PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI中国供应商线上会议2020

PSCI Virtual China Supplier Conference 2020

PSCI 最新发展和管理体系环节

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.

会议须知 Practicalities

- 视频直播可切换为仅音频 Switch to audio feed only for better connection
- 茶歇 Breaks
- 提问环节：请在直播页面点击Q&A下的链接向嘉宾提问（密码为PSCIChina）
- 反馈调查 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.

虽然竞争对手之间的一些活动既是合法的，也对行业有利，但在我们公司有业务的美国、英国及其他国家的反垄断/反竞争法下，竞争对手的集体行动天生会受到怀疑。竞争对手之间的协议不需是正式的以造成反垄断法下的问题，但可包括任何正式或非正式，隐秘或公开形式的谅解，从而使得每位参与者都有理由期望，其他参与者将遵循一个特定的行动或行为路线。本次会议的每位参与者有责任注意，对任何看起来有可能像是违背反垄断法的协议的主题都将不予讨论。每位参与者也有责任，在第一时间避免提起不当的、如以下所指定的讨论主题。

本次会议的唯一目的是，提供一个对议程中所列出的主题表达各种观点的论坛，并且参与者应紧紧围绕这一议程进行讨论。在任何情况下，都不许将本次会议作为一种手段，让竞争公司之间达成任何明示或暗示的的谅解，从而趋向于限制竞争，或以任何可能的方式削弱成员就影响竞争的事宜行使其独立的业务判断能力。

应当特别避免的讨论主题是：

（一） 限价；
（二） 产品折扣、回扣、定价政策、生产水平或销售和市场营销条款、以及客户和地域分配；
（三） 标准设置（如果其目的是限制产品的供应和选择，限制竞争，限制进入某一行业，阻碍创新或抑制竞争对手的竞争能力）；
（四） 以一种可能抑制或限制竞争的方式管理道德准则的实施；
（五） 集体抵制；
（六） 专利有效性；
（七） 正在进行的诉讼；
（八） 特定的研发、销售和市场营销活动或计划，或保密产品、产品开发、生产或测试策略或其它专有知识或信息。

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

制药供应链组织PSCI
THE PHARMACEUTICAL SUPPLY CHAIN INITIATIVE (PSCI)

介绍

An Introduction

AGENDA 议程

THE VISION & INTRODUCTION 愿景及介绍

MEMBERSHIP 我们的会员

THE CHALLENGE 我们面临的挑战

PSCI PRINCIPLES & HOW WE WORK PSCI原则和工作方式

WHAT WE DO 我们做的事情

OUR IMPACT & 2020 HIGHLIGHTS 我们的影响力 & 2020年亮点

ADVISORY PANEL & PARTNERS 顾问组和合作伙伴

WE WILL HELP YOUR SUPPLY CHAIN! 我们将帮助您的供应链!

Speaker Bio嘉宾介绍

- **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.
- Caroline is also an experienced Safety, Health and Environment professional undertaking sites audits for both internal and external supply network.

- **Caroline O'Brien** PSCI主席
- 阿斯利康 (AstraZeneca)全球质量审计-亚太区总监，目前位于日本大阪, 负责管理亚太团队以及阿斯利康生产工厂、承包商和供应商的审计，尽职调查和其他需要专业经验的审计。
- 此前，曾担任运营合规总监，其职责包括制定和领导全球运营和供应链中合规策略的实施。
- Caroline还是一位经验丰富的安全、健康和环境专业人士，负责内部和外部供应网络的现场审核。

PSCI: THE VISION PSCI愿景

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.

我们的愿景是建立和促进负责任的做法，这些做法将不断地改善我们供应链中的道德，人权与劳工，健康，安全和环境可持续成果。

THE MEMBERSHIP 我们的会员

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

45家会员组织已经认可PSCI愿景并承诺在其供应链中推动持续改善

Members as of August 2020
截止至2020年8月的会员组织

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

THE CHALLENGE 我们面临的挑战

ADDRESSING THE CHALLENGE 应对挑战

INTERNATIONAL STANDARDS / FRAMEWORKS
国际标准/框架

International Labour Organization

THE GLOBAL GOALS
For Sustainable Development

CAMPAIGNS
运动与风潮

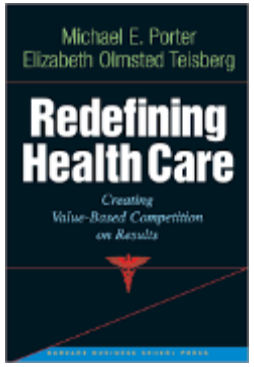
Nordea

Sum Of + Us

LEGISLATION
法规

THE UK MODERN SLAVERY ACT 2015

PATIENTS & VALUE BASED HEALTHCARE
患者和基于价值的保健



PRESSURE FROM BUYERS
来自买家的压力

SPHS
INFORMAL INTERAGENCY TASK TEAM

NHS

ADDRESSING THE CHALLENGE 应对挑战

THE PSCI PRINCIPLES PSCI原则

ETHICS 道德

- Anti-bribery and corruption 反贿赂和贪污
- Fair competition 公平竞争
- Animal welfare 动物福利
- Data privacy and security 数据保护和隐私
- Patient safety and access to information 患者安全与信息获取
- Avoidance and management of conflicts of interest
  利益冲突的避免和管理

HUMAN RIGHTS AND LABOR 人权与劳工

- Freely chosen employment 自由选择的工作
- No child labor 不使用童工
- Legal treatment of young workers 合法对待青年工
- Non-discrimination 反歧视
- Fair treatment 公平待遇
- Wages, benefits and working hours工资，福利和工时
- Freedom of association
  结社自由

HEALTH AND SAFETY 健康安全

- Worker protection 工人保护
- Process safety 工艺安全
- Proper control of合理管控危险化学物 hazardous substances
- Emergency preparedness and response 危机准备和应对
- Communication of hazard information
  危险信息的沟通

ENVIRONMENT 环境

- Environmental authorizations and reporting 环境资质和报告
- Management of waste and emissions 废弃物和排放的管理
- Spills and releases prevention 溢出和泄露预防
- Resource efficiency资源利用效率
- Sustainable sourcing and traceability 可持续采购和可追溯性
- Managing the release of pharmaceuticals into the environment
  管理释放到环境中的药物

MANAGEMENT SYSTEMS 管理体系

- Commitment and accountability 承诺和问责制
- Legal and customer requirements 法律和客户要求
- Risk management 风险管理
- Documentation 文档记录
- Training and competency培训和竞争力
- Continual improvement 持续改进
- Identification of concerns 识别问题
- Effective communication
  有效沟通

HOW WE WORK 我们的工作方式

Plus, 15 topic-specific Sub-Teams
另外还有15个特定主题的子小组

WHAT WE DO 我们的工作方式

- A common voice for our industry. 我们行业的共同声音。
- **Set expectations** for ethics, labour, health & safety, environment, management systems (The PSCI Principles & Implementation Guidance). 设定对道德，劳工，健康与安全，环境，管理体系的期望（《PSCI原则与实施指南》）。
- Build supplier capability **建立供应商能力**
  - Conferences 供应商会议
  - Resource library 资源库
  - Webinars 网络研讨会

我们在2019年举办了7场网络研讨会，在2020年迄今为止举办了8场网络研讨会。今年，我们总共吸引了450多名观众。

- Define common **supplier assessment tools** (audit framework, SAQ, …). 定义通用的供应商评估工具（审核框架，SAQ等）
- **Audit and promote audit sharing** to reduce burden on the industry and drive continuous improvement. 审核并促进审核共享，以减轻行业负担并推动持续改进。

ACCELERATING OUR DIGITAL OFFERING
加速我们的数字化进程

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

右边的数据将2019年与上一年进行了比较。 如您所见，我们的影响力持续增长。

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).

2020年，为了响应COVID-19，我们加快了资源的数字化进程，提供了线上会员会议和供应商会议，并为供应商启动了社区平台（更多信息请参见下一页）。

- As a result, we expect to report even higher engagement in 2020.
  因此，我们希望2020年参与度更高

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
THE LINK: 社区平台

Our online platform for members and suppliers 我们的会员和供应商在线平台

For suppliers 对于供应商来说:

- Hear and comment on the **latest industry news** 获取并评论最新的行业新闻
- Share audits with multiple PSCI members 与PSCI会员客户分享审核报告
- Access **tools, training** and other **resources** 访问工具，培训和其他资源
- Register for **events and activities** 报名活动和会议
- Check out the latest work of PSCI 了解PSCI最新的工作成果和动态

BUILDING A SUPPLIER COMMUNITY 建立供应商社区

The Link isn't just for members. The Link for Suppliers provides the following benefits to our supplier community The Link社区平台不仅仅针对会员，供应商Link平台为我们的供应商提供以下好处:

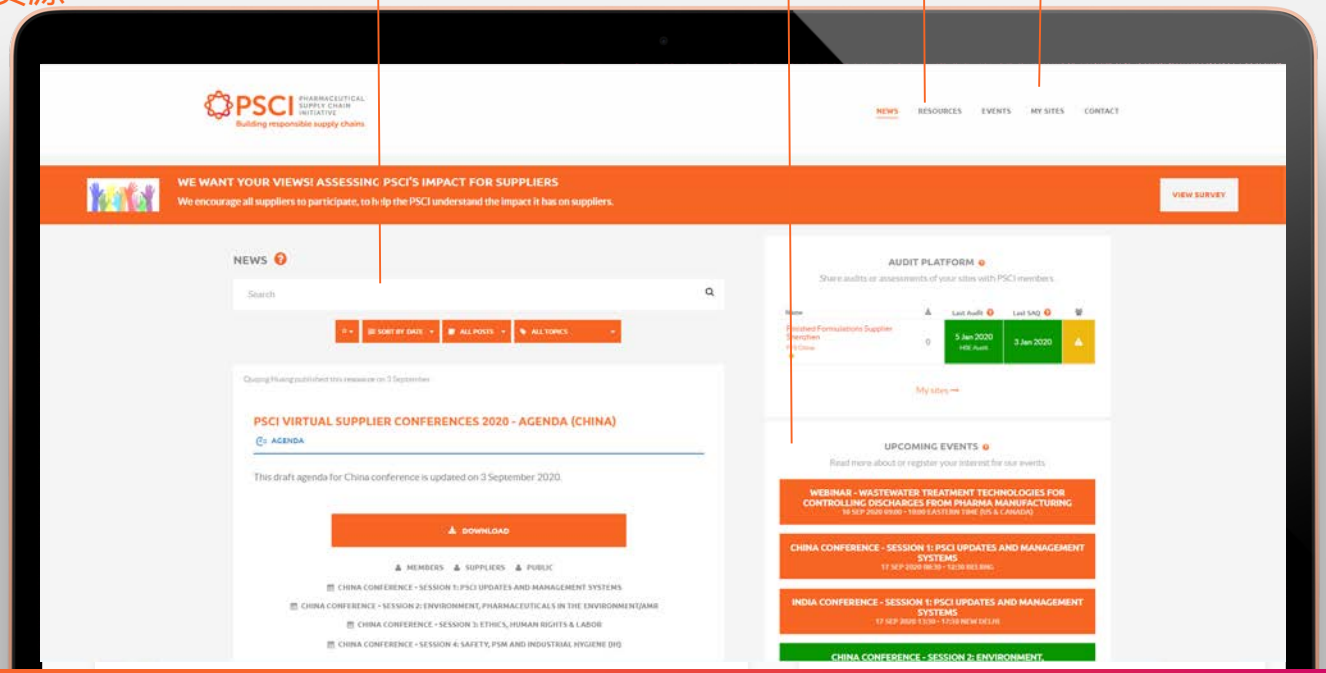
- Gain greater visibility and control over **shared supplier audits**
  更好地了解和管理共享的供应商审核
- Be the first to hear about PSCI developments and updates to audit tools
  第一时间了解PSCI开发和审核工具的更新
- Access **PSCI tools, trainings and resources**, improving their capabilities and knowledge of responsible supply chains 访问PSCI工具，培训和资源，提高其能力和负责任供应链的知识

FIND TRAINING AND TOOLS 查看培训和工具

REGISTER FOR PSCI EVENTS AND WEBINARS 报名 PSCI 活动和会议

MANAGE SITE INFORMATION AND SHARE AUDITS 管理工厂信息和上传并分享审核报告

VIEW AND SHARE THE LATEST NEWS 查阅最新行业和 PSCI 新闻



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2020 HIGHLIGHTS 2020年亮点

- **Two regional teams** formalized – one in India & one in China 正式成立了两个区域团队-一个在印度，一个在中国
- 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. 我们为印度和中国的供应商举办了首届全线上供应商大会，并举办了首届全线上会员会议，吸引了来自44家成员公司的140多名与会者。
- 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! 推出The Link，这是我们为会员和供应商提供的最新的最新社区和审核共享平台，可以访问所有PSCI资源，新闻，培训，审核以及更多内容!
- A project to support the **revitalization of the Musi River area** in Hyderabad, India 支持印度海得拉巴穆西河地区复兴的项目
- A project on pharmaceutical **raw materials human rights impact** 制药原料人权影响项目
- Developed topic **focussed maturity models** and **training curricula** for suppliers 为供应商开发了针对主题的成熟度模型和培训课程

2020 HIGHLIGHTS 2020年亮点

- **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). 更多的网络研讨会涵盖了广泛的话题（计划2020年为11个，2019年为7个，2018年为3个，涉及全球数百个成员和供应商）
- Building **partnerships** and engaging with external stakeholders including through our excellent **Advisory Panel** 建立合作伙伴关系并与外部利益相关者互动，包括通过我们出色的专家顾问团
- Roll-out of **peer-to-peer mentoring** scheme. 推出会员间导师方案
- Continuing to build on solid **membership growth**, particularly welcoming mid-sized pharma companies, and consequently **expanding our Board** from 5 to 7 Directors. 继续依靠稳固的会员人数增长，特别是欢迎中型制药公司，并因此将董事会从5名董事扩大到7名董事。

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

欢迎辞：PSCI中国小组
Welcome from China sub team

张怡 Yi Zhang
PSCI中国小组领导团成员，EHS&S外部供应商经理，强生（中国）
PSCI China sub team co-lead, EHS&S Manager External Supply, Johnson & Johnson

AGENDA 议程

China sub team overview 中国小组介绍

PSCI Partners in China PSCI在中国的合作伙伴

PSCI Wechat PSCI微信公众号

Supplier Self-Initiated Audits 供应商自发审核

The Link for Suppliers 供应商社区平台 – The Link

嘉宾介绍 Speaker Bio

目前公司职位：强生EHS&S 外部供应商经理
11年EHS从业经历， 5年杜邦工厂，3年半西门子供应链。
主要职责：提升和改善本地EHS能力，实施积极的风险识别及缓解措施。

教育背景：同济大学环境工程硕士
中国注册安全/环境工程师

Zhang Yi – J&J, Manager, EHS&S, External Supply
improving EHS&S management systems and knowledge
developing local EHS&S capabilities
deploying pro-active risk identification/mitigation

- 12 years in EHS, 5 years in Dupont site, 3.5 years in Siemens supply chain
- Major in environment engineering, master, Tongji University, Shanghai
- Certified National Safety/Environment Engineer

PSCI中国小组介绍 China sub team overview

- 来自12家会员公司的26位成员

26 members from 12 member companies: Bayer, BI, BMS, Centrient, Elanco, Gilead, GSK, J&J, Novartis, Pfizer, Sanofi, STA Pharma

- 4位领导团成员 4 co-leads

PSCI中国小组活动 China sub team activities

- 自2018年以来支持中国供应商大会
- 为PSCI自我评估问卷和其他PSCI材料中文翻译提供支持
- 2020年开始向本地供应商提供中文网络研讨会
  - 6月，可燃粉尘 – Tracy Zhou,强生 （已结束）
  - 9/10月，安全领导力
  - 12月/2021年1月，危险反应

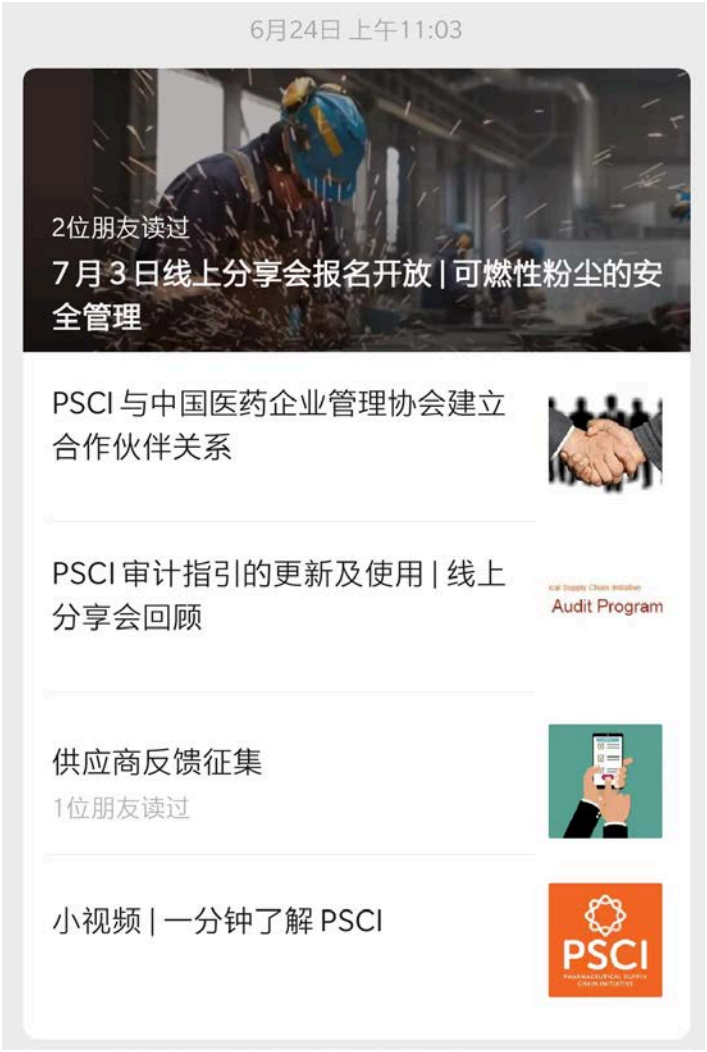
- Support China supplier conference since 2018
- Support translating PSCI Self Assessment Questionnaire and other PSCI materials to Chinese
- Start to deliver Chinese webinars to local suppliers in 2020
  - June, Combustible dusts by Tracy Zhou from J&J (DONE)
  - September/October, Safety leadership
  - December/January, Hazardous reaction

PSCI在中国的合作伙伴 PSCI Partners in China

- 中国医药企业管理协会 (CPEA) & 中国外商投资企业协会药品研制和开发行业委员会(RDPAC) EHS小组
- 积极参与这两个组织的活动
  - PSCI中国小组的两名成员是《医药行业EHS指南》的作者，该指南于2016年在CPEA EHS年度会议上发布。
  - PSCI中国小组代表在每次CPEA EHS年度会议上介绍了不同的材料，例如关于EHS审核，IH管理和EHS管理系统的常见发现。
  - 在CPEA EHS管理专业委员会中担任专家。
  - 在5月于杭州举行的第30届RDPAC EHS组会议上以及6月在上海举行的CPEA EHS管理专业委员会会议上介绍了PSCI。
- 与这两个组织建立了官方沟通渠道。

- CPEA & RDPAC EHS Group.
- Actively involved in activities in these 2 organizations.
  - Two PSCI China group members were writers of an EHS Guidance in Pharmaceutical Industry which was published in 2016 on CPEA EHS Annual Meeting.
  - PSCI China group representatives presented different materials such as common findings on EHS audits, IH Management, and EHS Management system on each CPEA EHS Annual Meetings.
  - Contributed as an expert in CPEA EHS Management Professional Committee.
  - Presented PSCI introduction in 30th RDPAC EHS Group Meeting in May in Hangzhou and in CPEA EHS Management Professional Committee meeting in Jun in Shanghai.
- Built an official communication channel with these 2 organizations.

PSCI微信公众号 PSCI Wechat



欢迎扫码关注

供应商自发审核 Supplier Self-Initiated Audits

供应商自发安排PSCI审核:

- 供应商现已可以自发安排PSCI审核
- 通过使用PSCI审核流程和PSCI认可的审核公司确保审核质量
- 通过在安全的PSCI平台上与客户共享审核报告来减轻审核负担
- 在您方便的时候进行操作，并选择审核范围 – EHS /管理系统和/或道德/劳工
- 积极主动 – 识别风险和改进机会
- 根据PSCI原则改善表现

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: 社区平台

我们的会员和供应商在线平台

对于供应商来说:

- 获取并评论最新的行业新闻
- 与PSCI会员客户分享审核报告
- 访问工具，培训和其他资源
- 报名活动和会议
- 了解PSCI最新的工作成果和动态

建立供应商社区

The Link社区平台不仅仅针对会员，供应商Link平台为我们的供应商提供以下好处:

- 更好地了解和管理共享的供应商审核
- 第一时间了解PSCI开发和审核工具的更新
- 访问PSCI工具，培训和资源，提高其能力和负责任供应链的知识

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

The PSCI 供应商能力建设愿景与规划

我们对供应商学习框架的规划

鲍国祥，内外部环境健康安全审计总监，百时美施贵宝制药（Bristol-Myers Squibb）

*该演讲内容由PSCI能力建设委员会准备

嘉宾介绍

- **鲍国祥** Lamy Bao
  - 现工作于施贵宝制药有限公司，任内外部环境健康安全审计总监
  - 在中美上海施贵宝制药工厂有3年环境健康安全经理经历
  - 先后任职于联邦快递，特灵空调，辉瑞制药
  - 19年环境健康安全工作经验
  - 安全工程硕士毕业，注册安全工程师

我们的发展现状

45 家成员企业每年花费四千亿美元，用于 100,000 余家供应商的采购

供应链企业可持续发展能力及成熟度区别较大 - 部分供应商引领全球实践，部分则处在发展初期

供应商知识储备与技能对可持续发展实践的持续完善至关重要

我们如何设计学习框架及路径以：

- 促进成熟度的提高
- 实现技能发展

The PSCI 的愿景

我们的愿景是建立并推动负责任实践，以实现在伦理与道德、人权与劳工、健康与安全、环境等方面可持续发展的制药及医疗健康行业供应链。

如何实现我们的愿景

- **作为行业引领者共同发声**

- 在伦理与道德、人权与劳工、健康与安全、环境、管理体系方面**设立预期目标**（The PSCI 原则与实践指引）.

- **供应商能力建设**
  - 供应商会议
  - 共享资源
  - 线上研讨会

- 建立统一的**供应商测评工具**（审计框架、供应商自评问卷等）

- **对供应商进行审计并推进审计报告共享机制**以减少行业重复审计的压力并推进持续改进

我们的发展情况

- **供应商培训：**分别在中国及印度举办大型供应商会议，400余家供应商代表参加会议
- **邀请供应商参与，**鼓励同行间的学习并扩大影响力
- 参与欧洲及亚洲的外部活动，共进行十二场**公开演讲**
- 共举办七场线上研讨会，并录制作为供应商学习资源
- 线上资源库内容不断丰富，2019年实现125,000 的下载量

2019年于杭州举办为期三日的中国供应商会议

来自 Takeda 的 Frank Buijs于荷兰 Association of Innovative Medicines 介绍 PSCI

我们对自己的提问

- 我们如何走得更远，并持续改进线上内容的学习架构?
- 如何结合线上及线下培训?
- 我们如何实现规模及影响力的指数型增长?
- 如何平衡组织机构的学习与个人学习?
- 如何更好的链接‘成熟度’与‘技能’的概念？
- 如何根据供应商对于各议题不同程度的理解提供更好的内容?

供应商能力建设愿景

起点
伦理与道德
人权与劳工
健康与安全
环境
管理体系
1. 入门知识
意识提升，提出负责任实践的重要性
2. 应用工具
方法及路径的指导
3. 专题内容
关注具体内容
4. 专家资源
提供专家指导，提供解决方案，建立合作
专家

PSCI学习模型

	第一级: 入门知识	第二级：应用工具	第三级：专题内容	第四级：专家资源
内容描述	第一级为关键议题的入门知识 – 各供应商均应具备一定程度的理解	第二级针对关键议题提供更具体的视角，关注各领域的细节及挑战、提供应用工具方面的建议	第三级将对有意成为可持续发展领导者的供应商有特别意义。本级内容将包含一系列专题模块， 并结合相关领域的最新思考，如废弃物管理相关的 CHWMEG、绿色化学相关的 GCIPR、水资源的WRI。我们也将从PEG汲取行业经验及知识，如正在制定中的温室气体指引	第四级内容为可持续发展实践中领先的供应商设计，为其提供与行业领导者接触的机会并从中受益。内容将可能涉及供应商在技术层面面临的具体挑战、或为供应商与行业领导者提供平台，探讨具体的共益项目或合作倡议的机会
交付办法	供应商可在线查看/下载简短而具设计感、内容充实的指导文件	同步录制的线上视频及专利内容/外部内容链接	含问答环节的线上研讨会，可作为视频资源获取	探内容将根据具体议题设计
环境团队模型的案例：**The PSCI 环境相关原则**	• The PSCI **各项原则的内容是?** • **预期如何?** • **审计与合规**	• **根据各项原则准备审计** • **案例学习**	• **客户预期（The PSCI 原则以外）**	• **待定**
环境团队模型的案例：**气候变化**	• **什么是气候变化?** • **温室气体的来源** • **测量的基础知识**	• **碳足迹测算** • **scope 3?**	• **制定碳排放相关战略**	• **待定**

组织机构成熟度

供应商成熟度

起点	发展	执行	领导
• 法律合规 • 制定必要政策 • 满足最低标准	增加 审计报告/基本准则/完成风险测评 • 识别关键风险及最大影响 • 绩效评估及追踪体系 • 管理职责合理分配 • 设定目标	增加 • 明确核心员工责任的流程 • 员工意识及培训 • 目标普遍完成 • 改进项目 • 外部核查 • 发展外部合作伙伴 • 公共报告及其他透明度实践 • 风险得到充分管理	增加 • 可持续发展文化 • 外部认可及奖励 • 承担倡导角色 • 全供应链的策略 • 跨行业的外部伙伴 • 支持合作伙伴/客户的成长. • 可持续发展激发创造力 • 可持续发展引导的差异化定位及商业优势

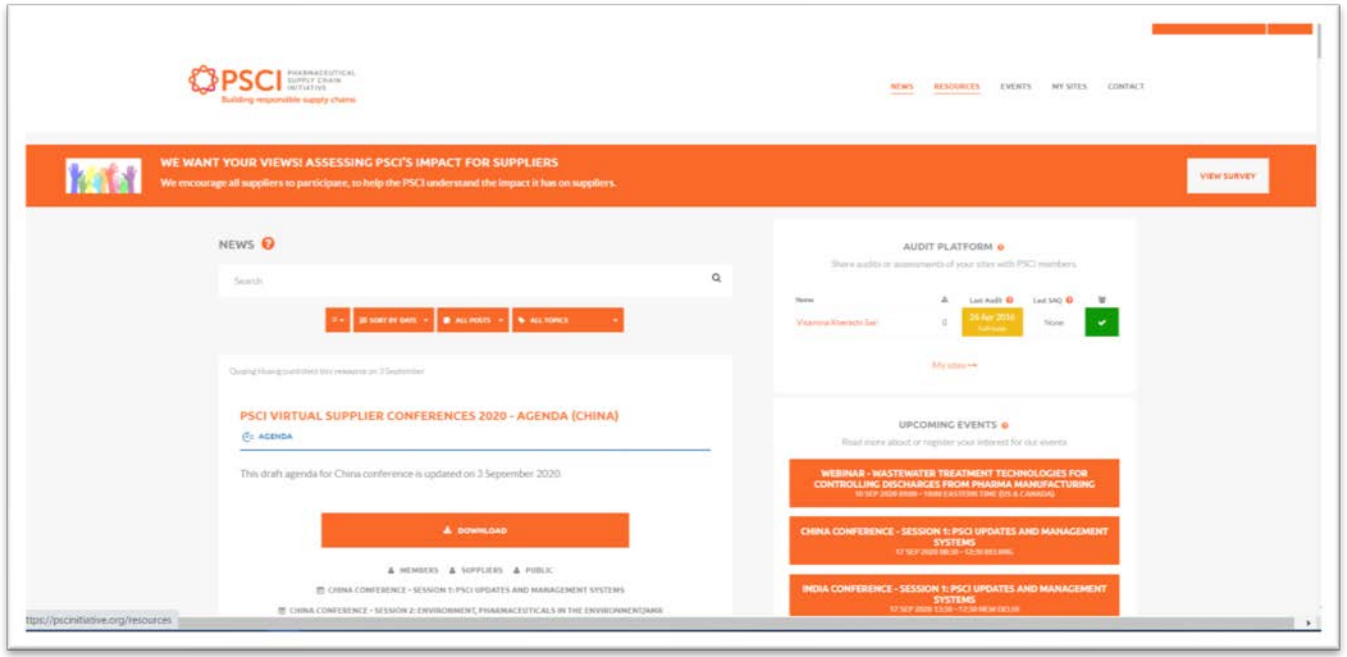
学习模型

第一级: 入门知识	第二级：应用工具	第三级：专题内容	第四级：专家资源
关键议题的入门知识	**面临的挑战, 工具及相关技术**	**基于机构领导与管理的专业内容**	**行业领导者资源，或与行业领导者的联合倡议/共益项目**
供应商可在线查看/下载简短而具设计感、内容充实的指导文件	同步录制的线上视频及专利内容/外部内容链接	含问答环节的线上研讨会，可作为视频资源获取	探讨与内容将根据具体议题设计
入门知识将说明最低标准，引导供应商为可持续实践做出准备并提升其对关键议题的可持续发展意识	**供应商在制定计划的过程中可借助此类应用工具（含审计框架，风险评估工具及实操指导）.**	**供应商已针对关键风险建立应对体系并致力于体系的持续完善. 相关案例为供应商带来启发，专题内容用以填补知识空缺**	**头部供应商在学习过程中分享经验；建立专家网络，合作促进可持续的供应链发展**

	第一级: 入门知识（可供下载的供应商指导）	**第二级: 应用工具**（线上学习视频及链接）	**第三级：专题内容**（链接外部资源的线上课程）
The PSCI **环境相关原则**	• The PSCI **各项原则的内容是?** • **预期如何?** • **审计与合规**	• 根据各类原则进行准备 • 案例学习	• 客户预期（The PSCI 原则之外）
环境管理	• **制定环境相关政策** • **EMS基础知识** • **绩效评估**	• 标准与认证 • 设定目标	• 建立基于科学的目标
合规和预防	• **理解相关立法及责任范围** • **安全的操作流程** • **管理溢出及泄露**	• 意外发生时如何应对 • 溢出及泄露管理的最佳实践	• 实时监控及市民科学（citizen science）
气候变化	• **什么是气候变化?** • **温室气体的来源** • **测量的基础知识**	• 碳足迹测算 • scope 3	• 建立碳排放相关战略
能源效率	• **能耗管理** • **行为调整** • **可实现效率提高的领域**	• 工厂设计的完善 • 可再生能源的机遇	• 可再生能源的机遇
绿色物流	• **什么是绿色物流** • **物流配送的影响** • **公务出行**	• 陆运 vs 海运 vs 空运 • 新技术 (如电动车等)	• EV100原则
包装	• **包装类型** • **理解包装的影响** • **塑料**	• 回收实践的机遇 • 合理的包装尺寸与优化	• 减塑
原材料	• **原材料采购** • **关键材料及问题** • **客户预期**	• 重要的原材料标准 • 理解原材料追踪问题	• 矿物资源冲突
水资源	• **水资源管理** • **水资源质量** • **减少水资源消耗**	• 理解水资源相关风险 • 水资源稀缺程度测算	• 绿色化学与 ZDHC
废弃物	• **废弃物等级** • **废弃物管理基础知识** • **废弃物管理**	• 制定废弃物管理政策 • 回收和再利用的机遇	• 零废弃物填埋
PiE & AMR	• **管理API 排放的重要性** • **制定跟公司相关标准并且符合PSCI 对PiE/AMR的要求** • **制定API排放限值**	• PiE/AMR的风险评估技术 • 减少API流失的技术 • 液体、固体废弃物排放，零液体排放	• 废水处理运作与维护 • API排放和（或）废水治理有效性分析 • 合规审核和准备PiE/AMR审计

获取学习资源

- **我们推出了 The Link 线上交流平台。**作为领先的行业社区及审计共享平台，**成员企业及供应商可以在此获取PSCI 的各类资源、新闻、培训、审计及更多其他内容**



供应商如何从中受益

- 我们希望供应商力争达到 The PSCI 原则的各项标准
- 我们将为供应商提供大量的免费资源，协助其实现目标
- … 我们围绕最重要的可持续发展议题进行内容设计
- … 为供应商提供24小时可及的线上学习资源
- … 从入门知识到世界领先的负责任实践，也包含应用工具
- … 同时链接供应商成熟度模型及评估工具

下一环节嘉宾介绍

“当下高等教育最热门的趋势是... MOOC learning.

