PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

PSCI Audit Update

Dr. Birgit Skuballa

Head of HSE Audits & Supplier Management

Bayer AG

Bio

Dr. Birgit Isabelle Skuballa

- **Current position** and responsibilities: Bayer AG, Corporate HSE, Head of HSE Audits & Supplier Management
- **Location:** based in Leverkusen, Germany
- **Background:** PhD in Organic Chemistry (University of Karlsruhe); post-doc at Nagoya University (Japan); ISO14001/OHSAS18001/17025 Lead Auditor; global Bayer HSE Audit Team Lead
- **Experience**: 24+ years within Pharma/Chemical Industry (Schering AG / Bayer); including 4+ years as Process Development Chemist at an API production site, 3 years HSE Management System Responsible and global Responsible Care Coordinator, short time assignment at a pharmaceutical finishing site in Italy, 5 years GMP/Quality Auditor for internal/external API sites and global HSE Auditor; after acquisition of Schering AG by Bayer HealthCare leading the HSE Audit and MS Group for the Healthcare Division for 7 years, including global HSE Data Management for the Bayer Annual Report; 3 years leading the global function for HSE MS, Audit Strategy & Planning for all Bayer Divisions (Pharma/ Consumer/ Animal Health/Crop) for 3 years; after acquisition of Monsanto by Bayer now leading the global function for HSE Audits and Supplier Management covering all divisions/businesses at Bayer.
- **Contact information:** birgit.skuballa@bayer.com

AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATE

GENERAL PSCI AUDIT PROCESS

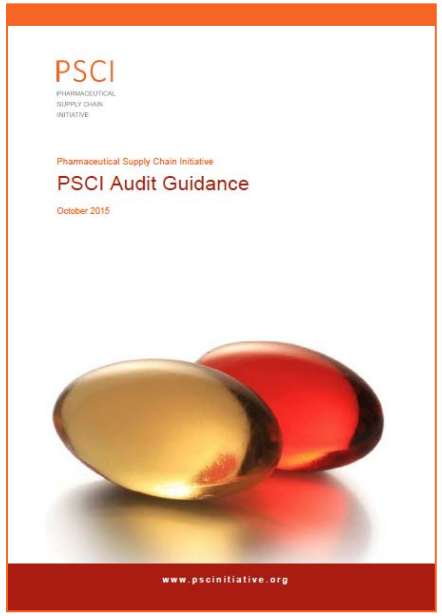
AUDIT REPORT WRITING

WHY DO WE AUDIT?

- PSCI Audits are designed to assess a supplier's performance against the PSCI Principles as well as against international standards and agreements, and local regulatory requirements in the areas of: Ethics, Labor, Health & Safety, Environmental Protection and Management Systems.
- The PSCI Shared Audit Program provides a framework and methodology to ensure PSCI Audits are carried out in accordance with PSCI Standards, thereby delivering a credible, transparent and consistent audit approach.
- Our goal is to ensure that the PSCI auditing model and tools become the norm for our industry.
- We encourage members to use the PSCI tools and their suppliers to share the results.

PSCI AUDIT PROGRAM GUIDANCE

- Provides the methodology on how PSCI Audits are conducted and managed
- Gives a detailed overview of the audit process
- Clarifies auditor qualifications and roles/responsibilities



Contents

WHO CARRIES OUT PSCI AUDITS?

- In order to ensure the integrity of the audit process, PSCI Audits are carried out either by **professional and independent 3rd party audit firms incl. qualified auditors** or by PSCI member internal auditors.
- PSCI has currently approved **eleven professional, independent 3rd Party Audit firms** to conduct PSCI Audits, see https://pscinitiative.org/auditCollaboration
- On the contact details of the 3rd Party Audit firm it is indicated for which supplier categories and which audit type the firm is approved , e.g.:
  - Audit Firm 1 — Approved for: Type A, B & C Audits; All Audit Topics
  - Audit Firm 2 — Approved for: Type A, B & C Audits; Health & Safety; Environment; Management Systems
  - Audit Firm 3 — Approved for: PSCI Type A; All Audit Topics

EXPECTATIONS OF PSCI AND PSCI MEMBERS

A Standard Framework Agreement with each of our current and future 3rd party audit firms is in place, which outlines the PSCI expectations on conducting PSCI Audits, covering the following aspects:

- Audit performed according to latest audit program and documentation is complete with all required data in English
- Audit documentation does not contain customer-supplier relationship, competitive sensitive information, or personally sensitive data
- Audit firm pre-screens and proposes appropriate auditors per criteria for Supplier type A, B & C as per PSCI audit guidance document.
- Audit firm ensures that Auditors are familiar with and trained on Key PSCI Audit documents/webinars
- Audit firm conducts internal quality assurance review of audit reports
- Audit firm has feedback mechanism on auditors and take measures to ensure appropriate auditor conduct
- Escalation mechanism in place between PSCI (via PSCI Secretariat) & audit firm for issues
- Reasoning and method for audit firm removal from qualified PSCI Audit List (e.g. due to violations of agreement or guidance document)

PSCI GUIDANCE TOOLS FOR AUDITORS

Collaborative auditing embeds the PSCI Principles in our supply chain. The PSCI has developed guidance tools tailored for our industry for assessing performance and risk. These include:

- PSCI Principles
- PSCI Implementation Guidance
- PSCI Audit Guidance
- PSCI Introductory Training for Auditors - webinar
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - word
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - excel
- Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers (word and excel)
- PSCI SAQ & Audit Report Template Update - 20th February 2019 - webinar
- Introduction presentation for PSCI audit opening meeting
- Pre-Audit Document Request List
- Corrective Action Plan – excel and word
- Data Sharing Agreement
- PSCI Audit Sharing Platform Supplier User Guide
- PSCI Auditor Evaluation Tool

NEW! chinese translations available

AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATES

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

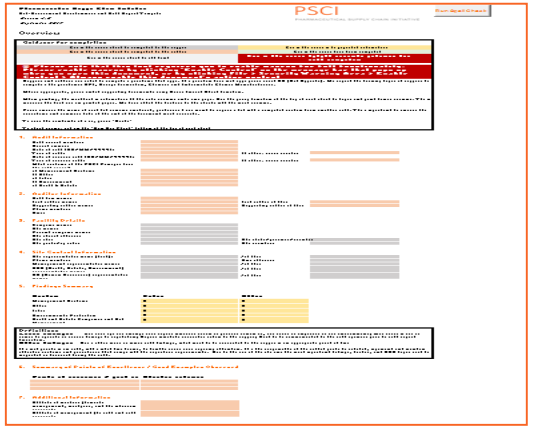
PSCI SUPPLIER CATEGORIES

For auditing purposes, suppliers are categorized according to their activities:

- "A" - service providers
- "B" - component & material suppliers
- "C" - core suppliers & contract manufacturers

PSCI SAQS & AUDIT REPORT PROTOCOLS

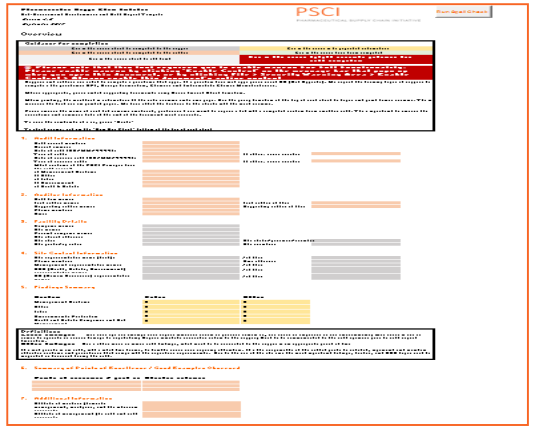
USE FOR "A" SUPPLIERS!!



Abbreviated PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Service Providers & General Manufacturers

https://pscinitiative.org/resource?resource=31

USE FOR "B" and "C" SUPPLIERS!!



Full PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers

https://pscinitiative.org/resource?resource=32

PSCI SAQ/ AUDIT TEMPLATES (WORD AND EXCEL)

Pharmaceutical Supply Chain Initiative (PSCI)
Self-Assessment Questionnaire and Audit Report
for Pharmaceutical Industry Suppliers
API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers

GUIDANCE FOR COMPLETION

Sections marked in orange need to be filled in by the supplier before the audit. Sections marked in grey will be filled by the audit team during / after the onsite audit. Please do not change the report format and do not change the answers given by the other party. Supplier and auditors are asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable). **We would expect the following types of suppliers to complete all the questions: API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers.**

AUDITOR AND AUDIT REPORT INFORMATION

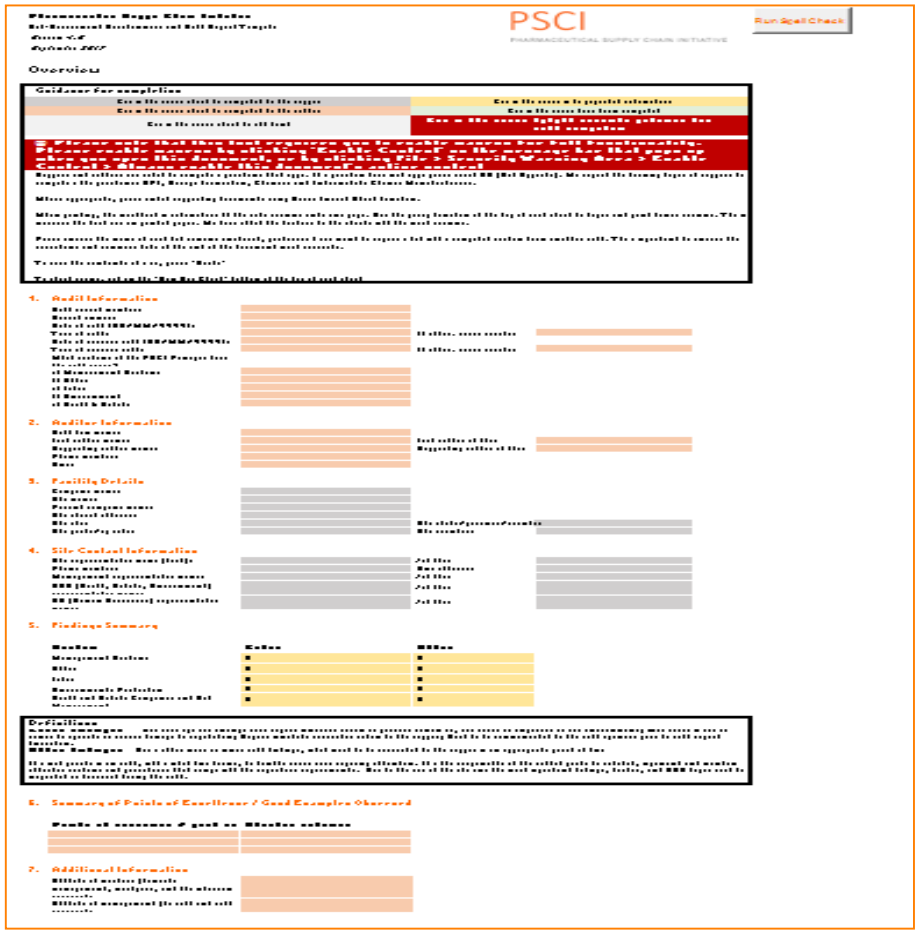
Report Number:			
Report Owner:	Note: this is the company paying for /sponsoring the audit. If a PSCI Member, the name should be removed before the report is uploaded to the PSCI audit sharing platform		
Date of Audit:	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify	**Date and Type of Previous Audit** (if applicable)**:**	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify
Audit Firm Name:			
Lead Auditor Name:		**Title:**	
Names of further auditors:		**Title:**	
Phone Number:		**Email Address:**	

