post your questions to [the Discussion site] by [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.				
<i>Linked resources</i> Q&A with the teacher				

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

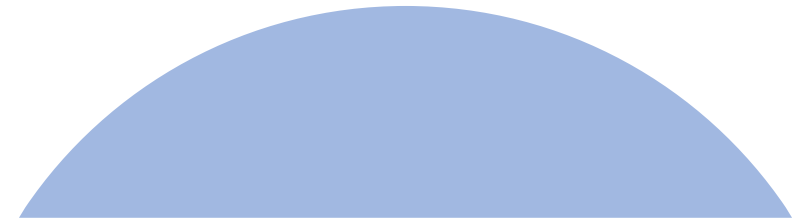
You can also Share it by creating a url to send to colleagues



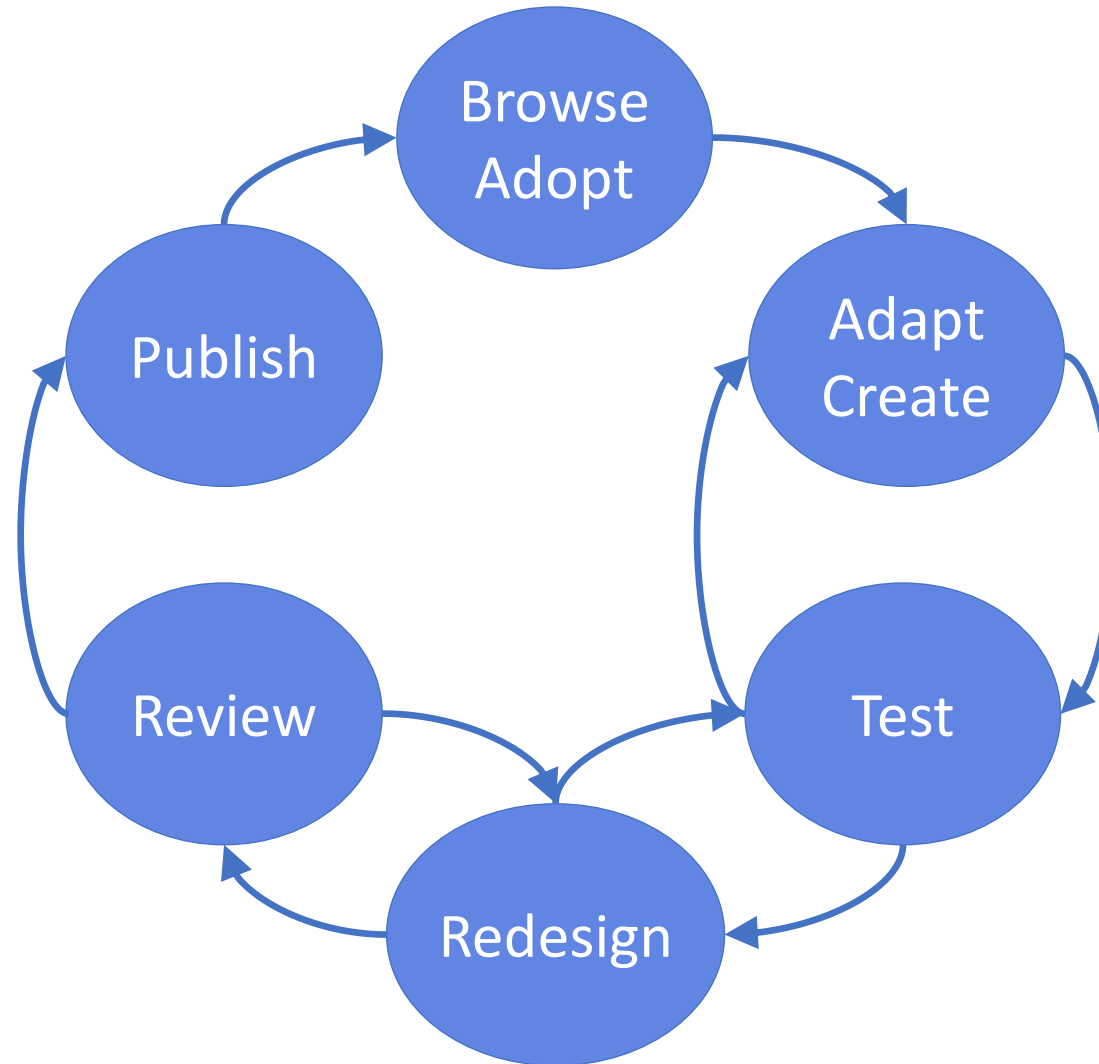
<https://www.ucl.ac.uk/learning-designer>



How can we build
knowledge about high
quality online learning?

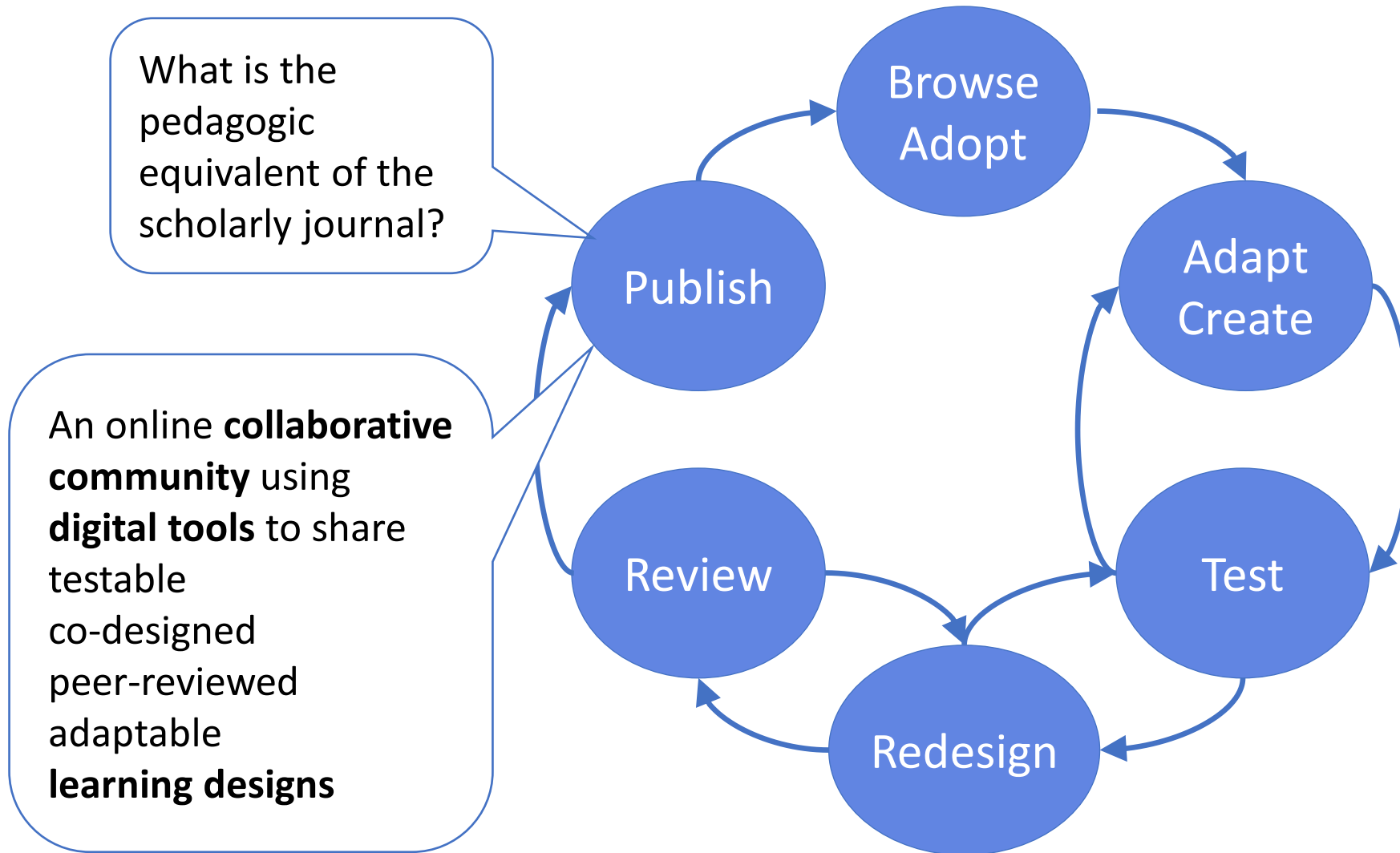


A community of practice: innovating, testing, and sharing new ideas for effective design