MOOCs 为大型开放式线上课程的简称，以实现民主化学习为目的

新冠期间人们线上学习的热情高涨。Coursera 一类的 MOOC 公司自三月以来新增一千万用户, edX 及 Udacity 也实现了相近的增长

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

Professor Diana Laurillard

伦敦大学学院知识实验室 (UCL Knowledge Lab)

UCL Knowledge Lab

The Future of Online Learning
在线学习之未来

Diana Laurillard

UCL Knowledge Lab

UCL 知识实验室

Why do we need high quality online learning?

为什么 我们需要高质量的在线学习内容?

What counts as high quality online learning?

什么才算是高质量的在线学习?

Outline 概述

- Why do we need high quality online learning?

  我们为什么需要高质量在线学习？

- What counts as high quality online learning?

  什么才算是高质量在线学习？

- What makes a good online learning design?

  什么是好的在线学习设计？

- Building knowledge about high quality online learning

  建立关于高质量在线学习的知识

Why do we need high quality online learning?

为什么我们需要高质量在线学习？

The UN Sustainable Development Goals
联合国可持续发展目标

Quality education for all underpins all the SDGs

全民素质教育是所有可持续发展目标的基础

Why do we need high quality online learning?
我们为什么需要高质量在线学习

Pandemics 疫情大流行

- Globally, over 1.2 billion children are out of the classroom 全球有超过12亿儿童离开了教室
- All university students will be studying at least partly online this year今年所有的大学生将至少在线进行部分的学习
- A collaborative global approach to health and wellbeing requires universal education一个全球合作地改善健康和幸福的方法需要普及教育

Sustainability 可持续性

- Around 2.4% of global CO2 emissions come from aviation. The industry is responsible for around 5% of global warming. 全球约2.4%的二氧化碳排放来自航空业。该产业要对5%的全球变暖负责。
- Globally, only 20% of the population have ever taken a flight. We frequent flyers contribute a very disproportionate share of emissions. 全球范围内，只有20%的人乘过飞机，经常乘飞机的人群所占的比例较小，但他们因此排放了大部分的温室气体，完全不成比例。
- Reducing air travel is one of the most effective things individuals can do to shrink their carbon footprints. 减少航空旅行是个人缩小碳足迹最有效的方法之一。

What counts as high quality online learning?

什么才算是高质量在线学习？

What counts as high quality learning?
什么才算是高质量在线学习?

The Conversational Framework对话框架理论

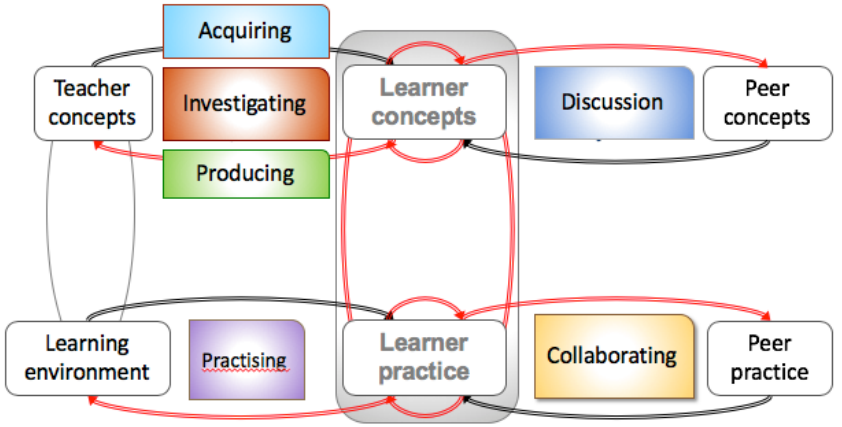
Derived from theories and research on learning and teaching (Laurillard, 2002, 2012)

来源于学习与教学的理论与研究(Laurillard, 2002, 2012)

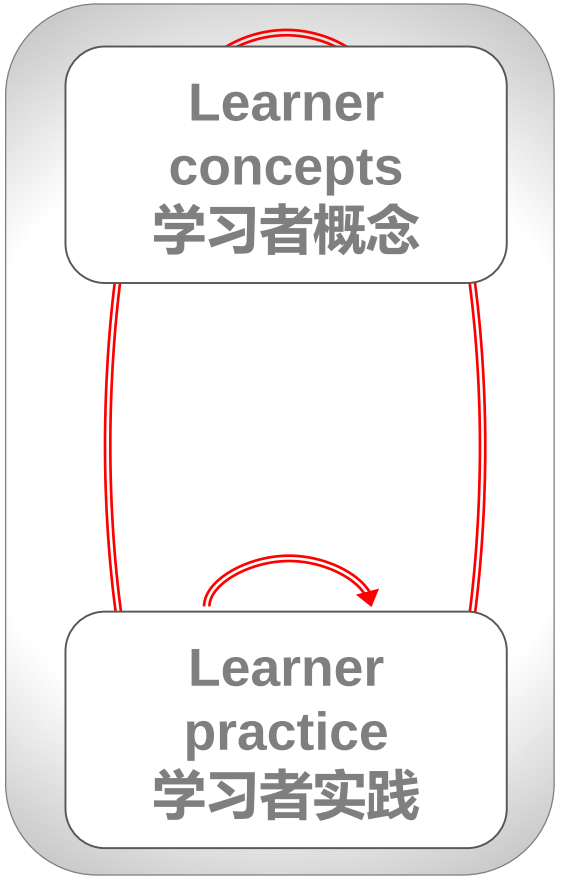
To represent the teaching-learning process as

将教—学过程表示为

- a series of iterative exchanges 一系列的反复交换
- between the learner and a 'teacher' and 学习者和教学者之间
- between a learner and their peers 学习者和同龄人之间
- at two levels of concepts and practices 在概念和实践的两个层面



What does it take to learn in formal education?
在正规教育中学习需要什么?



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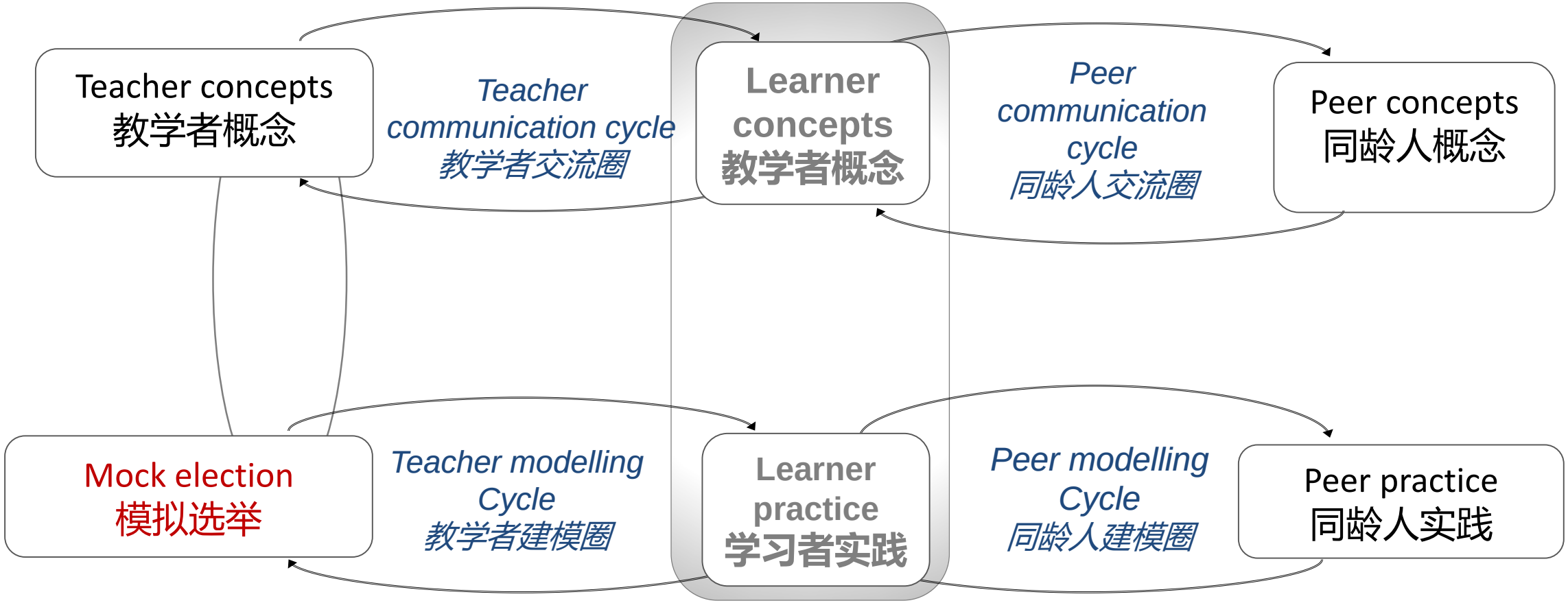
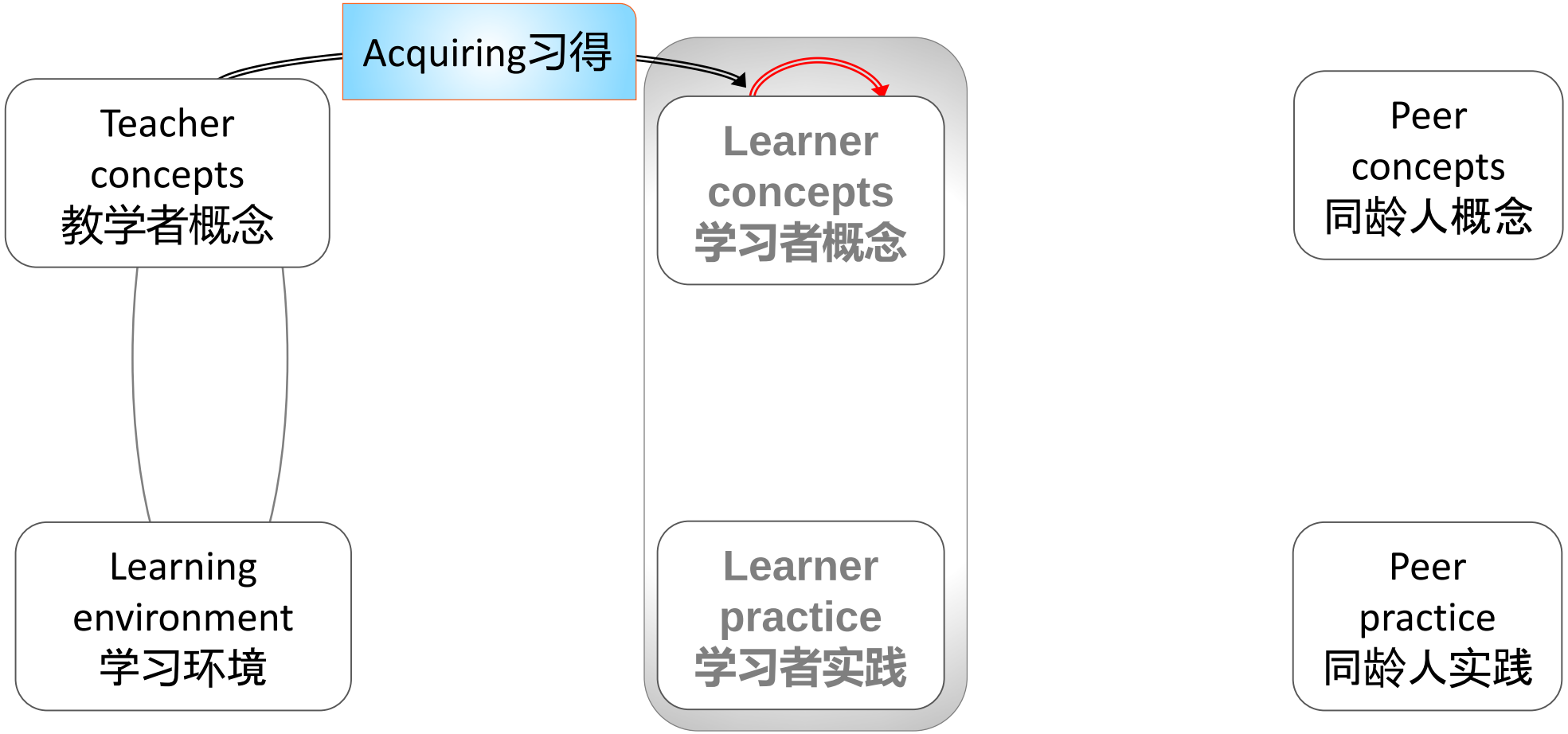
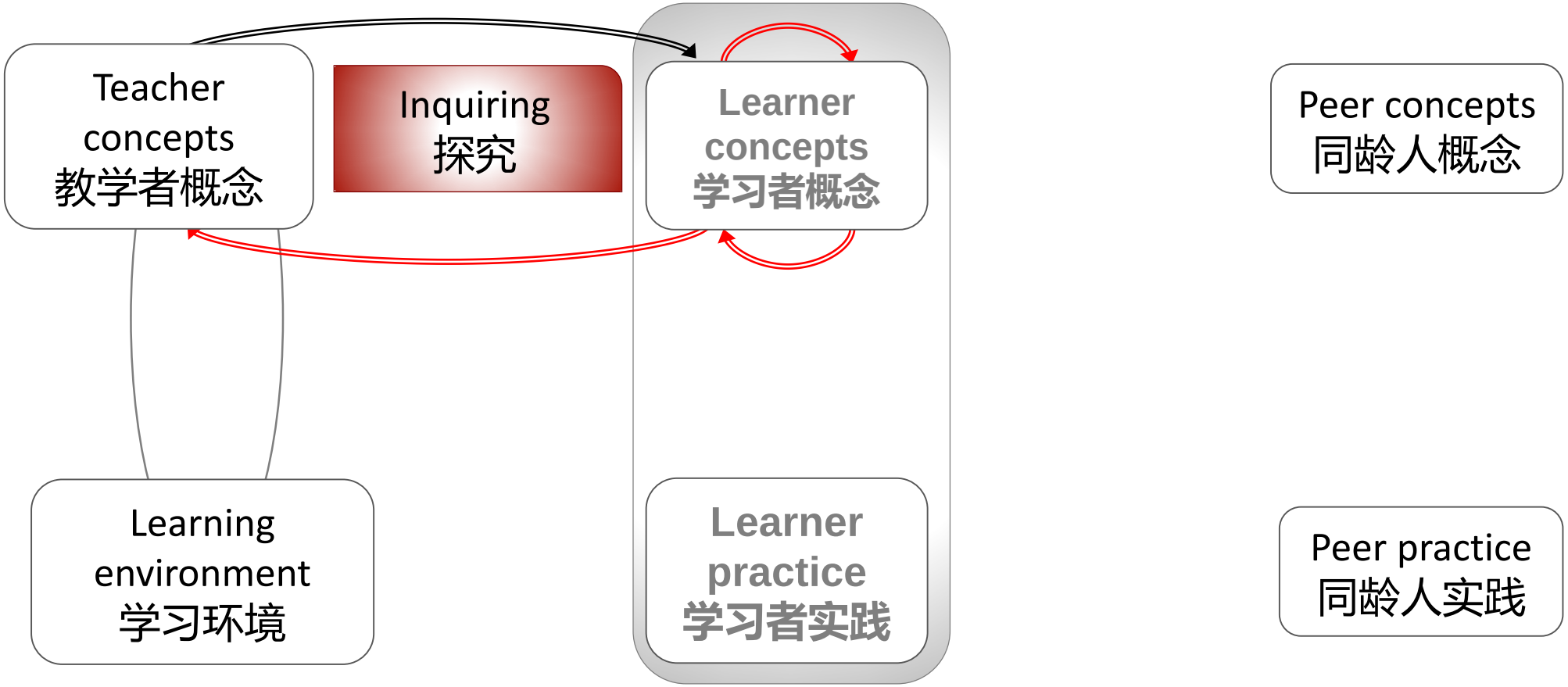


Types of learning mapped to the framework
与框架对应的学习类型



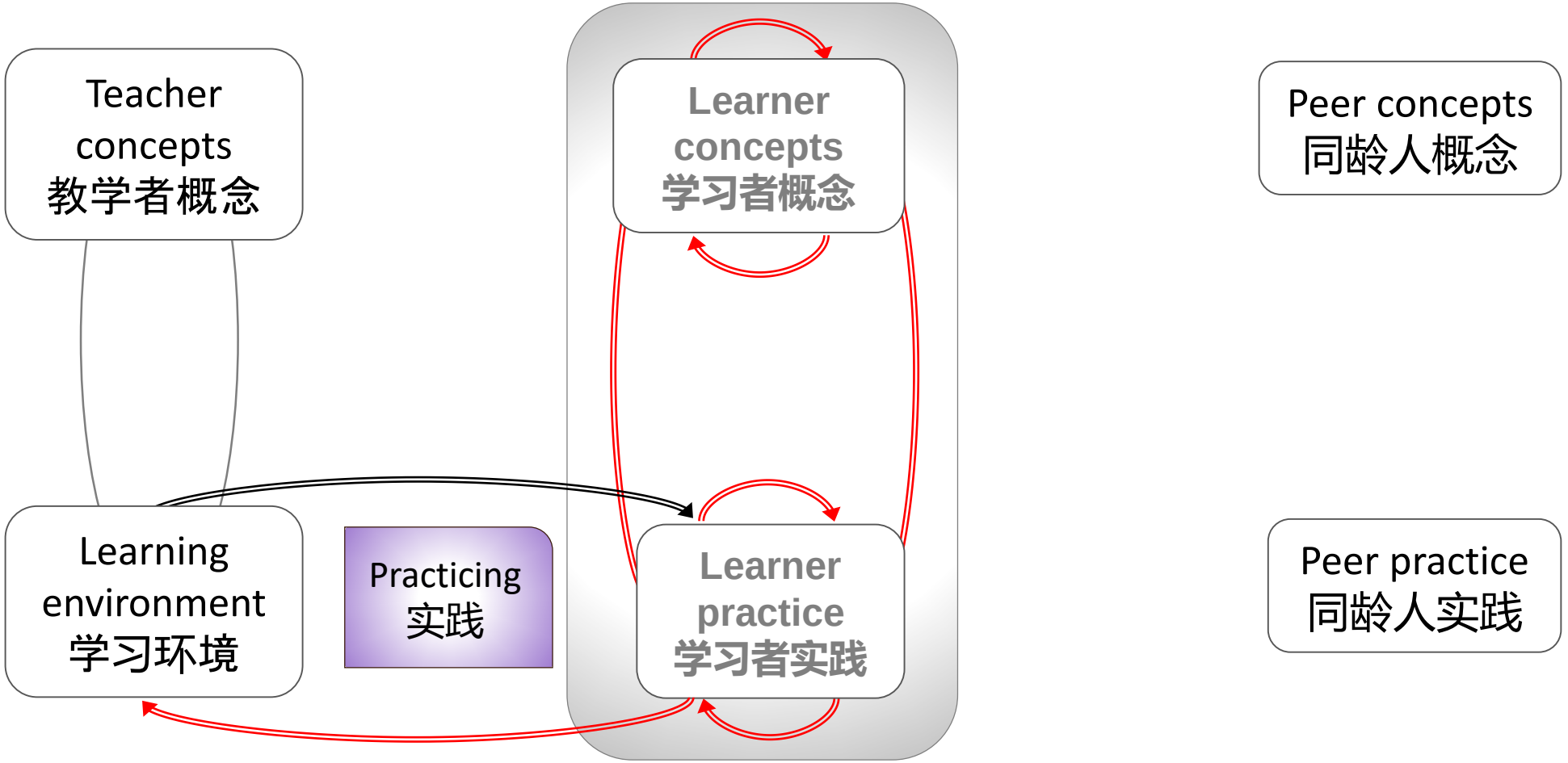
Learning through 'acquisition' 通过"习得"来学习