FACILITY DETAILS

Company Name:	
Site Name (if different):	

October 2016 *Version 4*

Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers



SAQ/ AUDIT TOOLS: OVERVIEW ON UPDATE

The SAQ/Audit tools (word and excel) have been updated from a few perspectives:

- New content
  - Now two methodologies for finding classification
    - Critical/"Others"
    - Critical/Major/Minor 

  - Revised questions
  - More auditor guidance

- New functionalities
  - Driven by revisions
  - Driven by feedback from member companies and approved auditors

WORD VERSIONS – Findings classifications

- **Findings classifications**, only the relevant executive summary should be filled in, depending on the findings classification required
  - Critical / Major / Minor
  - Critical / Other

Note:

for details on audit finding classification see section "Audit Report Writing"

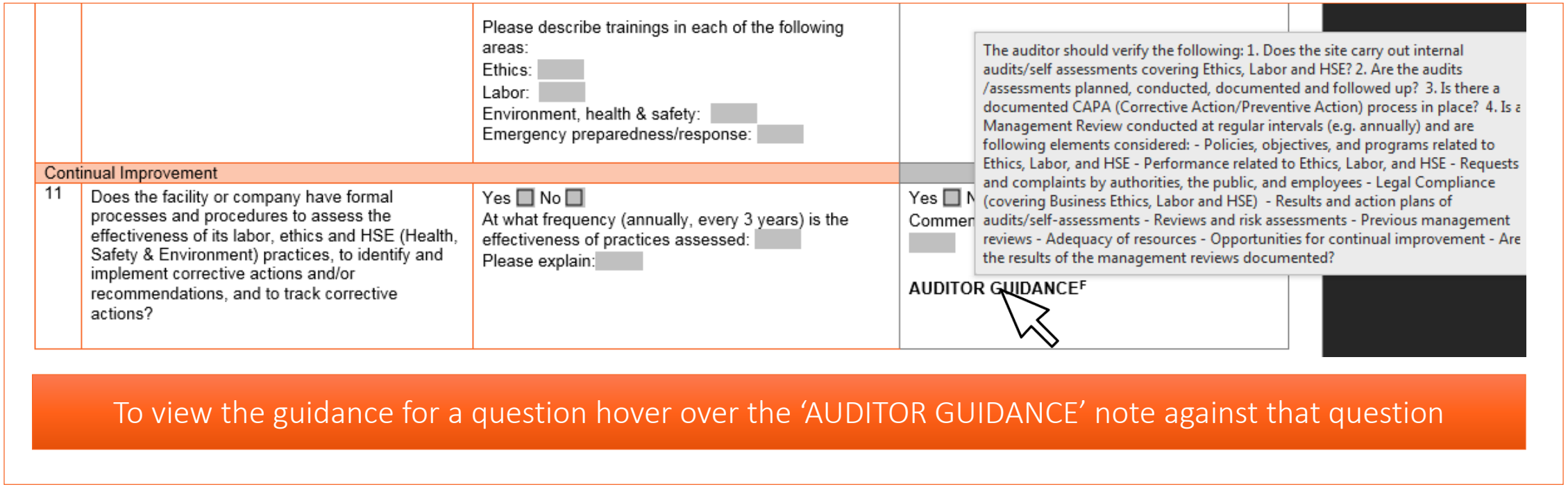
EXECUTIVE SUMMARY (FOR CRITICAL-OTHER)							
Overall findings		Please check applicable box(es) and indicate the number of findings					
		Critical	Number of Criticals	Other	Number of Others	No findings	Not reviewed
A	Management Systems	☐		☐		☐	☐
B	Ethics	☐		☐		☐	☐
C	Labor	☐		☐		☐	☐
D	Environmental Protection	☐		☐		☐	☐
E	Health & Safety Compliance and Risk Management	☐		☐		☐	☐

EXECUTIVE SUMMARY (FOR CRITICAL-MAJOR-MINOR)								
Overall findings		Please check applicable box(es) and indicate the number of findings						
		Critical	Number of Criticals	Major	Number of Major	Minor	Number of Minor	No findings	Not reviewed
A	Management Systems	☐		☐		☐		☐	☐
B	Ethics	☐		☐		☐		☐	☐
C	Labor	☐		☐		☐		☐	☐
D	Environmental Protection	☐		☐		☐		☐	☐
E	Health & Safety Compliance and Risk Management	☐		☐		☐		☐	☐

WORD VERSIONS – Auditor guidance (1)

Auditor guidance: the updated auditor guidance has been added to the tool using endnotes.

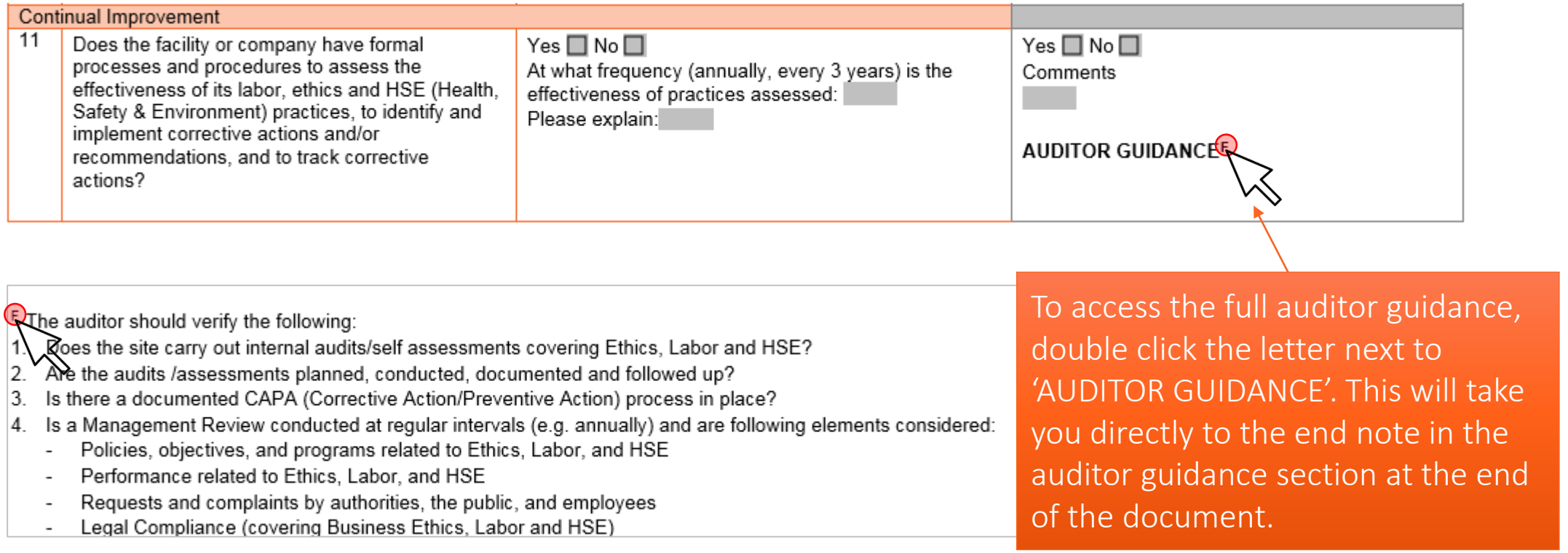
1) To view the guidance pop-up



To view the guidance for a question hover over the 'AUDITOR GUIDANCE' note against that question

WORD VERSIONS – Auditor guidance (2)

2) To view the full guidance text



Continual Improvement			
11	Does the facility or company have formal processes and procedures to assess the effectiveness of its labor, ethics and HSE (Health, Safety & Environment) practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions?	Yes ☐ No ☐ At what frequency (annually, every 3 years) is the effectiveness of practices assessed: Please explain:	Yes ☐ No ☐ Comments AUDITOR GUIDANCE F

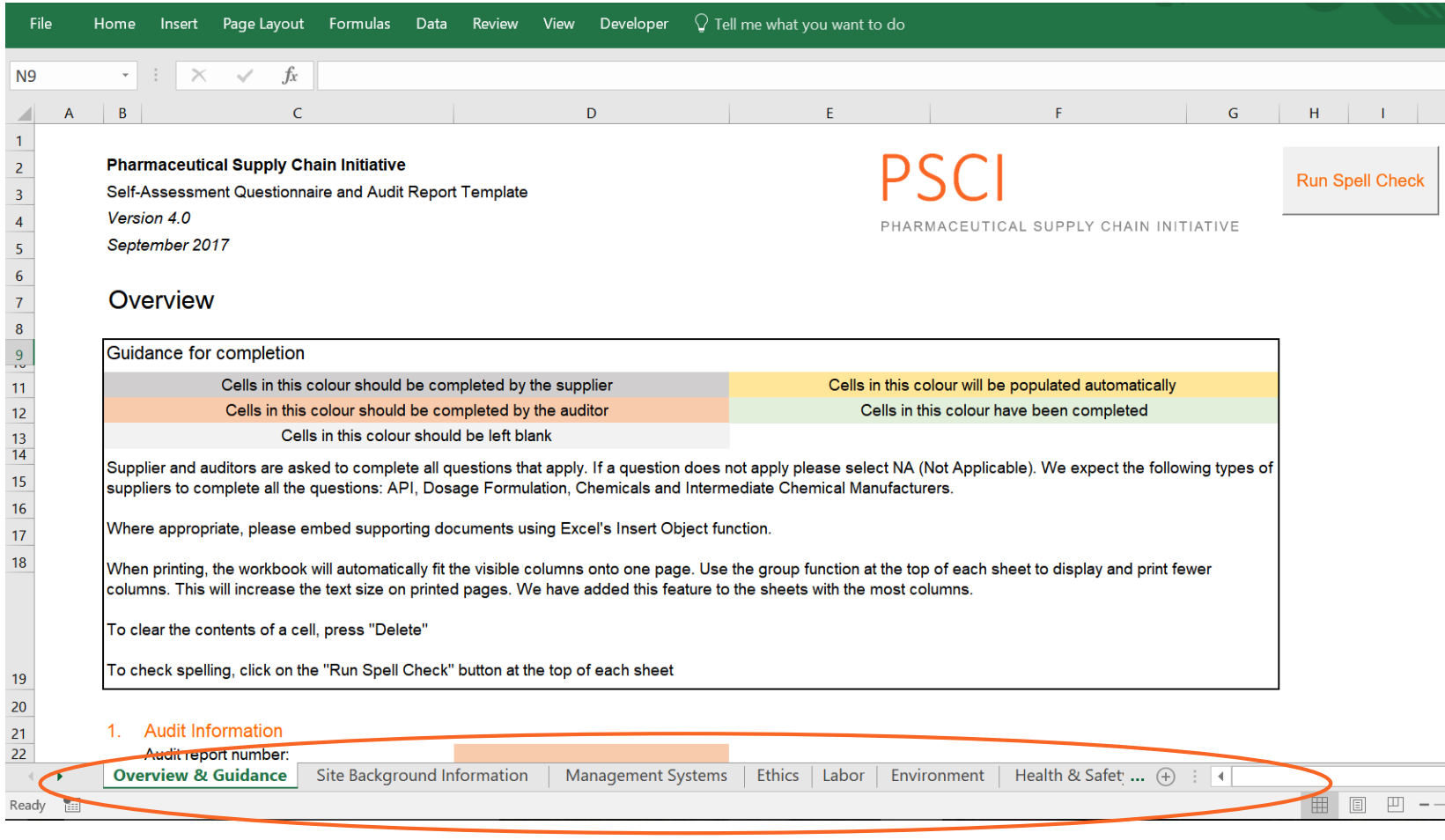
F The auditor should verify the following:

1. Does the site carry out internal audits/self assessments covering Ethics, Labor and HSE?
2. Are the audits /assessments planned, conducted, documented and followed up?
3. Is there a documented CAPA (Corrective Action/Preventive Action) process in place?
4. Is a Management Review conducted at regular intervals (e.g. annually) and are following elements considered:
   - Policies, objectives, and programs related to Ethics, Labor, and HSE
   - Performance related to Ethics, Labor, and HSE
   - Requests and complaints by authorities, the public, and employees
   - Legal Compliance (covering Business Ethics, Labor and HSE)

To access the full auditor guidance, double click the letter next to 'AUDITOR GUIDANCE'. This will take you directly to the end note in the auditor guidance section at the end of the document.