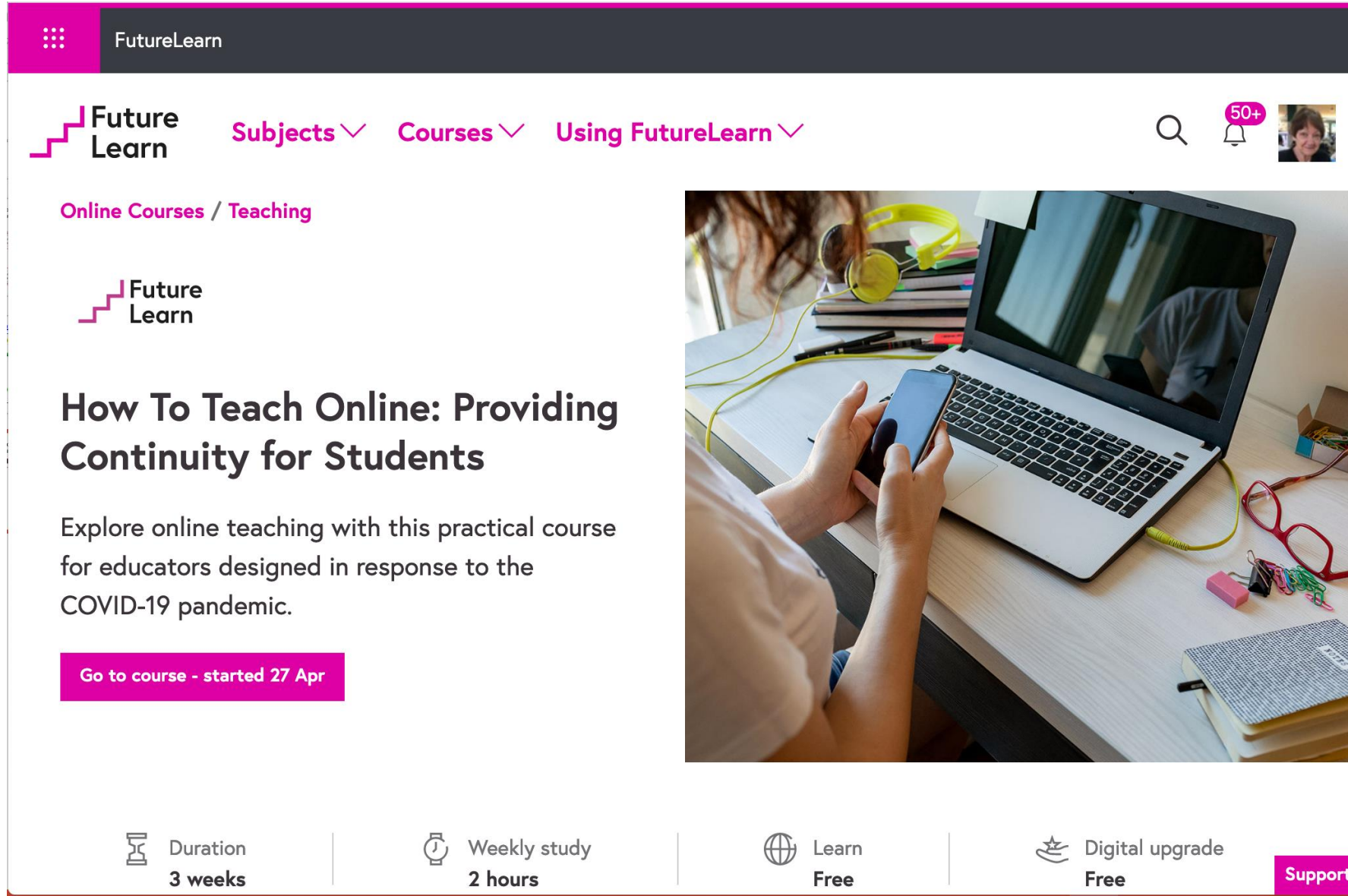
Building knowledge for science and scholarship

A community of practice: innovating, testing, and sharing new ideas for effective *online learning* design



Building knowledge of online learning design

Large-scale online courses to orchestrate collaborative knowledge development by education professionals



The image shows a screenshot of a FutureLearn course page. At the top, there is a navigation bar with the FutureLearn logo and menu items for 'Subjects', 'Courses', and 'Using FutureLearn'. A search icon, a notification bell with a '50+' badge, and a user profile picture are also visible. The main content area features the course title 'How To Teach Online: Providing Continuity for Students' and a description: 'Explore online teaching with this practical course for educators designed in response to the COVID-19 pandemic.' A pink button labeled 'Go to course - started 27 Apr' is positioned below the description. To the right of the text is a photograph of a person's hands holding a smartphone in front of a laptop on a desk. The bottom of the page contains four feature boxes: 'Duration 3 weeks', 'Weekly study 2 hours', 'Learn Free', and 'Digital upgrade Free'. A pink 'Support' button is located in the bottom right corner.

FutureLearn

Future Learn Subjects Courses Using FutureLearn

Online Courses / Teaching

Future Learn

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

Support

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

<p>جيد</p> <p>أضف تعليق</p>	<p>أضف تعليق</p>	<p>ممتاز</p> <p>مجهول 4</p> <p>أضف تعليق</p>	<p>برنامج بوربوينت</p> <p>استفاد طلابي من خلال برنامج powerpoint وكيفية إدراج الصوت مع الشرح الذي كلفتم بعمله خلال البرنامج.</p> <p>0 المفضلة</p> <p>تعليق واحد</p> <p>لجسبول 23 kul</p> <p>أضف تعليق</p>	<p>قام طلابي بصنع صورة او رسم خيالي يوضح التغييرات التي تطرأ على جسم الحيوان في التغير الكامل وغير الكامل. وقد استخدموا نموذج التقييم لمراجعة متطلبات الرسم التوضيحي.</p> <p>2 مفضل</p> <p>أضف تعليق</p>
<p>مميزه ورائعه</p> <p>0 المفضلة</p> <p>تعليق 2</p> <p>مجهول 26</p> <p>لجسبول 23</p> <p>أضف تعليق</p>	<p>نتيجة التعلم لطلابي هي الإستفادة من البرامج الموجودة والمجانبة على اختلافاتها المتعلقة بتصميم فيديو وذلك من أجل تطبيقها في المحتوى الدراسي وتمثيله بالفيديو اعتمدت على power point لشرح ذلك..لم أقرض على الطلاب أي وسيلة بل اريتهم مختلف الوسائل وهم أحرار...نتيجة التعلم ايجابية</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>أفكار جميلة</p> <p>مفضل 2</p> <p>تعليق واحد</p> <p>مجهول 26</p> <p>أضف تعليق</p>	<p>يستغرق تطبيق تكنولوجيا المعلومات والتعلم الكثير من الوقت. ومع ذلك ، أنا حريص على معرفة كيفية استخدامه</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>دورة رائعة</p> <p>1 مفضل</p> <p>أضف تعليق</p>
<p>استعمال شرائح العرض والفيديو و تعزيزها بتمارين تفاعلية</p> <p>أعتقد أن شرائح البوربوينت والأشرطة (الفيديو) المعززة بالتمارين التفاعلية لها أثر كبير في العملية التعليمية، تقيد المتعلم ويسهل على الأستاذ ضبطها واستعمالها.</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>مقاطع الفيديو تعزز ايصال المعلومه بطريقه جذابه وممتعه</p> <p>لبد من المعلم ان يتعلم فنون التصميم ليبدع بالمقاطع</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>حاليا شرائح أو رسوم متحركة</p> <p>أرى أفضل تقديم شرائح بـ Adobe Spark أو رسوم متحركة بـ animaker .</p> <p>أرى أنها عناصر ممتازة. عندما نتمكن من الحصول المعرفة اللازمة ، سأطلب تصميم موقع ويب.</p> <p>3 مفضل</p> <p>أضف تعليق</p>	<p>ممتاز</p> <p>ممتاز</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>استخدام الصور ومقاطع الفيديو التعليمية بالإضافة الى المقاطع او الصور الترفيحية تساهم في زيادة الدافعية لدى الطلبة وتسهل عليهم التعلم والتذكر</p> <p>1 مفضل</p> <p>أضف تعليق</p>
<p>حسن</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>مقاطع الفيديو تعزز ايصال المعلومه بطريقه جذابه وممتعه</p> <p>لبد من المعلم ان يتعلم فنون التصميم ليبدع بالمقاطع</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>أصبح برنامج ActivePresenter لتسجيل الشاشة صوت وصورة</p> <p>2 مفضل</p> <p>أضف تعليق</p>	<p>س</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>عمل جيد</p> <p>1 مفضل</p> <p>أضف تعليق</p>
<p>عرفان</p> <p>2 مفضل</p> <p>أضف تعليق</p>	<p>كيفية استغلال وقت الفراغ المتاح لنا نتيجة الحجر الصحي</p> <p>قدم فيديو لا يزيد عن 5 دقائق تشرح فيه طرق للاستفادة بوقت الفراغ الحالي</p>	<p>فريق مايكروسوفت</p> <p>0 المفضلة</p> <p>أضف تعليق</p>	<p>عمل جيد</p> <p>1 مفضل</p> <p>أضف تعليق</p>	<p>0 المفضلة</p> <p>أضف تعليق</p>

Large-scale online courses to orchestrate collaborative knowledge development by education professionals

padlet

Eileen Kennedy • 8d

Posts from observation skills padlet on Edraak

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

تجهيزات ال
شادي نجيب
من أكبر المشاكل في محيطي هي عدم تجهيز صفايات الأمطار في الطرق ومنظومة الصرف الصحي أو تجهيز أماكن الانتظار للمواصلات العامة بمظلات الحماية من المطر او الشمس . إضافة لعدم جودة الاسفلت في الطرق السريعة والكباري مما يسبب وجود نقر وحفر وتشوهات في الطرق بفعل عربيات النقل .