Types of learning mapped to the framework
与框架对应的学习类型



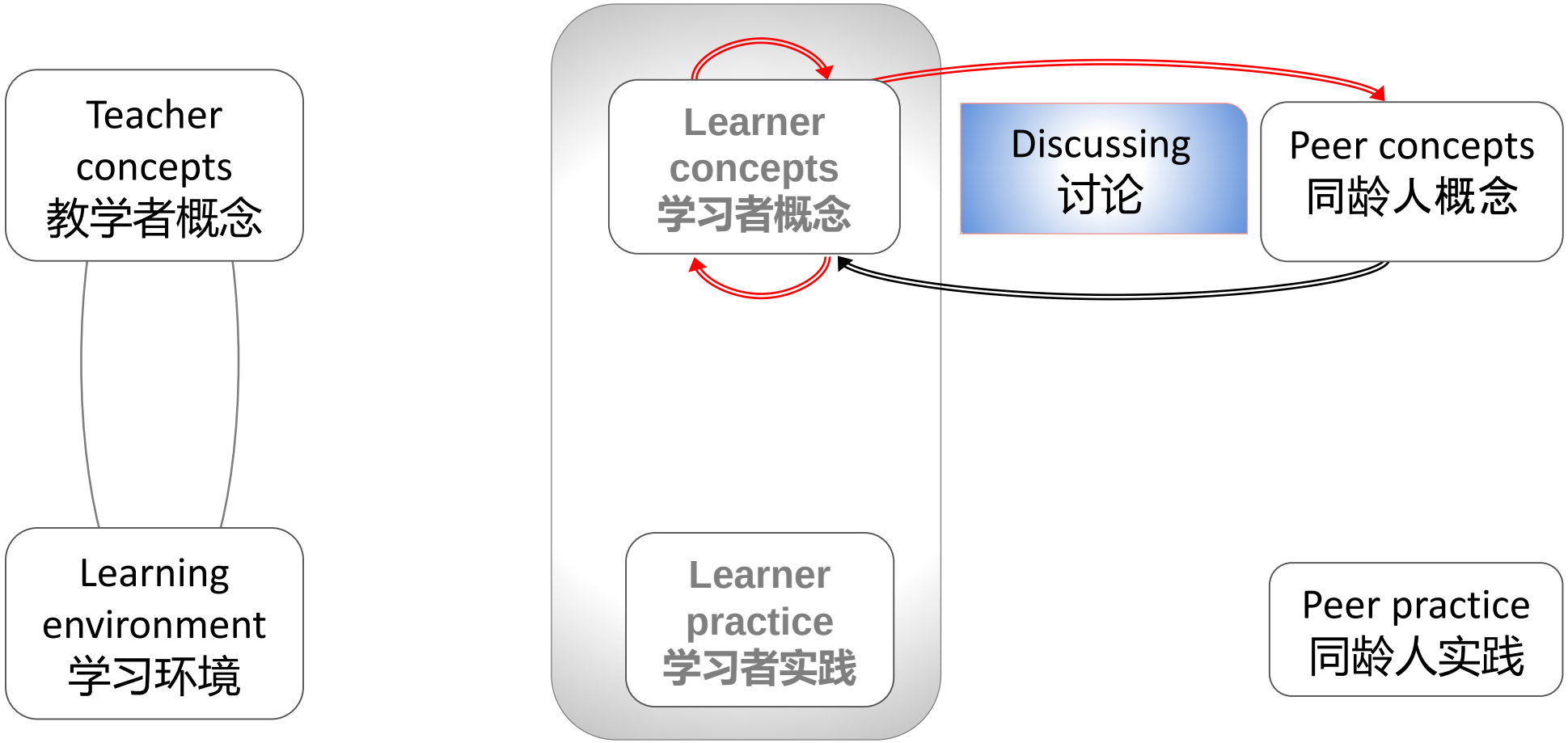
Learning through 'inquiry' 通过"探究"学习

Types of learning mapped to the framework
与框架对应的学习类型



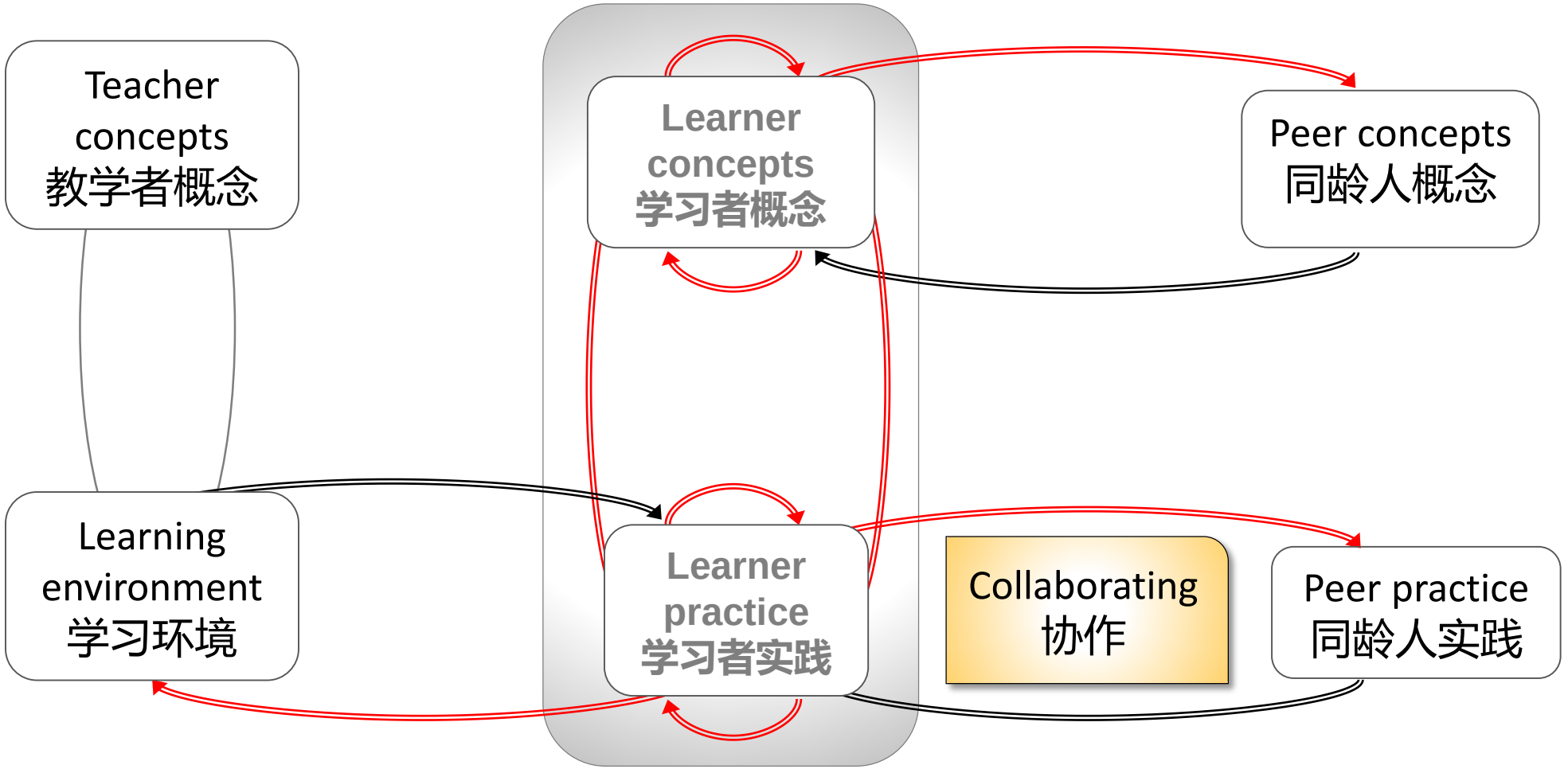
Learning through 'practice' 通过"实践"学习

Types of learning mapped to the framework
与框架对应的学习类型



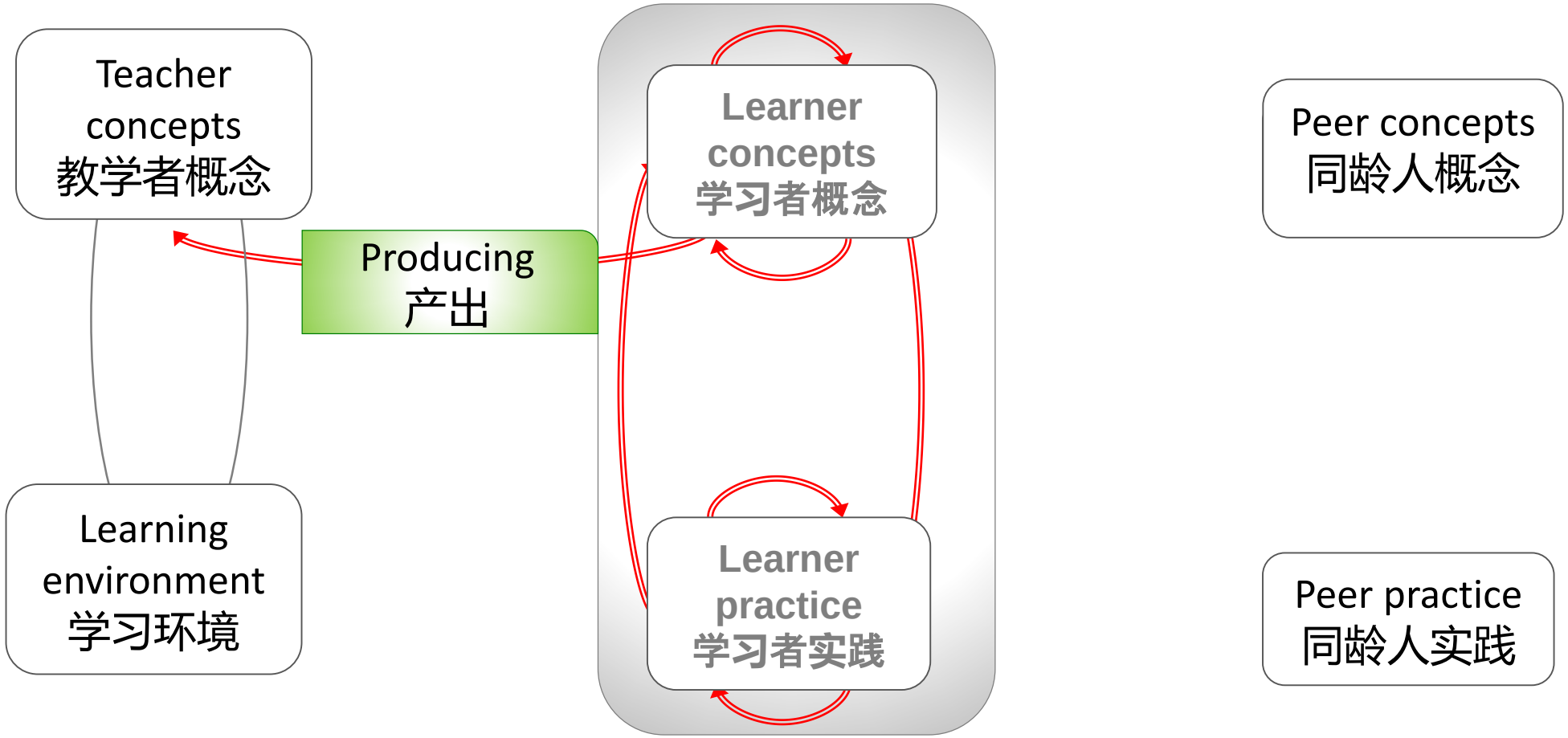
Learning through ‘discussion’ 通过“讨论”学习

Types of learning mapped to the framework
与框架对应的学习类型



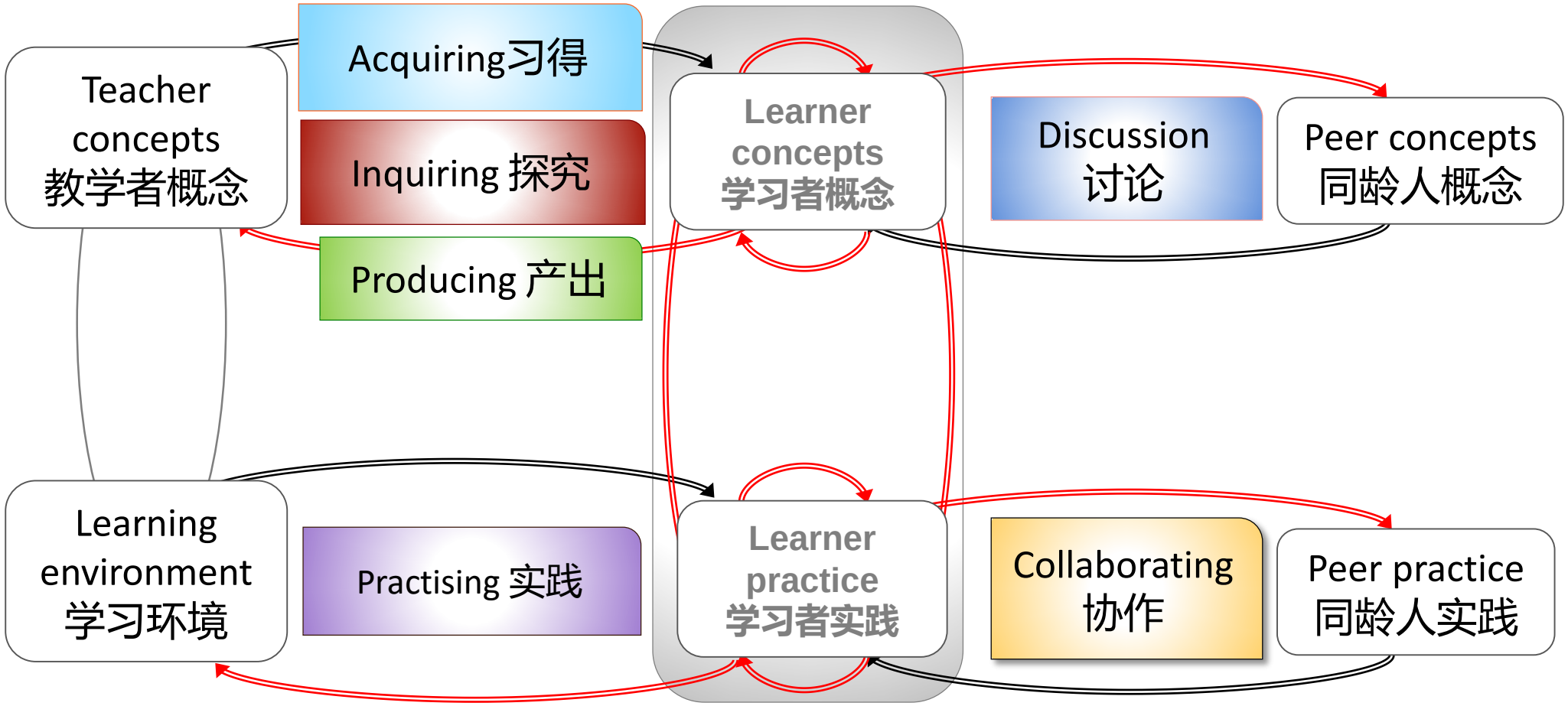
Learning through 'collaboration' 通过"协作"学习

Types of learning mapped to the framework
与框架对应的学习类型



Learning through 'production' 通过"产出"学习

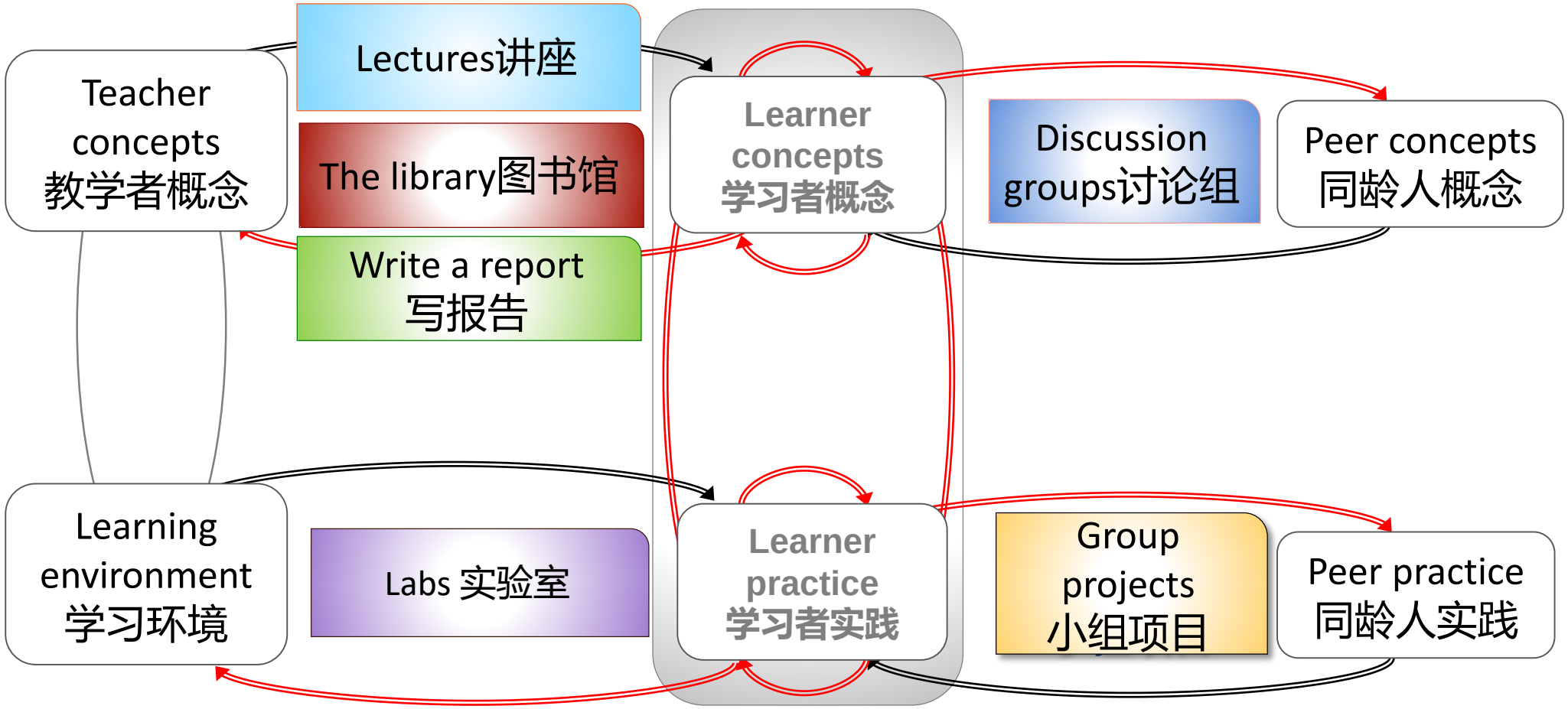
How does technology help? *Conventional methods*
科技在这有什么用？常规方法



These learning types are encouraged through a variety of conventional methods

通过各种传统方法驱动的这些学习类型

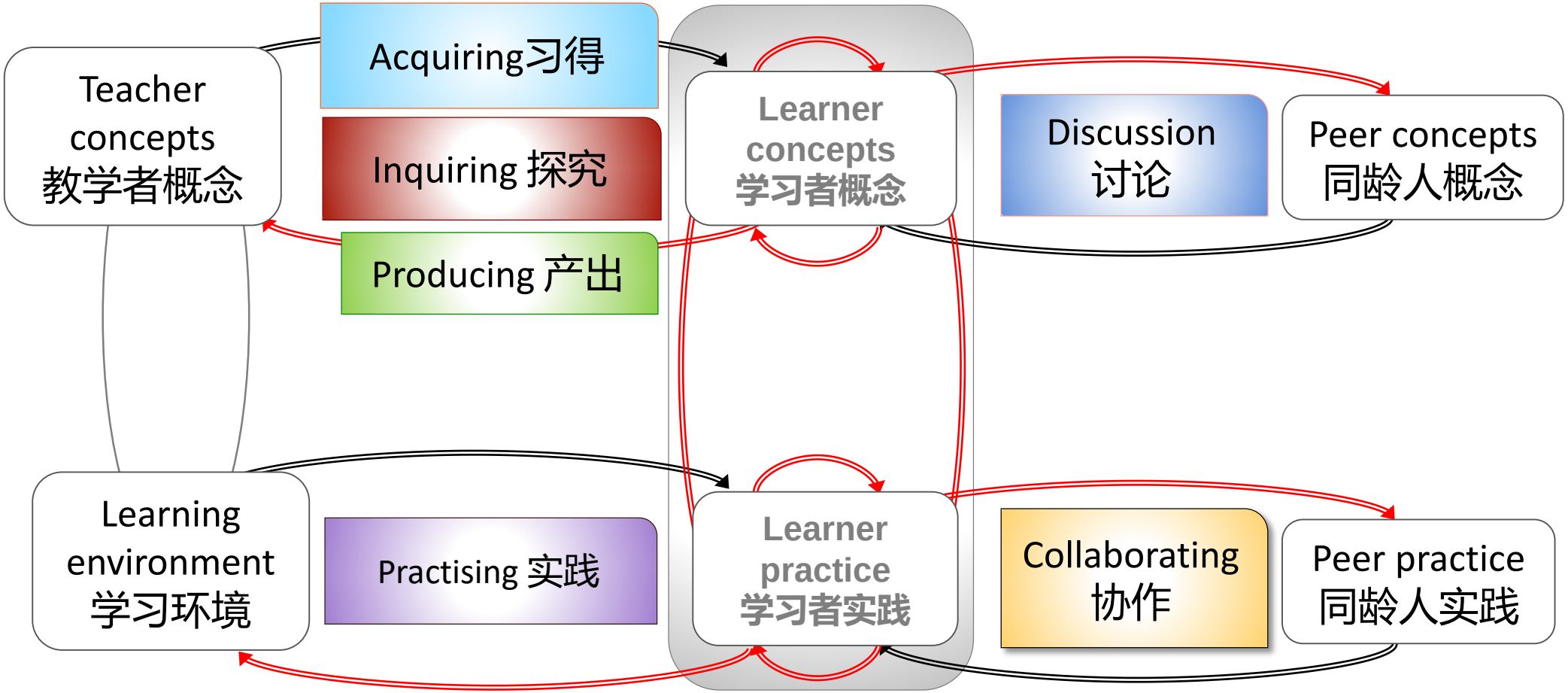
How does technology help? *Conventional methods*
科技在这有什么用？常规方法



These learning types are encouraged through a variety of conventional methods

通过各种传统方法驱动的这些学习类型

How does technology help CPD? Digital methods
科技如何助力CPD？数字工具



How does technology help CPD? Digital methods
科技如何助力CPD？数字工具

Digital images, videos 照片视频

Explore the internet 互联网信息搜索

Make website 制作网站

Test a digital model 测试一个电子模型

Teacher concepts 教学者概念

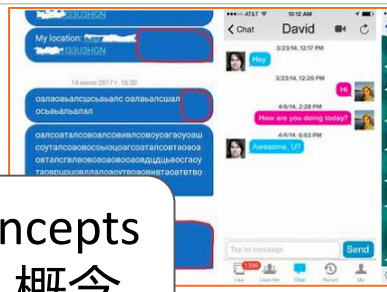
Learning environment 学习环境

Learner concepts 学习者概念

Learner practice 学习者实践

Text chat Menti 文字聊天

Draft a wiki 草稿一个 维基百科页面



Peer concepts 同龄人概念

Peer practice 同龄人实践

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

这些同样的学习类型现被各种数字工具驱动

What makes a good online learning design?

什么是好的在线学习设计？

What makes a good online learning design?
什么是好的在线学习设计?

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

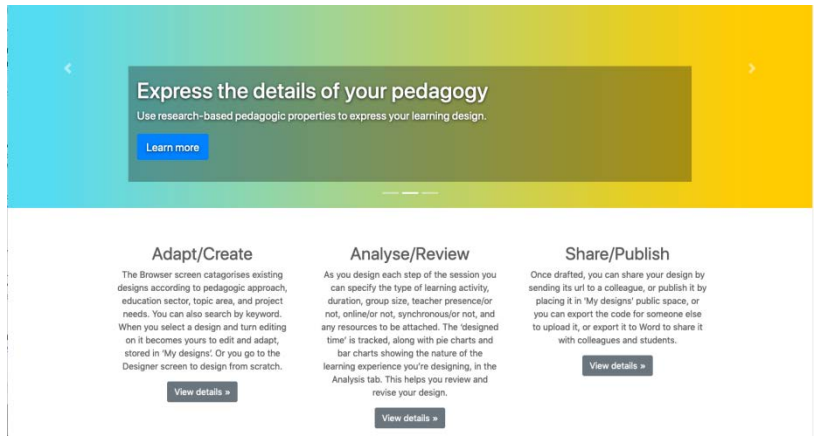
The Learning Designer 学习设计器

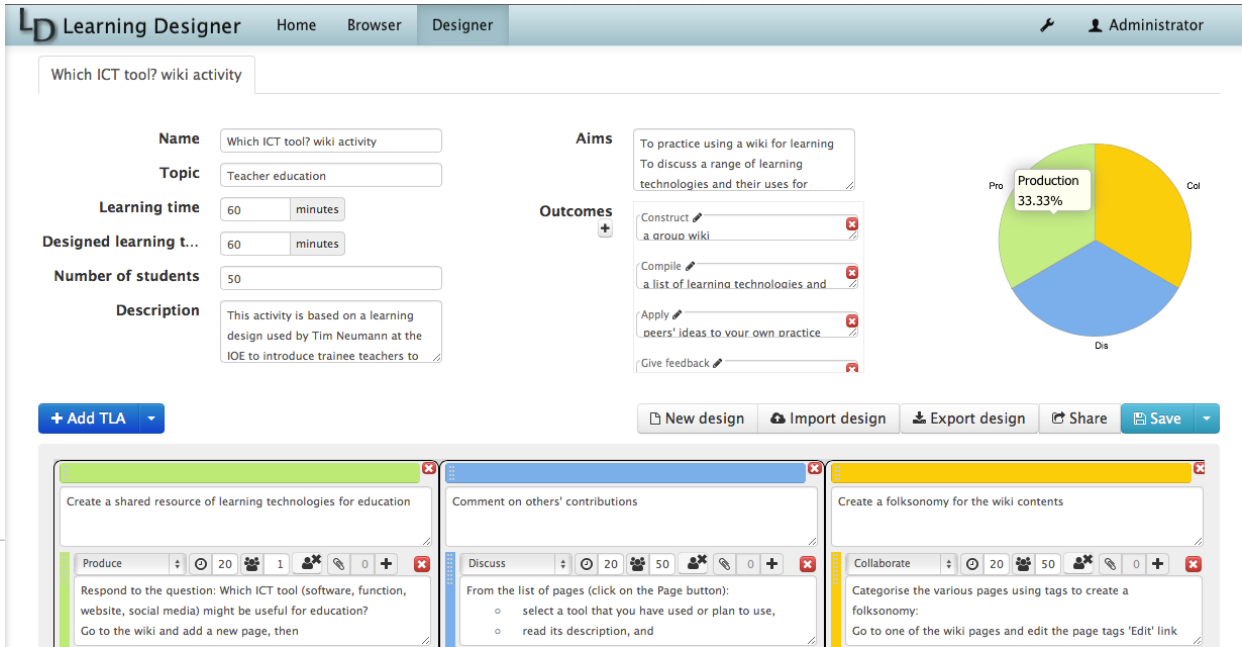
A free open online design tool to help with moving your teaching online.一款免费开放的帮你将教学移至线上的设计工具

Based on the six learning types from the Conversational Framework – a model of what it takes to learn.基于对话框架（学习所需模型）的六种学习类型

Supports teachers and educators to
可以支持教师和教育者

- design a sequence of blended and online teaching and learning activities设计一系列混合的在线教学活动
- analyse their pedagogic design分析他们的教学设计
- share their learning designs with each other彼此分享学习设计





Adapting a learning design 调整学习设计

Adapt/Create

The Browser screen catagorises 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 调整学习设计

Learning Designer Home Browser Designer

Home / Browser / Education sector / Vocational Education and Trai

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

Collaborative learning: Drafting a good assignment last modified on Sat 30 Ja
Edited by you

Developing your own ideas on a topic (conventional) v2 last modified on Sat
Edited by you

Developing your own ideas on a topic (blended) last modified on Sat 30 January
Edited by you

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

Understanding the workplace (Conventional) last modified on Fri 15 January 201
Edited by you

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

Using progress monitoring and metrics to assess work against schedule
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

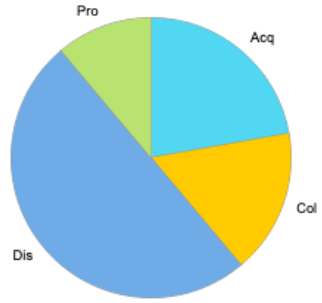
Apprenticeship Induction session last modified on Fri 16 March 2018 at 15:54:04
Edited by you

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		
Designed learning ti...	1 hour and 30 minutes	**Outcomes**	Knowledge, Application, Analysis
Size of class	25		
Description	This is a design for a class using wholly online methods. It...	**Editor**	diana



Turn editing on

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.

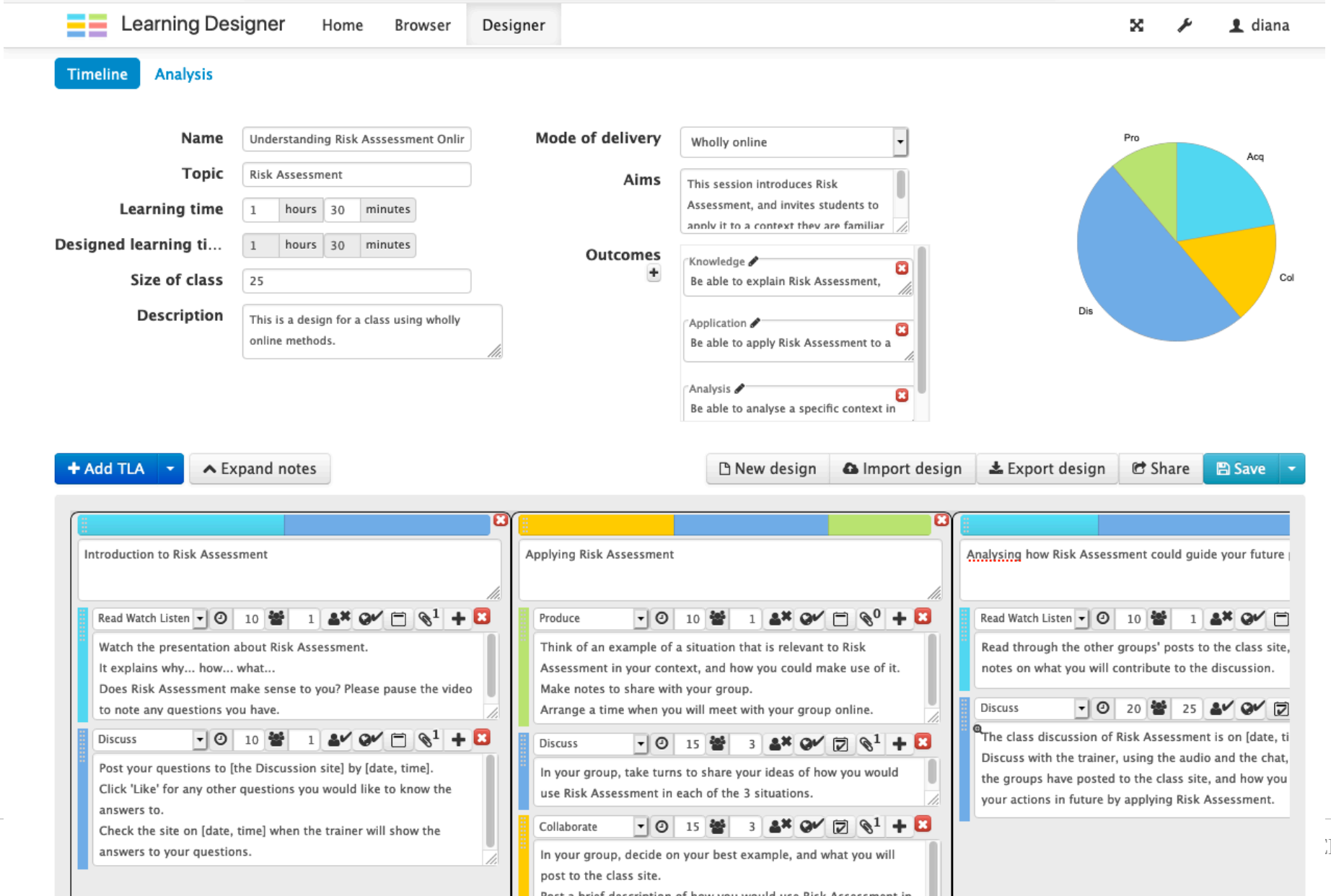
Collaborate 15 3 1
In your group, decide on your best example, and what you will post to the class site. Post a brief description of how you would use [the Topic] in which situation.

Analysing how [the Topic] could guide fut

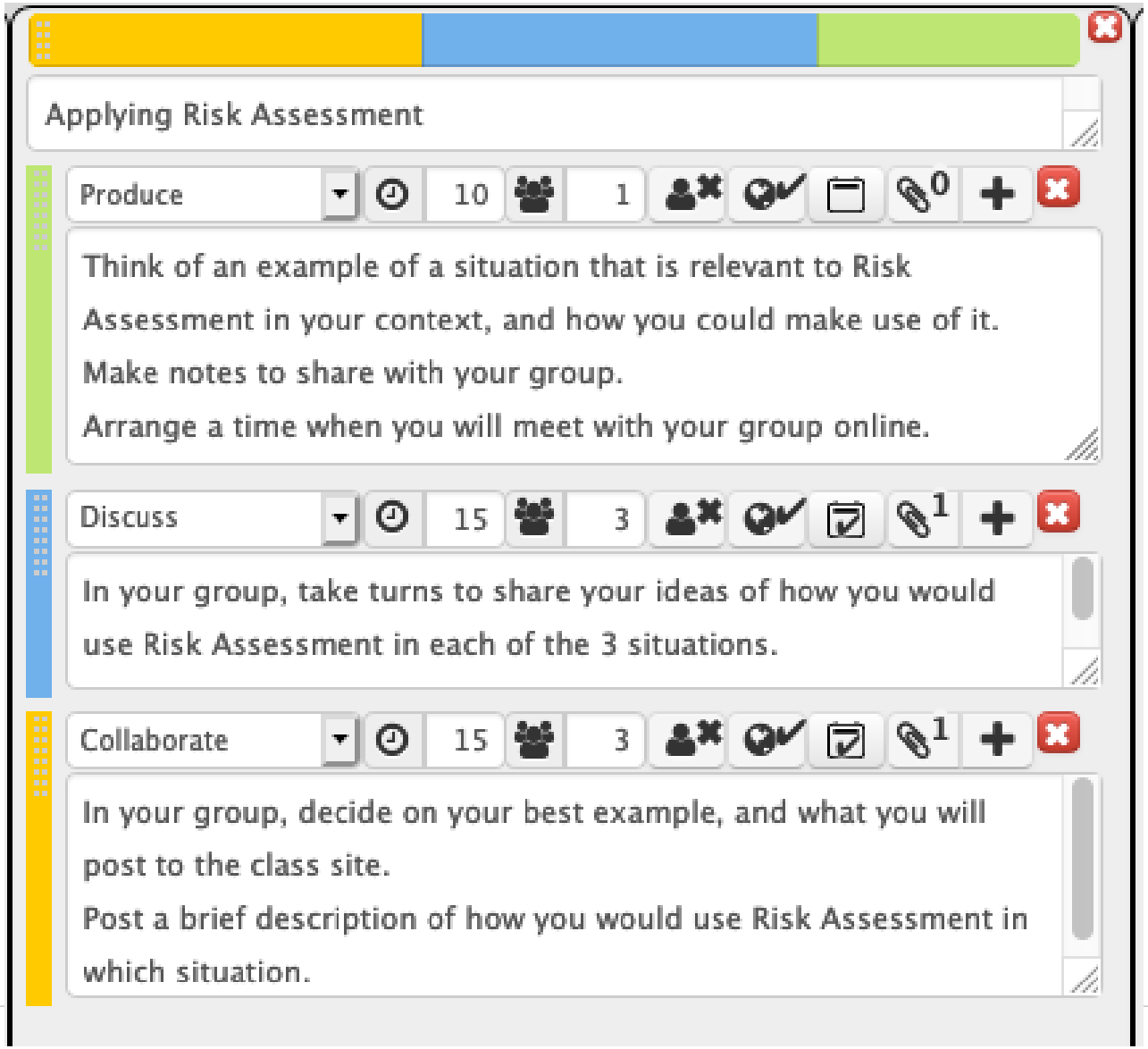
Read Watch Listen 10 1
Read through the other groups' posts t
and make notes on what you will contri
discussion.

Discuss 20 25
The class discussion of [the Topic] is or
Discuss with the teacher, using the aud
the examples the groups have posted t
and how you might change your actions
applying [the Topic].

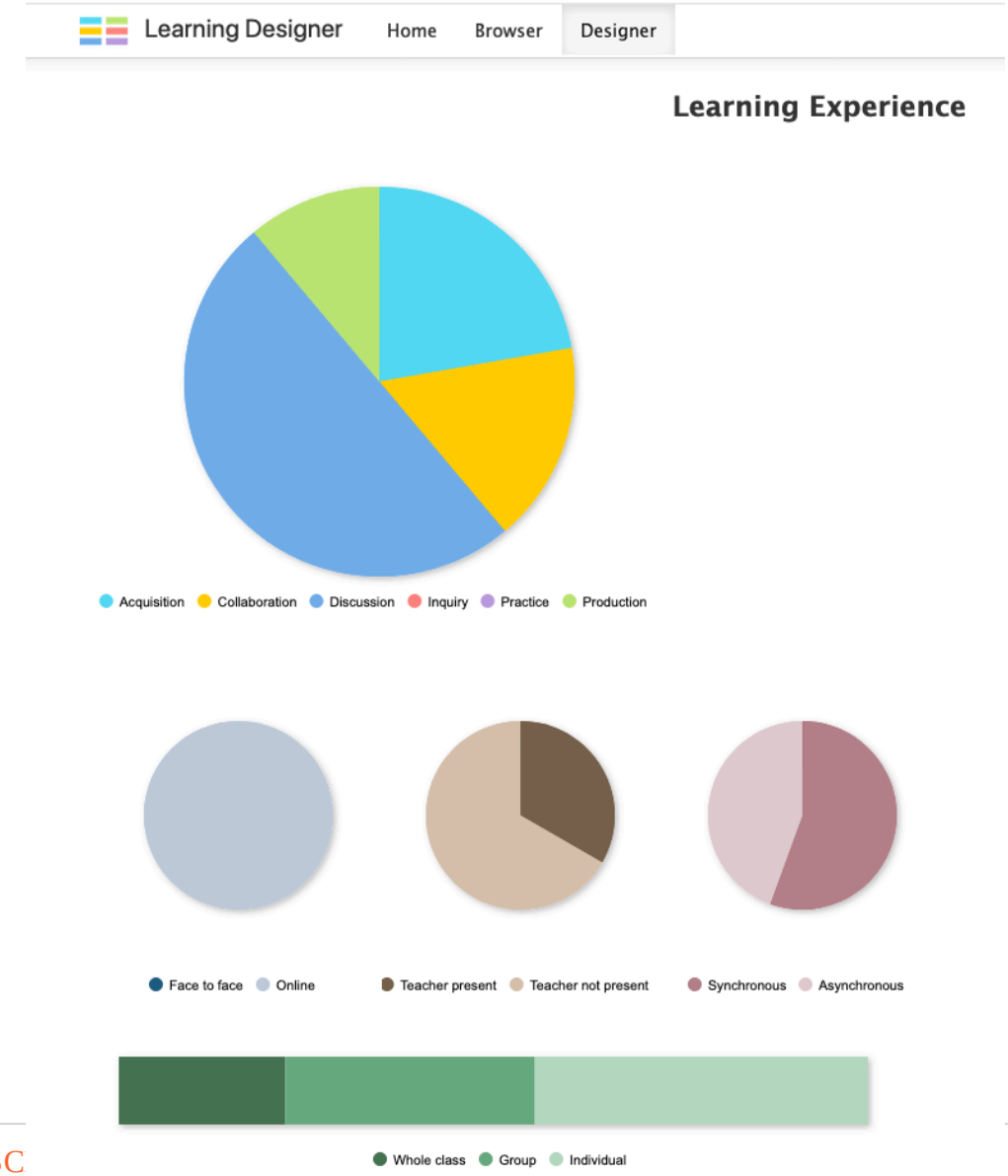
Adapting a learning design 调整学习设计



Adapting a learning design 调整学习设计



Analysing a learning design 分析学习设计



The pie-chart analyses the distribution of types of learning in the design, in this case, acquisition, collaboration and production, but mostly discussion.饼图分析了设计中学习类型的分布，在这种情况下，是习得、合作和产出，但主要是讨论。

There are no rules about what it should be, but now you have the opportunity to consider if that looks appropriate
没有关于它应该是什么的规则，但是现在你有机会考虑这是否合适

It is entirely online (pale blue), no f2f
它完全在线（浅蓝色），没有面对面的

There is some trainer presence (dark brown) to respond to questions, and conduct the plenary discussion有一些培训师在场（深棕色）回答问题，并进行全体讨论

More than half is synchronous (dark pink) - with a group and with the trainer
超过一半是同步的（深粉色）-与团队和培训师

There is mostly individual work (pale green), then groups, then whole class主要是个人作业（浅绿色），然后是小组，然后是全班

Sharing a learning design 分享学习设计

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.