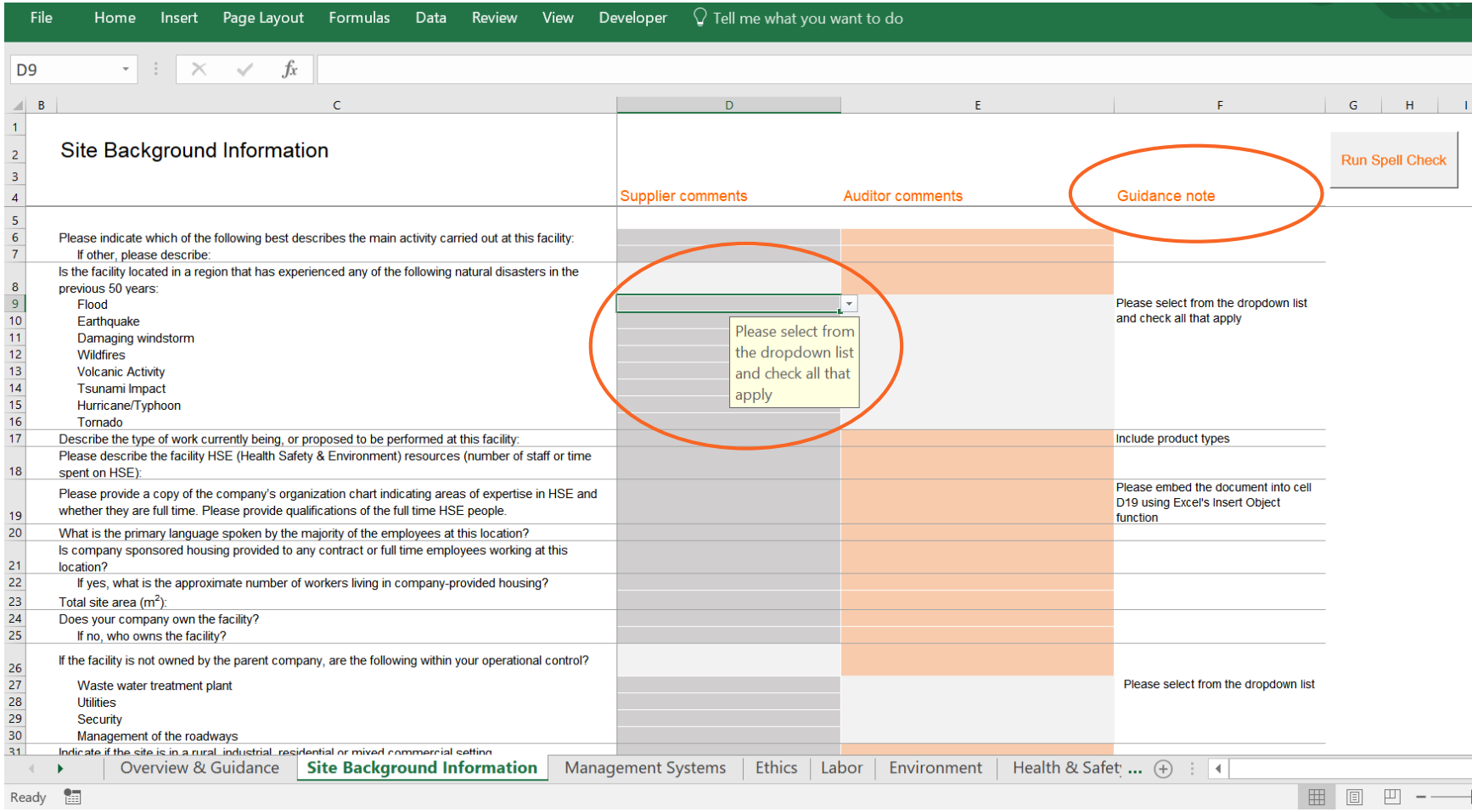
EXCEL TEMPLATE: KEY FEATURES (1)

- **Preferred tool** as we can drive overall evaluation of audit results better
- Separate tabs for the separate sections of PSCI Principles
- Extra tab for company specific questions (which can be removed before sharing)
- Colour coding to make obvious who should complete each section
- Integrated spell check function
- Green highlighting to track completed cells



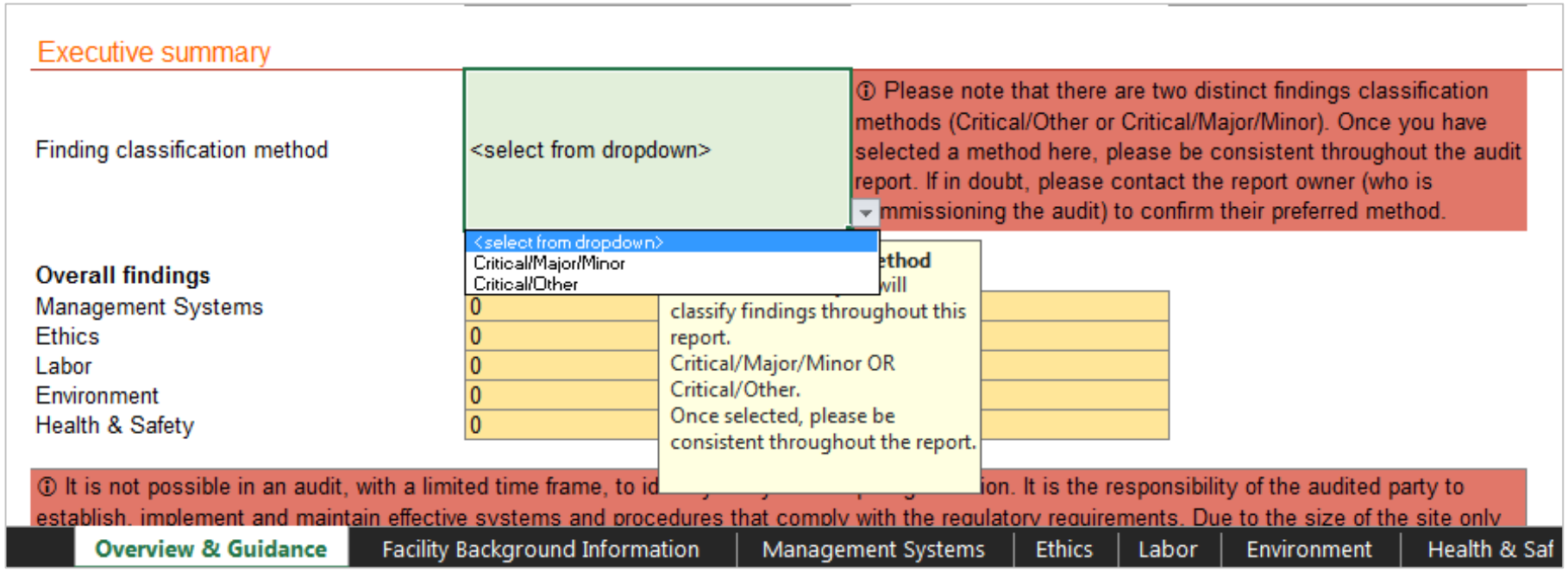
EXCEL TEMPLATE: KEY FEATURES (2)

- Detailed Auditor Guidance notes for questions covering higher risks
- Drop downs to standardise responses where appropriate



EXCEL VERSIONS –Findings classifications

- **Findings classifications**, in the excel version the classification method needs to be selected before starting the evaluation **and must not be changed in the process**. Select the findings classification required from the summary table on the 'Overview & Guidance' tab it will update automatically to:
  - Critical / Major / Minor
  - Critical / Other



EXCEL VERSIONS – Auditor guidance (2)

- **Auditor guidance**, the additional auditor guidance that has been added is included in an 'Additional Auditor Guidance' **column (K)** in the excel tool.

Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

ENVIRONMENT

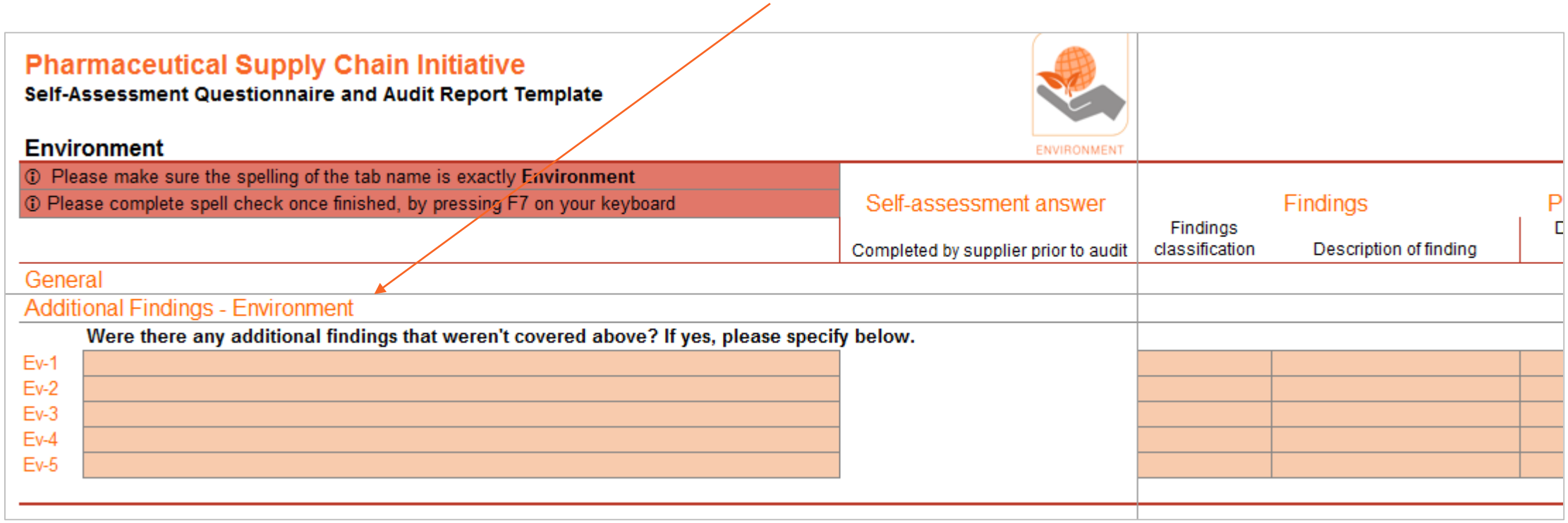
PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Environment