تجهيزات ال
One of the biggest problems in my environment is the lack of processing of rain storms in the roads and the sewerage system or the processing of waiting areas for public transport umbrellas protected from rain or sun. In addition to the lack of quality asphalt in highways and bridges, which causes the existence of tapping and digging and distortions in the roads by transport vehicles.

مهدى الحمصي
ان وجود سيارات مركونة على الرصيف مع وجود اصحاب محال يعرضون سلعهم على الرصيف امر يؤدي الى ازدحام الرصيف مع وجود عوائق تؤقر سلباً على ذو الاحتياجات الخاصة

The presence of the sidewalk owners of shops offering their goods on the sidewalk leads to congestion of the sidewalk with the presence of obstacles and afflicts negatively on the special needs

ساشارك بعض الصور من محيطي , حيث يمكنكم مشاهدة كيفية استغلال المجلات و التعدي على الارصفة المعدة خصيصا للمشاة , كما عدم وجود اماكن مخصصة لقطع الشارع وصعوبتها للاشخاص ذوي الاحتياجات الخاصة

التنقل أثناء النهار
The lack of traffic regulation and the lack of pedestrian crossing places cause many accidents for pedestrians, the elderly, children

التنقل أثناء النهار
عدم تنظيم المرور وعدم وجود أماكن

بعض التحديات من حولي
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

The UN Sustainable Development Goals



The future of online learning

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 **covers five areas** listed in PSCI Principles: Ethics, Labor & Human Rights, Health & Safety, Environment and Management Systems.
- 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>



ETHICS



HUMAN RIGHTS AND LABOR



HEALTH AND SAFETY



ENVIRONMENT



MANAGEMENT SYSTEMS



PSCI audit platform overview

Until
July 2020

644
Registered
suppliers

442
Uploaded
audits

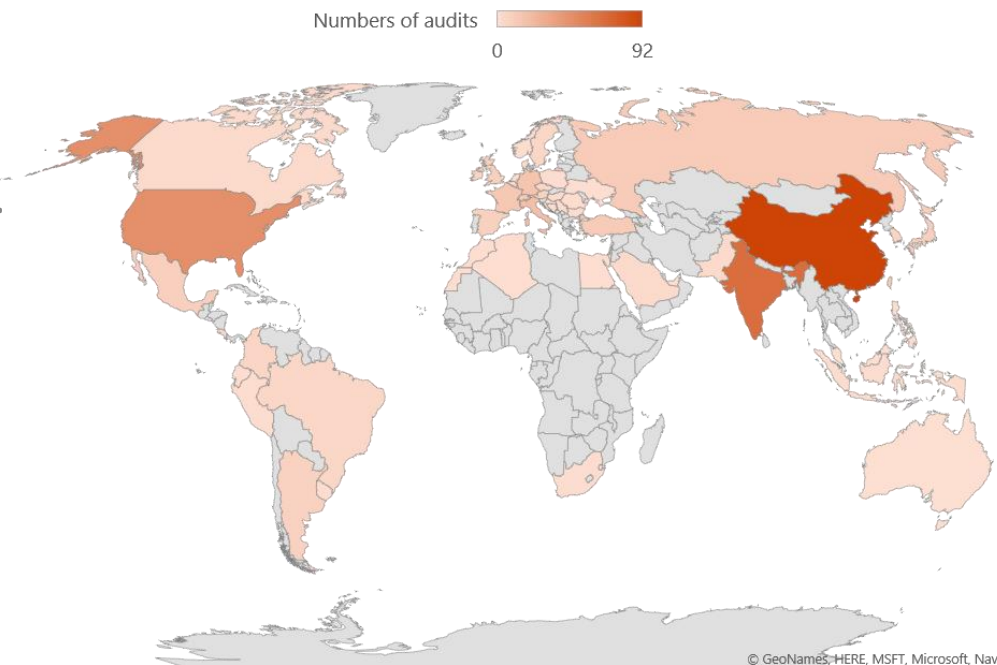
67%
Audited
within 3 years

66%
Shared
audits

2200+
Audit downloads

- 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%).

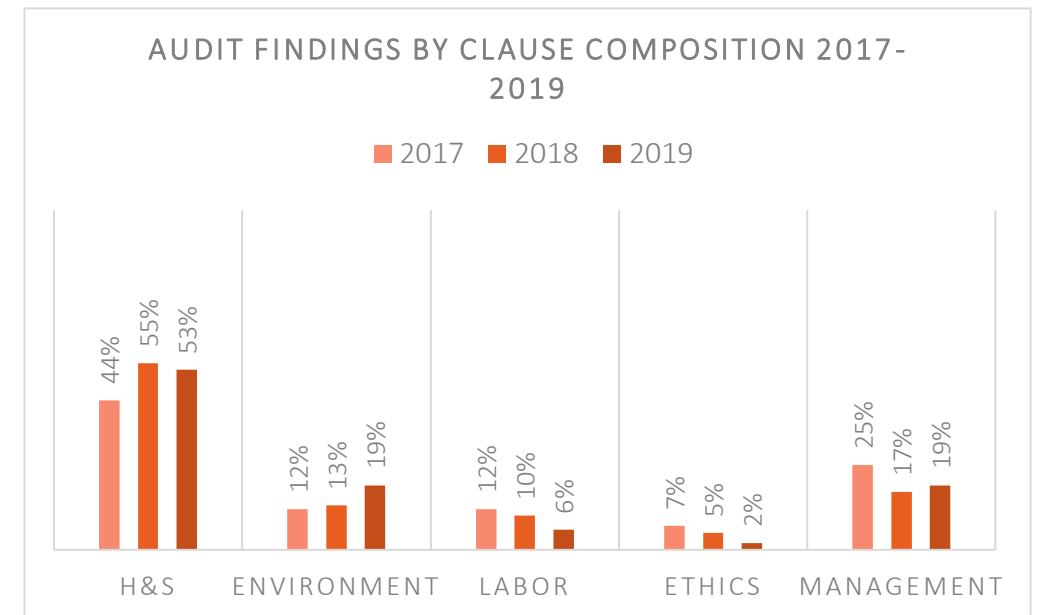
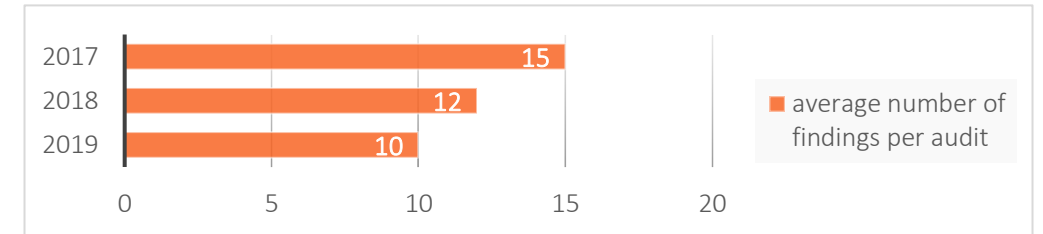
Audits distribution (until July 2020)



Powered by Bing
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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.



Critical = immediate attention required

Finding classification	2017	2018	2019
Critical*	1%	1%	1%
Major	4%	16%	14%
Minor	2%	22%	44%
Other	92%	61%	42%

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:

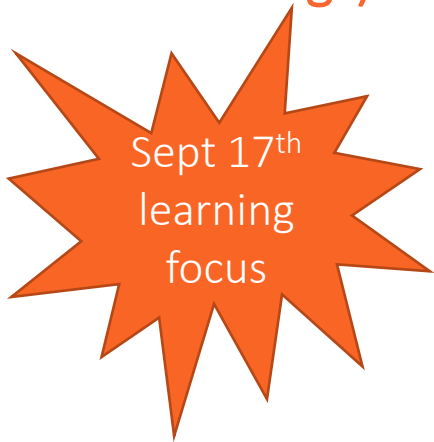
- No refresher training for ethics training
- No formal grievance process

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?

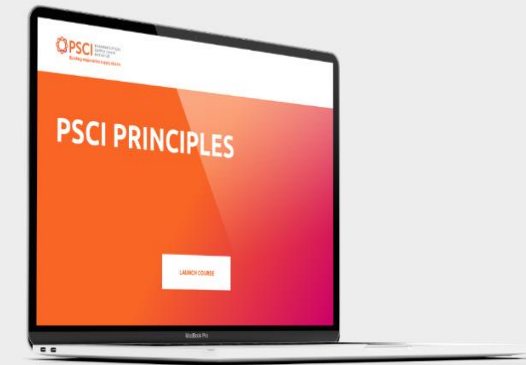
PSCI Audit Resources: Under What we do...