Linked resources

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.

Linked resources

Q&A with the teacher

On the Designer screen you can Export your design to Moodle (upcoming version) 在设计器屏幕上，您可以将您的设计导出到Moodle（即将发布的版本）

Or Export to Word, to send to learners, or discuss with others 或输出到Word，发送给学习者，或与他人讨论

You can also Share it by creating a url to send to colleagues 您也可以通过创建一个链接发送给同事来共享它

LD Learning Designer

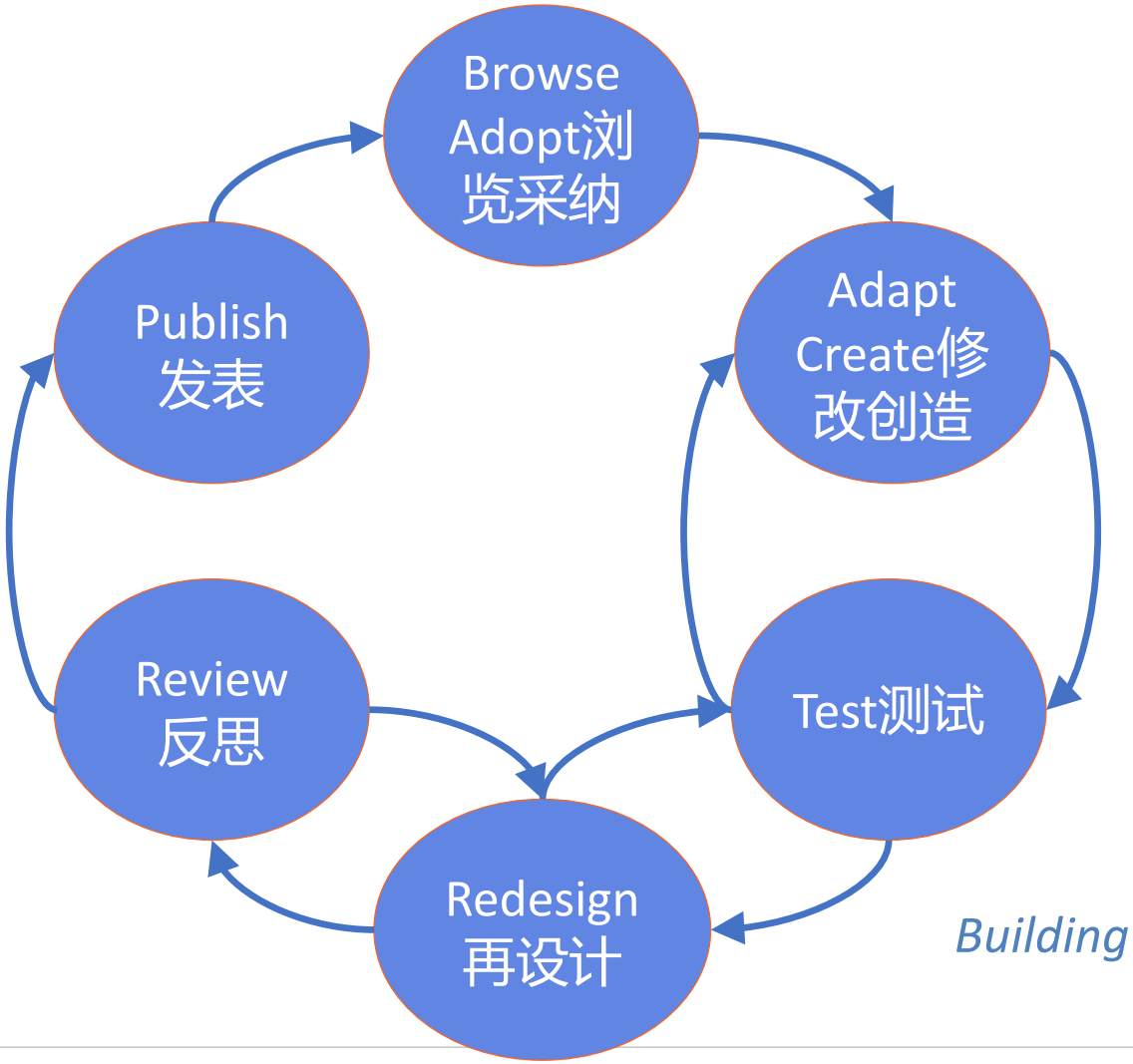
https://www.ucl.ac.uk/learning-designer

How can we build knowledge about high quality online learning?

如何建立关于高质量在线学习的知识？

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

实践社区：创新、测试和分享有效设计的新想法



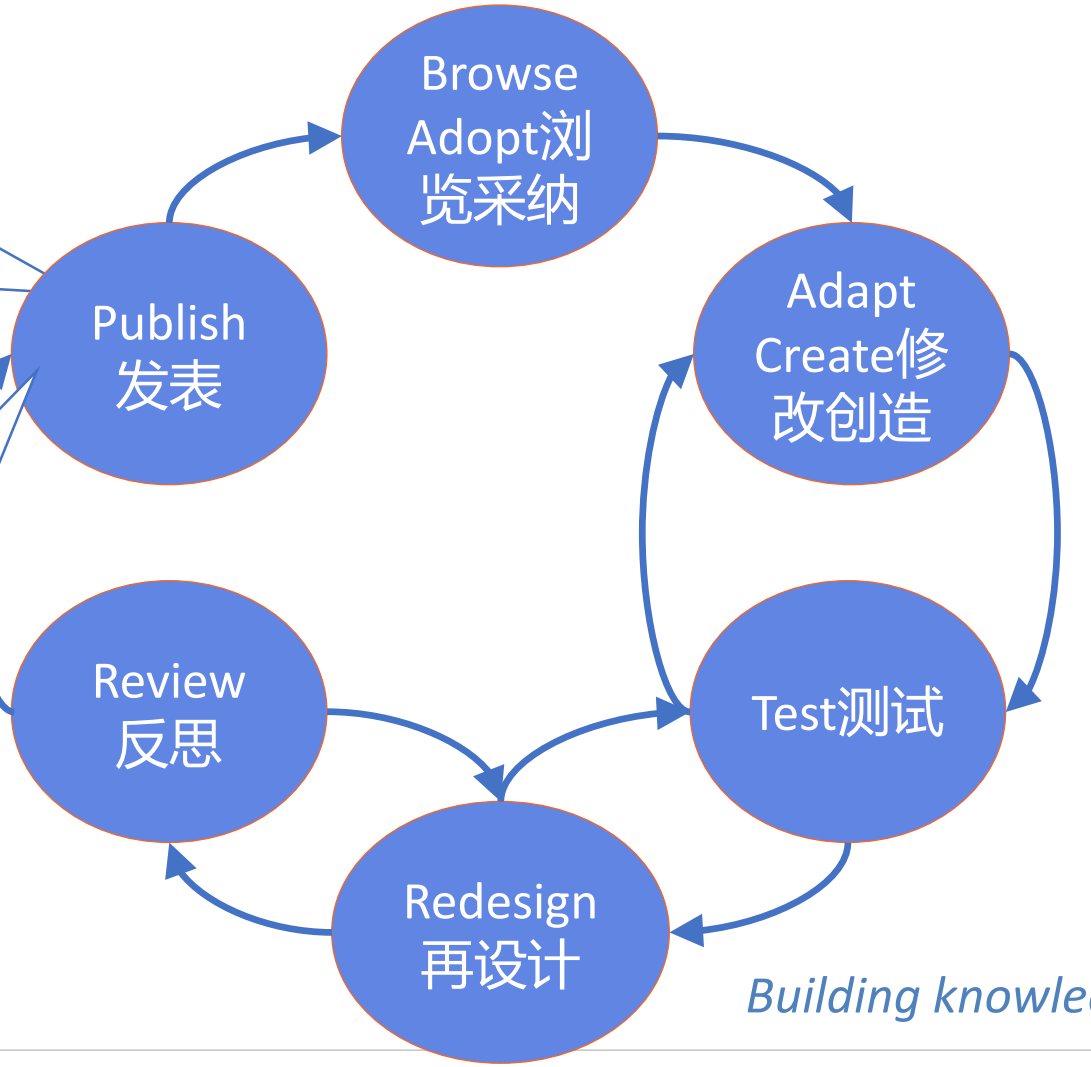
Building knowledge for science and scholarship

建立科学和学术知识

A community of practice: innovating, testing, and sharing new ideas for effective *online learning* design 实践社区：创新、测试和分享有效在线学习设计的新想法

What is the pedagogic equivalent of the scholarly journal?
什么是与学术期刊同等的教学法?

An online **collaborative community** using **digital tools** to share testable co-designed peer-reviewed adaptable **learning designs**
在线**协作社区**使用数字工具共享
可测试的
共同设计的
同行评审的
可适应的
学习设计



Building knowledge of online learning design
建立在线学习设计知识

Large-scale online courses to orchestrate collaborative knowledge development by education professionals 大型在线课程，由教育专业人士协作编配知识开发

FutureLearn

Future Learn Subjects Courses Using FutureLearn 50+

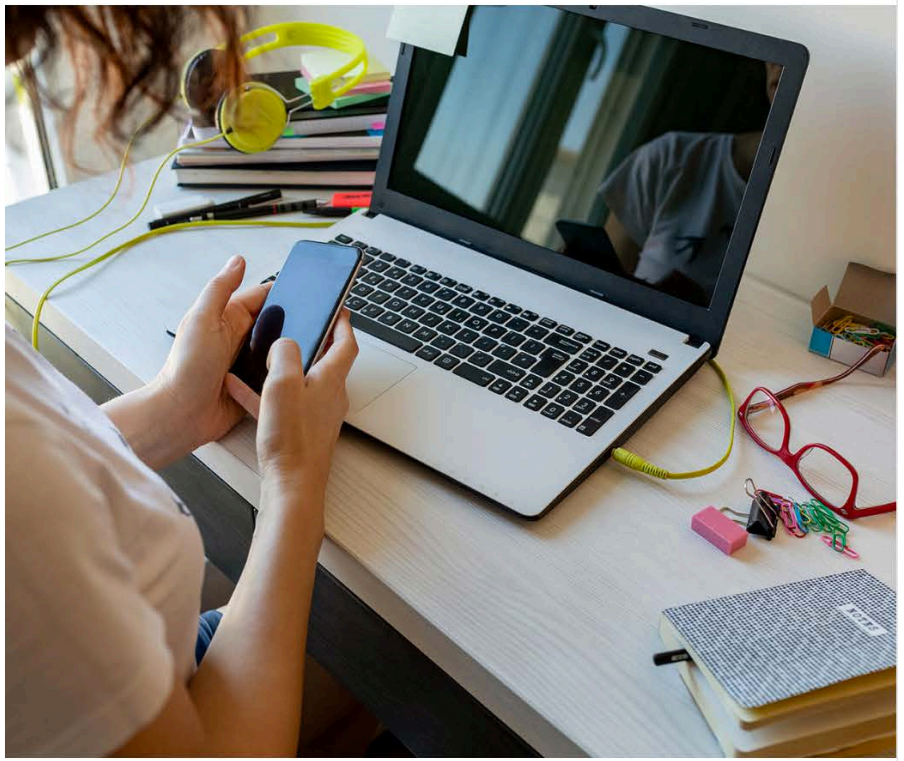
Online Courses / Teaching

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 大型在线课程，由教育专业人士协作编配知识开发

FutureLearn course ‘How to Teach Onllne’

Running since 23 March, >80,000 teachers from all sectors

Thousands of comments in discussions of every step

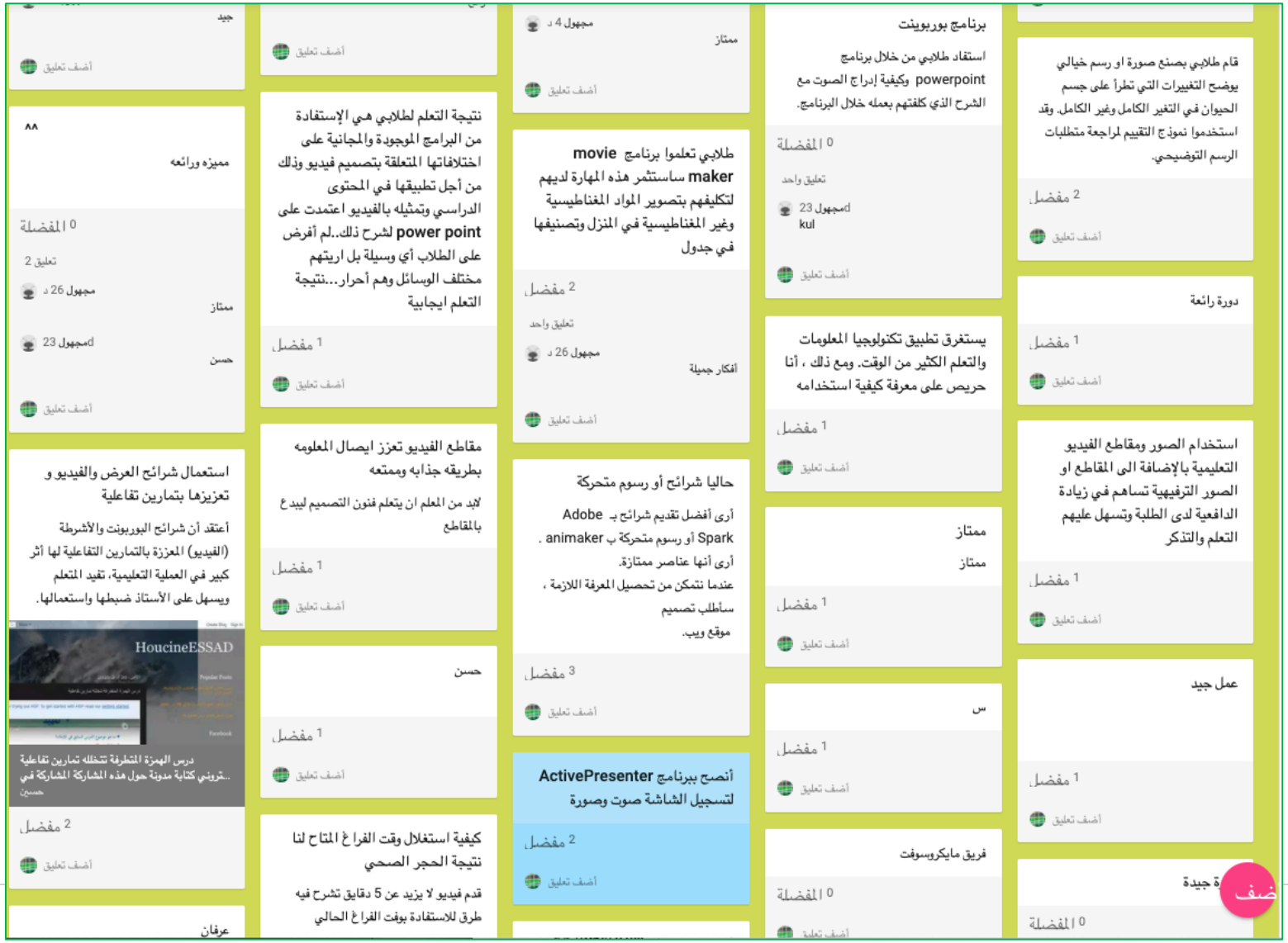
- Sharing ideas and problem solutions
- Professionals collaborating to build knowledge

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 大型在线课程，由教育专业人士协作编配知识开发



Large-scale online courses to orchestrate collaborative knowledge development by education professionals 大型在线课程，由教育专业人士协作编配知识开发

padlet

REMAKE SHARE

Eileen Kennedy • 8d

Posts from observation skills padlet on Edraak

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 .

التنقل أثناء النهار

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

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.

التنقل أثناء النهار

عدم تنظيم المرور وعدم وجود أماكن

مهدي 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

Th
ov
goods on the sidewalk leads to congestion of the sidewalk with the presence of obstacles and afflicts negatively on the special needs

يمكنكم مشاهدة كيفيه استغلال المجلات و التعدي على الارصفة المعدة خصيصا للمشاة , كما عدم وجود اماكن مخصصة لقطع الشارع وصعوبتها للاشهاص ذوي الاحتياجات الخاصة

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 spec
designed for pedestrians, as well

Participants applied their observation skills to collect data in their local environments, adding a photo and a note to explain their analysis.
参与者运用他们的观察技能收集当地环境中的数据，并添加一张照片和一张便条来解释他们的分析。

The UN Sustainable Development Goals
联合国可持续发展目标

UCL Knowledge Lab
UCL知识实验室

The future of online learning
在线学习之未来

We need high quality online learning to reach all who need it, and for sustainability

我们需要高质量的在线学习，以惠及所有需要它的人，以保证可持续性

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

高质量的在线学习将致力于使学习者成为学习的积极参与者

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

一个好的学习设计将包含一系列的学习类型

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

我们现在有技术来建立关于高质量在线学习的社区知识

休息

BREAK 1

休息时间为10分钟，会议将于 10:00 继续进行

Conference resumes at 10:00. Please come back in 10 minutes

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Shared Audits
PSCI共享审计报告

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

我们从供应商学到了什么以及它如何影响我们的能力建设工作

蒋磊

高级主任, 合全药业

PSCI审计委员会成员及中国小组成员

本次分享内容由来自Elanco的Shelly Shope女士准备，Shelly同时也是PSCI能力建设委员会负责人之一

Speaker Bio

- 蒋磊

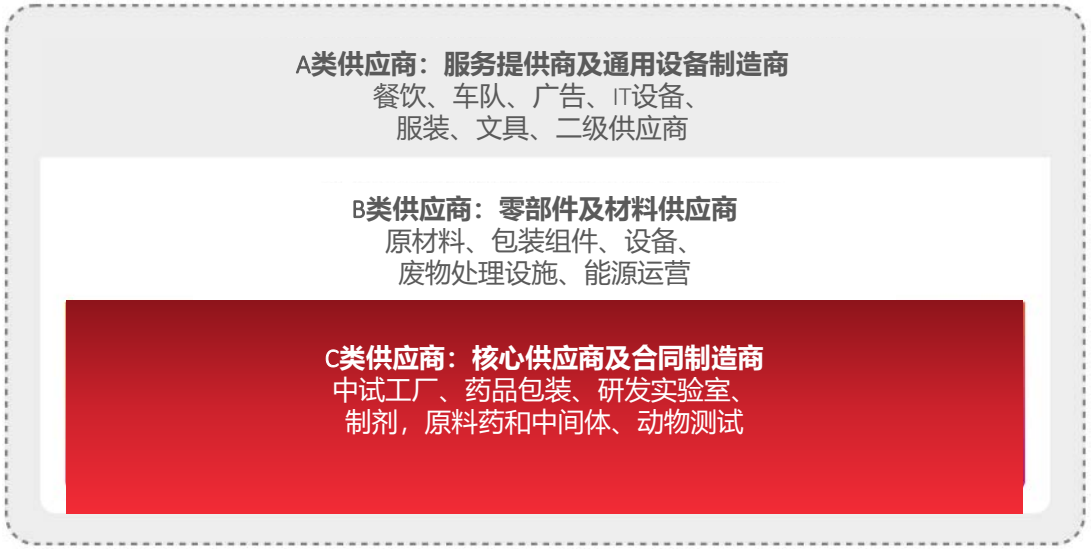
- 现就职于合全药业，任API生产部EHS高级主任
- 工作经历：
  - 西安利君制药有限公司，质量控制
  - 西安杨森制药有限公司，质量控制，安全管理，供应链EHS管理
  - 上海诺华贸易有限公司，供应链EHS管理
  - 强生（苏州）医疗器材有限公司，EHS管理

- 联系方式
  - Jiang_lei0901@wuxiapptec.com

PSCI审计报告共享

- **审计报告共享** PSCI成员的供应商在经过同一套标准审计后，可在PSCI审计报告共享平台上传审计报告，并分享给多家PSCI成员，减少对同一供应商的重复审计，提高效率。

- PSCI审计标准包含PSCI原则所涉及的**五个方面**：道德，劳工与人权，健康与安全，环境和管理体系。
- 适用于制药与医疗健康行业的**所有类型的供应商**
- **和能力建设项目共同**支持供应商的持续提升
- 如何开展PSCI审计
  https://pscinitiative.org/sharedAudits



PSCI审计共享平台

截至
2020年7月

644位
注册供应商

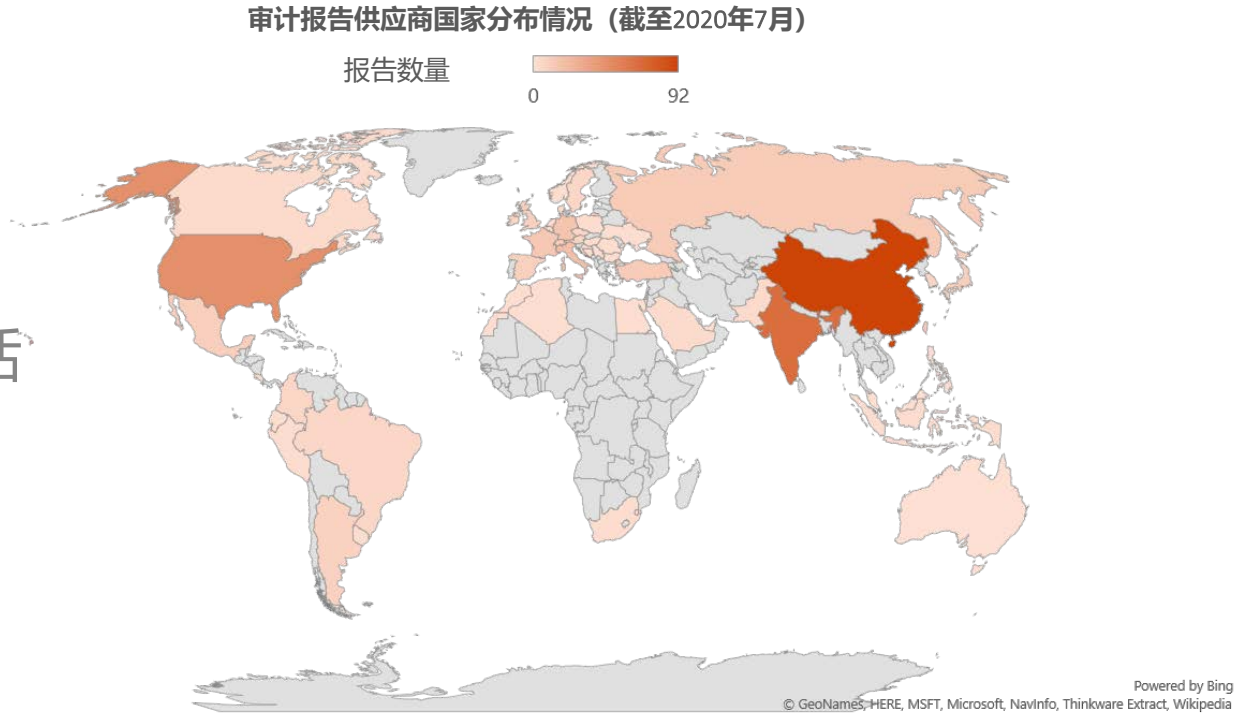
442份
审计报告上传

67%
的报告在三年内审计

66%
的报告实现共享

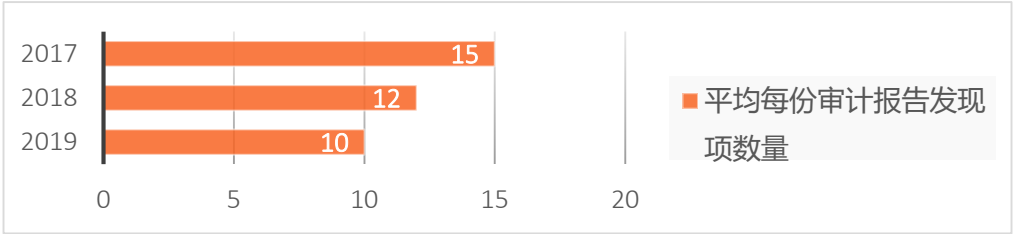
2200余次
报告下载

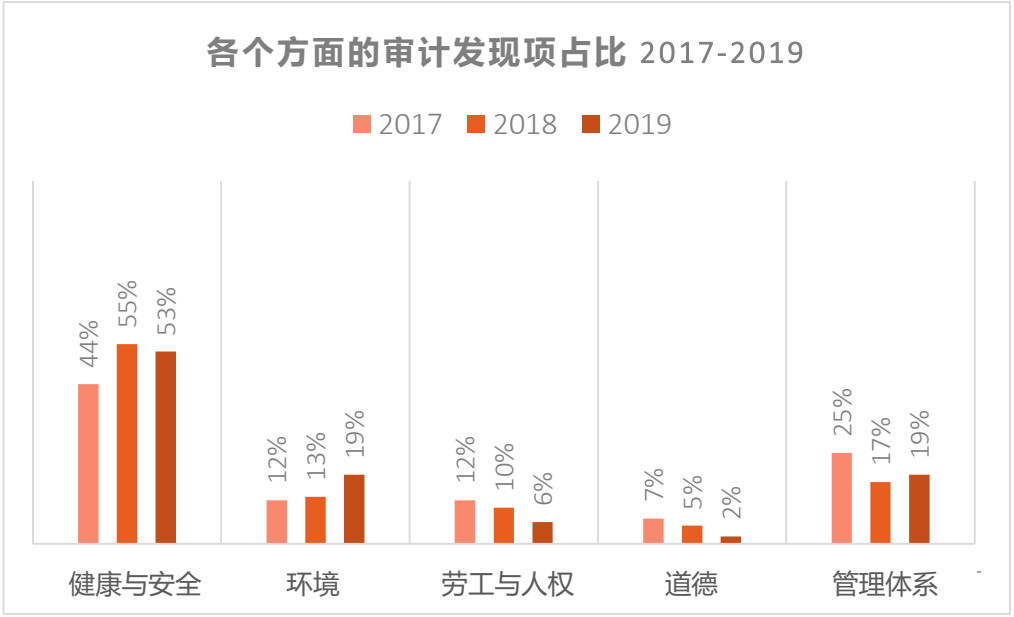
- 过去三年审计报告上传稳步增长。受疫情影响，2020年供应商可开展远程审计以及关闭整改报告中的审核发现项。
- 平台上65%的审计报告来自核心供应商，包括原料药、制剂和化学品供应商。
- 约半数审计报告来自中国、印度、美国。



审计报告发现（2017-2019）

- 平均每份审计报告的发现项数量在逐年递减。
- 健康与安全方面的发现项数量最多，占2019年全部发现项的半数以上，其次是管理体系和环境方面。
- 值得引起注意的是：环境方面的发现项在逐年**递增**。
- 道德和劳工与人权的发现项在逐年递减，两者共占2019年全部发现项的8%左右。可能原因包括：环境健康安全（HSE）审计数量增加、审计员不具备社会责任方面的证书和经验、或者是HSE审计报告和全面审计报告（HSE+劳工/道德）关注重点不同。





审计发现分析 (2018-2019)

- 2018-2019年执行的审计报告中，超过70%的发现项都来自原料药、化学品和制剂供应商，其中一半供应商来自中国和印度。
- 最多发现项的方面如下：
  - #1 – **健康与安全**
  - #2 – **环境**
  - #3 – **管理体系**
  - #4 – **人权与劳工**
  - #5 - **道德**

关键发现项意味着需要立刻关注

- 每年大约有1%的发现项是关键发现项（Critical findings）
  - 之所以关键发现项占比很低，其中一个原因是当供应商在整改关键发现项时，供应商和PSCI成员会选择不分享审计报告
- 2018年PSCI审计标准新增了“严重不符合/一般不符合”（Major/Minor）发现项类别
- 在过去两年，关键发现项主要存在于**健康与安全**、**环境和人权与劳工**方面，尚未出现在道德和管理体系方面。

发现项类别	2017	2018	2019
关键发现项	1%	1%	1%
严重不符合	4%	16%	14%
一般不符合	2%	22%	44%
其他发现项	92%	61%	42%

常见关键发现项和严重不符合（Critical & Major）
如果您也有以下问题，请主动关注、积极整改

- 健康与安全
  - #1: 接触和个人防护用具
    - 员工有不可接受的接触风险 和/或 未对药物粉尘进行风险评估
    - 个人防护用具防护不足、数量不够或员工/承包商未经过相关培训
  - #2: 安全生产有严重疏漏
    - 接地/跨接/防爆电气分类方面存在重大差距；没有弧闪评估
    - 未使用密闭空间作业许可证，或即便使用，许可证也未填写完整
    - 没有上锁/挂牌程序，也没有承包商安全批准程序或培训
    - 过道上机械缺少防护，尚未制定机械防护标准流程
    - 热加工（动火）作业许可证显示未遵守作业完成后的检查等相关程序
    - 托盘架有明显掉落伤及人员的风险
  - #3: 过程安全
    - 未展开危险及可操作性分析（HAZAOP）或分析给出的建议未实施也无相关计划
    - 反应安全性的过程安全信息明显缺失
    - 可能产生高能的单元操作和集尘器未进行可燃粉尘危害评估
    - 惰化有关的做法和程序导致惰化不充分（例如方箱，料桶，工艺容器和研磨工艺）
  - #4: 紧急响应
    - 应急设备和警报器不工作或未进行定期维护
    - 高危区域未安装应急设备，无烟雾探测器或其他防火警报系统
    - 消防演练未覆盖全部员工，没有记录经验教训，也无相应的措施

专题学习机会：

请参加中国供应商线上会议第四场：安全，过程安全管理及工业卫生（2020年10月29日）

常见关键发现项和严重不符合（Critical & Major）
如果您也有以下问题，请主动关注、积极整改

- 环境
  - #1: 溢出控制/泄漏
    - 危险化学物或废弃物或地下储罐过量填充无二次围堰
    - 无防溢套件或无防溢流程
    - 地面有明显的曾经发生或正在发生的泄漏
    - 泄压阀未连接到收集系统，无法保证在排放到环境前进行了处理
  - #2: 废水
    - 未测量符合性参数或超出该参数，或没有遵守所需监控频率
    - 未评估原料药排放对环境的影响
    - 污泥未妥善保存以防止溢出、人员接触或意外排放到环境
  - #3: **危险废弃物**
    - 缺失危险废弃物处置记录
    - 空溶剂桶未清理直接处置
    - 危险废弃物产生量超出有关部门许可量
    - 装有化学品的桶存储在废料场的软土上，没有防日晒雨淋或溢出的设施
    - 未经许可在现场焚烧废弃物，和/或使用没有资质及资质不全的供应商处理危险废弃物
  - #4: 许可证
    - 某车间的环评或其他许可缺失
    - 申请了环评、竣工验收，但未收到回复便开始作业

专题学习机会：

请参加中国供应商线上会议第二场：环境，环境中药物残留及抗微生物药物耐药性（2020年9月24日）

常见关键发现项和严重不符合（Critical & Major）
如果您也有以下问题，请主动关注、积极整改

- 人权与劳工
  - 加班未按照当地法律足额支付加班费
  - 收取员工押金
  - 无法展示工资单、津贴福利和工时的记录
  - 未制定劳工相关的政策或者无相关书面信息
  - 无童工相关政策或未保留员工年龄证明记录

- 道德
  - 无针对道德方面的温习培训 (refresher training)
  - 无正式申诉流程

专题学习机会：

请参加中国供应商线上会议第三场：道德，人权及劳工（2020年10月15日）

常见关键发现项和严重不符合（Critical & Major）
如果您也有以下问题，请主动关注、积极整改

- 管理体系
  - 没有制定业务连续性计划，或计划未经测试和过时
  - 对纠正预防措施和事故调查没有进行监督
  - 没有EHS相关的变更管理
  - 没有流程评估自身供应商的EHS风险
  - 无效的自我审核，无法确保实践与EHS制度和政策相符（基于其他发现）

为什么您会有这些关键和重大发现项?