ⓘ Please make sure the spelling of the tab name is exactly **Environment** ⓘ Please complete spell check once finished, by pressing F7 on your keyboard		Self-assessment answer Completed by supplier prior to audit	Additional Auditor Guidance Where provided, it is mandatory to follow the guidance.
General			
31	**Does the facility have written environmental policy, procedures, and practices?**		
i.	Environmental policy?		
ii.	Environmental procedures?		
	Comments		
	If yes, please provide a copy of the policy and list of the procedure titles.		
32	**Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?**		ⓘ Describe any formal or informal programs or procedures to reduce environmental impacts, noting any improvements made in recent (3) years. Does the supplier disclose environmental emissions and impacts to CDP?
	If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years		

EXCEL VERSIONS – Additional findings

- **Space for additional findings**, this is provided at the end of every section. This is aimed at including space for auditors to provide additional findings against a topic, like Environment that do not fit against a specific question.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

ENVIRONMENT

Environment

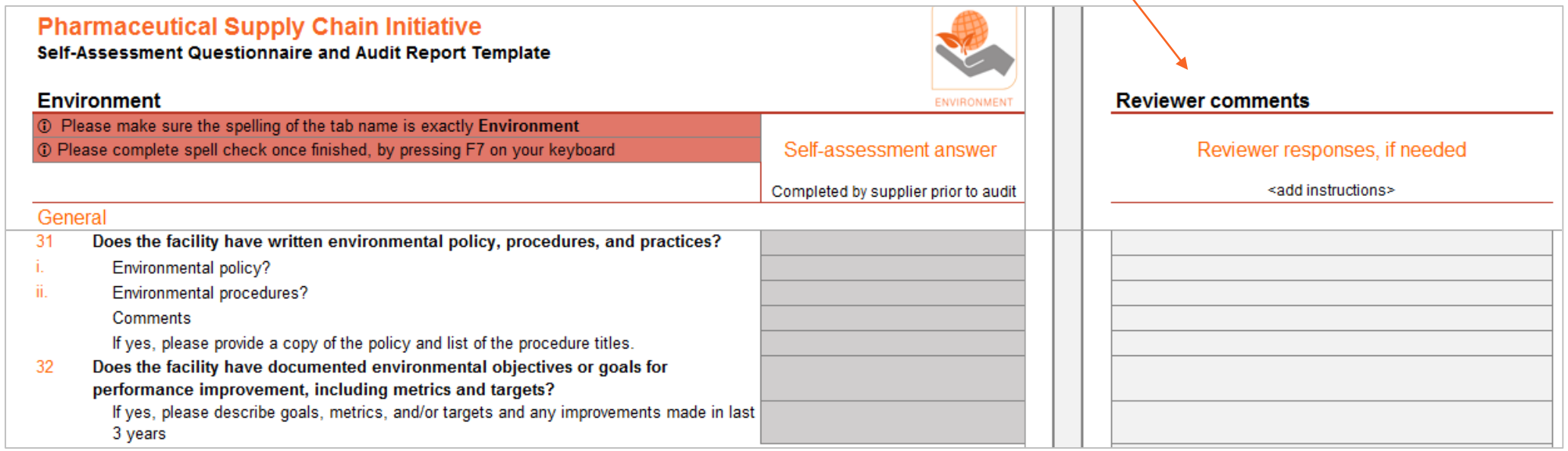
ⓘ Please make sure the spelling of the tab name is exactly **Environment**

ⓘ Please complete spell check once finished, by pressing F7 on your keyboard

	Self-assessment answer	Findings		P
	Completed by supplier prior to audit	Findings classification	Description of finding	D
General				
Additional Findings - Environment				
Were there any additional findings that weren't covered above? If yes, please specify below.				
Ev-1				
Ev-2				
Ev-3				
Ev-4				
Ev-5				

EXCEL VERSIONS – Reviewer comments

- **Reviewer comments**, we've included an additional column (O) at the very right of each form for reviewer responses. This is intended to be a column where a reviewer can comment against questions if they have comments.



Pharmaceutical Supply Chain Initiative

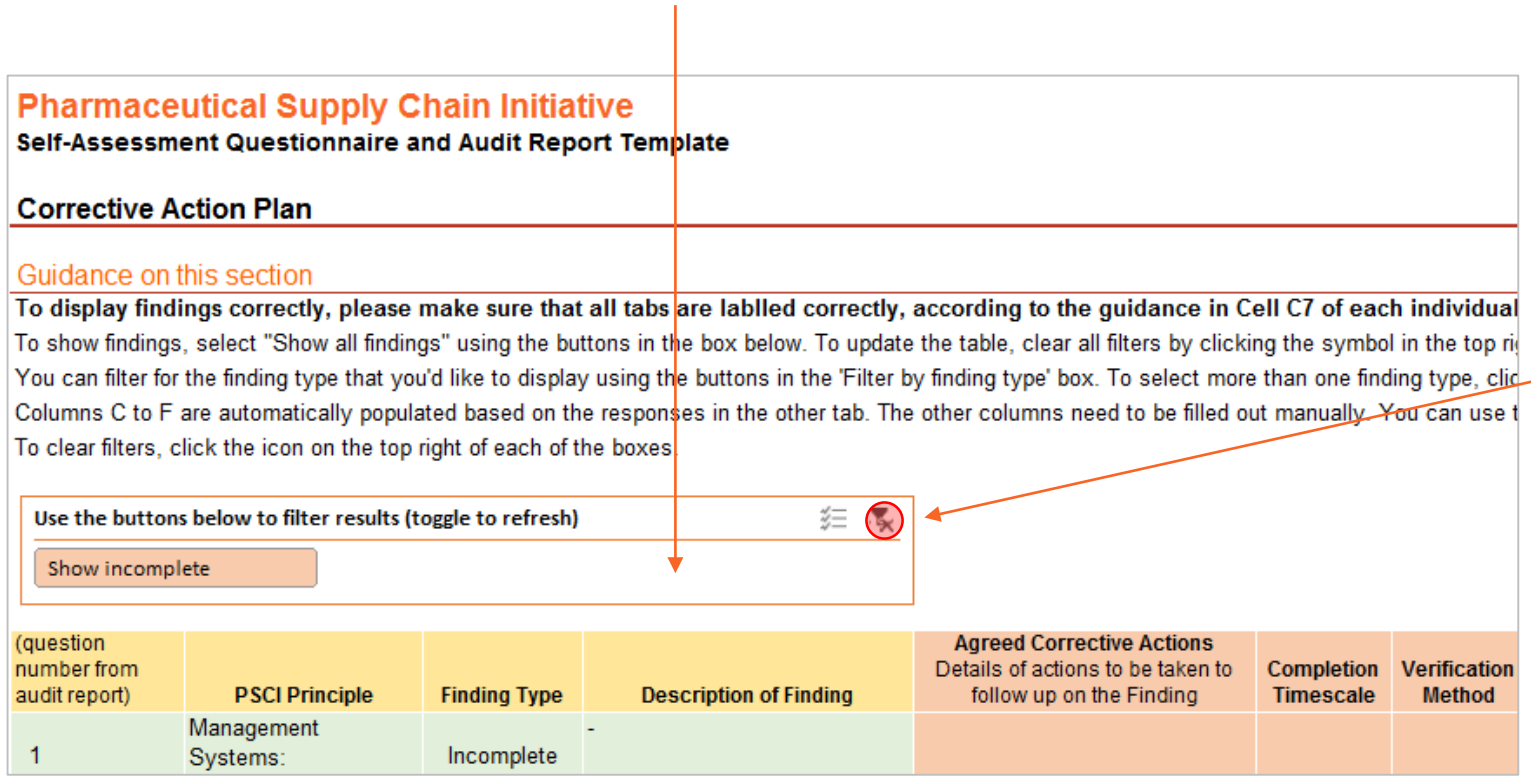
Self-Assessment Questionnaire and Audit Report Template

ENVIRONMENT

Environment			
ⓘ Please make sure the spelling of the tab name is exactly **Environment**			**Reviewer comments**
ⓘ Please complete spell check once finished, by pressing F7 on your keyboard		Self-assessment answer	Reviewer responses, if needed
		Completed by supplier prior to audit	<add instructions>
General			
31	**Does the facility have written environmental policy, procedures, and practices?**		
i.	Environmental policy?		
ii.	Environmental procedures?		
	Comments		
	If yes, please provide a copy of the policy and list of the procedure titles.		
32	**Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?**		
	If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years		

EXCEL VERSIONS –CAP sheet updated

- **CAP sheet updated**, we've removed the Macro from the CAP sheet. The CAP sheet functionality is similar, but there are a few minor changes to how it works. Now findings can be filtered using the option menu at the top of the table.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

Corrective Action Plan

Guidance on this section

To display findings correctly, please make sure that all tabs are labllled correctly, according to the guidance in Cell C7 of each individual

To show findings, select "Show all findings" using the buttons in the box below. To update the table, clear all filters by clicking the symbol in the top ri

You can filter for the finding type that you'd like to display using the buttons in the 'Filter by finding type' box. To select more than one finding type, clic

Columns C to F are automatically populated based on the responses in the other tab. The other columns need to be filled out manually. You can use t

To clear filters, click the icon on the top right of each of the boxes.

Use the buttons below to filter results (toggle to refresh)

Show incomplete

(question number from audit report)	PSCI Principle	Finding Type	Description of Finding	Agreed Corrective Actions Details of actions to be taken to follow up on the Finding	Completion Timescale	Verification Method
1	Management Systems:	Incomplete	-			

In order to go back to reset the view, select this button

EXCEL VERSIONS –Other updates

- **Excel unlocked,** some of the restrictions caused issues when using it, so we've unlocked the excel sheets in order to make using them simpler.

  Please take care NOT to:

  - **Change any questions,** similarly to the word version
  - **If combining sheets keep to the original sheet names,** *or the CAP sheet won't work correctly*

- **Spell check updated,** we've removed the spell check Macro, as it was causing compatibility issues. Users now need to need to spell check using F7. This is clearly indicated at the top of each sheet where the spell check macro button used to be.

COMPLETING THE PSCI PROTOCOLS

TIPS/HINTS FOR AUDITORS

- Please do not change the report format and do not change the answers given by the supplier in the SAQ sections
- Auditors are generally asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable)
- If – e.g. in case of time constraints - some questions cannot be covered, this needs to be indicated as well.
- Comments of the auditors should not be a simple copy and paste of the SAQ answer provided by the supplier or should not be a turn around of the audit question to an answer Comments should reflect auditors actual observations during onsite audit
- Please insert photographs when applicable and feasible, following the instructions as mentioned in the audit protocols