 Document ABBREVIATED PSCI SAQ & AUDIT REPORT TEMPLATE FOR SERVICE PROVIDERS & GENERAL MANUFACTURERS (EXCEL VERSION) 	 Document ABBREVIATED PSCI SAQ & AUDIT REPORT TEMPLATE FOR SERVICE PROVIDERS & GENERAL MANUFACTURERS (WORD VERSION) 
 Document AUDIT GUIDANCE FOR PSCI AUDITS 	 Document CORRECTIVE ACTION PLAN TEMPLATE (WORD VERSION) 
 Document AUDIT GUIDANCE FOR PSCI AUDITS 	 Document CORRECTIVE ACTION PLAN TEMPLATE (WORD VERSION) 
 Document DATA SHARING AGREEMENT 	 Document FULL PSCI SAQ & AUDIT REPORT TEMPLATE FOR CORE SUPPLIERS, EXTERNAL MANUFACTURERS, COMPONENT AND MATERIAL SUPPLIERS (EXCEL VERSION) 
 Document FULL PSCI SAQ & AUDIT REPORT TEMPLATE FOR CORE SUPPLIERS, EXTERNAL MANUFACTURERS, COMPONENT AND MATERIAL SUPPLIERS (WORD VERSION) 	 Document PRE-AUDIT DOCUMENT REQUEST LIST 
 Document PSCI AUDITOR EVALUATION TOOL 	 Document PSCI SHARED AUDIT PROGRAM BROCHURE 

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>



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

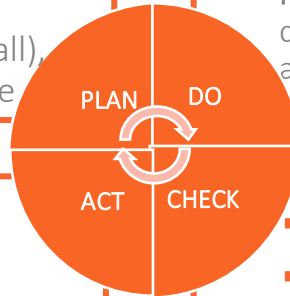
Key focus areas to ensure a holistic approach to our pandemic response...

- 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

- 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

- 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

- **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.



Photo – partitions provided in buses

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

Example 2 – Phases of response



Monitoring and Pre-Impact Phase

No known case, or isolated cases in the country / state



Screening/Protection Phase

Multiple confirmed case(s) in country or localized outbreak in the local community in the vicinity of the site



Active Case Phase

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



Phased Resumption Post Pandemic Peak

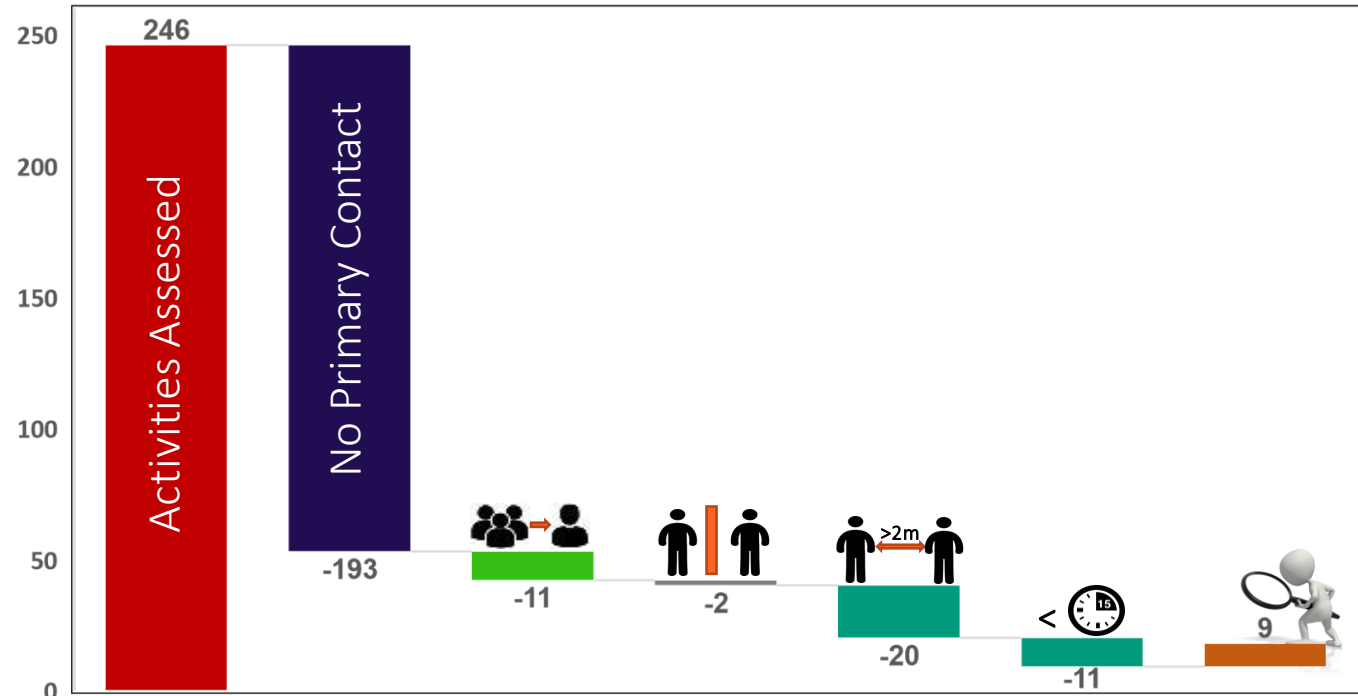
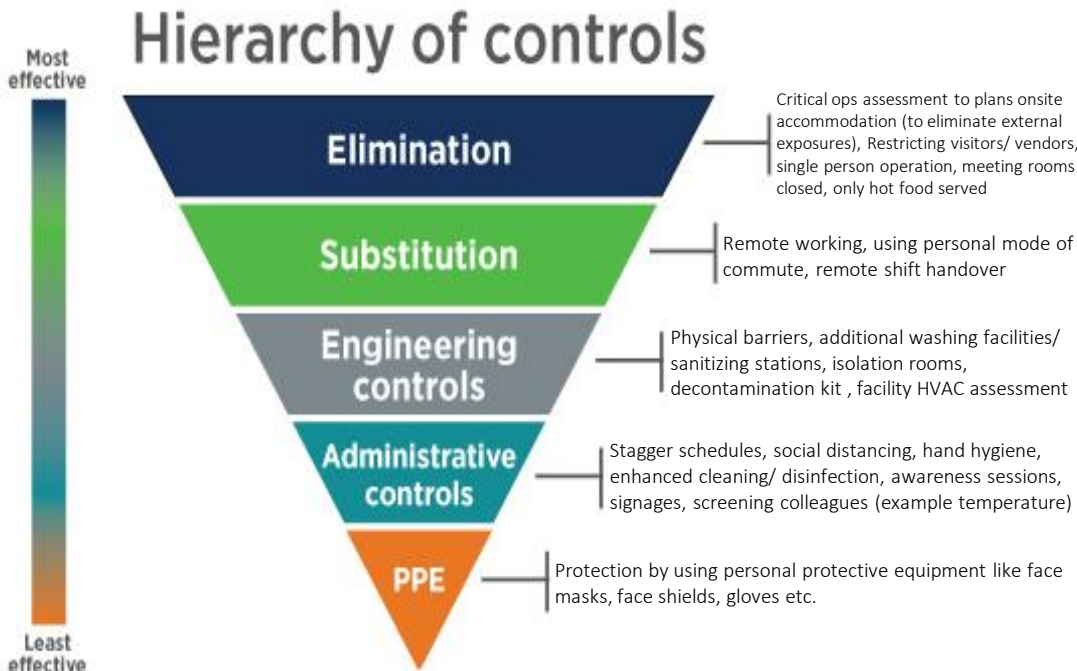
Focuses on the planning for phased resumption of business operations and easing of restrictions limiting personnel at sites

Closely linked with local community transmission status

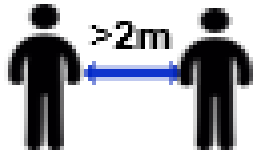
Example 3 – Risk Assessment to minimize onsite primary contacts



COVID-19: Site Operations - Primary Contact Assessment & Mitigation								
Sl.No	Department	Activities	No. of persons working/involving	Zero Primary contacts (Yes/ No)	If No What additional controls required	Mitigation/Remarks	Pre implementation	Post implementation



Example 4 – Controls to increase social distancing



Team working on a project with digital support



Queuing at entry



Cafeteria – seating spread out, timing staggered



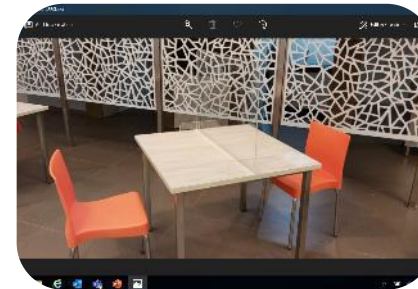
2-screens setup for simultaneous calibration



Partitions in inspection areas



Partitions in manufacturing area



Cafeteria - partition on dining tables



Plexiglass seat partitions in buses

Example 5 – Training and communication

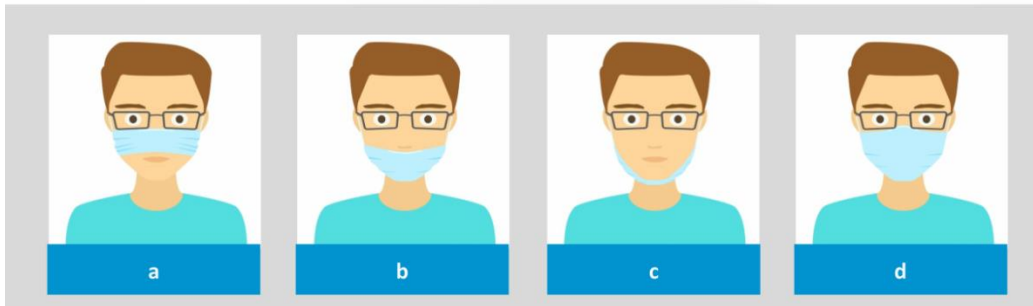
Training

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.