PSCI能通过什么方式来促进更完善的EHS文化和管理体系?

审计过后 – 您是否想了解产生发现项的根本原因? 或者只是解决发现项中的问题?

PSCI审计相关资源

简略版PSCI服务提供商和一般制造供应商自我评估问卷（Excel版本）	简略版PSCI服务提供商和一般制造供应商自我评估问卷（Word版本）
PSCI审计指引	整改计划模板（Word版本）
数据共享协议	完整版PSCI核心供应商，外部制造，成份和原料供应商自我评估问卷（Excel版本）
完整版PSCI核心供应商，外部制造，成份和原料供应商自我评估问卷（Word版本）	审核前文件要求清单
PSCI审计员评估工具	PSCI审计报告共享介绍

以上资源可在PSCI官网下载: https://pscinitiative.org/sharedAudits

PSCI在线学习工具

通过在线学习工具，帮助成员公司和供应商了解这些原则。点击此处免费进入该工具。

PSCI已批准的审计公司

为了确保审计质量和完整性，PSCI审计由PSCI成员公司内部的审计员或由专业且独立的第三方审计公司进行。 PSCI已批准12家专业，独立的第三方审核公司进行PSCI审核：点击此处获得审计公司列表

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

康龙化成新冠疫情防控工作经验分享

倪柳倩
康龙化成（北京）新药技术股份有限公司（Pharmaron Beijing Co., Ltd.）

嘉宾介绍

- 倪柳倩

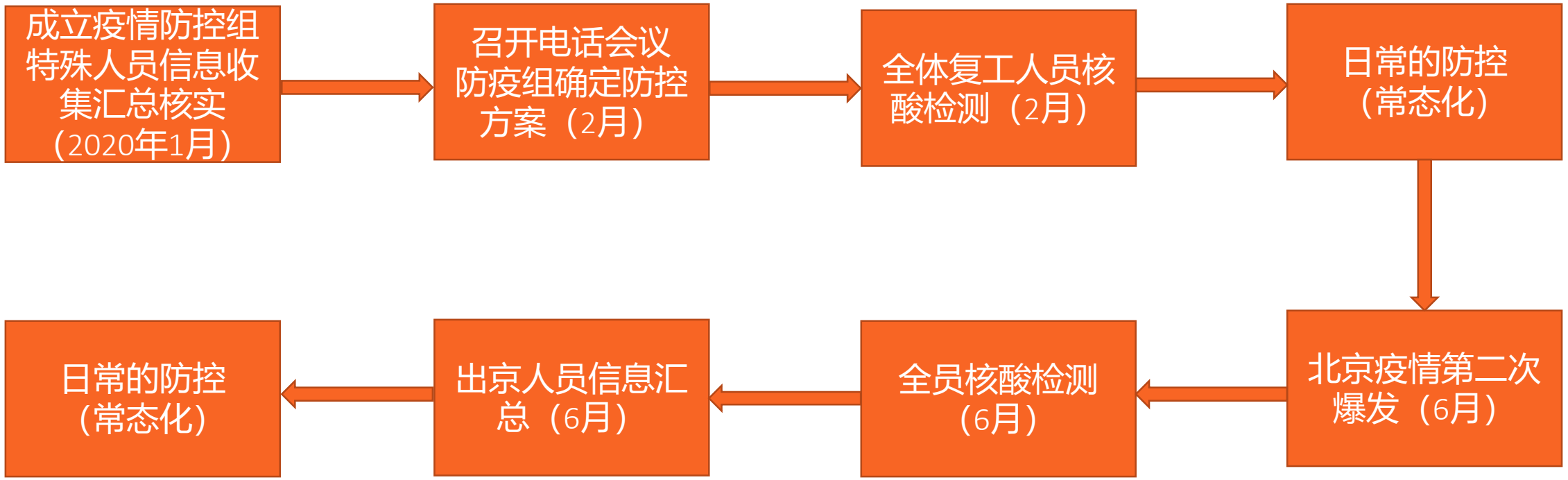
- 现就职于康龙化成（北京）新药技术股份有限公司
  EHS部门工程师
- 工作经历
  从事8年安全生产管理工作
  参与并主要负责新冠疫情期间的防疫工作
  负责康龙化成BDA园区的消防与应急管理工作

- Contact information 联系方式
- TEL：010-57330040
- Email：liuqian.ni@pharmaron-bj.com

分享内容

1. 康龙化成疫情防控时间线
2. 疫情防控小组
3. 日常防疫工作
4. 专项防疫工作
5. 捐款活动
6. 特殊员工关怀

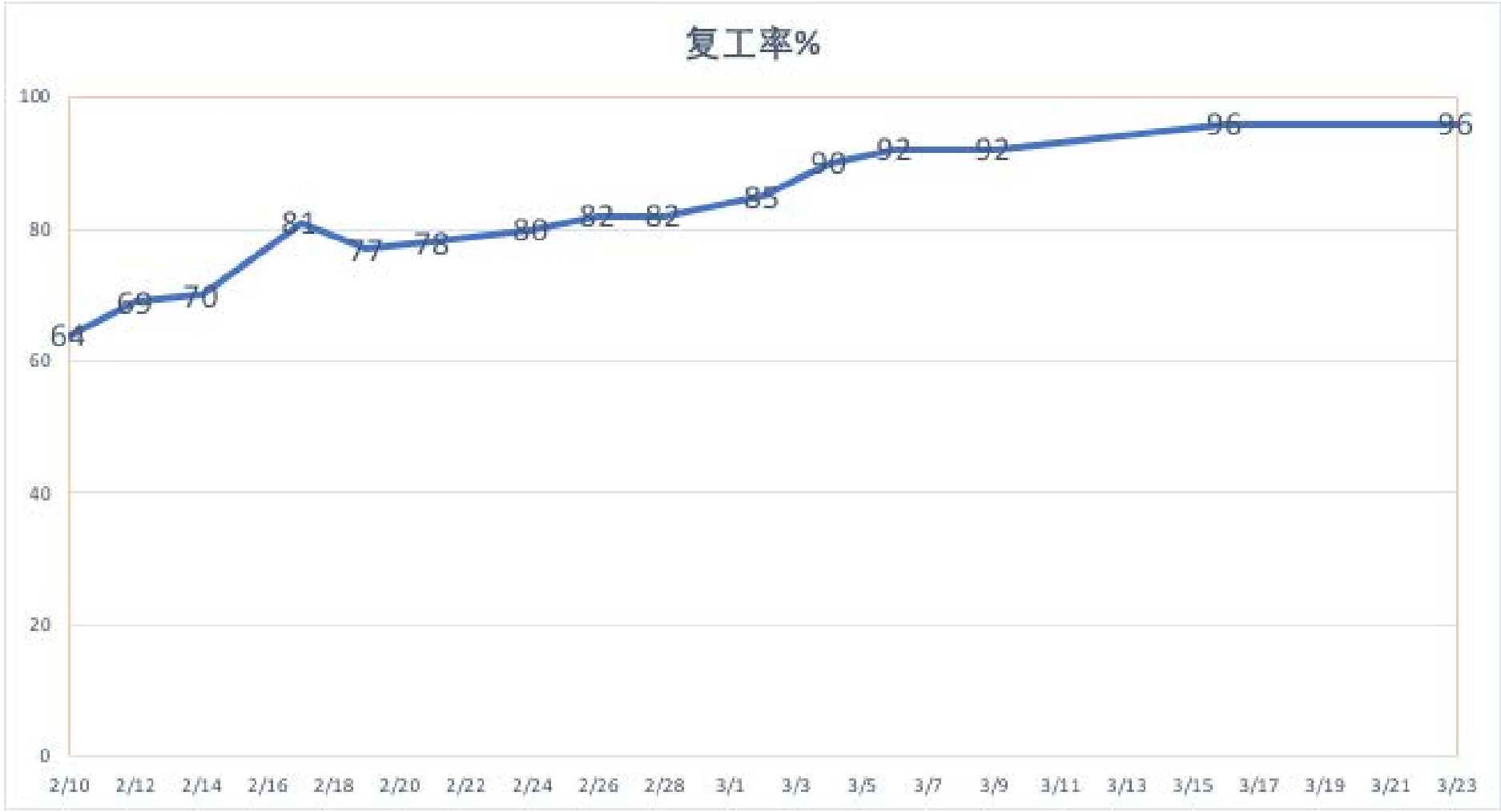
疫情防控时间线


成立疫情防控组特殊人员信息收集汇总核实（2020年1月）
召开电话会议防疫组确定防控方案（2月）
全体复工人员核酸检测（2月）
日常的防控（常态化）
北京疫情第二次爆发（6月）
全员核酸检测（6月）
出京人员信息汇总（6月）
日常的防控（常态化）

疫情防控小组

防疫领导小组
防疫办公室
EHS
行政部
HR
公共事务部
采购部
工程部
• 入园体温检测
• 异常人员监控
• 核酸检测
• 应急处置
• 外来人员管控
• 就餐管理
• 园区消毒
• 公司员工信息汇总
• 特殊人员监控
• 疫情期间员工薪酬福利管理
• 收集政府部门发布的关于防疫的相关要求
• 报送政府部门所需材料
• 采购防护、消毒物资
• 保证新风系统的正常运行

复工率


复工率%
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日常防疫工作

- 1. 入园体温检测
- 2. 工作时间体温异常人员登记
- 3. 外来人员管控
- 4. 异常人员分析处理
- 5. 就餐管理
- 6. 日常消毒

入园体温检测

1. 每天在公司各个出入口对每位员工进行体温检测

注：体温超过37.3度，等待两分钟后，再进行第二次检测，超过三次视为异常，不得进入公司

2. 手部进行消毒

3. 检查员工佩戴口罩情况

工作时间体温异常人员登记

在室外通风良好位置设立体温检测点，如有员工感觉身体不适，可以随时进行体温检测，如确有发热症状，将使用发热人员专用车辆送往医院就诊。

外来人员管控

1. 体温测量

2. 人员消毒

3. 北京健康宝查验

4. 填写入园登记表（包括：来访地、隔离史、接触史、14日内途径地点）

异常人员分析处理

1. 根据北京市防疫政策，任何外地来京人员都必须隔离14天，并要求向公司EHS部门报备，按社区的要求居家隔离

2. 有直接接触和间接接触湖北人员的员工需向EHS提供相关信息，并提供隔离时间和接触隔离日期。

3. 出现发热或咳嗽症状的员工，要求立即去医院就医，症状消失及持有医院出具的核算证明才可以返岗复工。

4. 根据社区（村）要求进行隔离。

该员工7日8日体温在37度到37.3度之间，村医诊断为感冒，未做任何检查。2月9日返京当晚，因身体不适，10日未上班，11日早上体温检测为36.3度，下班后仍感觉身体不适，12日与13日未上班。因其宿舍无体温计，体温未知。13日晚体温36.9度。基本排除新冠肺炎的可能性。

3号从内蒙古自驾回京，于2月10日返岗，下午身体忽冷忽热且有头痛，经测温为37.4℃，下班后回家测量体温为37.4℃，睡前体温36.8℃。隔离期为2月4日至2月17日，隔离期已满，且身体无不适，于2月18日返岗。

就餐管理

1. 分楼宇发餐
2. 限制办公区域就餐人数
3. 错峰就餐

一、午餐为盒装套餐：主食：米饭、馒头，由于特殊时期发餐形式改变无法提供汤粥及水果，请给予理解。回民员工请持餐卡到18号楼一层餐厅领取回民餐。

二、发餐时间：11:50至12:20，请领餐的同事错峰领取

三、发餐地点：

1号楼：一层北门（后门）门厅；

2号楼：A\B\C段一层门厅；

3号楼：A\B\C段一层门厅；

5、6号楼：5号楼东侧门厅；

7、8号楼：中间一层大厅；

9、15号楼：15号楼一层南门厅；

16号楼，一层南门厅；

17号楼，一层南门厅；

10、12、18号楼，在18号楼餐厅一层；

日常消毒

1. 消毒区域：公司出入口、公司内部道路、办公区域、卫生间、实验区域、班车。

2. 消毒液配备依据:根据《北京经济技术开发区新型冠状病毒感染的肺炎防控指导手册（第四版）》

专项防疫工作

- 1. 防疫宣传
- 2. 全员核酸检测
- 3. 建立隔离室
- 4. 设立防疫专用车

员工防护手册

防护手册内容

1.工作场所防护（上班途中，办公室防护，会议防护，食堂防护等）。

2.个人防护知识（个人清洁防护要求，口罩佩戴要求）。

3.公司相关的防疫要求。

隔离观察点

公司共设置5个隔离点（两个室内隔离点、三个室外隔离点）

隔离点配备物资如下：

1. 配备3M口罩
2. 消毒酒精
3. 温度计
4. 防疫手册

防疫专用车辆

公司设立专门的应急救援车辆，同时对人员进行防疫安全培训，如发现发热人员，可以迅速启动应急预案，将人员送往距离最近的医院就医。

核酸检测

公司秉承“早发现、早报告、早隔离、早治疗”的理念，共进行了两次全体员工的核酸检

第一次为新冠肺炎高发期，共检测3702人

第二次为新发地疫情爆发，检测共计 4892人。

所有参加检测的员工均为阴性，完全排除了我公司人员感染新冠肺炎的风险。

捐款活动

守望相助康龙心　抗灾抵疫化成情

2020年1月29日，面对湖北武汉的疫情严峻形势，康龙第一时间成立抗击疫情工作组，作为有社会责任感的企业公民，公司向武汉市红十字基金会捐出了三百万人民币。

康龙化成向武汉红十字会捐赠三百万，共抗疫情

这一个不同寻常的春节假期，新型冠状病毒感染的肺炎疫情牵动着每一个人的心。一方有难，八方支援，康龙化成面对疫情迅速做出响应，并在第一时间组建了“抗疫情工作组”，积极研究商讨一切与“防疫情、保安全、利员工、尽善举”有关的事宜。

康龙化成一直是具有强烈社会责任感的企业公民，在正月初四根据自身实际情况研究决定资金捐助以尽绵薄之力。经过多方联系，在短短不到二十四小时的时间里，公司向武汉市红十字基金会捐出了三百万元人民币善款，支援武汉，共抗疫情！

作为一家从事新药研发服务的上市公司，康龙化成将不遗余力地为人类健康和疾病防治做出自己应有的贡献。相信全国人民在“众志成城、大爱无疆”的感召中一定能够战胜一切灾疫！

武汉加油，中国加油！！

捐款活动

康龙化成抗疫捐款倡议书

大疫当前，在这场没有硝烟的战斗中，没有局外人和旁观者，唯有团结一心、同舟共济，方能凝聚磅礴之力，打赢疫情阻击战。在此，公司倡议大家积极响应国家号召，以奉献传递爱心，以爱心凝聚力量，踊跃捐款，为疫情防控工作奉献一份力量！

如果您有捐赠的意向，请按下列操作表达您的爱心：

1.采取自愿原则，金额不限（其它渠道已捐款的，建议不再捐赠）。

2.请在“康龙化成信息化平台”里的“个人中心”选择“爱心捐助”输入捐款金额，员工所捐金额将从3月薪资中扣除，体现在4月15日发放的薪资中。

3.捐款认捐时间截止到2020年3月10日晚上20点，届时捐款平台将关闭进行最终汇总。

4.公司公共事务部及法务部会将善款汇款到中华慈善总会，并将收款凭证在公司公众号公布。

乌云不可遮日，阴霾终将散开，唯善意和努力不会被辜负，让我们一起守望，待到春和景明时，并肩再看繁花开！

康龙化成（北京）新药技术股份有限公司

2020年03月04日

公司倡议员工为新冠病毒的防控捐助一份爱心，截止至2020年3月10日，共计捐款2083600元，全部汇至中华慈善总会。

康龙化成 PHARMARON

守望相助　同心克艰

康龙化成给捐助员工的致谢函

致全体捐助员工：

大疫当前，全国上下齐心协力抗病毒，危难时刻，华夏儿女匹夫担当献爱心。康龙化成积极投身其中不遗余力，在全集团内发起了“青山一道，同担风雨”抗疫捐款的倡议活动。此活动得到了员工们的积极响应，大家纷纷献出自己的一份爱心，用实际行动诠释了“一方有难，八方支援”的仁者博爱情怀。从疫情爆发以来到目前为止，康龙人共先后累计捐献出二百零八万三千六百元善款，已汇至中华慈善总会“抗击新冠肺炎，中华慈善总会在行动！”项目的指定账户，其中党员捐款部分由开发区企业党委代收后缴至中央组织部。

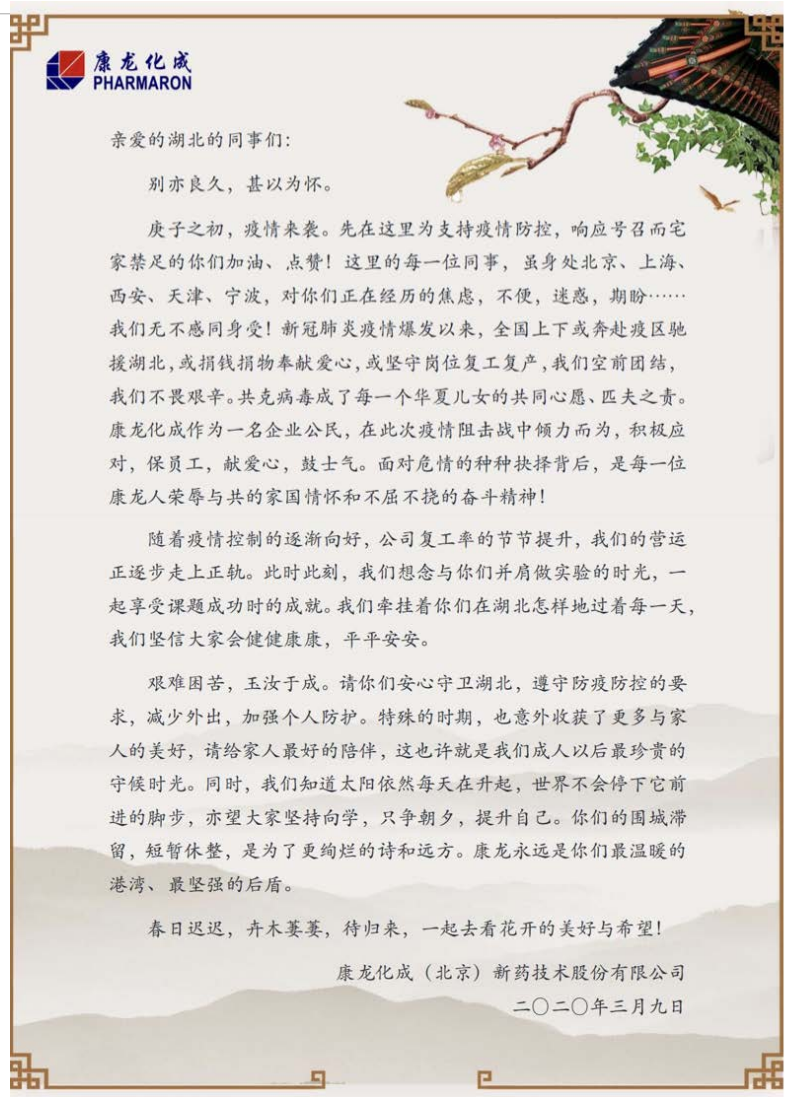
至此，公司感谢每一位伸出援手、献出爱心的你们，讴歌每一份真挚无私、上善若水的柔情。在全面复工复岗的新阶段，希望康龙化成全体员工加强个人防护，保障自身安全，做好自己、做真自我，不负韶华、慨当以慷。让我们一起守望相助、再接再厉，以文明、科学之力打赢这场防疫阻击战。“阳光总在风雨后，请相信有彩虹”！

康龙化成（北京）新药技术股份有限公司

二〇二〇年三月十二日

特殊员工关怀

公司对处于湖北无法复工的员工，给予关怀及鼓励，并与员工保持联系，公司期盼着每名康龙人回家。



康龙化成
PHARMARON

亲爱的湖北的同事们：

别亦良久，甚以为怀。

庚子之初，疫情来袭。先在这里为支持疫情防控，响应号召而宅家禁足的你们加油、点赞！这里的每一位同事，虽身处北京、上海、西安、天津、宁波，对你们正在经历的焦虑，不便，迷惑，期盼……我们无不感同身受！新冠肺炎疫情爆发以来，全国上下或奔赴疫区驰援湖北，或捐钱捐物奉献爱心，或坚守岗位复工复产，我们空前团结，我们不畏艰辛。共克病毒成了每一个华夏儿女的共同心愿、匹夫之责。康龙化成作为一名企业公民，在此次疫情阻击战中倾力而为，积极应对，保员工，献爱心，鼓士气。面对危情的种种抉择背后，是每一位康龙人荣辱与共的家国情怀和不屈不挠的奋斗精神！

随着疫情控制的逐渐向好，公司复工率的节节提升，我们的营运正逐步走上正轨。此时此刻，我们想念与你们并肩做实验的时光，一起享受课题成功时的成就。我们牵挂着你们在湖北怎样地过着每一天，我们坚信大家会健健康康，平平安安。

艰难困苦，玉汝于成。请你们安心守卫湖北，遵守防疫防控的要求，减少外出，加强个人防护。特殊的时期，也意外收获了更多与家人的美好，请给家人最好的陪伴，这也许就是我们成人以后最珍贵的守候时光。同时，我们知道太阳依然每天在升起，世界不会停下它前进的脚步，亦望大家坚持向学，只争朝夕，提升自己。你们的围城滞留，短暂休整，是为了更绚烂的诗和远方。康龙永远是你们最温暖的港湾、最坚强的后盾。

春日迟迟，卉木萋萋，待归来，一起去看花开的美好与希望！

康龙化成（北京）新药技术股份有限公司

二〇二〇年三月九日

特殊员工关怀

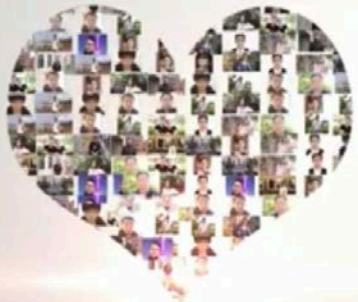
康龙化成 PHARMARON

王芸-天门
TSP

睽违日久，拳念殷殊。

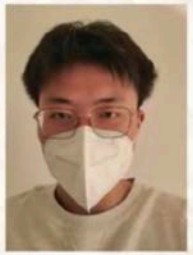
无比怀念和你们一起并肩做实验、写报告的日子，虽然现在疫情已逐步得到控制，但也请你们一定要照顾好自己和家人，大家都平安健康，期待疫情过后我们的重聚。

纵有疾风起，人生不言弃。急风骤雨之后，终会艳阳高照。春末，疫平，万物复苏！



湖北家人一切平安，期待回归康龙大家庭

康龙化成 PHARMARON



陈炳昆-黄冈
西安

为响应政府及公司号召，全家人足不出户，做好隔离防护工作，家人们在湖北一切安好。隔离期间，全家线上办公学习，自律生活，提升自己。

愿国泰民安，早日回归正常工作与生活。

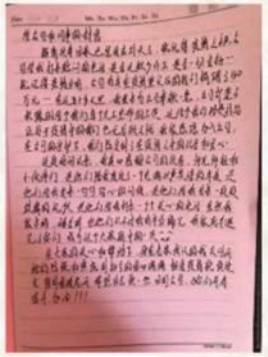
康龙化成 PHARMARON

程时茂-黄冈
宁波

我现在在老家，没法与我的同事一起工作，但是我怀念与他们并肩工作的日子，相信过不了多久，我们就可以再相聚了。疫情终将过去，春天总会到来，我相信在大家的鼓励与支持下，我们一定会胜利。

康龙化成 PHARMARON

高倩-武汉
宁波



康龙化成（北京）新药技术股份有限公司

公司研发领域主要集中在药物小分子有机合成、药物化学、分析化学、研发生物学、药物代谢及动力学、生物分析、制药工艺研究和开发生产、病理毒理等方面，涉及新药研发临床前的各个环节，是中国第一家拥有符合欧美GLP临床前毒理学服务能力的CRO企业。

我们为全球制药及生物技术公司提供临床前的药物研发服务，拥有国际顶尖的科研管理团队和科研水平，一直与北美、欧洲、日本的各医药公司保持长期、稳固的合作关系。

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

中国《新化学物质环境管理登记办法》的最新进展介绍

Update of China's MEE Order No.12 and Draft Guidance

LINGZHEN DONG, Ph.D.
PRODUCT STEWARDSHIP DIRECTOR
ASIA PACIFIC REGION
JOHNSON & JOHNSON CHINA LTD.

Sept. 17, 2020

Disclaimer: The information in the presentation is not official regulatory information. Please refer to MEE's website for official regulations.
Compliance with local regulatory requirements is the responsibility of companies and their local business areas.

AGENDA 大纲

- 《新化学物质环境管理登记办法》（12号令）及《新化学物质环境管理登记指南》（征求意见稿）简介 Brief Introduction of “Measures for Environmental Management Registration of New Chemical Substances” (MEE Order No.12) and the Guidance (draft for public consultation)
- 《中国现有化学物质名录》增补近况 <Inventory of Existing Chemical Substances in China>（IECSC）Supplementation Update
- 化学物质环境风险评估与管控条例 (WTO通报稿) – 相关条款 Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification Version)
- 总结和建议 Summary and Recommendations

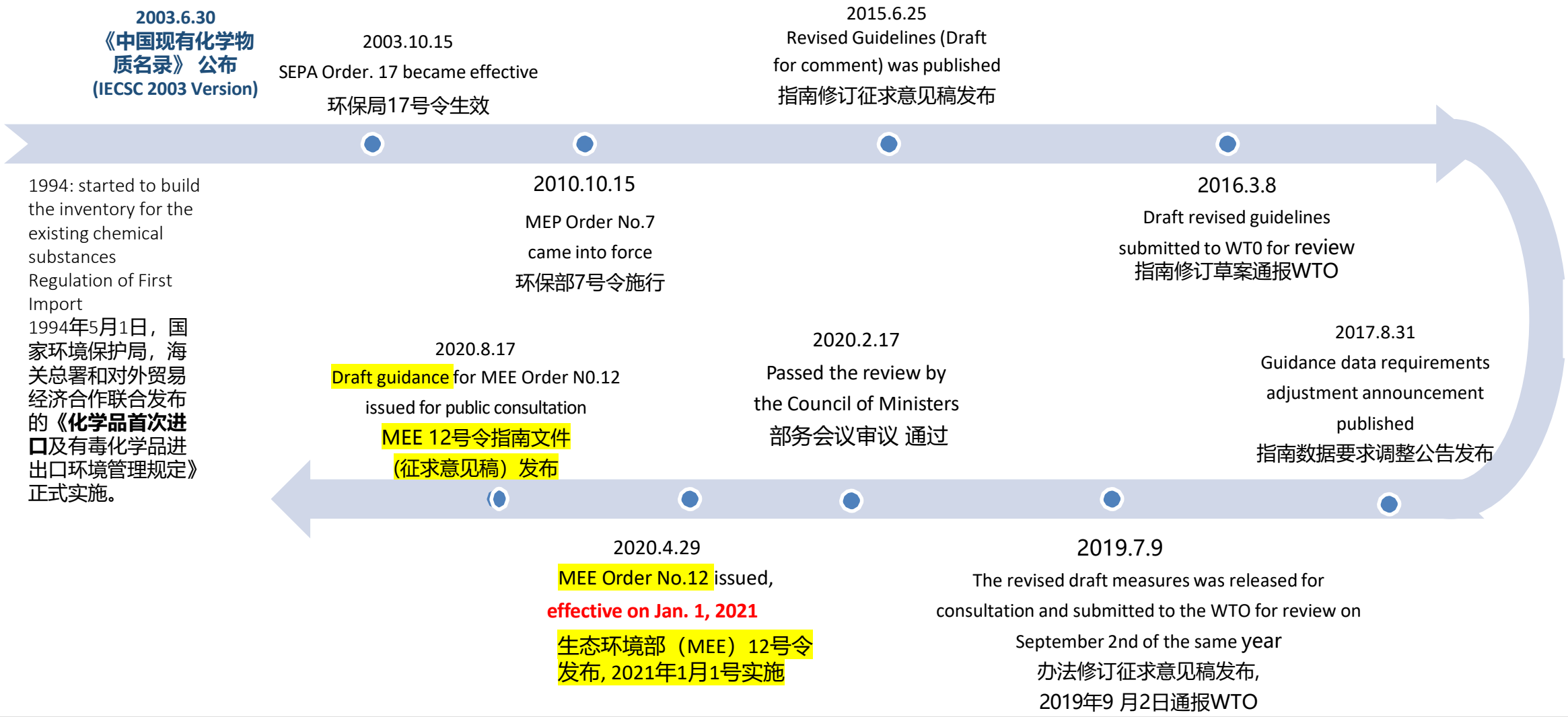
嘉宾介绍 Speaker bio

- **董玲珍** Lingzhen Dong
- 亚太区EHS&S产品监管总监, 强生（中国）有限公司
- 教育背景：化学博士
- 工作经历：
  - 于2013年加入强生
  - 在化工行业工作超过20年（罗门哈斯和 陶氏化学）
  - 从事过的工作包括研发、毒理/生态毒理、 法规事务/产品监管、研发中心管理、中国区经理（罗门哈斯）及 亚太区EHS和可持续发展总监（罗门哈斯、 陶氏 和强生）
  - 在美国工作了10年; 在中国/亚太区工作超过15年
- 联系方式： ldong20@its.jnj.com; +86-21-33379452

- AP Product Stewardship Director, Johnson & Johnson China Ltd.
- Education: BS, MS & PhD in Chemistry
- Past experience:
  - Working in J&J since 2013
  - >20 years in Chemical Industry-Worked in Rohm and Haas Company (acquired by Dow Chemical) and Dow Chemical
  - Different functions: R&D, Toxicology/Ecotoxicology, Regulatory Affairs and Product Stewardship, R&D Site Management, China Country Management (Rohm and Haas), and AP EHS & Sustainability (Rohm and Haas, Dow and J&J)
  - >15 years in China/Asia Pacific region and 10 years in the U.S.