AGENDA

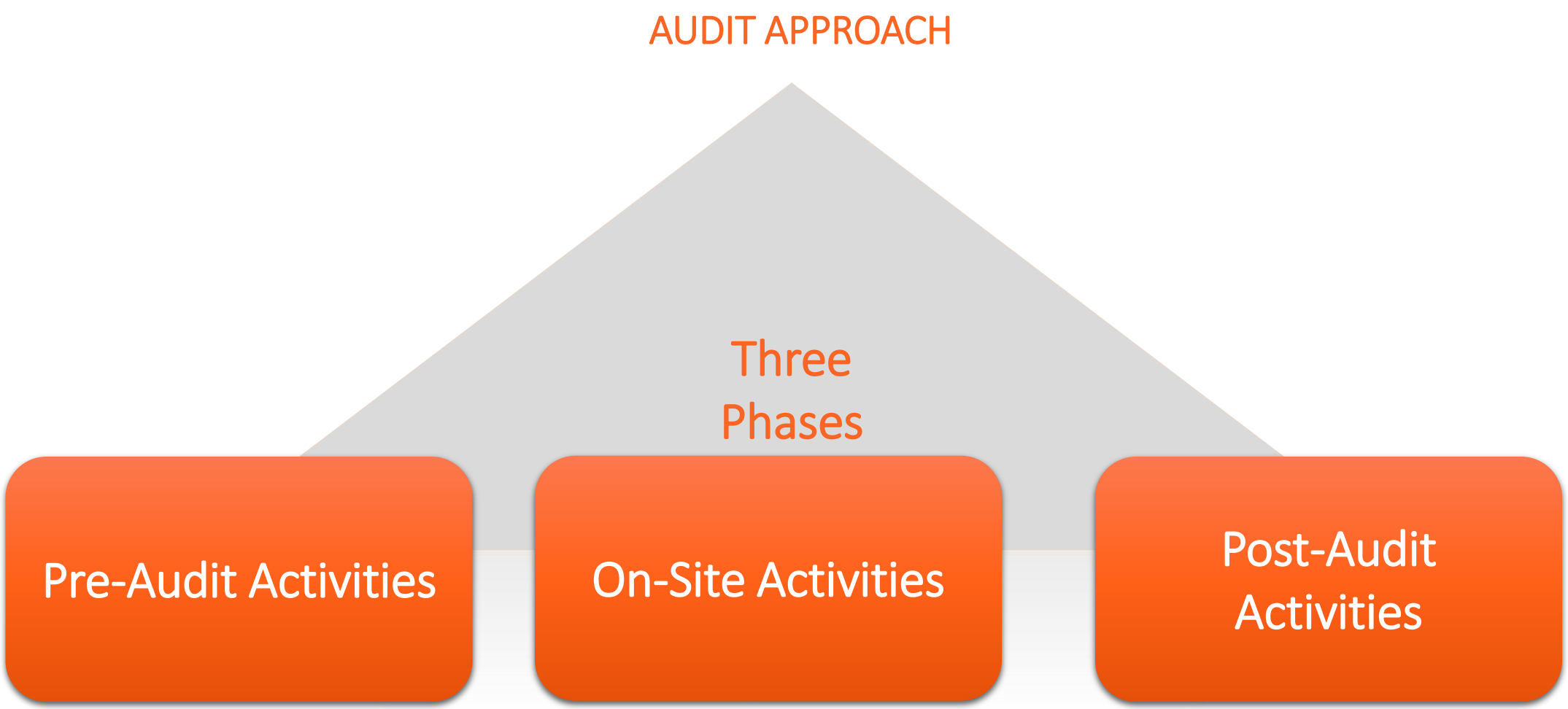
OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATE

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

GENERAL PSCI AUDIT PROCESS

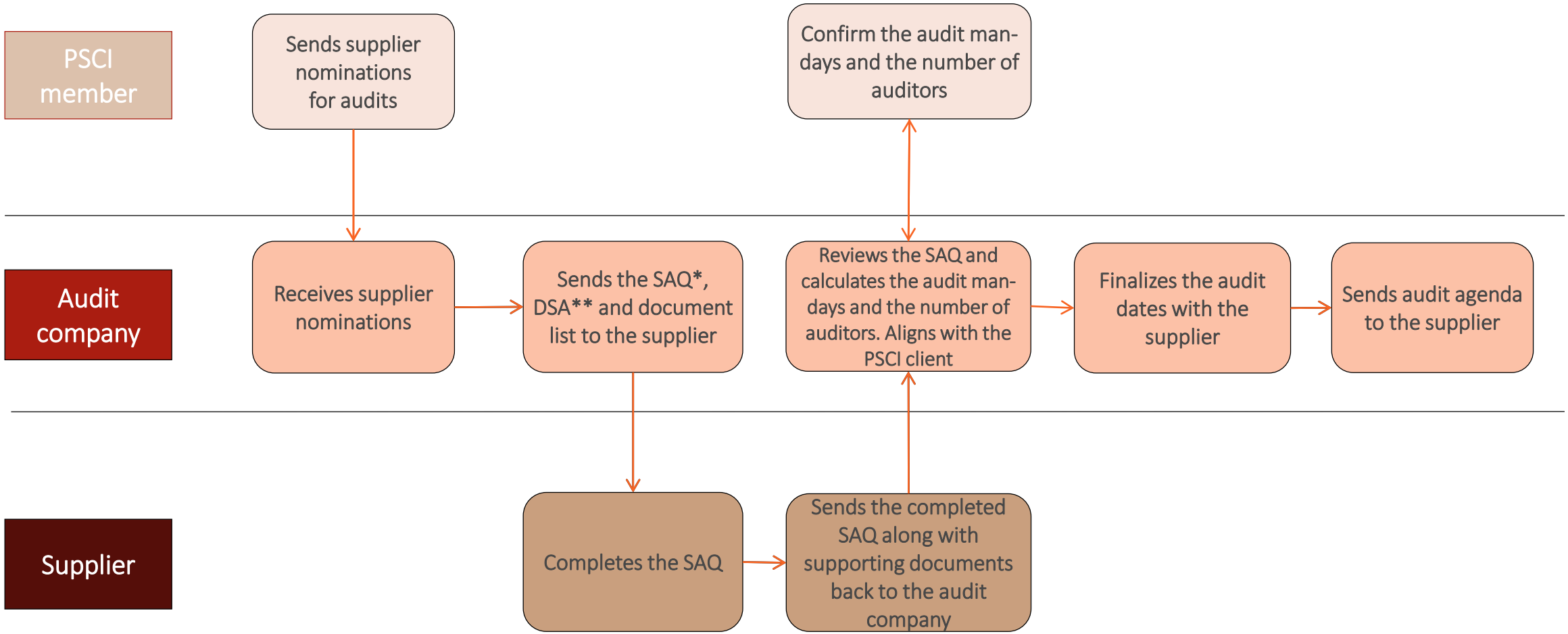


AUDIT PREPARATION

TIPS/HINTS FOR AUDITORS

- Study the PSCI SAQ (and the provided documents)
- Ask for any additional information if needed from the supplier
- Check with the client if there are any special topics that need to be considered
- Provide the supplier with an agenda and a tailored PSCI Pre-Audit Document checklist
- Check the website of the auditee
- Carry out background research about the auditee,
  e.g. media reports about environmental issues (for China: IPE database, relevant databases or reports about fatalities, accidents, incidents, loss of primary containments, news about legal issues etc.
- Check if there are any special instructions upon arrival
  (be prepared to show identification if required, ask where to sign in, who to ask for upon arrival…)
- Check if any special personal protective equipment is required

EXAMPLE PRE AUDIT ACTIVITIES



*SAQ – Self assessment questionnaire **DSA – Data sharing agreement

AUDITOR PREPARATION

TIPS/HINTS FOR AUDITORS

- Dress appropriately for the audit
  (e.g. no high heels or open toes shoes)
- Bring your own safety shoes (and other PPE if relevant)
- Respect company‘s opening and closing time/shift timings
- Most important: arrive on time!

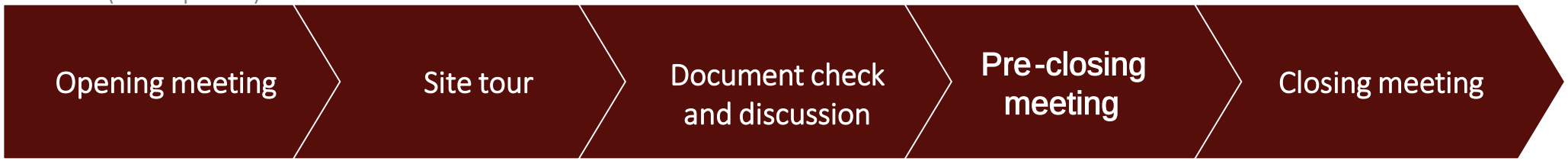
PSCI ONSITE AUDIT PROCESS (HSE PART)

Opening meeting

- includes a short introduction of the audit team by the lead auditor and the scope of the audit.
- Involved parties: site/plant management, HSE, engineering, production and others (as required)

Pre-closing meeting:

- Internal discussion among the auditors
- preparation of the CAP (Corrective Action Plan)



Site t our: covers production and other relevant infrastructure areas e.g. waste, waste water, technical areas, utilities. Exchange/discussions with employees and management

Document review e.g. as listed in the in the PSCI document list

Discussions with technical experts and management (e.g. HSE, engineering, production)

Presentation

- of best practices and points for improvement
- summary of the CAP
- and as a sign of agreement signing it by both parties

OPENING MEETING

TIPS & HINTS FOR AUDITORS

- Be on time!
- Thank the management for hosting the audit
- Introduce yourself and audit team and ask the others participants to introduce themselves (facilitated by business cards & list of attendees)
- Provide a brief background about PSCI in case the company is unaware
- Explain the purpose and the benefits of the PSCI Audit
- Explain the audit plan (including areas to be inspected); be flexible if needed
- Ask the auditee to provide an overview of their facility and processes
- Ask if you may take photographs of selected areas (do not insist taking photographs if the auditee denies it)
- Ask for safety instructions and evacuation plan if not provided by the company.

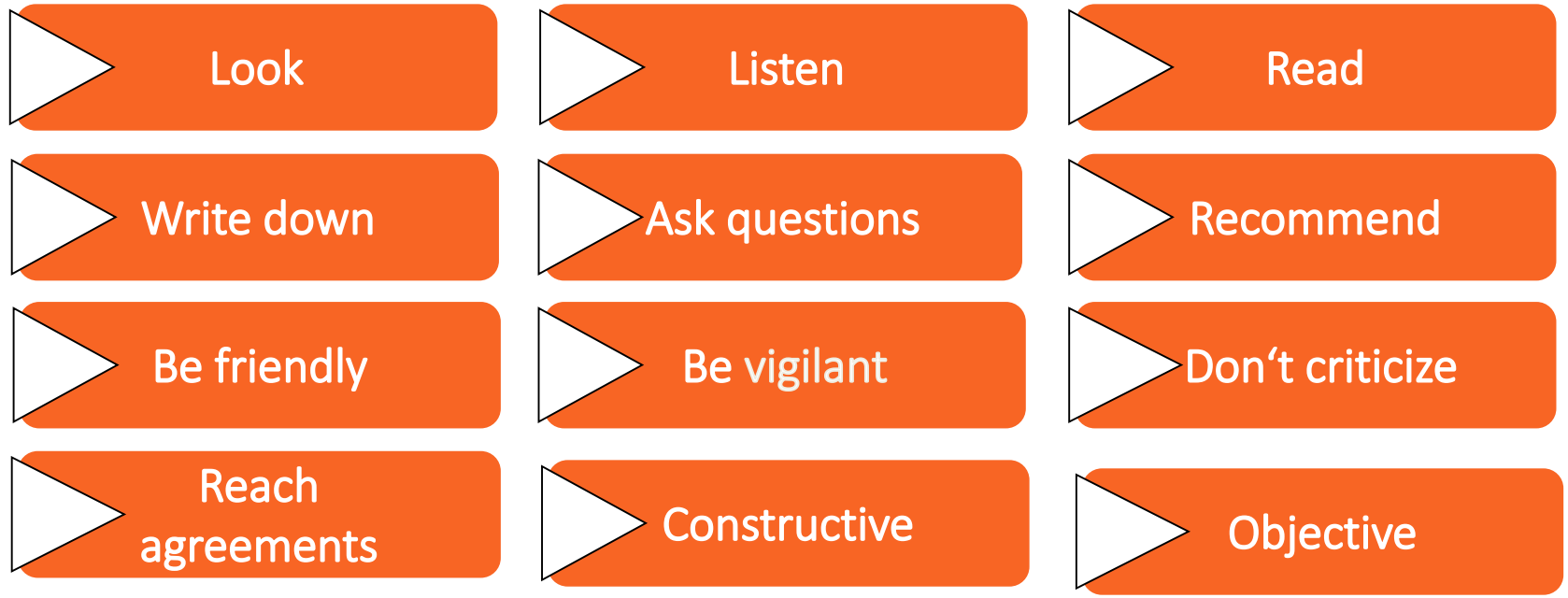
PHYSICAL INSPECTION OF THE FACILITY

TIPS & HINTS FOR AUDITORS

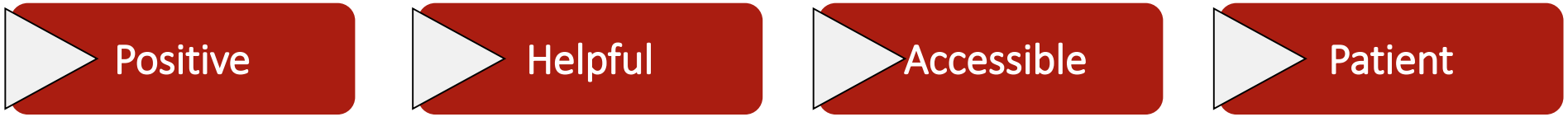
- Good time management is key, especially during site tours
- Allow for sufficient time for the site tour, do NOT spend the majority of time with document review in the office
- Ask for a site map for the tour to help you with the site orientation
- Keep in mind that gowning procedures in pharmaceutical finishing plant may require a significant amount of time
- Inspect main production areas, but be careful to reserve time for other areas (e.g. warehouses, waste storage/treatment, waste water treatment units and other utilities are also important to visit)
- Try to inspect critical activities especially those with high risk potential e.g. construction activities, inspection & sampling, loading/unloading, material handling and transfer, waste packing and pick-up, confined space entry
- Observe the facility also from the outside