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



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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.

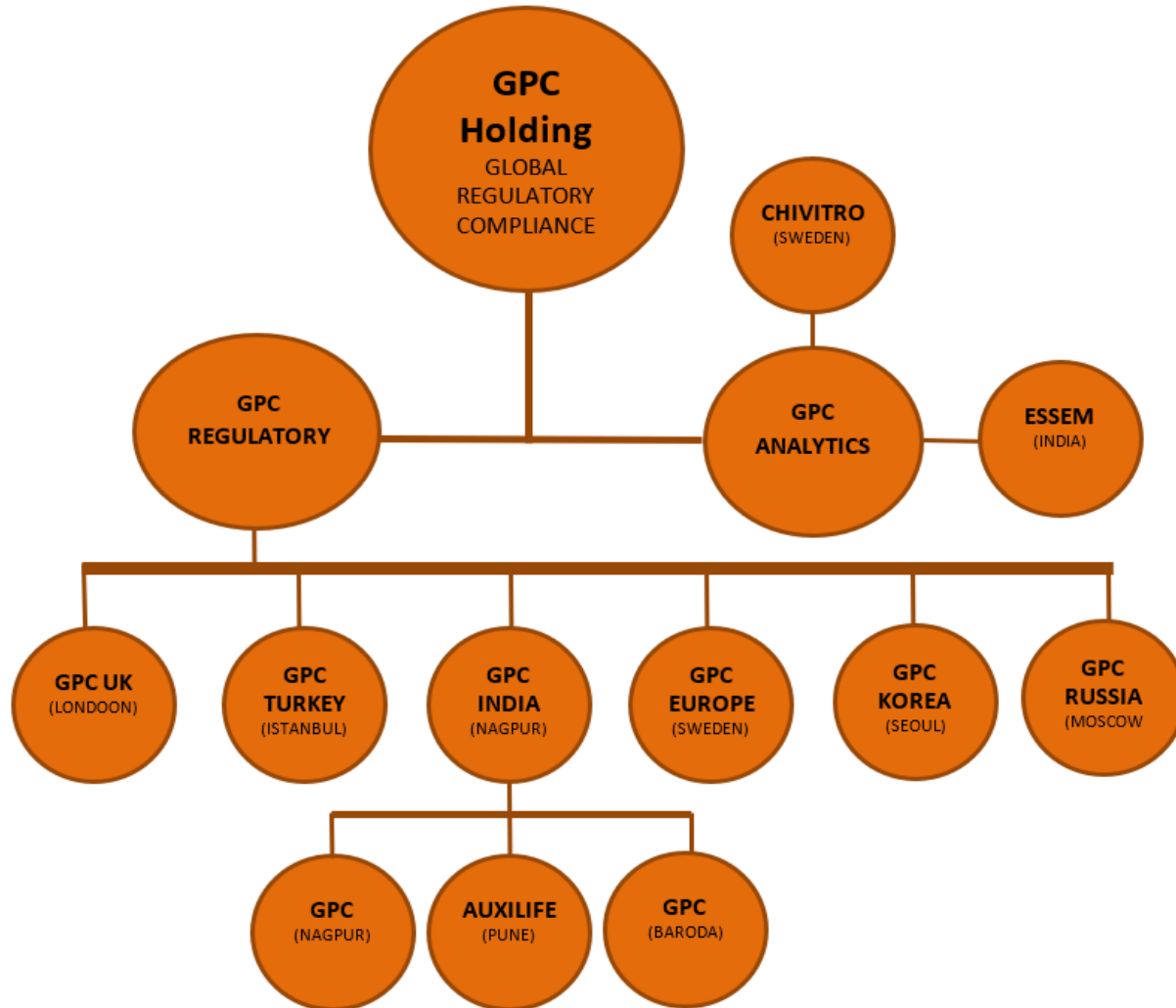
Our over 1000 Happy Clients are a testimony to the great rapport we share with them and the fine quality that we offer in our services. This is also reflected in the fact that we have about 99% customer retention.

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!

GPC Engagement with Indian CMSR



ICMSR – Key words, Objective, Scope, Authorities

Key Words	Substance ; Substance in Mixture; Mixture; Articles; New Substance, Existing Substance; Priority Substance ; Hazardous Substance; Chemical Accident; Intermediates ; Isolated Storage ; Industrial Activity; Occupier ; Manufacturer ; Importer	
Objective & Scope	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	
	Provide safety procedures for the Manufacture, handling and Import of Hazardous Chemicals and preparedness and management of Chemical Accidents; Ensure a high level of protection to human health and the environment.	
Authorities	<p>The National Chemical Authority with 4 key organs to implement the Rules:</p> <ul style="list-style-type: none"> • Steering Committee • Scientific Committee • Risk Assessment Committee • Chemical Regulatory Division 	
	Chemistry Unit Toxicology Unit Chemical Accident Unit Packaging & Labeling Unit	Techno-legal Unit Priority Substance Unit Information Technology Unit Socio-Economic Unit

India Chemicals (Management & Safety) Rules

Chapter	Title
I	Definitions, Objective & Scope
II	National Chemical Authority
III	Notification Registration & Restrictions on Use
IV	Safety & Accident Preparedness
V	Labelling & Packaging
VI	Miscellaneous (Penalties and Enforcement)

India Chemicals (Management & Safety) Rules

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

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

Timeline & Obligation under ICMSR



Notification Of Substances ≥ 1 ton/year



Registration of Schedule II Chemical Substance (**750**) ≥ 1 ton/ year



Evaluation Of files and Substances



Restriction & Prohibition Of Unacceptable Substances



Authorization Of Substances of concern by Committee



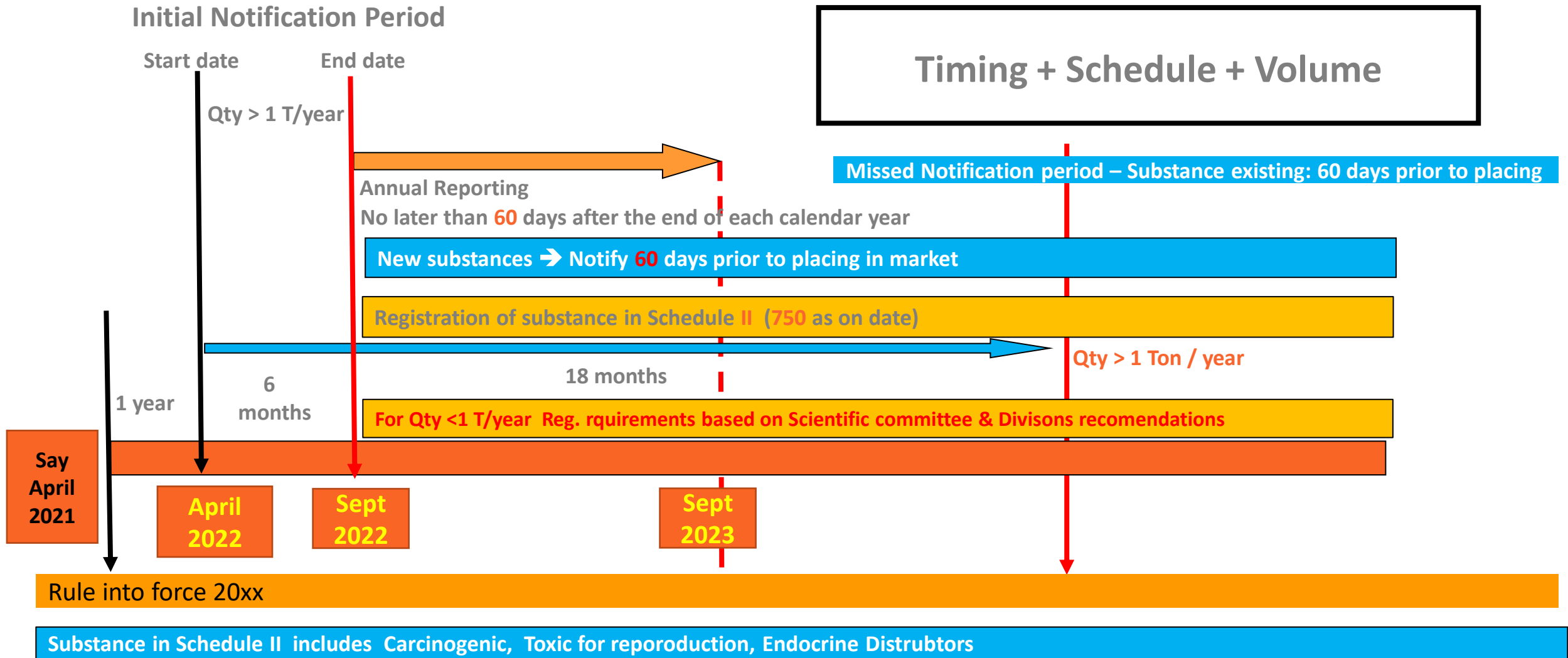
Annual Reporting - No later than 60 days after the end of each calendar year