中国新化学物质法规进展一览

China New Chemical Substances Management Regulation ("China REACH") Development Timeline



范围调整 Scope Adjustment

Good News for the Pharm Industry： APIs will be exempted!
However, Excipients have not been exempted (still being advocated).

Substance Scope 物质范围

1、 Chemical substances that have been listed in the “Inventory of Existing Chemical Substances in China (IECSC)” and are subject to environmental management for new uses, when they are used for industrial purposes other than permitted uses“, should be registered。 “已列入《中国现有化学物质名录》并实施新用途环境管理的化学物质，用于允许用途以外的其他工业用途” 时，应当办理登记；

2、 MEE Order 12 does not apply to the following chemical substances or products:下列化学物质或者产品不适用《办法》，不需要办理新化学物质环境管理登记：

（1）Pharmaceuticals (including active pharmaceutical ingredients (APIs), pesticides (including pesticide active ingredients), veterinary drugs, cosmetics, food, food additives, feed, feed additives, fertilizers and other products;
医药（含原料药）、农药（含农药原药）、兽药、化妆品、食品、食品添加剂、饲料、饲料添加剂、肥料等产品；

（2）Radioactive materials. 放射性物质。

However, if it is changed to other industrial use and contains new chemical substance, it shall be registered.
但是, 但它们改变为其他工业用途且属于新化学物质的, 应当办理登记。

3、 "Products or formulations with specific functions, such as adhesion promoters, chelating agents, flocculants, surface treatment agents, etc., chemical substances produced by chemical reactions to achieve their specific functions", registration can be exempted. “具有特定功能的产品或配制品，如粘合促进剂、螯合剂、絮凝剂、表面处理剂等，为实现其特定功能而发生化学反应产生的化学物质” ，豁免登记.

4、One of the anhydrous form of chemical substance and its hydrate has been listed in the “IECSC“, another can be exempted registration.无水形式的化学物质和其水合物，两者其一已列入《名录》 的可豁免登记。

Refer to the Guidelines for details 参看《指南》了解其他豁免情况

范围调整 Scope Adjustment

Region Scope 地域范围

1. Engage in research, production, import, processing and use of new chemical substances **within the territory** of the People's Republic of China (except HK, Macao, Taiwan).

在中华人民共和国**境内**从事新化学物质研究、生产、进口和加工使用活动。（港澳台除外）

2. Except for imported new chemical substances that are stored in the **special customs supervision area** and have not undergone any processing (such as sub-packaging, selection, etc.) (Including 6 types of special areas within the bonded zone and export processing zone)

进口后在**海关特殊监管区**内存放且未经过任何加工（如分装、挑选等）即全部出口的新化学物质除外。（含保税区和出口加工区之内的6种特殊区域）

Registration certificate holder (for foreign export type)
登记证持有人 （对于境外进口类型）

Only Representative (Chinese Agency)
唯一代表（中国代理）

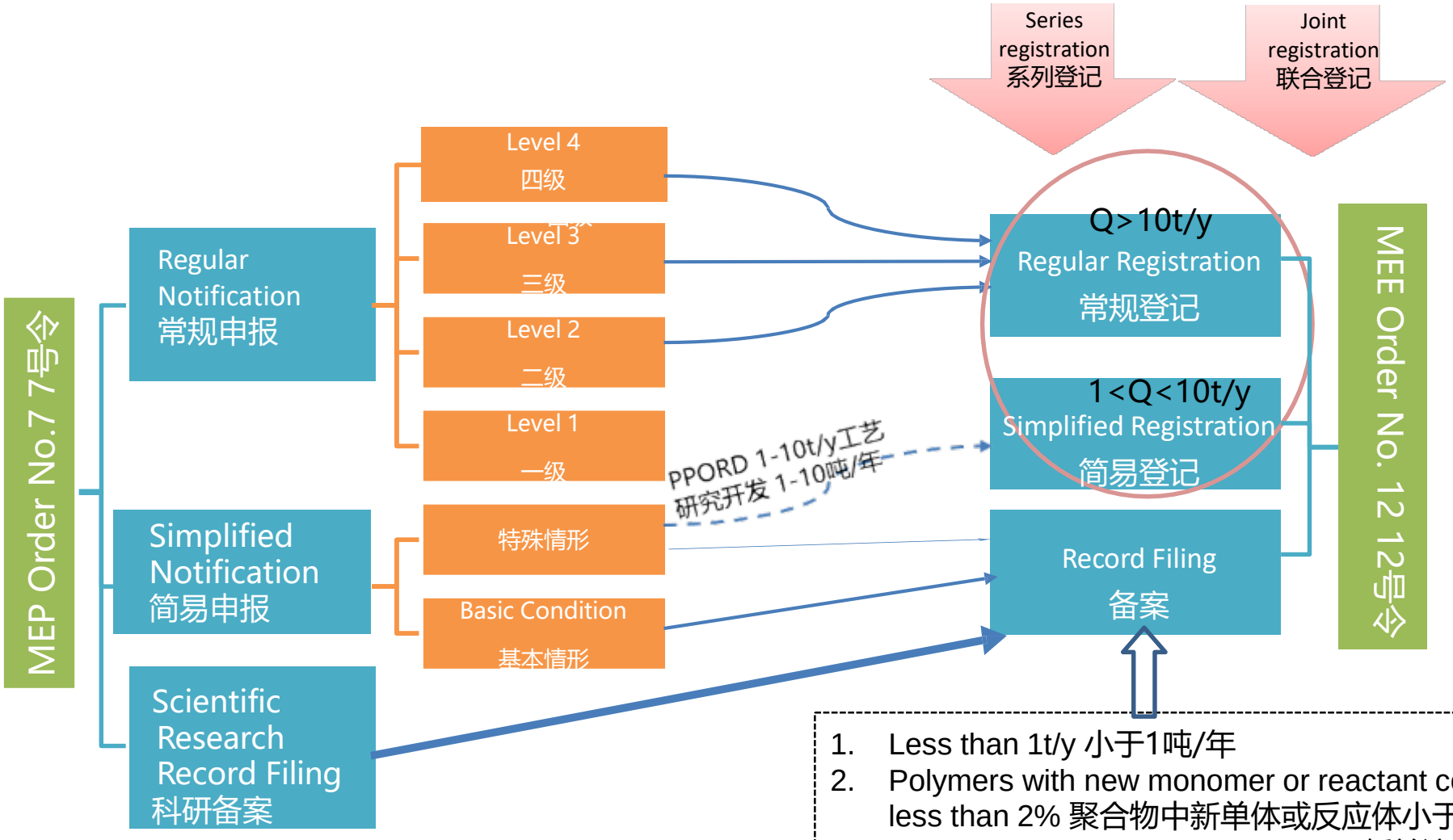
MEP Order No.7
7号令

Changes to
变更为

Foreign exporter can use an agent in China to do registration and be the registration certificate holder
登记证持有人（境外出口商通过代理人登记）

MEE Order No.12
12号令

申报类型调整为登记类型 Registration Types



1. Less than 1t/y 小于1吨/年
2. Polymers with new monomer or reactant concentration less than 2% 聚合物中新单体或反应体小于2%
3. PLC (Polymer with Low Concern) 低关注聚合物

12号令登记类型及材料要求

Registration Type and Material Requirements of MEE Order No.12

Registration Type 登记类型	Substance Scope 物质范围	Registration material requirements 登记材料要求
Regular Registration 常规登记	New chemical substances with an annual output or imported quantity of above 10 tons per year 新化学物质年生产量或者进口量10吨以上	Regular registration application form, application form attachments (including legal person certificate or business license, agency contract or agreement, authorization letter, test report or information, environmental risk assessment report, social-economic benefit analysis report (belonging to high-hazard new chemical substances), etc.) 常规登记申请表、申请表附件（包括 法人证书或营业执照，代理合同或协议、授权书、测试报告或者资料、环境风险评估报告、社会经济效益分析报告（属于高危害新化学物质的）等）
Simplified Registration 简易登记	New chemical substances with an annual output or an imported quantity between 1 to 10 ton per year 新化学物质年生产量或者进 口量1吨以上不足10吨	Simplified registration application form, attachments to the application form (including legal person certificate or business license, agency contract or agreement, power of attorney, test report or information, determination conclusion and basis for persistence, bioaccumulation and toxicity of the applied substance, etc.) 简易登记申请表、申请表附件（包括法人证书或营业执照，代理合同或协议、授权书、测试报告或者资料、申请物质的持久性、生物累积性和毒性的判定结论及依据等）
Record Filing 备案	New chemical substances with an annual output or an imported quantity of less than 1 ton per year 新化学物质年生产量或者进口 量不足1吨	Filing form, attachments to filing form (including legal person certificate or business license, agency contract or agreement, authorization letter, etc.) 备案表、备案表附件（包括法人证书或营业执照、代理合同或协议、授权书、等）
	Polymers with new monomer or reactant concentration less than 2% or PLC (no tonnage limit) 新化学物质单体或者反应体含量不超过2%的聚合物或者属于低关注聚合物（无吨位限制）	In addition to the above filing materials, also submit: List of monomers/reactants, molecular weight distribution diagram, polymerization reaction mechanism process, explanation materials for discriminating that the applied substance does not belong to the exclusion of polymer filing, etc. 除上述备案材料外，还应提交： 单体/反应体列表、分子量分布图、聚合反应机理过程、 申请物质不属于聚合物备案排除情形的判别说明材料等

登记流程 (时间表) Registration Workflow

Reistration Type **登记类型**	Regular Registration **常规登记**（WD=Working Day; M=Month)	Simplified Registration **简易登记**	Record Filing **备案**
SCC Review 形式评审	5WD 5个工作日	5WD 5个工作日	Random Check 随机抽查
Technical Review by expert committee 技术评审	60D 60日	30D 30日	/
Correction (If required) 补正(如有)	6M (one submission) 6个月（一次性）	6M(one submission) 6个月（一次性）	Not Specified 未规定
MEE Approval MEE 审批	20+10WD 20+10个工作日	20+10WD 20+10个工作日	/
Public Consultation 公示	at least 3WD 至少3个工作日	at least 3WD 至少3个工作日	/
Public Notice 公开	20WD 20个工作日	20WD 20个工作日	Make Public Notice Periodically 定期公开
Timeline 总周期	4-12M 4-12个月	3-10M 3-10个月	Can start the activity after submission (record filing) 提交即可开展活动

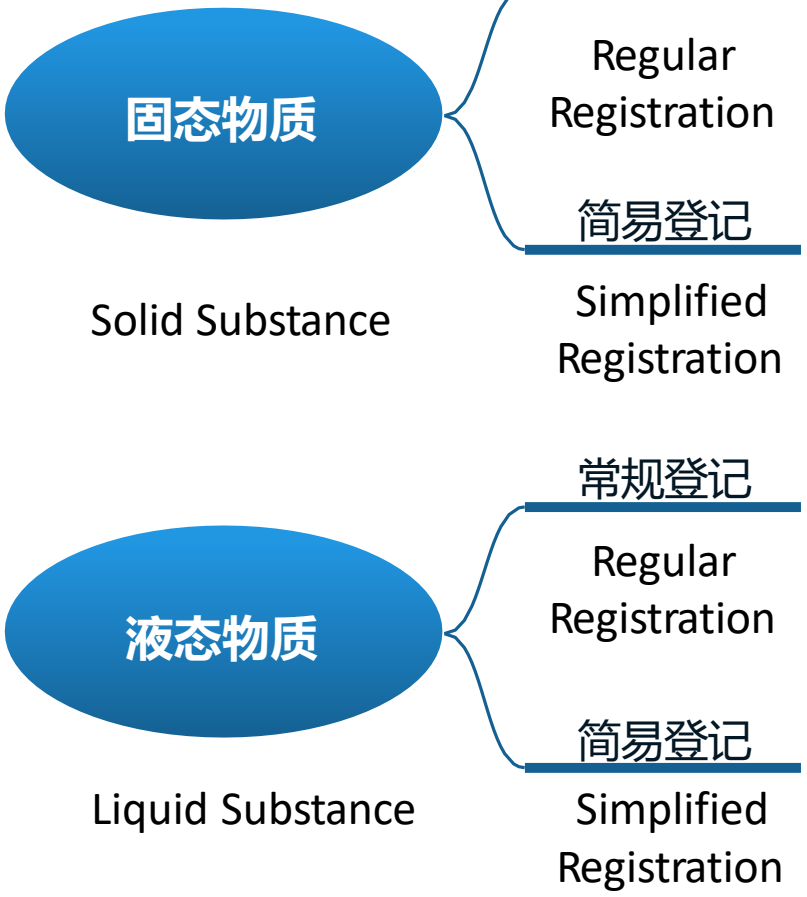
SCC= MEE's Solid Waste and Chemical Management Center
固体废物与化学品管理技术中心 (简称： 固管中心)

数据要求-12号令

Data Requirement-MEE Order No.12

数据要求-理化特性

Data Requirement-Physical and Chemical Properties



图谱、熔点/凝固点、密度、水中溶解度、正辛醇/水分 配系数、粒径、有机溶剂中的稳定性和降解产物的特性、**解离常数**、**亨利常数**

Spectrum, Melting/Freezing Point, Density, Solubility in Water, n-Octanol/ Water partition coefficient (log Kow) , Particle Size, Stability in Organic Solvents and Degradation Product Characteristics, Dissociation Constant, Henry's Constant

图谱、熔点/凝固点、密度、水中溶解度、正辛醇/水分配系数

Spectrum, Melting point/freezing point, density, solubility in water, log Kow

图谱、**熔点/凝固点**、沸点、密度、蒸汽压、水中溶解 度、正辛醇/水分配系数、pH值、表面张力、有机溶剂中的稳定性和降解产物的特性、**解离常数**、**亨利常数**

Spectrum, Melting/Freezing Point, Boiling Point, Density, Vapor Pressure, Solubility in Water, log Kow, pH, Surface Tension, Stability in Organic Solvents and Degradation Product Characteristics, Dissociation Constant, Henry's Constant

图谱、**熔点/凝固点**、沸点、密度、蒸汽压、水中溶解度、正辛醇/水分配系数、pH值

Spectrum, Melting/Freezing Point, Boiling Point, Density, Vapor Pressure, Solubility in Water, log Kow, pH

数据要求-健康毒理特性

Data Requirement-Toxicity properties

Toxicity (Regular Registration) 健康毒理学 （常规登记）

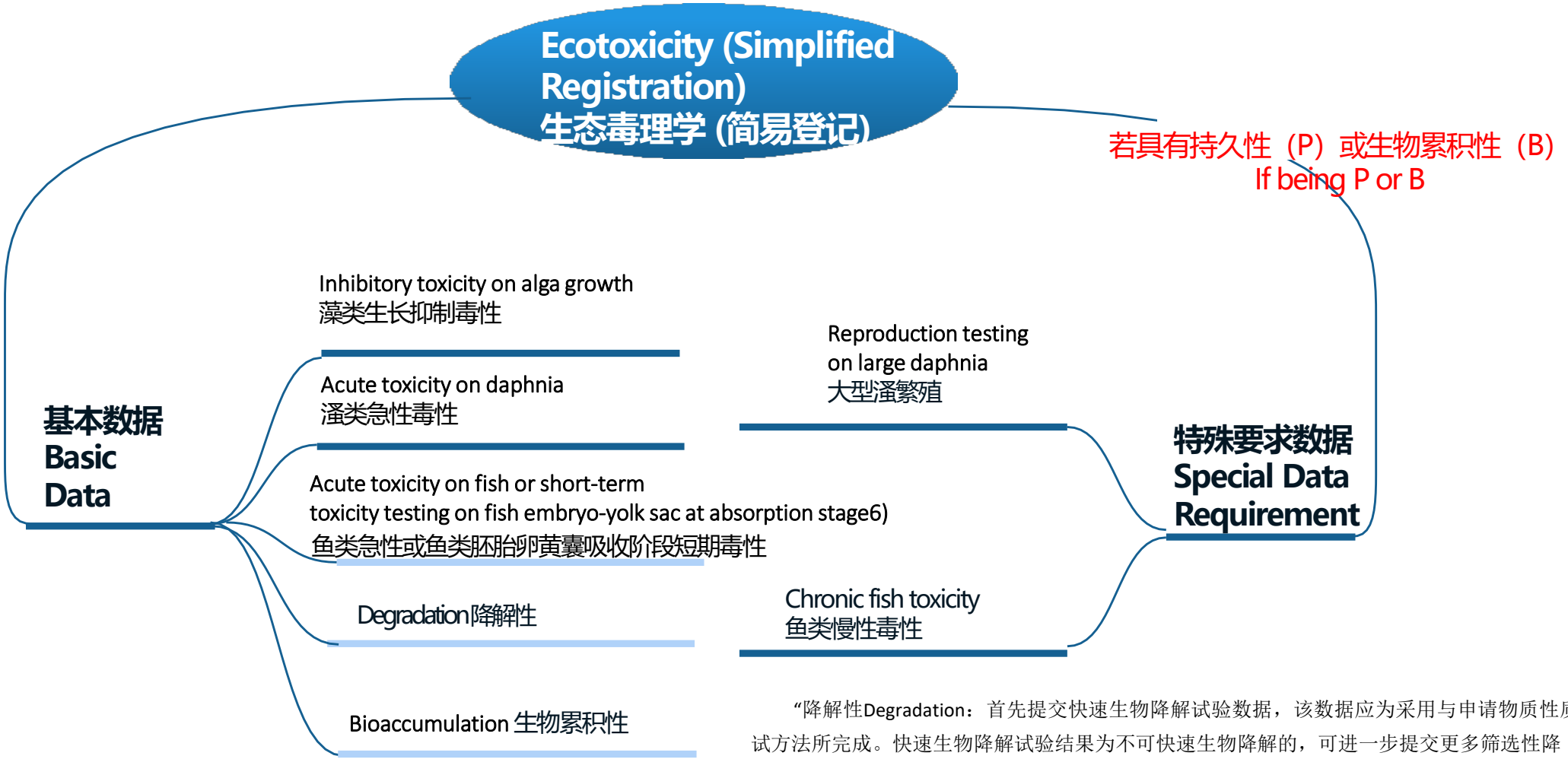
(Refer to Table 2 Minimum Required Data for Toxicology

指南中 表2 健康毒理学最低要求数据)

数据项目	基本数据 Basic data	特殊要求数据 Special requirement data
急性毒性 Acute Toxicity[1)]	√	√
皮肤刺激 Skin Irritation	√	√
眼刺激 Eye Irritation	√	√
皮肤致敏 Skin Sensitization	√	√
致突变性 Mutagenicity[2)]	√	√
反复染毒毒性 Repeated dosing	√[3)]	√[4)]
生殖/发育毒性 Reproductive /developmental Tox	√[5)]	√[6)]
毒代动力学 Toxicokinetics[7)]		√
慢性毒性Chronic toxicity [8)]		√
致癌性 Carcinogenicity [9)]		√
其他 Others[10)]	√	√

数据要求-生态毒理特性

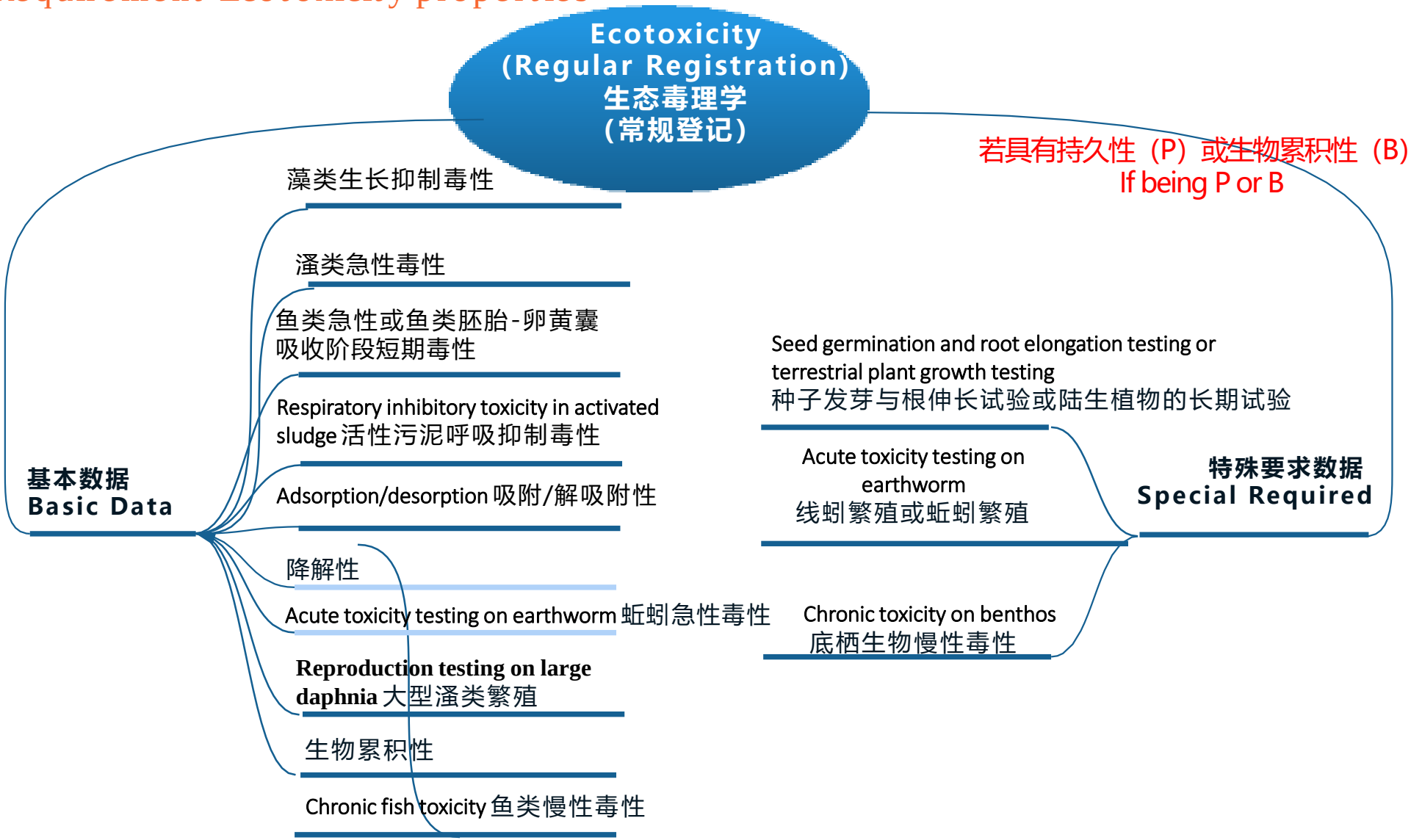
Data Requirement-Ecotoxicity properties



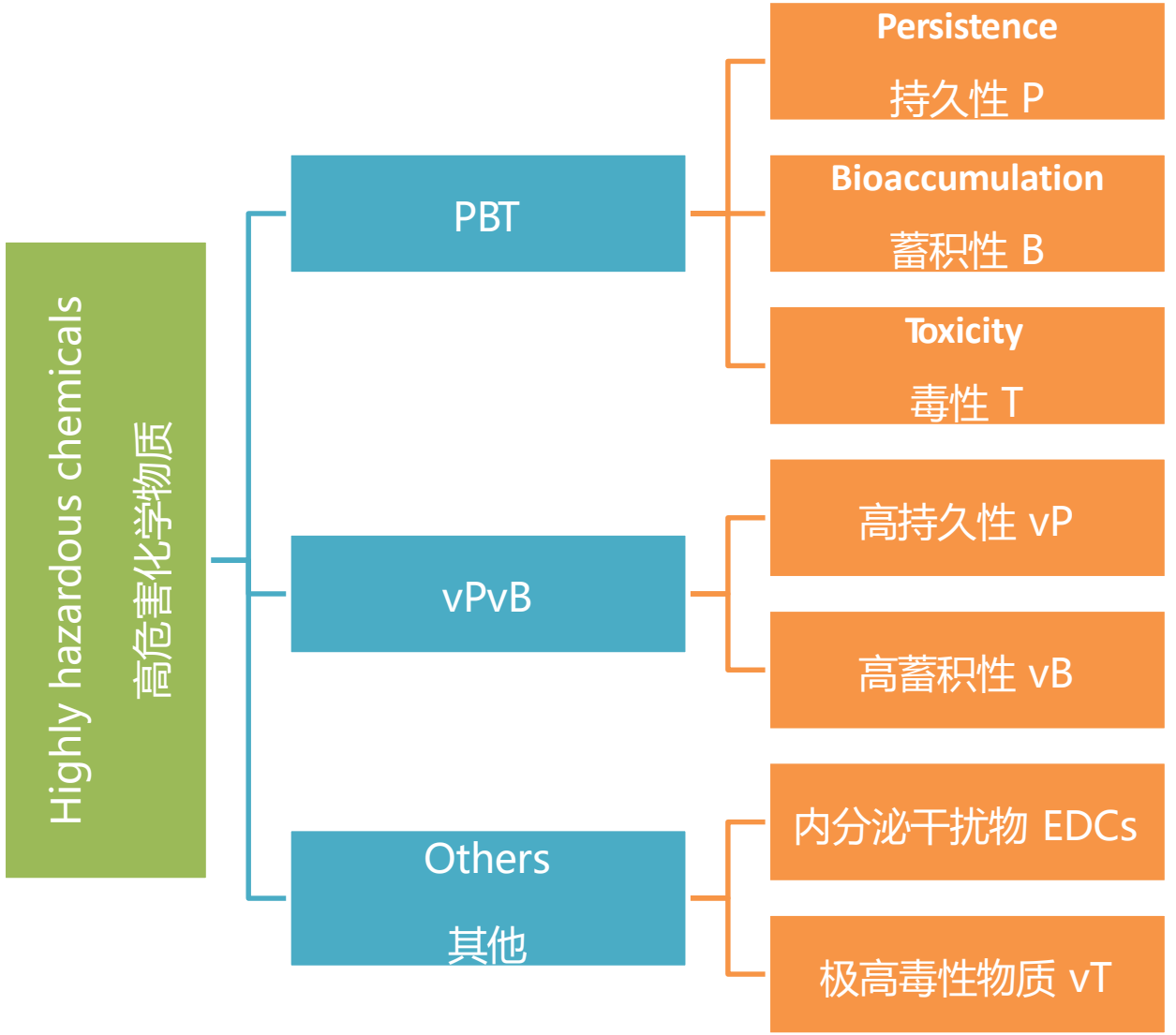
“降解性Degradation：首先提交快速生物降解试验数据，该数据应为采用与申请物质性质相适应的 测试方法所完成。快速生物降解试验结果为不可快速生物降解的，可进一步提交更多筛选性降 解数据，如强化快速生物降解试验、固有生物降解试验、水解、光解等降解数据，以识别是否具有持久性特性。”

数据要求-生态毒理特性

Data Requirement-Ecotoxicity properties



高危害化学物质
Highly Hazardous Chemicals



PBT、vPvB化学物质筛选标准

PBT and vPvB chemical substance screening standards

P	• If the chemical substance can be rapidly biodegraded , it can be screened and judged as not P and vP; • If the degradation rate of 302B 7d is ≥70% or the degradation rate of 302C 14d is ≥70%, , it can be screened and judged as not p; • If the chemical substance can be hydrolyzed or photolyzed, it can be screened and judged as non-P; • 若化学物质能快速生物降解，可筛选判定非P和vP； • 若OECD 302B 7d降解率≥70%或OECD 302C 14d降解率≥70%，可筛选判定非p； • 若化学物质能水解或光解，可筛选判定非P；
B	• If the chemical substance's log Kow≤4.5, , it can be screened and judged as not B and vB; • If the chemical substance's log Kow>4.5, , it can be screened and judged as potential B; • BCF> 2000, it can be judged as B; BCF= Bio-Concentration Factor • BCF> 5000, it can be judged as vB; • 若化学物质log Kow≤4.5，可筛选判定非B和非vB； • 若化学物质log Kow>4.5, 可筛选判定潜在B； • 生物富集因子＞2000，可判定是B； • 生物富集因子＞5000，可判定是vB；
T	• Acute aquatic toxicity EC50 or LC50 <0.1mg / L, it can be screened and judged aspotential T; (SR) • Acute aquatic toxicity EC50 or LC50 <0.01mg / L, it can be screened and judged as T; (SR) • Chronic aquatic toxicity NOEC or EC10<0.01mg / L, can be judged as T; (RR) • Carcinogenic 1A or 1B, can be determined as T; (RR) • Mutagenic 1A or 1B, can be judged to be T; (RR) • Reproductive toxic substances with 1A 1B or category 2, can be judged to be T; (RR) • Specific target organ toxicity (repeated exposure) category 1 or 2, can be judged as T. (RR) • 急性水生毒性EC50或LC50＜0.1mg/L，可筛选判定潜在T；（简易登记） • 急性水生毒性EC50或LC50＜0.01mg/L，可筛选判定是T；（简易登记） • 慢性水生毒性NOEC或EC10＜0.01mg/L，可判定是T；（常规登记） • 致癌物1A或1B类，可判定是T；（常规登记） • 致突变物1A或1B类，可判定是T；（常规登记） • 生殖毒性物1A、1B或2类，可判定是T；（常规登记） • 特异性靶器官毒性（反复接触）类别1或类别2，可判定是T。（常规登记）