BEHAVIOR DURING AN AUDIT

What an auditor should do:



How an auditor should behave:



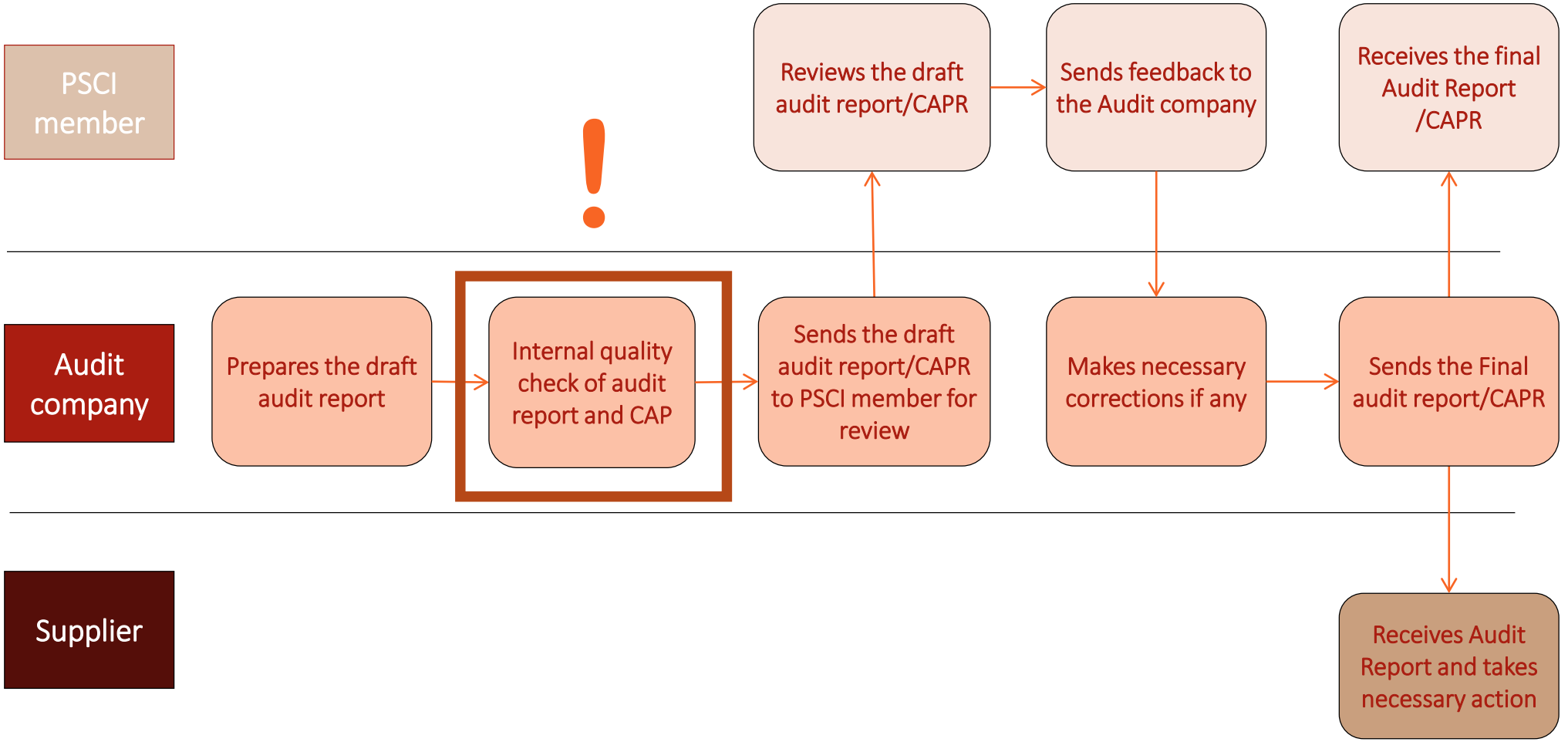
CLOSING MEETING (1)

- Thank the management for their time, patience and openness and indicate how this contributes to fostering the mutual relationship and building trust;
- Re-confirm the purpose of the audit;
- Mention good working practices that have been observed during the audit;
- Explain that the audit was based on a sample examination of their site and that it is the site's responsibility to conduct a deeper investigation into their programs;
- Explain which findings and improvement potentials have been observed during the audit, and discuss possible corrective actions;
- Remind the supplier that they may challenge/discuss findings (or provide factual evidence that a finding was incorrect) in this meeting, but any issues they have agreed to will not be changed later;
- Besides listing the findings, ensure that any agreements or disagreements are clearly recorded on the Preliminary Corrective Action Plan;

CLOSING MEETING (2)

- If possible: Obtain the signature of the site management on this Preliminary Corrective Action Plan Report;
- Explain the next steps; Drafting of PSCI Audit Report and PSCI Corrective Action Plan, Quality control of the audit report, finalization of the PSCI Audit Report and Corrective Action Plan Report and distribution to supplier and to the respective PSCI member;
- Encourage the management of the site to allow for sharing of the PSCI Audit Report and Corrective Action Plan Report with other PSCI member companies
  (either by signing the PSCI Data Sharing Agreement or by sharing online via the PSCI audit sharing platform)

EXAMPLE POST AUDIT ACTIVITIES



AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATE

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

AUDIT REPORT WRITING

Note: Audit Report writing already starts during the audit!

- Ensure that notes are accurate (all are potentially “discoverable”)
- Document all evidence reviewed (even if it is not a finding)
- Take photos of documents & situations, if allowed
- Document where a photo was taken
- Note title/job description/area of interviewees
  (but never give names in the audit report)
- Note specific ID # for the SOP, other documents, equipment etc.
- Give # reviewed of total # available

WRITING AUDIT FINDINGS (1)

TIPS & HINTS FOR AUDITORS

- Use full sentences and keep them short, to the point
- Report facts, not opinions
- Define all acronyms when used the first time
- Do not make legal conclusions (e.g., “not compliant…”)
- Limit the use of adjectives (e.g. “always,” “every,” “any,” “none”)
- Do not exaggerate or overstate
- Use everyday language, avoid technical jargon
- Consider language like “was not available,” “no evidence of,” versus “there was no…”
- Use “active voice”
  OK: wastewater operator performs weekly wastewater sampling at the outfall point for criteria A, B, & C. The results are shared monthly with the local authority as per permit.
  Not OK: sampling was performed of the wastewater

WRITING AUDIT FINDINGS (2)

Following basic questions should be considered while writing a finding:

- **Who?** is involved in the finding
- **What?** is the subject of the finding
- **When?** did the finding take place
- **Where?** was the location of the finding
- **How?** did the finding come about and examples
- **How often?** does the finding happen: a single event/case or a systematic error

And: Challenge significance of each observation by asking **"So what?"**

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
There was minimal on-site compliance with Corporate or department contractor safety policy and procedures.	
Some of the air sources were being operated without proper permits and some are not adequately maintained.	
The facility's central SDS file was very neat and accessible to those employees who should see it. Not all materials used or stored by the facility have MSDSs in the central file. Those SDSs reviewed appeared complete and contained the appropriate information.	
Bob Miller was neither familiar with the company's SOP on Hazardous materials nor could he identify where DSs were located.	

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

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There was minimal on-site compliance with Corporate or department contractor safety policy and procedures.	Not specific. Does not describe the problem in detail so that the factory can correct it.
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The facility's central SDS file was very neat and accessible to those employees who should see it. Not all materials used or stored by the facility have SDSs in the central file. Those SDSs reviewed appeared complete and contained the appropriate information.	What does SDS mean? Audit findings and good observations are combined here. Do not use words like "not all" and "appears".
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Bob Miller was neither familiar with the company's SOP on Hazardous materials nor could he identify where SDSs were located.	Avoid using names and personal accusations.

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	
It seemed that the emergency routes in the warehouse were too narrow.	
An operator reported work permits were not always issued when staff enter confined spaces. This violates the site´s confined space entry program.	
The chemical hygiene plan was found deficient and should be improved. This is a serious concern.	

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The chemical hygiene plan was found deficient and should be improved. This is a serious concern.	“Deficient” sounds opinionated; “serious” – avoid extreme wording

CLASSIFICATION OF AUDIT FINDINGS (1)

- Critical Findings: Are very high risk findings that require immediate action to protect human life, the health of employees or the environment; May result in loss of license to operate or serious damage to reputation; Require immediate corrective action by the supplier; Need to be communicated to the audit sponsor prior to audit report finalization.
- Other Findings: Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time.
  - Major Findings: Findings that may pose major impacts to workers, the community, or the environment. Findings that may pose major regulatory non-compliances or illustrate systemic program gaps.
  - Minor Findings: Findings that may pose minor impacts to workers, the community, the environment. Findings that may pose minor regulatory non-compliances.
- Non-Finding remarks: Are where the auditor wishes to raise an important comment, but this comment would not constitute any type of finding.
- **NOTE:** When writing the audit report, please choose **one** of the two classification methodologies (i.e. either critical/other OR critical/major/minor and consistently stay with it within the report.

CLASSIFICATION OF AUDIT FINDINGS (2)

Examples for Critical Findings:

- Operation of a solvent storage facility without legally required permit
- Intentional shut-down or bypassing of important safety installations

Examples for Other Findings (Minor, Major - depending on further information provided)

- Inspection of portable fire extinguishers not carried out monthly
- Not all safety data sheets are available in local language
- Hazard communication labeling missing on some bottles and drums
- Facilities respirator protection program lacks fit testing
- Safety training missing in a some cases and for some topics

EXCERSIZE: CLASSIFICATION OF AUDIT FINDINGS

Are these critical, other (major) or other (minor)?

- The safety data sheets for the cleaning agents 1273 and 1322 used in the production area were only available in English and not in the local language.

  OTHER (MINOR)

- 4 out of 5 emergency exit doors in the raw material warehouse and 4 out of 7 emergency exit doors in the canteen were found locked by padlocks.