Information in the supply chain



Chemical Properties & Uses : Up & down - Supply chain

Timeline & Obligation under ICMSR



Fees : Notification & Registration

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

Sr. No.	Rule		Payable entity (MSMEs)	Payable by all other entities	
1	8 (5)	Notification by tonnage band	1-10 TPA	10	25
			10- 100 TPA	30	75
			100 - 1000 TPA	80	200
			> 1000 TPA	250	600
2	10 (10)	Registration by tonnage band	1-10 TPA	15	37
			10- 100 TPA	45	112
			100 - 1000 TPA	120	300
			> 1000 TPA	375	900
3	16 (5)	Request for authorization for use of a restricted substance	1000	1000	
4	17 (3)	Request for confidentiality	5	100	
5	19 (4)	Filing an appeal	10	100	

Fees : Update Notification & Registration

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

Sr. No.	Rule		Payable entity (MSMEs)	Payable by all other entities	
1	8 (5)	Updating tonnage band	From 1- 10 TPA To 10 - 100 TPA	20	50
			From 1- 10 TPA To 100 - 1000 TPA	70	175
			From 1- 10 TPA To > 1000 TPA	240	575
			From 10- 100 TPA To 100-1000 TPA	50	125
			From 10- 100 TPA To >1000 TPA	220	525
			From 100- 1000 TPA > 1000 TPA	170	400

Fees : Joint Registration

Approx.: Fees for Joint Registration per Registrant (RS. '000)				
Sr. No.	Rule	Tonnage band	Payable entity (MSMEs)	Payable by all other Entities
1	10 (10)	1-10 TPA	10	25
		10- 100 TPA	30	75
		100 - 1000 TPA	80	200
		> 1000 TPA	250	600

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



Notify all substances that are placed in Qty > 1 TPA



Notification is not Free



Key data required: Spectra, Hazard Classification, Uses, DU if any, Tonnage Band, Storage Capacity, SDS (Rule 9(2))



Annual update by **1st March** each year – tonnage (actual); new/change information; if tonnage change (fee difference)



Registration within other regulations / Acts – are also required to Notify with ICMS Rules

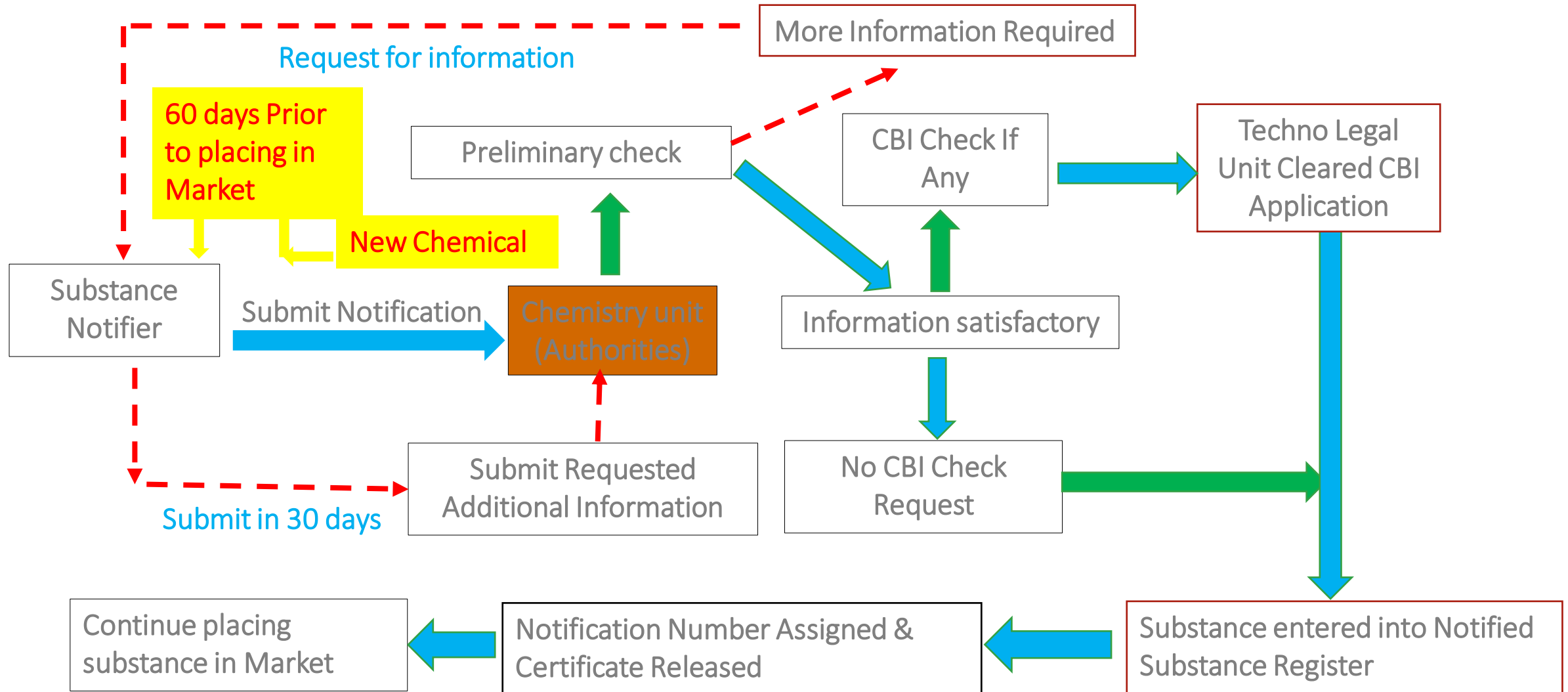


Late Notification

New Substance (**60** days prior to placing)

Existing Substance: **if missed notification window – 60 days prior to placing it in market.**

Notification Process:

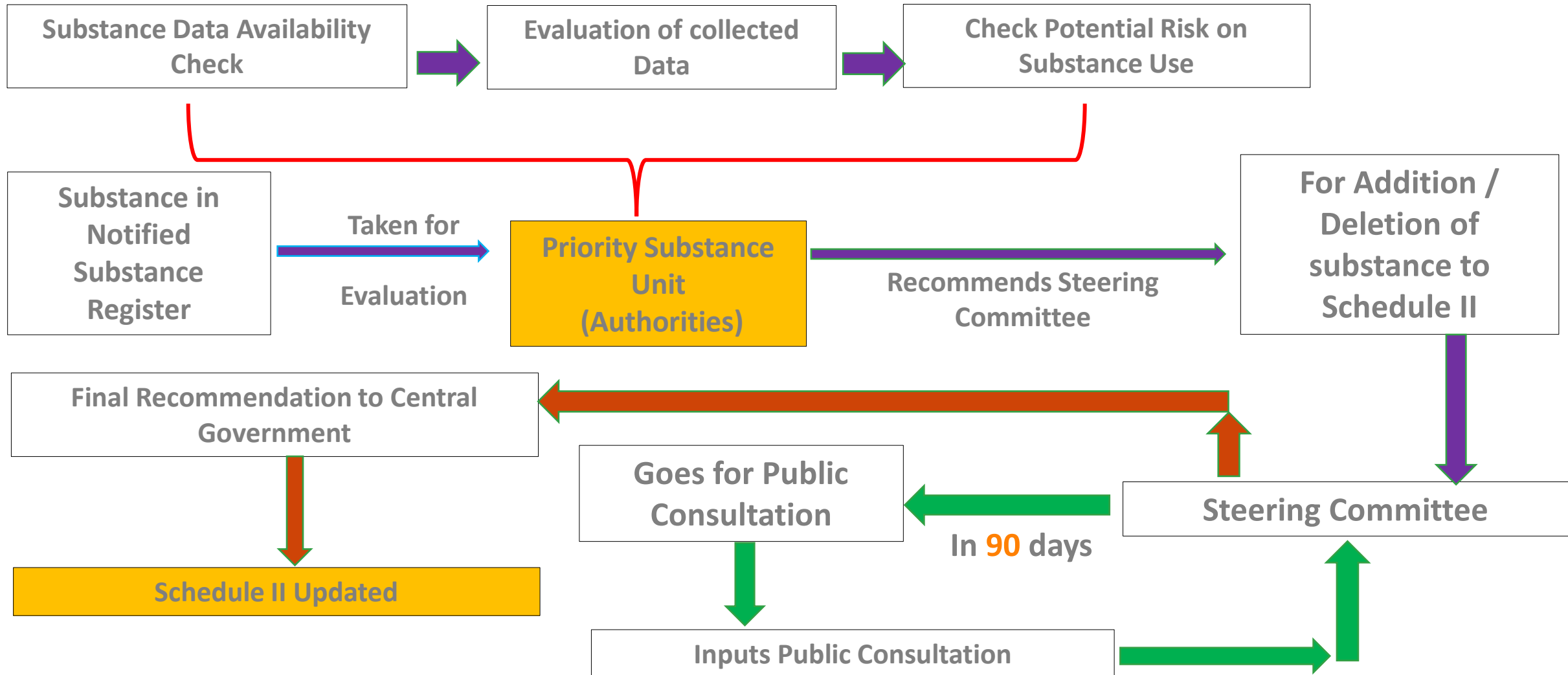


Actionable for PSCI members - Notification

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



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.