数据豁免条件 Data Exemption

1、 Delete the exemption clauses for Auto-ignition temperature, Flash point, Oxidation, Flammability, and Explosive endpoints; 删除自燃温度、闪点、氧化性、燃烧性、爆炸性数据豁免条款；

2、新增: Newly added:

Endpoint 数据节点	Exemption Condition 豁免条件
Dissociation constant 解离常数	Unstable in water (hydrolysis half-life less than 12h) or easily oxidized in water 在水中不稳定（水解半衰期小于12h）或在水中易被氧化
Sediment-water chironomid toxicity test 底栖生物慢性毒性	With low adsorption（eg: logKoc<3） 吸附性很低（如 logKoc<3）

3、The chronic toxicity test can be exempted if it is only used for intermediate purposes (newly added) ; 慢性毒性数据豁免条件增加一项，即若仅用作中间体用途的也可豁免该项测试;

4、 Deleted “Fish 14-day extended toxicity test”; 删除“鱼类14天延长毒性试验”要求；

5、 For the toxicity of terrestrial organisms, it is clear that the long-term toxicity test of earthworms is the "Enchytraeid reproduction test OECD 220 "or " Earthworm reproduction test OECD 222", and delete "Soil microbial influence test"; 对于陆生生物毒性，明确蚯蚓长期毒性试验为线蚓繁殖试验或蚯蚓繁殖试验，删除土壤微生物影响试验;

6、 Deleted the exemption condition of "Earthworm acute toxicity test", which is water solubility>1mg/L or log Koc<3.5. 删除依据水中溶解度大于1mg/L或logKoc小于3.5豁免蚯蚓急性毒性试验的条款。

测试机构资质要求
Qualification Requirements of Testing Laboratory

China Domestic Laboratory 境内测试机构

1.Qualification accreditation of inspection and testing should be obtained according to law for Physical and chemical testing institutions.
2. Health toxicology testing institutions should also comply with good laboratory practice standards (notified by one of several different Chinese Authorities)
3. Ecotoxicology testing institutions should also comply with good laboratory practice standards and Relevant requirements from MEE.
1、物理化学性质测试机构应当依法取得检验检测机构资质认定；
2、健康毒理学测试机构通过国家食品药品监督管理总局药物非临床研究质量管理规范（GLP）认证管 理的机构、经中国疾病预防控制中心质量考核合格的化学品毒性鉴定机构、农业农村部公告的农药登记 试验单位、通过中国国家认证认可监督管理委员会批准的良好实验室规范（GLP）评价的机构。
3、生态毒理测试机构符合良好实验室管理规范(GLP)和生态环境部化学品测试机构管理相关要求

Non-Domestic Laboratory 境外测试机构

1. Physical and chemical testing institutions should comply with ISO17025 standard or good laboratory practice standards.
2. Health toxicology and ecotoxicology testing institutions should meet internationally accepted requirements for good laboratory Practice. (GLP)

1、物理化学性质测试机构应当符合ISO17025标准认可或良好实验室管理规范要求。
2、健康毒理学、生态毒理学测试机构应当符合国际通行的良好实验室管理要求

环境风险评估报告
Environmental Risk Assessment Report

New requirement under MEE Order No.12

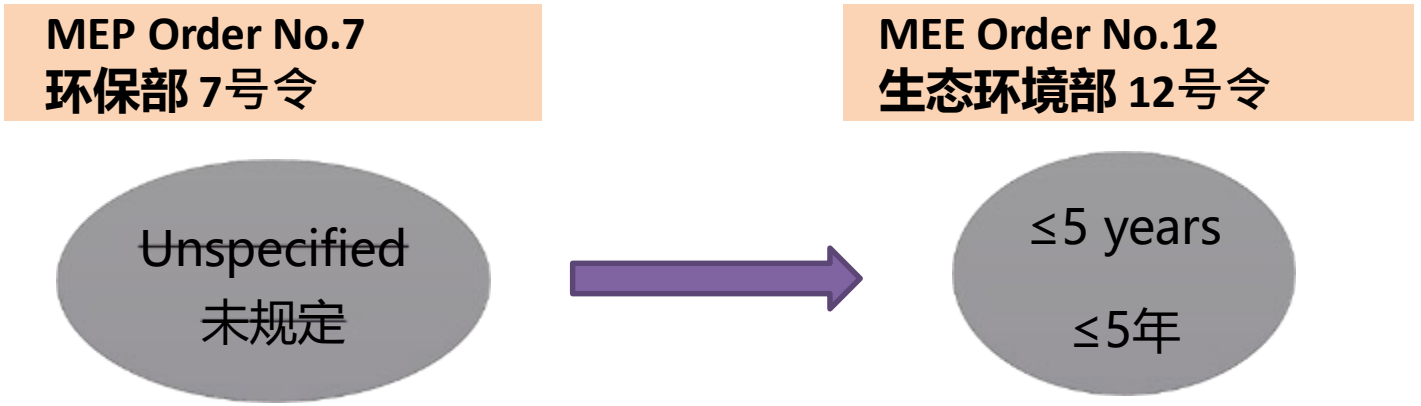
For Regular Registration >10t/a only; 仅常规登记 >10吨/年需要

Can be exempted if new chemical<100 t/a without eco-toxicity and toxicity classification according to the hazard assessment, and it is non P or B； 危害评估表明申请物质无生态环境和人体健康危害分类，且不具有持久性、生物累积性，同时申请量小于100 吨的，可豁免。

The preparation technical unit shall bear relavate responsibilities for its own environmental risk assessment report, affix an official seal, and implement credit management. Critics notified, three-year ban. 编制技术单位对其编制的环境风险评估报告承担相应责任, 加盖公章, 实施信用管理。被通报批评者，三年内禁止申报。

Both human health and ecological environment adopt (semi) quantitative assessment; Add special instructions for exposure scenarios of consumer use and waste disposal; PBT/vPvB special substances focus on the identification of discharge and exposure characteristics and all possible exposure pathways. 人体健康及生态环境均采用（半）定量评估; 增加消费者使用和废物处置等暴露场景的特别说明; PBT/vPvB类特殊物质重点开展排放和暴 露特征识别及所有可能的暴露途径。

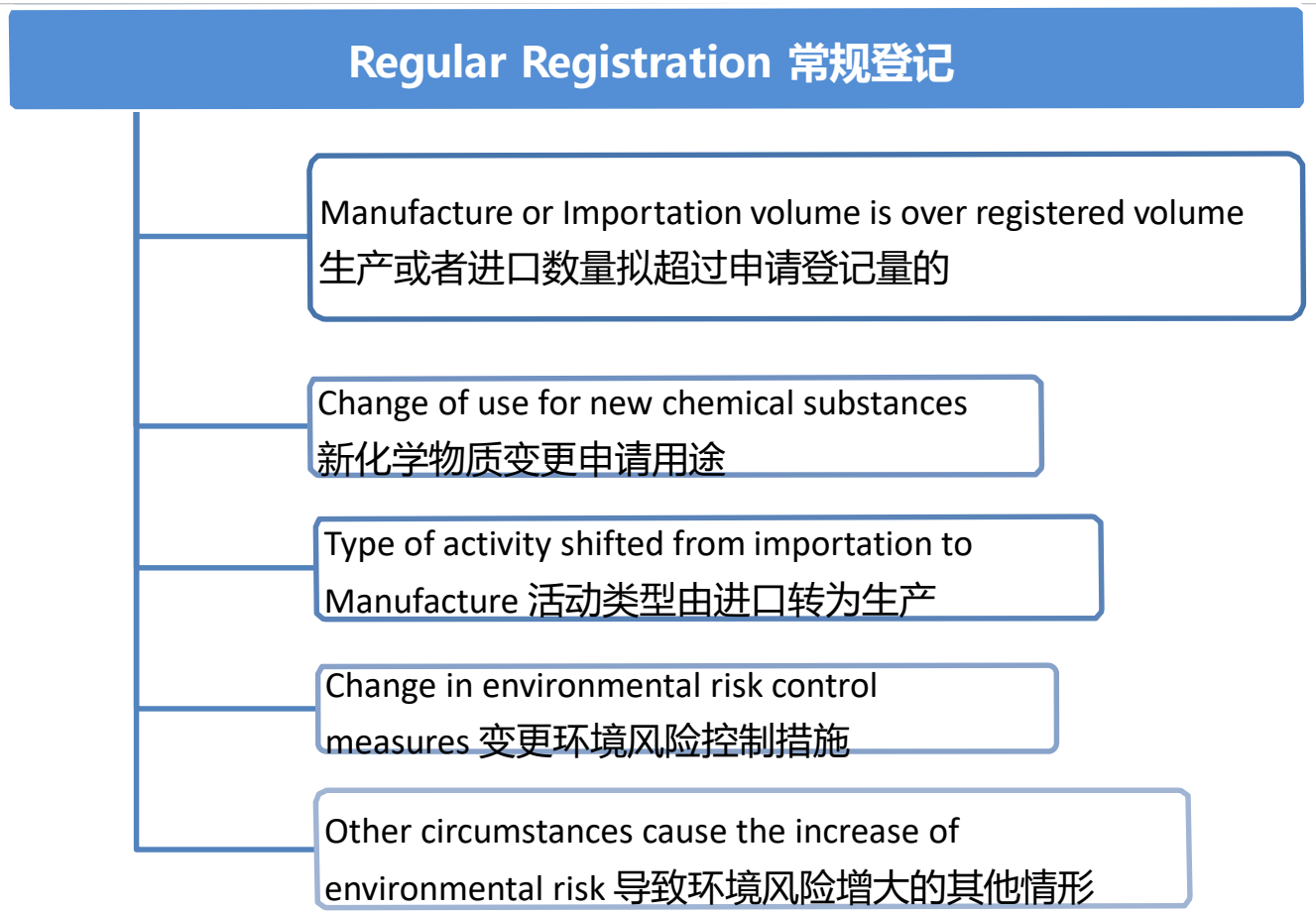
调整保密期限
Adjustment of Confidentiality Time Period



- The period of confidentiality of identification information such as the name of the substance shall not exceed five years from the date of registration or record filling. The extension application shall not exceed another five years.物质名称等标识信息 保护期限自登记或者备案之日起不超过五年。延期申请最多不超过五年。

- Substances that have been listed in the confidential section of "Inventory of Existing Chemical Substances in China" before the implementation of MEE Order No. 12, the confidential period of the identification information is up to December 31, 2025. 12号令施行前已列入《中国现有化学物质名录》并实施物质名称等标识信息保护的，标识信息的保护期限最长至2025年12月31日止。

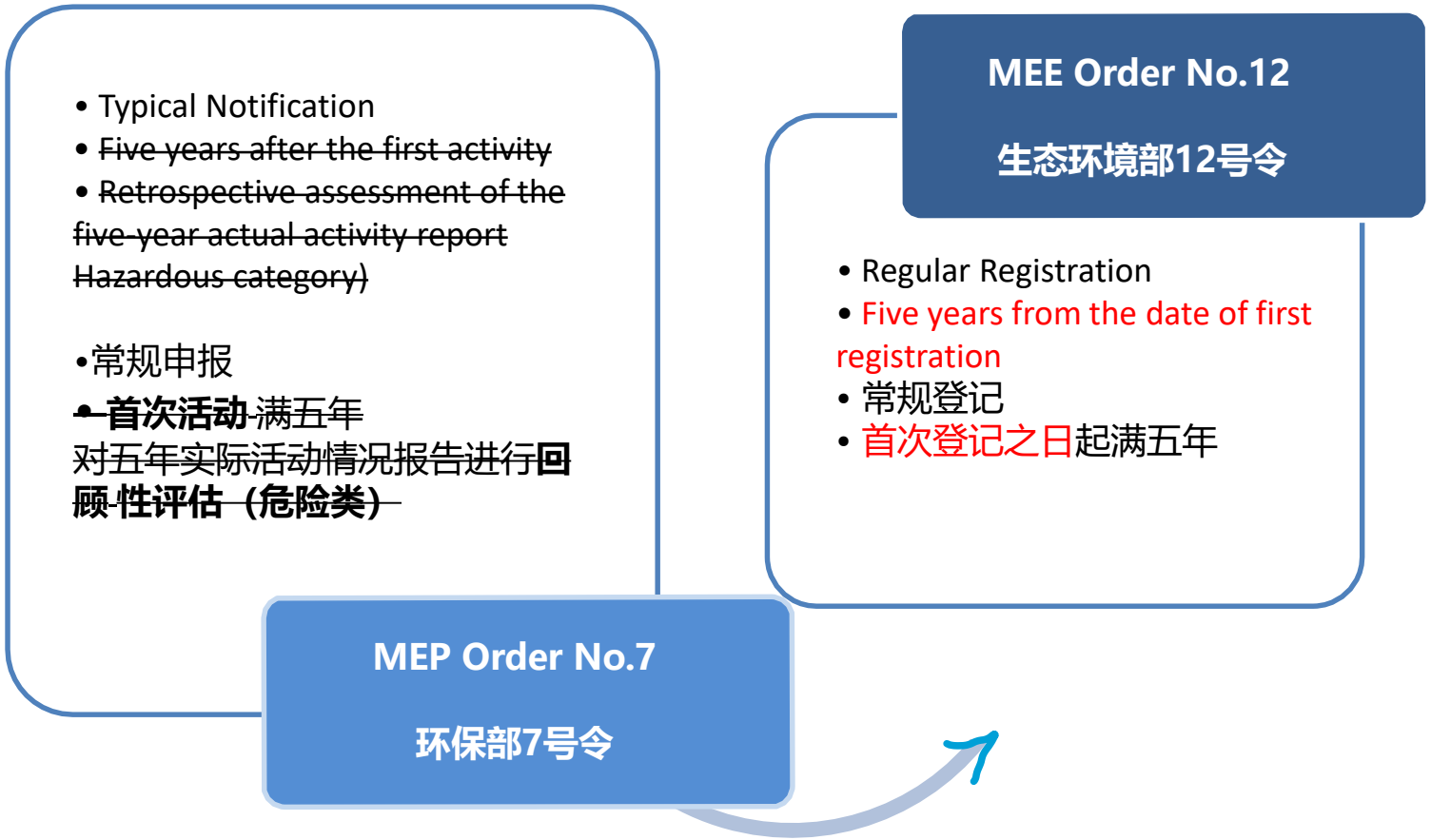
需重新办理登记的情形
Circumstances Requiring Re-registration



The registration certificate is changed according to the simplified registration procedure, and there is no review by the expert committee (except for the change of substance identification info)

登记证变更按简易登记程序办理，无专家委员会评审环节（物质标识信息变更除外）

加入《名录》程序简化
Simplified Procedures for Entering the Inventory



For chemical substances that have been produced, sold, processed/used, or imported within the territory of the People's Republic of China before October 15, 2003, relevant enterprises may apply for additional inclusion in the IECSC.
2003 年10 月15 日前已在中华人民共和国境内生产、销售、加工使用或者进口的化学物质，相关企业可申请增补列入《中国现有化学物质名录》。

活动报告要求
Activity Reporting Requirements

- Typical Notification
- Within 30 days from the date of first production or import and transfer to the process user
- 常规申报
- 首次生产或者进口并向加工使用者转移之日起三十日内

- Regular Registration
- Simplified Registration
- Within 60 days from the date of first production or import and transfer to the processing user
- 常规登记
- 简易登记
- 首次生产或者进口并向加工使用者转移之日起六十日内

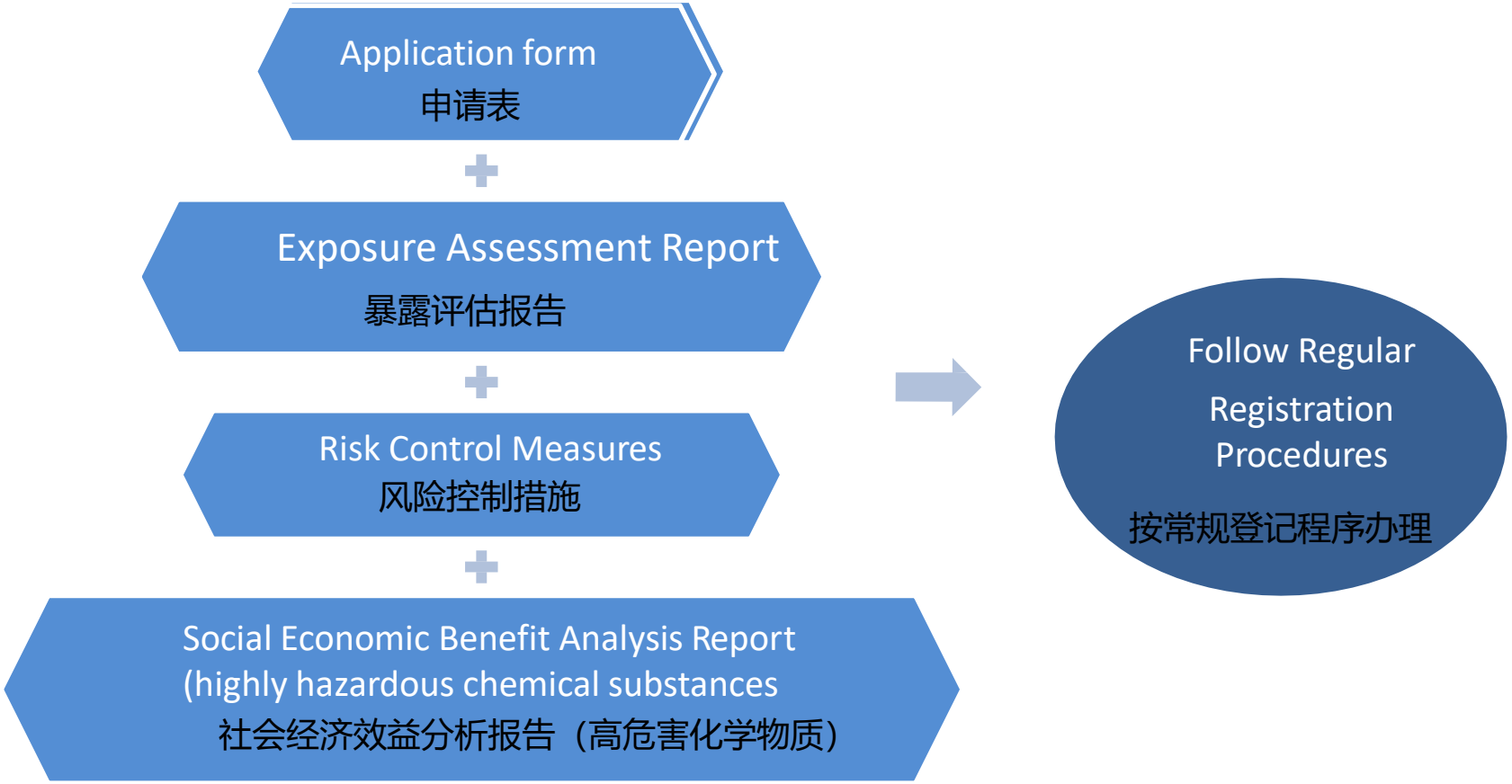
Order No. 7 7号令	Report Type 报告类型	Order No.12 12号令
√	First activity report 首次活动报告	√
√	Every activity report 每次活动报告	×
√	Annual activity report 年度活动报告	√
√	Five-year report on actual activities 五年实际活动情况报告	×

- Before Feb 1st ever year
- Simplified notification
- Typical notification (Hazardous category)
- 每年2月1日前
- 简易申报
- 常规申报（危险类）

- Before April 30th every year
- Regular Registration (whether it is required to submit is up to the information on registration certificate)
- 每年4月30日前
- 常规登记（登记证上规定是否需提交）

新用途管理 New Use Management

- Application materials and registration procedures for new use registration
- 申请新用途登记所需材料及登记程序



登记证内容
Registration Certificate Contents

MEE Order No.12

生态环境部 12号令

- Registration Type 登记证类型
- Register and Agent info 申请人和代理人名称
- Identification info like CN/EN names or category name 新化学物质中英文名称或类名等标识信息
- Application purpose 申请用途
- Registration volume 申请登记量
- Activity Type 活动类型
- Environmental risk control measures 环境风险控制措施

Simplified or Regular Registration Certificate
简易或常规登记证

- Limiting new chemical emissions or emission concentrations 限定新化学物质排放量或者排放浓度
- Requirements for implementing new-use environmental management when listed in IECSC 列入《名录》时实施新用途环境管理的要求
- Annual Report requirement 年度报告要求
- Other environmental management requirements 其他环境管理要求

Highly hazardous/PB/PT/BT substances Regular registration certificate Additional specification of one or more of these
高危害/PB/PT/BT类物质 常规登记证 额外载明其中一项或多项

《指南》： 实施新化学物质环境管理制度前的化学物质增补列入《名录》
Guidance: IECSC Supplementation after Jan. 1, 2020

（八）化学物质列入《名录》

1. **实施新化学物质环境管理制度前的化学物质增补列入《名录》**

依据《办法》第三条规定，2003 年 10 月 15 日前已在中华 人民共和国境内生产、销售、加工使用或者进口的化学物质，相 关化学物质生产、进口、加工使用企业可申请增补列入《名录》。

申请人应通过网上登记系统提交增补申请表和相关证明材 料。相关证明材料包括化学物质的经销发票、进出口报关单、行 业统计材料、化工年鉴、管理部门印发的文件、公开出版物以及 其他能证明该化学物质在 2003 年 10 月 15 日前已在中华人民共 和国境内生产、销售、加工使用或者进口的材料。

经审核认为申请材料不符合要求的，不予增补。符合增补要 求的化学物质，在生态环境部政府网站进行公示。

VIII. Chemical Substances Listed in the Inventory

1. Chemical substances, before the implementation of the new environmental control system for chemical substances, supplemented and listed in the Inventory

According to Article 3 of *the Measures*, for chemical substances that have been produced, sold, processed, used or imported within the territory of the People's Republic of China before October 15, 2003, enterprises engaged in the production, import, processing and use of the relevant chemical substances may apply to be added to *the Inventory*.

The Applicant shall submit the supplementary application form and relevant supporting materials through the online registration system. Relevant supporting materials include sales invoice of chemical substances, import and export declaration forms, industry statistical materials, chemical yearbook, documents issued by administrative departments, public publications and other materials that can prove that the chemical substances have been produced, sold, processed and used or imported within the territory of the People's Republic of China before October 15, 2003.

《中国现有化学物质名录》增补情况 -2019至今

IECSC Supplementation Status since 2019

增补范围：2003年10月15日前已在中华人民共和国境内合法生产或者进口且未列入《名录》的化学物质 所需材料：申请表：企业信息，化学物质信息和用途，证明材料 证明材料：经销发票、进出口报关单、行业统计材料、化工年鉴、管理部门印发文件、公开出版物等
申请截止日期：2019年9月30日

China's Ministry of Ecology and Environment (MEE) has reopened the supplementation of IECSC （Inventory of Existing Chemical Substances in China).

Scope: Only substances manufactured in or imported into China before Oct. 15, 2003 would be eligible.

Documents required: Application form, Enterprise information, Chemical substance information and use/application

Supporting Documents: Distribution invoices, import and export declaration forms, industry statistics, chemical industrial yearbooks, government documents, publications and other legal documents.

Deadline: Sept. 30, 2019

增补材料提交情况: 截止至2019年10月15日, MEE共收到317家公司（协会）申请将1562个物质增补列入《名录》。MEE会分多批次公示和批准符合要求的化学物质进入名录。目前MEE只于2020年5月6日发布了第一批156个化学物质进入名录。固管中心老师在2020年9月3日的培训中提到许多增补内容并不符合要求。

Based on MEE's update as of Oct. 15, 2019, there were 1562 chemical substances nominated from 317 enterprises(trade associations). MEE SCC will release approved chemical substances in different batches. So far MEE only announced 1 batch on May 6，2020 with a total of 156 chemical substances approved and included into IECSC, including some Pharmaceutical APIs and intermediates.

Based on MEE SCC at the training workshop held on Sept. 3, 2020, many nominations do not meet the requirements/criteria(incorrect nomenclature, missing CAS number, etc.).

《新化学物质环境管理登记办法》违法处罚
MEE Order No. 12 Punishment

Anyone violating the relevant provisions of MEE Order No.12 shall be punished by the MEE or the local MEE/EPB, according to the Chapter 5 of MEE Order No.12.
违反《办法》相关规定的，应按《办法》第五章法律责任相应情形，接受生态环境部或地方生态环境主管部门处罚。

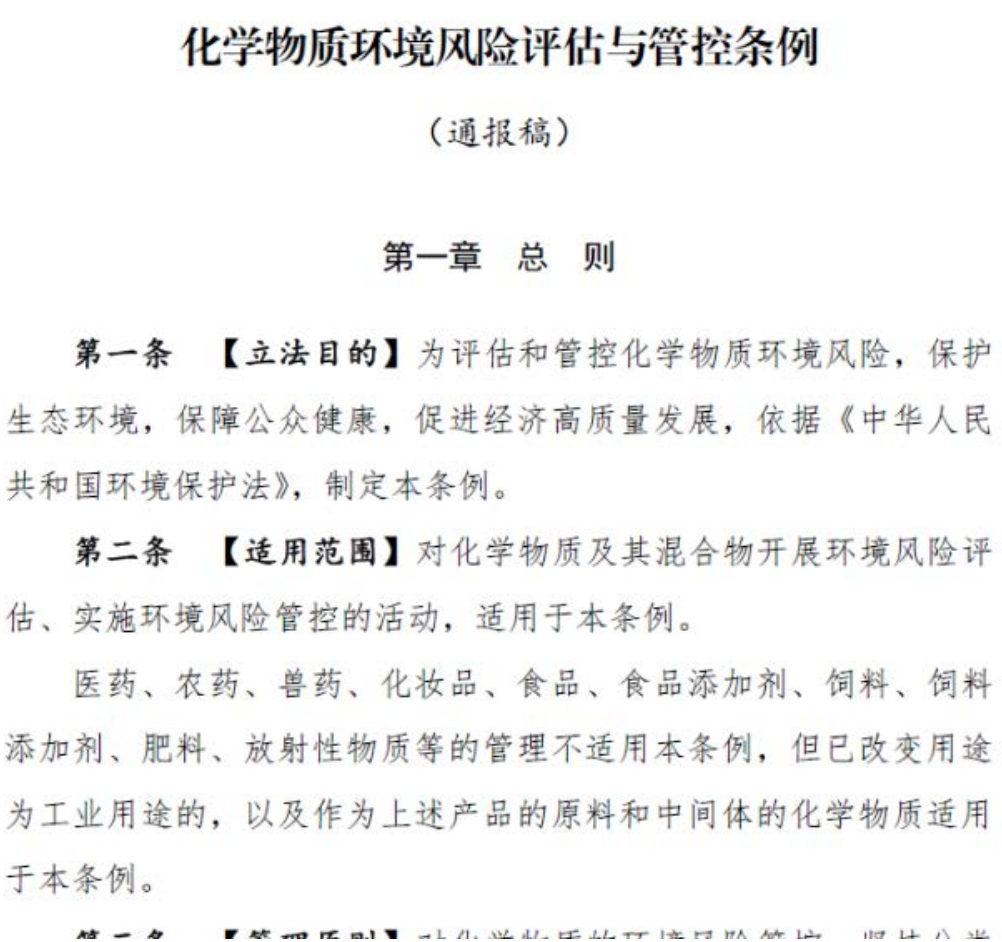
- Order correction
- A fine between 10000 to 30000 RMB
- Joint punishment for dishonesty
- New applications will not be accepted within three years
- 责令改正
- 处一万元以上三万元以下的罚款
- 失信联合惩戒
- 三年内不再受理新申请

Sept. 2019 "Regulations on Environmental Risk Assessment and Control of Chemical Substances (WTO Notification version)"
The fines would be between 0.5 million to 2 million RMB; if a crime is constituted, and criminal responsibility shall be investigated.

2019年9月《化学物质环境风险评估与管控条例》(WTO通报稿)
最高200万元罚款; 构成犯罪的，追究刑事责任。

Attention!!! 化学物质环境风险评估与管控条例（WTO通报稿）第二条

Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification Version) – Article 2



化学物质环境风险评估与管控条例

（通报稿）

第一章 总 则

第一条 【**立法目的**】为评估和管控化学物质环境风险，保护生态环境，保障公众健康，促进经济高质量发展，依据《中华人民共和国环境保护法》，制定本条例。

第二条 【**适用范围**】对化学物质及其混合物开展环境风险评估、实施环境风险管控的活动，适用于本条例。

医药、农药、兽药、化妆品、食品、食品添加剂、饲料、饲料添加剂、肥料、放射性物质等的管理不适用本条例，但已改变用途为工业用途的，以及作为上述产品的原料和中间体的化学物质适用于本条例。

This is a higher level of regulation than MEE Order No. 12.