  CRITICAL

- Eye showers and/or eye wash bottles were not available in the following areas where corrosive liquids are handled: Cleaning room of Quality Control Laboratories and Microbiological Laboratory (corrosive cleaning liquids), cleaning room of non-hormonal production building A100 (corrosive cleaning liquid) Battery charging rooms in warehouse A, B and C (acids)

  OTHER (MAJOR)

THANK YOU!

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+55 (11) 94486 6315

PSCI

@PSCInitiative

For more information about the PSCI please contact:

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

info@pscinitiative.org

+55 (11) 94486 6315

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.

carnstone
partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

General Safety

DR. BIRGIT SKUBALLA
CORPORATE HSE - HEAD OF HSE AUDITS & SUPPLIER MANAGEMENT
BAYER

Bio

Dr. Birgit Isabelle Skuballa

- **Current position** and responsibilities: Bayer AG, Corporate HSE, Head of HSE Audits & Supplier Management
- **Location:** based in Leverkusen, Germany
- **Background:** PhD in Organic Chemistry (University of Karlsruhe); post-doc at Nagoya University (Japan); ISO14001/OHSAS18001/17025 Lead Auditor; global Bayer HSE Audit Team Lead
- **Experience**: 24+ years within Pharma/Chemical Industry (Schering AG / Bayer); including 4+ years as Process Development Chemist at an API production site, 3 years HSE Management System Responsible and global Responsible Care Coordinator, short time assignment at a pharmaceutical finishing site in Italy, 5 years GMP/Quality Auditor for internal/external API sites and global HSE Auditor; after acquisition of Schering AG by Bayer HealthCare leading the HSE Audit and MS Group for the Healthcare Division for 7 years, including global HSE Data Management for the Bayer Annual Report; 3 years leading the global function for HSE MS, Audit Strategy & Planning for all Bayer Divisions (Pharma/ Consumer/ Animal Health/Crop) for 3 years; after acquisition of Monsanto by Bayer now leading the global function for HSE Audits and Supplier Management covering all divisions/businesses at Bayer.
- **Contact information:** birgit.skuballa@bayer.com

AGENDA

Training / Competency

Incident Management

Machine Safety

Hazard Signage

Personal Protective Equipment

Circulation inside / outside of buildings

Training / Competency

«There is no formal evidence that H&S training to employees is provided»

«The company has not provided HSE training to their employees confirmed through management interview»

«Workers are not formally trained for emergency preparedness and response and for health & safety topics.»

Some findings from the shared reports...

Training / Competency

Training Program

- What to look for ?
  - SOP, concept (word or PowerPoint file)...
- When / how
  - During dedicated section
  - During review of high risk activities
- What good looks like
  - Topics mentioned in SAQ should be found in the training concept (see list on the right)
  - Strategy to capture new hires in the program

Emergency preparedness/response
New employee orientation (HSE)
Annual HSE refresher training
Pre-start up process HSE training
Hazard Communication
Process Safety Management
Health Practices
Environmental Practices

Training / Competency

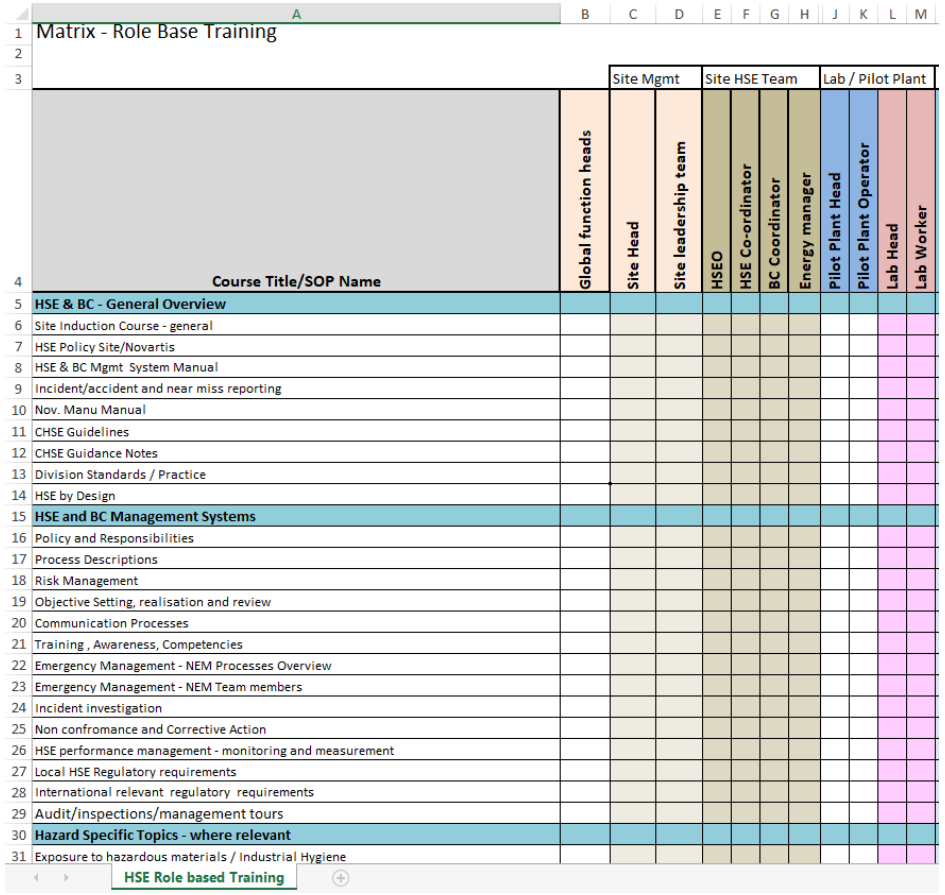
Training for activities with higher risks

- What to look for ?
  - Training regarding Risk Assessment and activities with higher risks like Working at Heights, Confined Space Entry, Working with Hazardous Energies...
- When / how
  - When reviewing a program dealing with higher risks, e.g. PHA (Process Hazard Analysis).
  - Check the training records of the team that perform the analysis
- What good looks like
  - Formal training took place
  - Enough opportunities to practice and get/keep proficiency

Training / Competency

Training Matrix

- What to look for ?
  - Description which roles get which trainings
- When / how
  - When reviewing the topic
- What good looks like
  - At role or individual level
  - Usually 0.5% of working time (10h for full FTE)
  - External audience (contractors) is captured



Matrix - Role Base Training

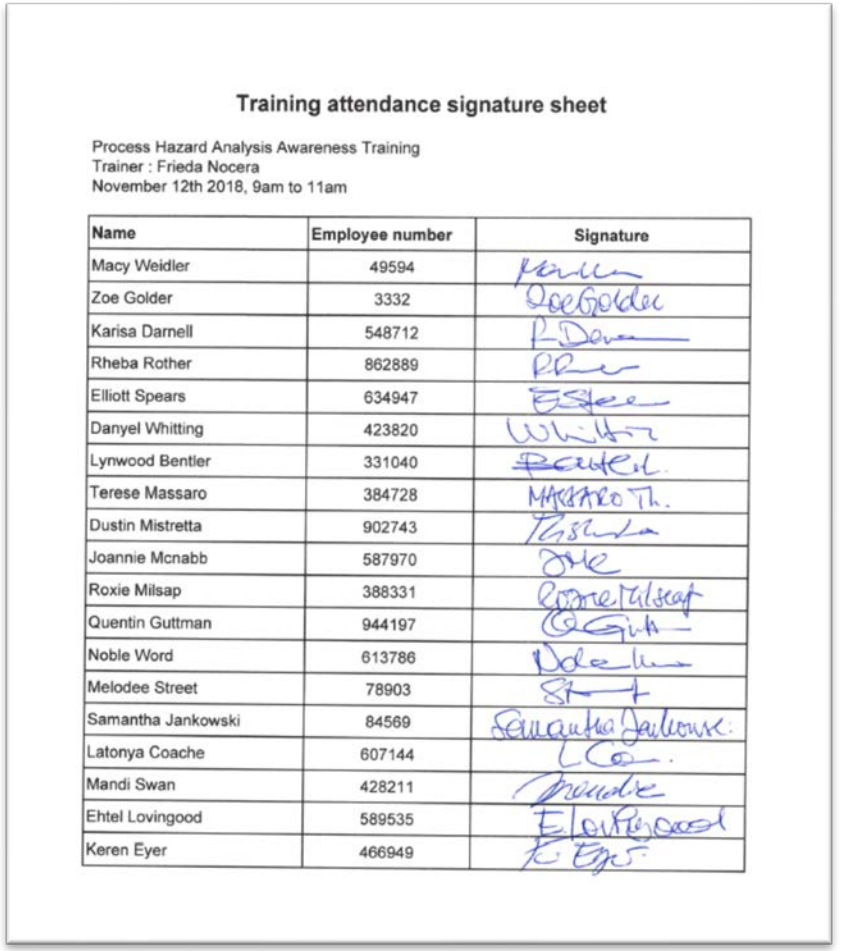
Course Title/SOP Name	Global function heads	Site Mgmt: Site Head	Site Mgmt: Site leadership team	Site HSE Team: HSEO	Site HSE Team: HSE Co-ordinator	Site HSE Team: BC Coordinator	Site HSE Team: Energy manager	Lab / Pilot Plant: Pilot Plant Head	Lab / Pilot Plant: Pilot Plant Operator	Lab / Pilot Plant: Lab Head	Lab / Pilot Plant: Lab Worker
HSE & BC - General Overview											
Site Induction Course - general											
HSE Policy Site/Novartis											
HSE & BC Mgmt System Manual											
Incident/accident and near miss reporting											
Nov. Manu Manual											
CHSE Guidelines											
CHSE Guidance Notes											
Division Standards / Practice											
HSE by Design											
HSE and BC Management Systems											
Policy and Responsibilities											
Process Descriptions											
Risk Management											
Objective Setting, realisation and review											
Communication Processes											
Training , Awareness, Competencies											
Emergency Management - NEM Processes Overview											
Emergency Management - NEM Team members											
Incident investigation											
Non confromance and Corrective Action											
HSE performance management - monitoring and measurement											
Local HSE Regulatory requirements											
International relevant regulatory requirements											
Audit/inspections/management tours											
Hazard Specific Topics - where relevant											
Exposure to hazardous materials / Industrial Hygiene											

HSE Role based Training

Training / Competency

Training Records

- What to look for ?
  - Attendance list, IT-system proof of attendance...
- When / how
  - When reviewing the topic
- What good looks like
  - Associate are identified by name or number
  - Associate have signed the sheet
  - IT-system is qualified for this task



Training attendance signature sheet

Process Hazard Analysis Awareness Training
Trainer : Frieda Nocera
November 12th 2018, 9am to 11am

Name	Employee number	Signature
Macy Weidler	49594	
Zoe Golder	3332	
Karisa Darnell	548712	
Rheba Rother	862889	
Elliott Spears	634947	
Danyel Whitting	423820	
Lynwood Bentler	331040	
Terese Massaro	384728	
Dustin Mistretta	902743	
Joannie Mcnabb	587970	
Roxie Milsap	388331	
Quentin Guttman	944197	
Noble Word	613786	
Melodee Street	78903	
Samantha Jankowski	84569	
Latonya Coache	607144	
Mandi Swan	428211	
Ehtel Lovingood	589535	
Keren Eyer	466949	