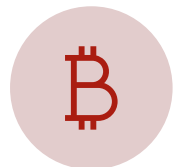
Technical Dossier
needs to be
prepared.



Chemical Safety
Assessment
(report) for > 10
TPA.



Exposure Scenario
Assessment
(report) for < 10
TPA.



Registration fee is
applicable –
Company Size &
Tonnage



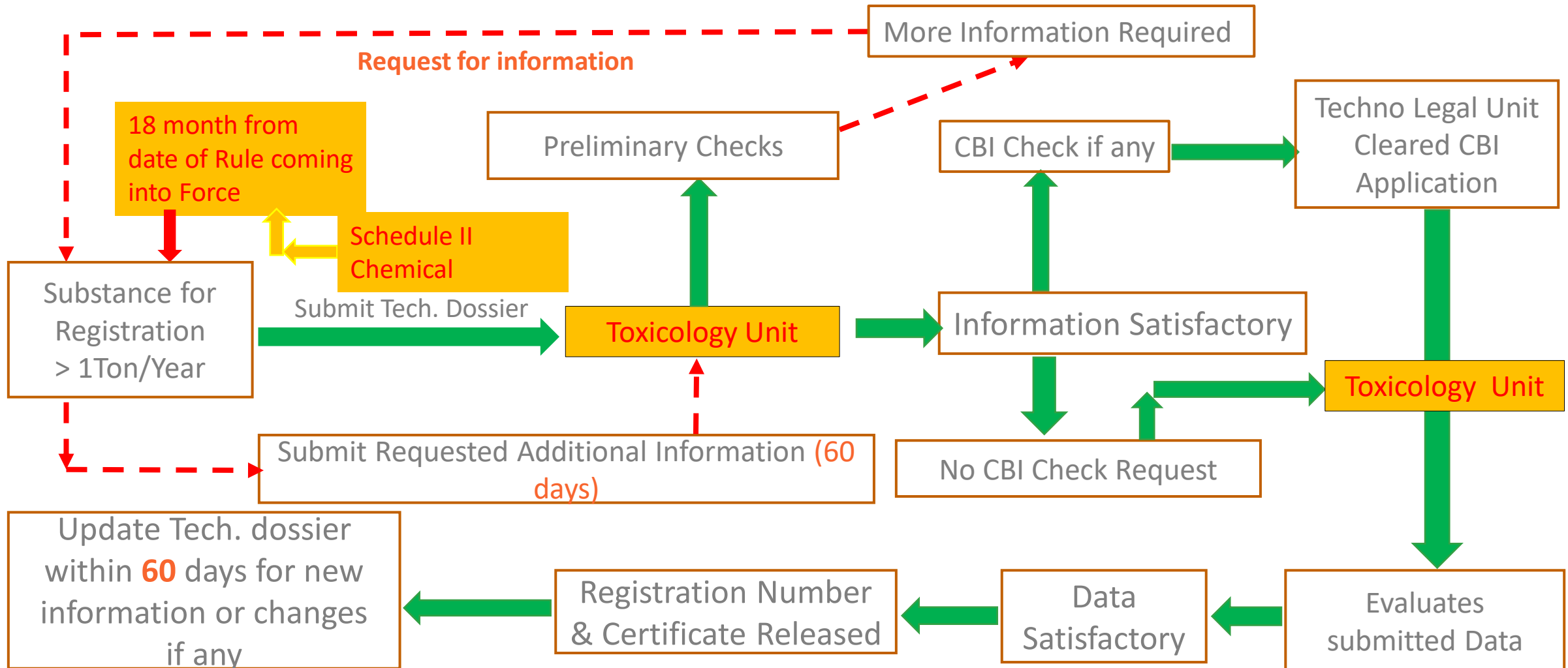
Option to jointly
submitting the
registration,



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



Actionable for PSCI members – Priority Substance



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)

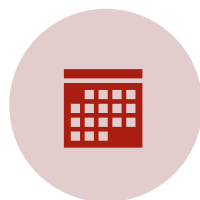
Actionable for PSCI members : Evaluation & Restriction Process



Actionable for PSCI members – Transported Intermediate



Transported Intermediates - Substances listed in Schedule II



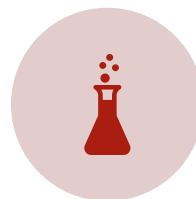
< 1000 TPA (Only Phys - Chem data in Technical Dossier)



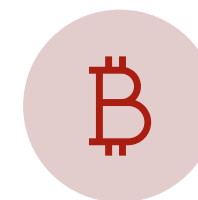
> 1000 TPA (full Registration and Chemical Safety Report)



Intermediates not in Schedule II



No Registration obligation



Only Notification obligation

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

Actionable for PSCI members – Occupier Notifies Industrial Activity



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)

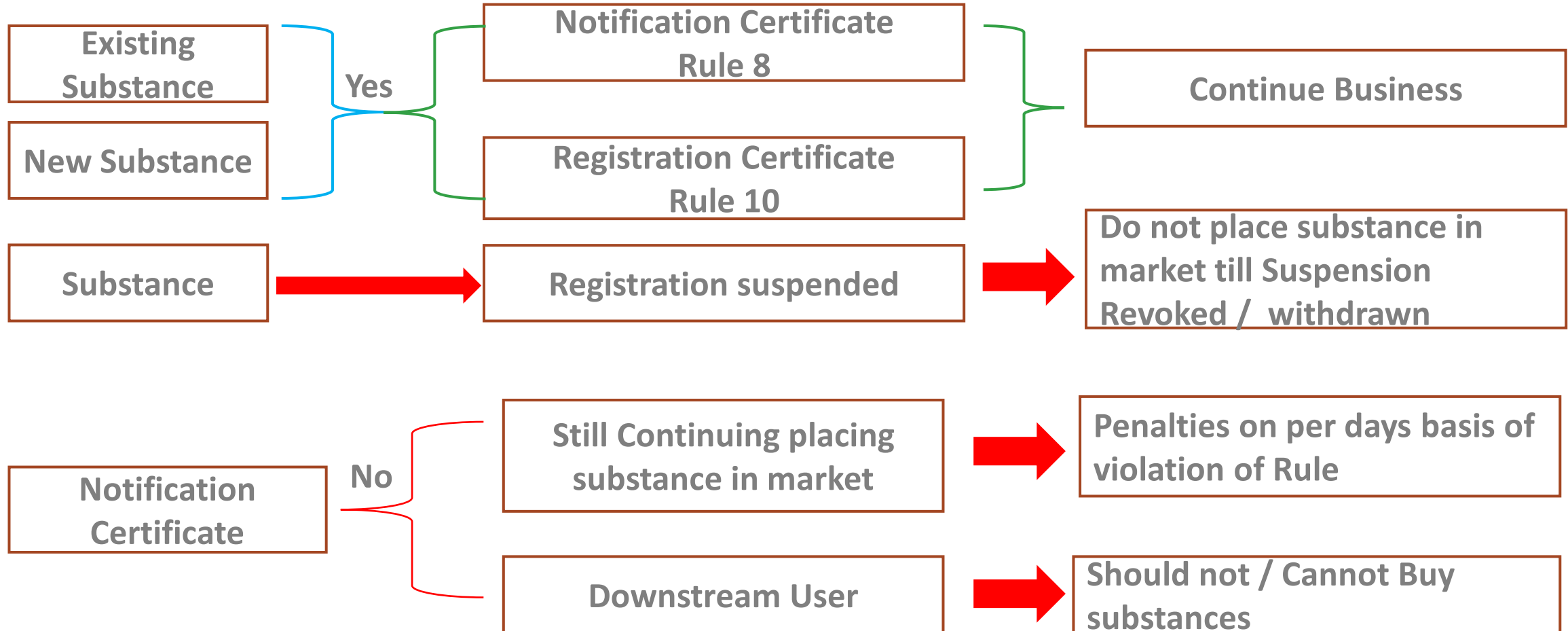


Onsite / off-site Emergency Preparedness Plan within 3 months; (on-site - mock drill every 6 month)



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



Do not Miss Notification & Registration Deadline once The Rule is into Force!