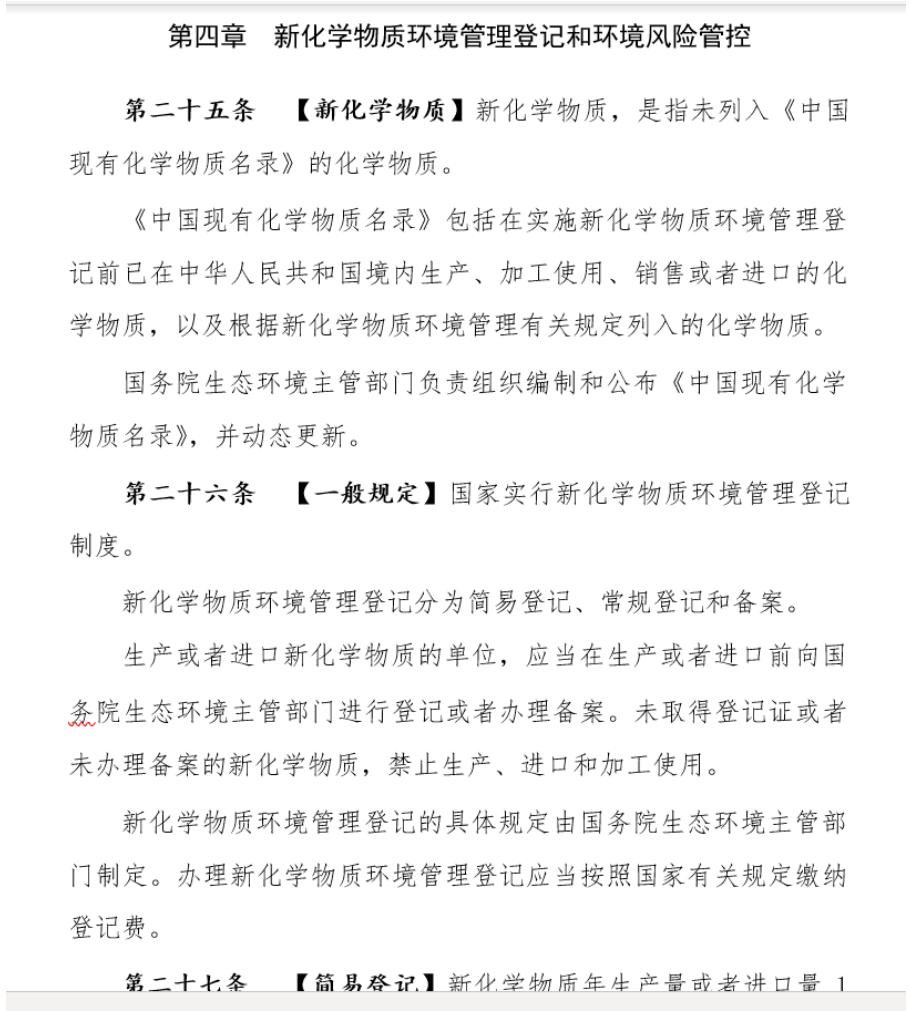
The WTO Notification **（世贸组织通报稿）** made in Sept. 2019.

Changes made from its initial version issued for public consultation (**征求意见稿**) in Jan. 2019, incorporating some industrial feedbacks

Article 2: The management of pharmaceuticals, pesticides, veterinary medicines, cosmetics, food, food additives, feed, feed additives, fertilizers, and radioactive materials, etc. shall be governed by other relevant laws and regulations. However, the environmental management of the above-mentioned substances that are to be used for other industrial purposes, as well as that of activities related to chemical substances as raw materials and intermediates of the above products is also governed by this regulation.

Attention!!! 化学物质环境风险评估与管控条例 (WTO通报稿）第二十六条

Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification) – Article 26



第四章　新化学物质环境管理登记和环境风险管控

第二十五条　【新化学物质】新化学物质，是指未列入《中国现有化学物质名录》的化学物质。

《中国现有化学物质名录》包括在实施新化学物质环境管理登记前已在中华人民共和国境内生产、加工使用、销售或者进口的化学物质，以及根据新化学物质环境管理有关规定列入的化学物质。

国务院生态环境主管部门负责组织编制和公布《中国现有化学物质名录》，并动态更新。

第二十六条　【一般规定】国家实行新化学物质环境管理登记制度。

新化学物质环境管理登记分为简易登记、常规登记和备案。

生产或者进口新化学物质的单位，应当在生产或者进口前向国务院生态环境主管部门进行登记或者办理备案。未取得登记证或者未办理备案的新化学物质，禁止生产、进口和加工使用。

新化学物质环境管理登记的具体规定由国务院生态环境主管部门制定。办理新化学物质环境管理登记应当按照国家有关规定缴纳登记费。

第二十七条　【简易登记】新化学物质年生产量或者进口量 1

Article 26 [General Provisions] The state shall implement the environmental management and registration system for new chemical substances.

The environmental management registration of new chemical substances is divided into simplified registration, regular registration and record filing.

An entity producing or importing new chemical substances shall register or file with the ecology and environment administrative department (MEE) of the state council before producing or importing them. The production, import, processing and use of new chemical substances without registration certificate or record filing shall be prohibited.

The specific provisions on the environmental management registration of new chemical substances shall be formulated by the ecology and environment department (MEE) of the State Council. The registration fee shall be paid in accordance with the relevant national provisions when handling the environmental management registration of new chemical substances.

Attention!!! 化学物质环境风险评估与管控条例 (WTO通报稿）第三十九条

(Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification version) – Article 39

第三十九条 单位法律责任

测试相关业务。

第三十九条 【单位法律责任（一）】生产、加工使用或者进口化学物质的单位存在以下违法行为的，应当由设区的市级以上地方人民政府生态环境主管部门责令限期改正，公告其违法行为，记载其不良记录，处以罚款；逾期未改正的，依法责令停产整治；情节严重的，报经有批准权的人民政府批准责令停业、关闭，并依法依规开展失信联合惩戒。

（一）违反第二十六条规定，未取得新化学物质环境管理登记证，违规生产、加工使用或者进口新化学物质的；

（二）违反第二十九条规定，未按要求办理新化学物质重新登记，违规生产、加工使用或者进口新化学物质的；

（三）违反第二十条和第三十三条规定，未经登记将化学物质用于新用途的。

有前款规定行为之一的，处五十万元以上一百万元以下的罚款；造成严重后果的，处一百万元以上二百万元以下的罚款。

第四十条 【单位法律责任（二）】存在下列违法行为的，由国

Article 39 Legal Liability (and Fines)

Article 39 If units that produce, process, use, and import new chemical substances commit the following illegal acts, the department of ecology and environment at or above the district level will order the units to make corrections within a time limit, and make public announcement of their violation, record their misconduct and impose fines; if it is not corrected within the time specified, it shall be ordered to suspend production for rectification; if the circumstances are serious, it shall be reported to the people's government for approval to stop their production and shut down the unit, and carry out joint punishment for their misconduct according to laws and regulations.

1. Violating the provisions of Article 26, failing to obtain a new chemical substance environmental management registration certificate, illegally producing, processing, or importing new chemical substances;
2. Violating Article 29, failing to re-register new chemical substances as required, illegally producing, processing or importing new chemical substances
3. In violation of Articles 20 and 33, chemical substances were used for new purposes without registration.

Any unit committing one of the acts mentioned above shall be fined from 500,000 yuan to 1 million yuan (CNY); if it has caused serious consequences, a fine from 1 million yuan to 2 million yuan shall be imposed.

总结 Summary

《办法》在管控重点、登记类型和材料要求、登记后的跟踪管理等方面进行了全面修订。

《指南》对《办法》有关条款进行了细化，明确了实施细则，包括登记范围、登记类型、登记程序、登记申请材料要求、聚合物特别规定和新用途环境管理登记、重新登记、登记证变更、撤回与撤销以及登记后跟踪管理等方面内容。

代理人选择： 境外申报人和代理人共同承担责任和义务。

企业的主体责任： 更加突出企业的主体责任，强化事中事后监管。

The Measures have been comprehensively revised in terms of key points of management and control, registration type and data/material requirements, and follow-up management after registration.

The Guidelines detail the relevant provisions of the Measures and clarify the implementing rules, including the scope of registration, type of registration, registration procedures, requirements for registration application materials, special provisions for polymers and registration of environmental management for new uses, re-registration, change of registration certificate, withdrawal and revocation, and follow-up management after registration.

Choice of agent: The overseas applicant and the agent shall bear joint responsibilities and obligations.

Responsibility of enterprises: more highlight on the responsibility of enterprises and the government will strengthen in-event and afterwards supervision.

建议 Recommendations

1. 如果企业在2003 年 10 月 15 日前已在中国境内生产、销售、加工使用或者进口的化学物质还没有列入《名录》，请尽早按要求申请增补列入《名录》

- Nominate any chemical substances manufactured or imported (not in IESCS yet) prior to Oct. 15, 2003 to MEE SCC with supporting documents so they can be supplemented to IECSC

2. 持续追踪法规条例和《指南》及《名录》的更新, 及时了解国家对化学物质的管理要求

- Track regulatory changes, updated guidance and the inventory (IECSC) update, and understand regulatory requirements for chemical substances management

4. 建立企业内部化学物质数据库，对已使用的化学物质（原材料和产品）进行合规排查

- Establish an internal chemical inventory/database and review their regulatory compliance status

5. 重视化学品法规的合规，针对企业实际情况和业务计划制定合规管理计划；特别是在引入新化学物质之前，先确认合规后，再进行生产或贸易(及加工使用)

- Focus on the compliance with the applicable chemical substance regulations and develop a compliance management plan based on the current status and future business plan; Confirm compliance before manufacturing or import activities（and processing and use)，especially for any new chemical substances introduced

6. 完成申报后义务包括活动情况记录/报告、信息传递和信息公开、资料保存、在4月30号之前做年报等。

- Fulfill required obligations after obtaining the registration certificate including activities record/report, information communicating to the downstream users, record retention, and annual report by April 30 if applicable.

休息
BREAK 2

休息时间为10分钟，会议将于 11:50 继续进行

Conference resumes at 11:50. Please come back in 10 minutes

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

管理体系和成熟度模型介绍

江戎
诺华（Novartis）大中国区供应商健康安全环境风险管理主管
PSCI中国小组领导团成员

*该演讲内容由PSCI管理系统能力建设组准备

嘉宾介绍

Kelley Jiang （江戎）

Novartis, Head HSE Supplier Assurance & Risk China Region –CN,JP,KR,SEA

- 10 + years in EHS, 8 years on site, 2 years in supply chain
- Major in Biomedical Engineering; MSc. Of SHE Technology, NUS
- Singapore registered Workplace Safety and Health Officer

目前公司职位：诺华 HSE 外部供应商管理 - 中国，日韩，东南亚

10余年HSE从业经历， 8年工厂，2年供应链。

生物医学工程; 安全环境健康技术硕士，新加坡国立大学

新加坡注册 WSHO

管理体系成熟度模型

Overview of Management Systems 管理体系成熟度模型简介

Maturity Model 成熟度模型

Details of Maturity Model 成熟度模型详述

Areas of Concern from PSCI Assessments – Management Systems
PSCI审核-管理体系重点关注内容

Common Gaps from PSCI Assessments – Management Systems
PSCI审核-管理体系方面的常见发现

何为管理体系?

- 管理系统是组织用来确保其能够完成实现其目标所需的所有任务的策略，流程和程序的框架。
- 管理系统是组织管理业务的相互关联部分以实现其目标的方式。这些目标可以涉及许多不同的内容，包括产品或服务质量、运营效率、环境绩效和工作场所的健康与安全等。
- 从最基本的意义上讲，管理系统是组织确保完成任务的方式。
- 您的工作场所可能已经具有管理系统的基本要素；
- 包括原则、框架、责任、程序、培训和记录保存等。

管理体系示例

- ISO（国际标准化组织）是一个独立的非政府国际组织，拥有161个国家标准机构的成员。
- ISO标准的示例包括：
  - ISO 50001-能源管理
  - ISO9001-质量管理
  - ISO 14000系列-环境管理
  - ISO 45001-职业健康与安全
  - ISO 37001 –反贿赂管理系统
- SAI认证：
  - SA 8000 –社会责任
- 国际标准的作用：它们为产品、服务和系统提供了世界一流的规格，以确保质量、安全性和效率。

第三方认证的思辨

- 第三方认证可能对企业有利，例如：
  - 一些政府或其他供应合同可能要求或优先考虑具有外部认证的公司
  - 信息披露

- 然而，
  - 第三方认证需要反映出**现场的实际情况**；
  - 我们发现某些第三方认证过的工厂存在重大问题；
  - 在某些情况下，第三方认证更多地是对文档审核而不是对实际操作；
  - 我们发现一些第三方认证已过期；

建立管理体系的要点

- 贴合实际业务需要;
- 使工作场所更高效;
- 是可持续的;
- 与业务的其他关键组成部分集成在一起-例如质量、生产和客户服务;
- 可以为监督、审查、持续改进和合规性提供证据。

PSCI供应商自我评估问卷-管理体系部分

- Q1 - Commitment and Accountability 承诺与责任;
- Q2 - Q4 - Legal and Customer Requirements 法律和客户要求;
- Q5 – Q8 Risk Management 风险管理;
- Q9 – Documentation 文件管理;
- Q10 - Training and Competency 培训和能力;
- Q11 - Continual Improvement 持续改进.

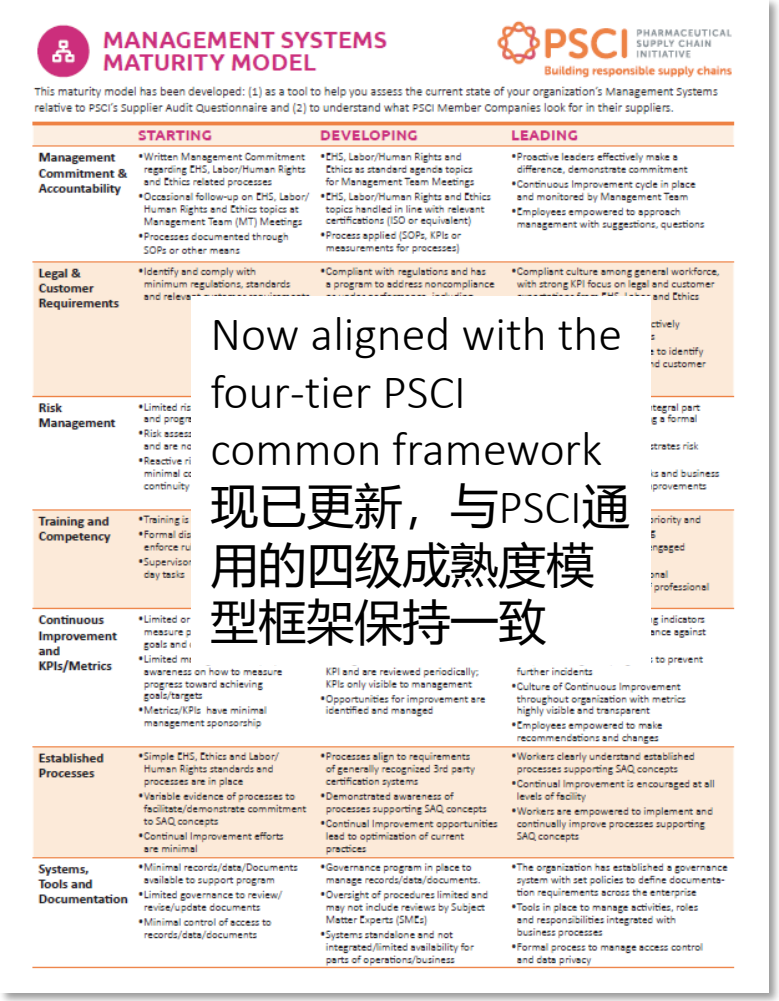
管理体系成熟度定义

- 成熟度基于以下方面:
  - 已建立的流程;
  - 治理
  - 系统或工具
  - 指标，KPIs

- 起点 (Starting Programs)：基本的知识和有限的流程
- 发展 (Developing Programs)：内部流程基本建立，正在提高工厂整体意识
- 执行 (Implementing Programs)：相关流程到位，关键人员的职责明确
- 领导 (Leading programs)：已建立完善健全的流程，管理体系融入业务中

管理体系成熟度模型

- 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	•Written Management Commitment regarding EHS, Labor/Human Rights and Ethics related processes •Occasional follow-up on EHS, Labor/Human Rights and Ethics topics at Management Team (MT) Meetings •Processes documented through SOPs or other means	•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)	•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	•Identify and comply with minimum regulations, standards and relev	•Compliant with regulations and has a program to address noncompliance	•Compliant culture among general workforce, with strong KPI focus on legal and customer
Risk Management	•Limited ris and progra •Risk assess and are no •Reactive ri minimal co continuity		
Training and Competency	•Training is •Formal dis enforce ru •Supervisor day tasks		
Continuous Improvement and KPIs/Metrics	•Limited or measure p goals and •Limited mu awareness on how to measure progress toward achieving goals/targets •Metrics/KPIs have minimal management sponsorship	KPI and are reviewed periodically; KPIs only visible to management •Opportunities for improvement are identified and managed	further incidents •Culture of Continuous Improvement throughout organization with metrics highly visible and transparent •Employees empowered to make recommendations and changes
Established Processes	•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	•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	•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	•Minimal records/data/Documents available to support program •Limited governance to review/revise/update documents •Minimal control of access to records/data/documents	•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	•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

现已更新，与PSCI通用的四级成熟度模型框架保持一致

管理体系成熟度模型的作用

- 管理体系成熟度模型的作用:
  1. 作为一个工具，帮助评估与PSCI供应商审核问卷相对应的组织管理
  2. 了解PSCI成员公司对供应商的期待
- 请与您在PSCI成员公司的联系人使用该成熟度模型，以确定您的组织的改进方面。

	Starting Program	Developing Program	Implementing Program	Leading Program
Commitment & Accountability	1. Written management commitment regarding EHS, Labor/Human Rights and Ethics 2. Occasional follow-up on EHS, Labor/Human Rights and Ethics topics at management team meetings	1. EHS, Labor/Human Rights and Ethics are standard agenda topics for management team meetings 2. Commitment and accountability are documented through SOPs or other mean	1. Specific senior managers are responsible and held accountable for implementing the commitments 2. Senior managers are actively involved in EHS, Labor/Human Rights and Ethics topics 3. Appropriate resources are allocated to ensure delivery of the commitments 4. EHS, Labor/Human Rights and Ethics topics are handled in line with relevant 3rd party certifications (ISO 14001, OHSAS 18000 or equivalent)	1. Proactive leaders effectively make a difference, demonstrate commitment and leadership on EHS, Labor/Human Rights and Ethics topics 2. The management team monitors continuous improvement 3. Employees are empowered to approach management with suggestions and questions

	起点	发展	执行	领导
承诺和责任	1. 关于EHS、劳工/人权和道德相关流程的书面管理承诺 2. 在管理团队会议上对EHS、劳工/人权和道德相关议题偶尔进行跟进	1. EHS、劳工/人权和道德规范纳入管理团队会议的常规议程主题 2. 承诺和责任以标准操作程序（SOPs）或其他方式记录	1. 任命具体的某位高级管理人员负责履行相关承诺并接受问责 2. 高级管理人员积极参与到EHS、劳工/人权和道德相关议题中 3. 分配了适当的资源以确保履行承诺 4. EHS、劳工/人权和道德议题的处理与相关第三方认证（ISO14001，OHSAS1800 或同等标准）保持一致	1. 领导者积极主动，能够有效地发挥作用并展示在EHS、劳工/人权和道德议题上的承诺和领导力 2. 管理团队监督持续的改进行动 3. 鼓励员工向管理层提出建议和问题

	Starting Program	Developing Program	Implementing Program	Leading Program
Legal & Customer Requirements	1. Identify and comply with minimum regulations, standards and relevant customer requirements	1. EHS, Labor/Human Rights and Ethics are included in Legal Register 2. Actively conduct due diligence to identify and comply with regulation and customer requirements	1. Program to address noncompliance or under performance, including customer requirements 2. Ongoing consultations and reviews of forthcoming legislation to identify potential changes in regulations	1. Compliant culture among general workforce, with strong KPI focus on legal and customer expectations on EHS, Labor/Human Rights and Ethics topics 2. Empowered culture that proactively anticipates regulatory changes 3. Beyond legal compliance culture

	起点	发展	执行	领导
法律及客户的要求	1. 明确并遵守法规、标准和相关客户的最低要求	1. EHS、劳工/人权和道德规范包含在法律登记中 2. 积极进行尽职调查，以确定并遵守法规并满足客户要求	1. 建立了相关程序去解决不合规或业绩不佳的情况，包含相关的客户要求 2. 持续跟进即将出台的法律法规，来了解潜在的法规变化	1. 整体员工有合规意识，并有有效力的KPI以满足EHS、劳工/人权和道德方面的法律要求和客户期望 2. 公司文化能够让员工积极预测法规的变化 3. 公司文化指导相关实践保持在合规线以上

	Starting Program	Developing Program	Implementing Program	Leading Program
Risk Management	1. Limited risk assessment process and program in place 2. Risk assessments are high level and not task specific 3. Reactive risk prioritization with minimal consideration for business continuity	1. All tasks are assessed, including permit to work used to control high risk activities 2. Incidents are investigated and analysed	1. Well defined process for risk assessment and business continuity in place, including scoring matrix 2. Adherence to risk management plans and procedures 3. Everyone gets involved in risk assessment, including workers 4. Proactive formal risk assessment process; potential problems are eliminated before they occur 5. Incident learnings shared with all management and staff levels	1. Risk Management becomes integral part of everyday business, including a formal change control program 2. Everyone consistently demonstrates risk management and awareness 3. Business routinely reviews risks and business continuity and implements improvements to reduce risk scores

	起点	发展	执行	领导
风险管理	1. 有比较有限的风险评估流程和计划 2. 风险评估比较宽泛，没有明确相关任务 3. 以被动应对风险为主，对业务连续性的考虑极少	1. 评估所有任务，包括用于控制高风险活动的许可证制度 2. 对事件进行调查和分析	1. 确定了风险评估和业务连续性的流程，包括评分细则 2. 遵守风险管理计划和程序 • 每个人都参与风险评估，包括工人 1. 建立积极主动的正式风险评估流程；在潜在问题发生之前就将其消除 2. 与所有管理层和员工共享的事件经验	1. 风险管理成为日常业务不可或缺的一部分，包含正式的变更控制计划 2. 每个人都一贯的展示风险管理和意识 3. 业务部门定期审查风险和业务连续性并进行改进，以降低风险评分

	Starting Program	Developing Program	Implementing Program	Leading Program
Documentation	1. Minimal records/data/documents available 2. Limited governance to review/revise/update documents 3. Minimal control of access to records/data/documents	1. Oversight of documentation/procedures limited and may not include reviews by Subject Matter Experts (SMEs) 2. Systems standalone and not integrated/limited availability for parts of operations/business	1. Governance program in place to manage records/data/documents 2. Formal process to manage access control and data privacy 3. Documents, policies, procedures and processes aligned across functional areas and result in one system for the entire enterprise	1. Established governance system with set policies to define documentation requirements across the enterprise, making sure that all documentation necessary to demonstrate conformance with the PSCI Principles and compliance with applicable regulations is available 2. Tools in place to manage activities, roles and responsibilities integrated with business processes

	起点	发展	执行	领导
文件管理	1. 留存最基本的记录、数据和文件 2. 审核、修订和更新文件的治理比较有限 3. 对记录、数据和文件的访问有基本的控制	1. 对文件或程序的监督有限，并且可能未将相关议题专家（SME）的审核纳入其中 · 系统独立且未集成，有限的用于部分运营/业务	1. 制定了管理计划以管理记录、数据和文件 2. 建立了管理访问控制和数据隐私的正式流程 3. 文档、政策、过程和流程在各部门之间保持一致，在公司内形成了一套完整的系统	1. 建立了文档管理治理系统，其中定义了整个公司的文档管理要求，确保能证明符合PSCI原则和适用法规的必要文档都得以保存 2. 用于管理活动、角色分工和职责的工具融入业务流程中

	Starting Program	Developing Program	Implementing Program	Leading Program
Training and Competency	1. Training is minimal, ad-hoc and reactive 2. Formal discipline is used to enforce rules 3. Supervisory Control of day to day tasks	1. Training curriculum in place and regularly reviewed 2. Cross-organisation training on different areas and tasks set to further develop workers	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	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

	起点	发展	执行	领导
培训和能力建设	1. 培训比较有限，是临时的和被动的 2. 有正式纪律用于执行规则 3. 有日常任务的监督控制	1. 培训课程到位，有定期审查监督 2. 对不同领域和任务进行交叉培训，以进一步培养员工	1. 建立了用于监控培训合规性的自动化系统 2. 将发展员工列于优先项，并在学习培训方面进行投资 3. 评估了开展核心培训项目的能力 4. 建立了各岗位的能力要求	1. 员工技能娴熟，表现出高水平的培训意识 2. 鼓励专业发展，积极参与相关的专业联盟，并持续进行教育

	Starting Program	Developing Program	Implementing Program	Leading Program
Continual Improvement	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	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	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)	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

	起点	发展	执行	领导
持续改进	1. 有限的持续改进行动 2. 用有限或反应性的KPIs来衡量实现目标和目标进展情况 3. 管理层或员工对如何衡量实现目标和目标进展情况的意识有限 4. 指标或KPIs只得到管理层较少的资助	1. 有可用于衡量某些目标的KPIs或指标，并衡量带有滞后性的指标 2. 管理层了解指标或KPIs，并定期对其进行审核; KPIs仅对管理层可见	1. 识别和管理改进机会，并带来当前实践的优化 2. 对事件进行适当的调查，并采取纠正措施计划（定期跟进以确保实施）	1. 使用领先/可预测和滞后性指标来衡量目标绩效 2. 整个组织有持续改进的文化，其指标是高度可见且透明的 3. 员工有权提出建议和变更 4. 鼓励在工厂各级进行持续改进 5. 员工有权执行并不断改进流程

	Starting Program	Developing Program	Implementing Program	Leading Program
Identification of Concerns	1. Limited identification of concerns 2. Role restricted to management	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 and intimidation 2. Concerns are investigated and corrective action taken if needed	1. Culture of reporting concerns embedded throughout all levels of the organisation	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

	起点	发展	执行	领导
识别问题	1. 有限的问题识别 2. 仅限于管理层	1. 允许和鼓励员工上报问题、非法活动或违反PSCI原则的程序，确保员工不会因此受到威胁或实际的报复和恐吓行为 2. 对问题进行调查，并在需要时采取纠正措施	1. 在公司内建立了上报问题的文化	1. 使用领先/可预测和滞后性指标来衡量目标绩效 2. 整个组织有持续改进的文化，其指标是高度可见且透明的 3. 员工有权提出建议和变更 4. 鼓励在工厂各级进行持续改进 5. 员工有权执行并不断改进流程

	Starting Program	Developing Program	Implementing Program	Leading Program
Communication	1. Communication is ad hoc and reactive; communication takes place on a need-to-know basis	1. Communication regular; the process is well defined and documented	1. Communication takes place using plural established audience appropriate communication channels	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

	起点	发展	执行	领导
沟通	1. 沟通是临时的和被动的；仅针对对方需要知道的事情进行沟通	1. 定期进行沟通；有确定的沟通流程并以书面方式记录	1. 通过多个已建立的、针对不同受众的沟通渠道进行沟通	1. 定期审核沟通流程、计划和渠道，以确保其有效性。与员工、承包商和供应商进行充分沟通，确保其并对PSCI原则和其他相关内容有良好的理解

PSCI审核关注以下方面

- 谁签署并批准管理系统的相关内容?
- 在工厂的情况与书面程序和法规要求相符吗?
- 工厂是否知晓其风险和监管义务?
- 工厂通常符合法规要求吗?
- 工厂是否有足够的资源用于安全、环境、劳工和道德相关部门?
- 工厂是否有能力落实安全、环境、劳工和道德方面的工作?
- 是否有针对以上内容的培训?
- 工厂是否具有自我检查或审核程序以确保其相关计划的执行?
- 是否有专人负责安全、环境、劳工和道德方面的工作?
- 存在的问题/差距以及原因?
- 工厂是否有意愿改善?
- 是否存在重大的系统故障或漏洞?

PSCI审核发现的常见问题

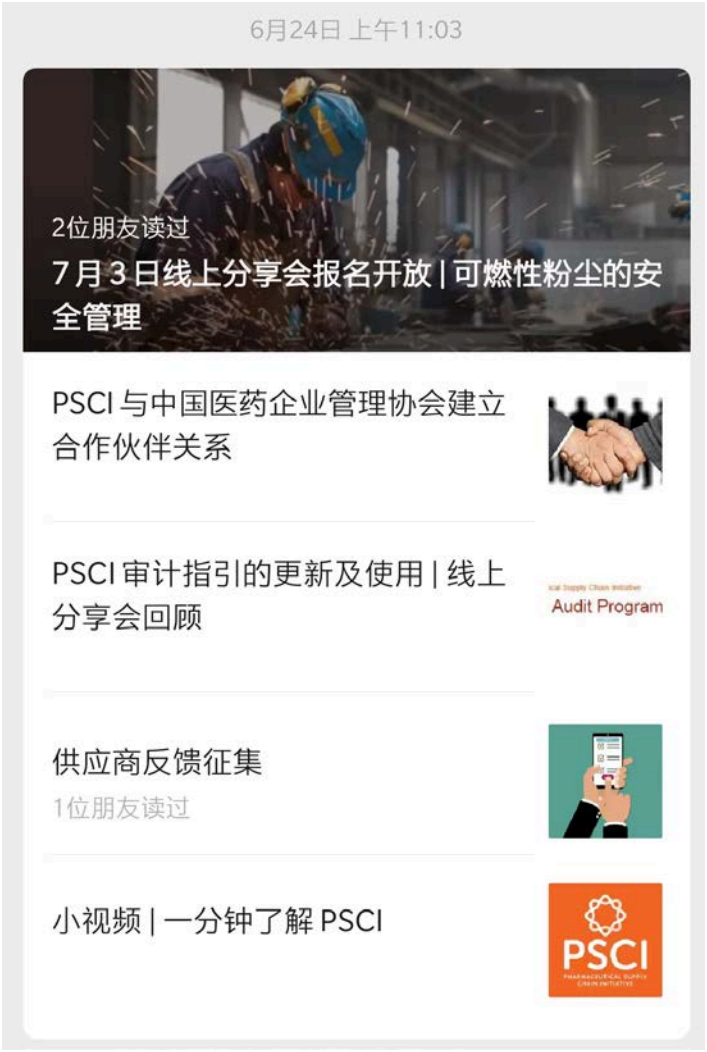
- 遵守法规：相关法规知识存在漏洞，不完整的和/或已过期的许可证和执照，没有与法规变更保持同步的系统
- 风险评估：工厂不了解或未进行风险评估
- 业务连续性计划：未制定该计划，未分析主要的风险，没有制定业务中断后的恢复策略，业务连续性计划未执行
- 变更管理：通常出于质量考虑，但对HSE、劳工和道德方面的考虑很有限
- 文件管理：制定、实施和形成文件的流程有限，未审核标准操作程序，未遵循标准操作程序，培训计划存在漏洞

感谢各位嘉宾和参会者对PSCI的支持

Thank you for working with the PSCI

- 请扫描二维码填写参会意见，帮助PSCI完善供应商能力建设
- To help the PSCI capability building work better for you, please scan the QR code to provide your feedback.

PSCI微信公众号 PSCI Wechat



欢迎扫码关注

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+44 (0) 7794 557524

PSCI

@PSCInitiative

We Chat

制药供应链组织PSCI

For more information about the PSCI please contact:

PSCI Secretariat
Carnstone Partners Ltd
Durham House
Durham House Street
London
WC2N 6HG

info@pscinitiative.org

+44 7794 557524

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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