Safety Culture- J&J Perspective

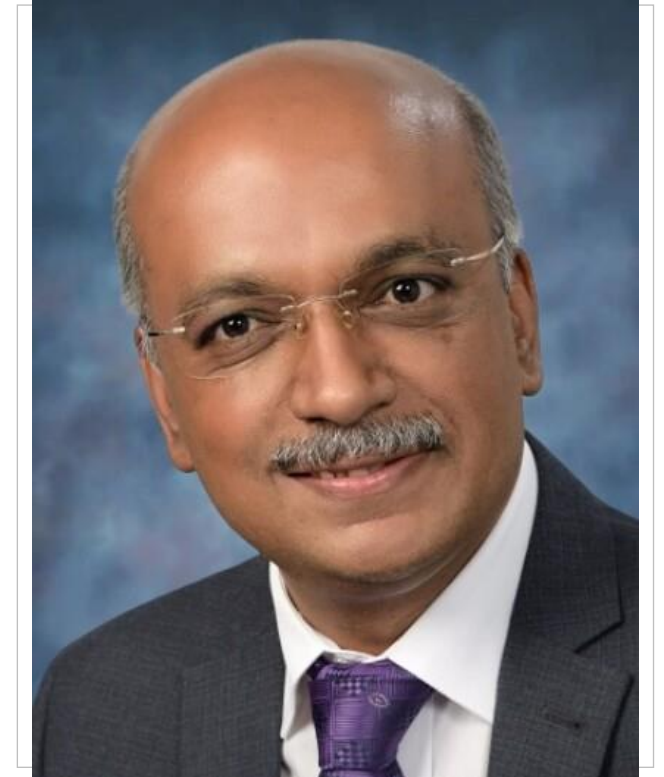
Dr. Raju Ingale

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

Head - What



Heart - Why



Hands - How



Life Saving Rules

Johnson & Johnson

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

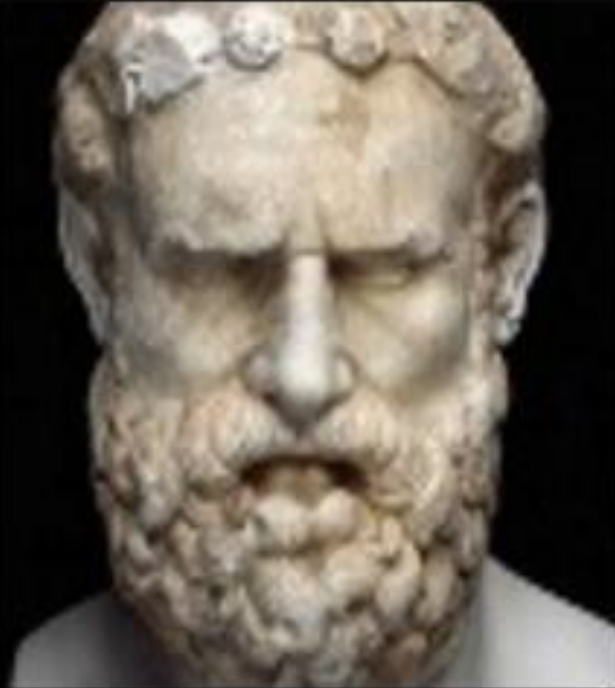


Never walk under a suspended load



Never use powered industrial vehicles unless authorised and only in an authorised way

Often in many situations... ..



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

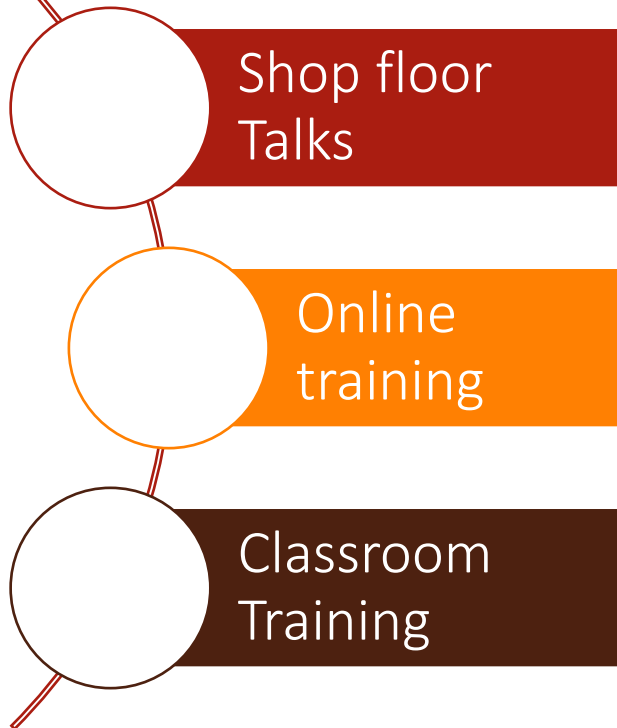
~ Archilochus

AZ QUOTES

Need for Tool-Box Talks



Modes of Conventional Training Methods in the Shop floor



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

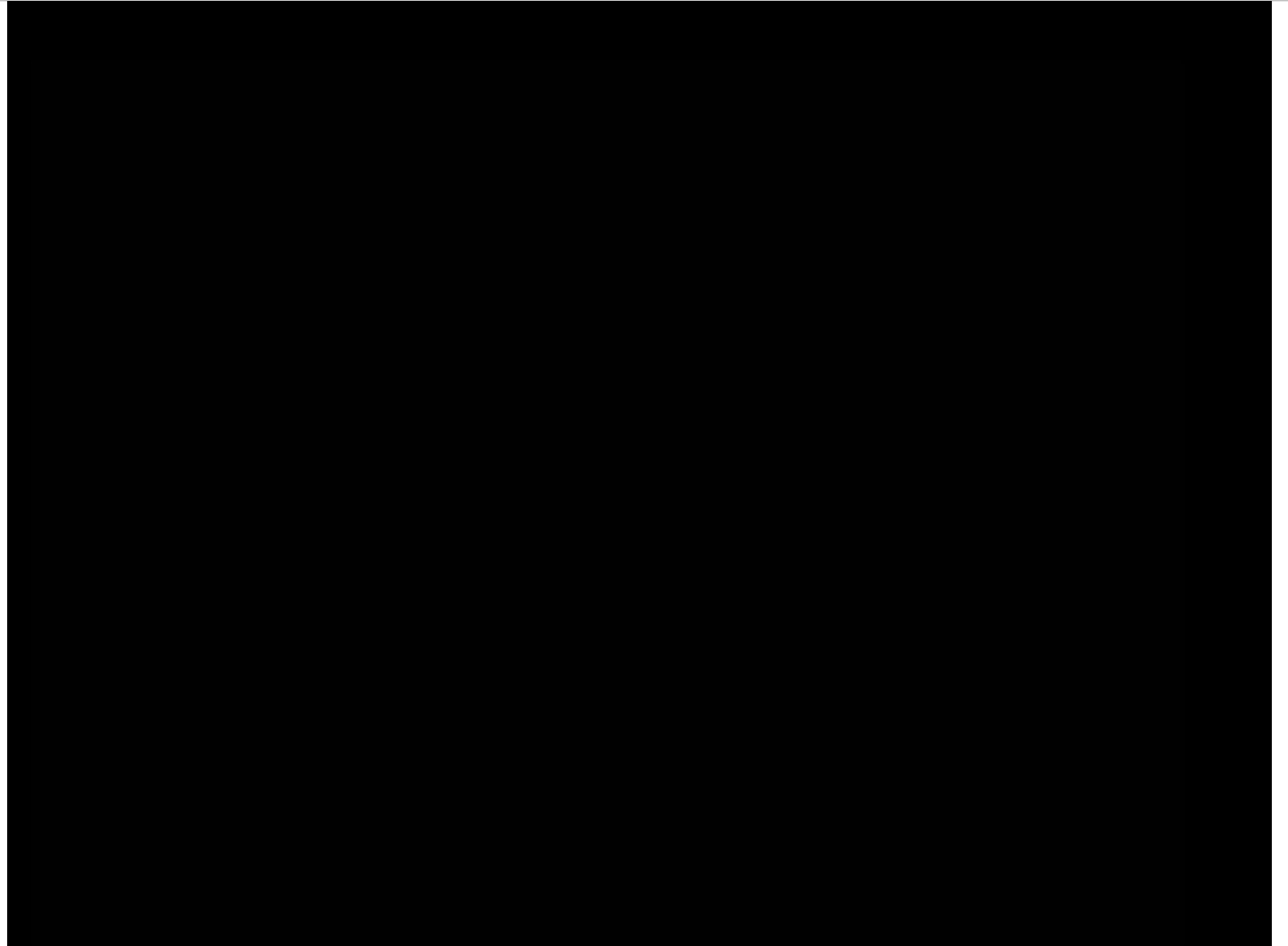


Why NAPO?

- 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

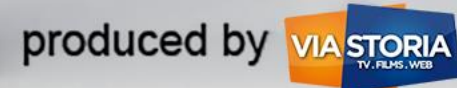
NAPO videos depicts hazards and risks very intuitively

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:



“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

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

Now aligned with the four-tier PSCI common framework

Maturity Model...

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

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

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

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

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

Areas of Concern from PSCI Assessments

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

Common Gaps in Management Systems from PSCI assessments

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

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!

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About the Secretariat

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

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