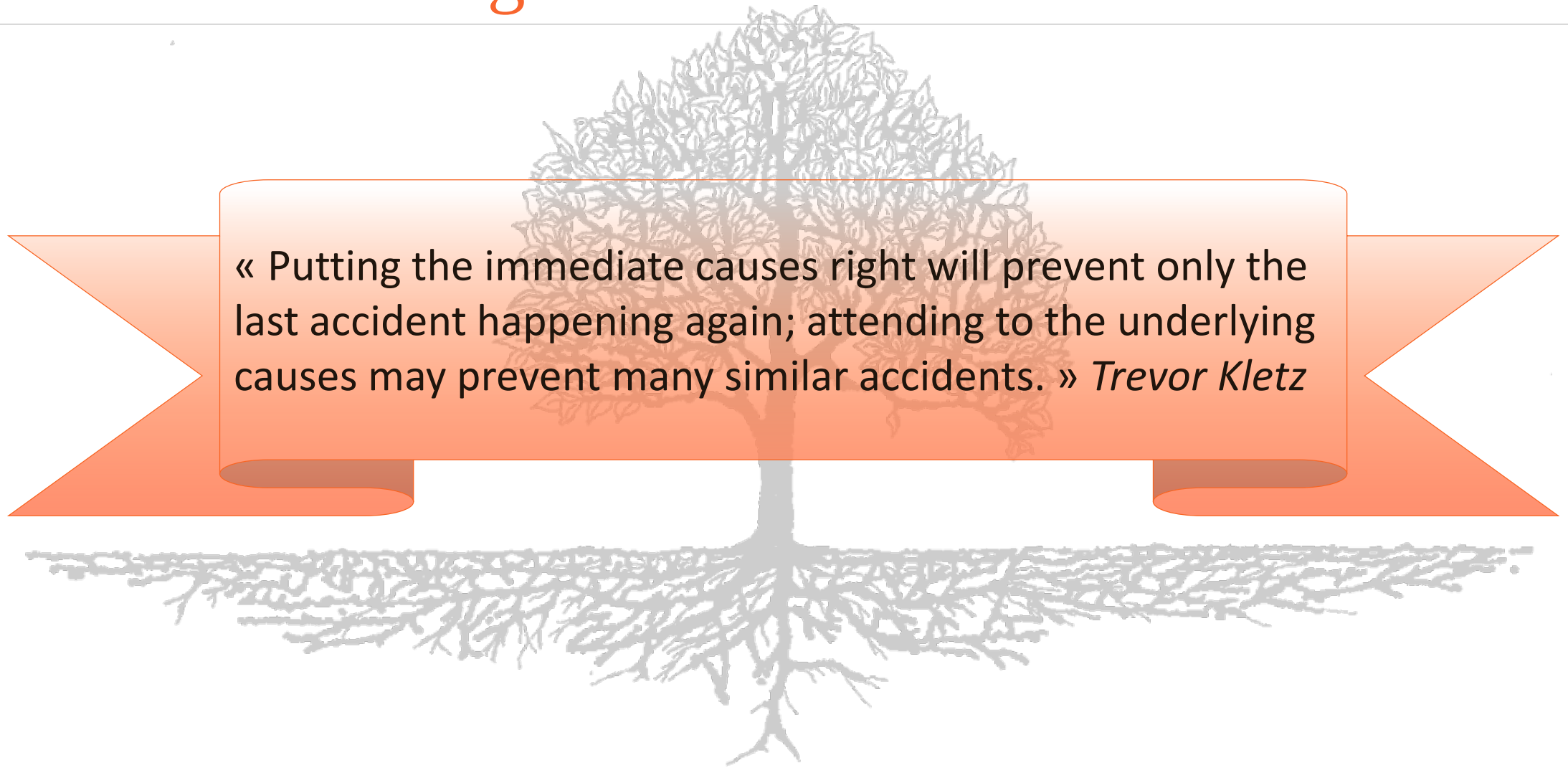
Incident Management

«Accident reporting of contractors is not mandatory as required by PSCI»

«Fire extinguisher is obstructed by the table in the kitchen during tour»

Some findings from the shared reports...

Incident Management



« Putting the immediate causes right will prevent only the last accident happening again; attending to the underlying causes may prevent many similar accidents. » *Trevor Kletz*

Incident Management

Reporting of accidents

- What to look for ?
  - Any kind of records ; could be paper based (cards, reports...) or through an IT-system
- When / how
  - During specific section or if an accident is mentioned then use this opportunity
- What good looks like
  - Check the number of reported events
  - Check the content's quality of a small sample

I was impressed when a voice on the office PA system announced, "This is a test of the PA system to ensure it will function correctly in case of emergency." My confidence faded when the voice added, "If you are unable to hear this announcement, please contact us."

How many ? (for a 500 FTE site)
TRCR of 1.0 = 5 cases per year
Near-Miss : 1 for 2 employees
250 per year = 20 per month

Incident Management

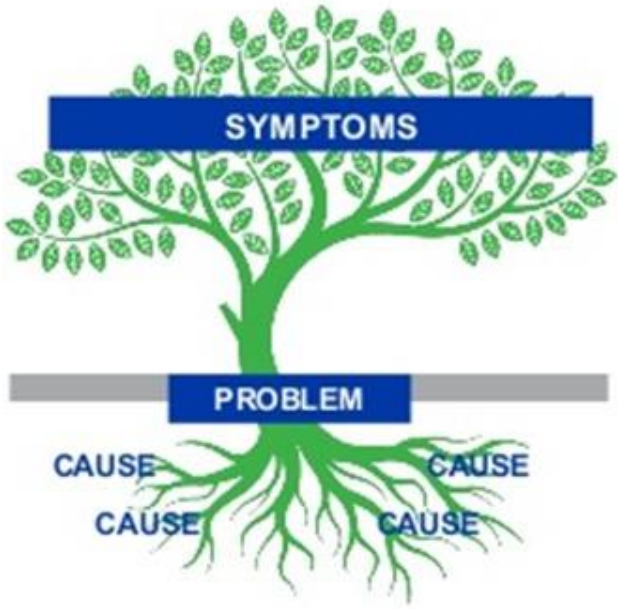
Near Miss

- What to look for ?
  - Same as for accidents : paper records or IT-system
- When / how
  - If a near miss is identified during site tour, use the opportunity
- What good looks like
  - Number (could indicate a good reporting culture), quality of content
  - Who exploits the near miss reports? are they tracked individually? any consolidation? any action plan derived from consolidated near miss?

Incident Management

Root-cause Analysis

- What to look for ?
  - Reports (root-cause analysis itself)
  - Trend analysis – systematic weaknesses ?
- When / how
  - During review of the topic
- What good looks like
  - Fitness of the used methodology
  - Adequate training of the team members
  - Root cause identified (no «human error»)



Incident Management

Action Plan and Follow-up

- What to look for ?
  - Action Plan itself
    paper, electronic document, IT-system
  - Any system to follow-up on actions
- When / how
  - During Incident Management or Risk assessment
  - Closure of actions can be checked during site tour
- What good looks like
  - Has to be effective : should be closed on time or escalated
  - Sufficiently large sample should be considered
  - System to make sure that individual Action Plans are not lost

Action Steps/ Tasks What will be done?	**Responsibility** Who will do it?	**Timeline** When will it begin and when will it be completed?	**Resources** What additional resources do you need?
Reserve two classrooms	**Michelé Robinson**	**Begin: 3/13 Completed: 3/13**	Rooms on campus
Schedule faculty for 'office hours' simulation	**Monica Edwards**	**Begin: 4/13 Completed: 5/13**	None
Schedule Library research visit	**Monica Edwards**	**Begin: 4/13 Completed: 5/13**	None
Schedule Financial Aid presentation	**Kris Hoffhines**	**Begin: 4/13 Completed: 6/13**	Financial aid representative commitment
Notify Success Services of student visits over a 2 week period	**Michelé Robinson**	**Begin: 4/13 Completed: 6/13**	None
Notify Career Center of student visits over a 2 week period	**Michelé Robinson**	**Begin: 4/13 Completed: 6/13**	None
Develop college readiness pre & post assessment	**Monica Edwards & Laura LaBauve**	**Begin: 5/13 Completed: 6/13**	Assessment tool

Machine Safety

«The worker protection for cone type rotary dryers was not effective. When it keeps rotating, operators can open the barrier door and approach it. [...] all the cone type rotary dryers were not equipped with interlock safety system for door barriers [...]»

«During facility tour it was noted that the machine does not have security device in danger zone»

Some findings from
the shared reports...

Machine Safety

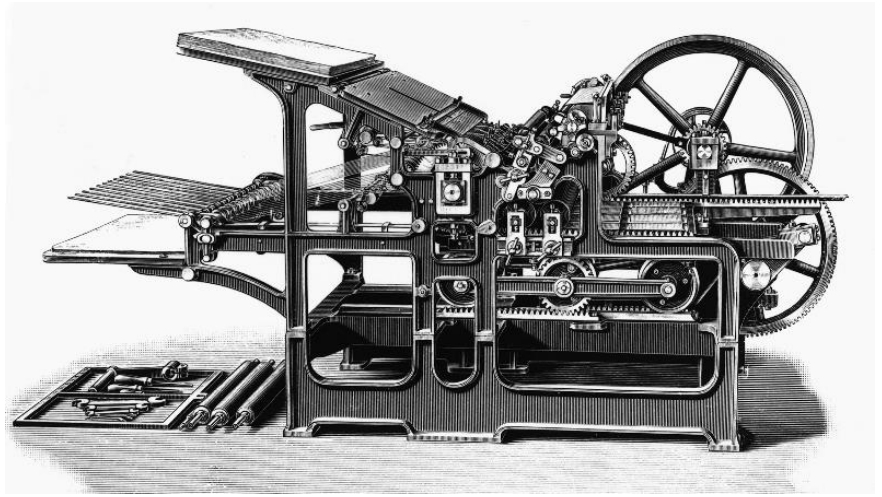
General

- What to look for ?
  - Adequate safety concept in place with regards to machinery-related hazards
- When / how
  - During site tour, check on general conditions/installation of machines.
  - Observe if controls and measures (e.g. necessary machine guarding in place) are in place and being adhered to during operation.
  - Pick one machine for review
- What good looks like
  - Declaration of Conformity available (for China: GB/T 15706).
  - All machines risk-assessed, appropriate risk reduction measures applied, tested prior to first use and maintained
  - Technical documentation available, including operating instructions in local language; machines operated by trained personnel
  - Periodic maintenance and inspections

Machine Safety

Risk Analysis for old equipment

- What to look for ?
  - «Old» machines should have been risked assessed and report should be available
- When / how
  - During site tour or after reviewing a new machine, ask «what about old ones?»
- What good looks like
  - Quality of risk assessment
  - Mitigation of identified risks implemented



Machine Safety

Modification of equipment

- What to look for ?
  - Obviously modified equipment
  - Machines / equipment trains
- When / how
  - Site tour
  - During review of documents related to risk assessment
- What good looks like
  - Quality of risk assessment

Hazard Signage

«The site has not displayed fire exit evacuation route map across the plant.»

«Site has not displayed chemical compatibility chart at warehouse»

Some findings from the shared reports...

Hazard Signage

Uniformity

- What to look for?
  - Any strategy for hazard signage, SOP
  - Example in the production / utilities area
- When / how
  - Ask question during site tour if issues are seen
- What good looks like
  - Same look and feel

Hazard Signage

Quality

- What to look for?
  - Signs in different languages, old, poorly visible
  - New machines might have signage in the language of the manufacturer, not the required local one!
- When / how
  - Ask question during site tour if issues are seen
- What good looks like
  - If associates are speaking different languages, pictures might be better compared to text
  - Signage needs to be visible and of good quality
  - Signage to be provided in local language

Hazard Signage

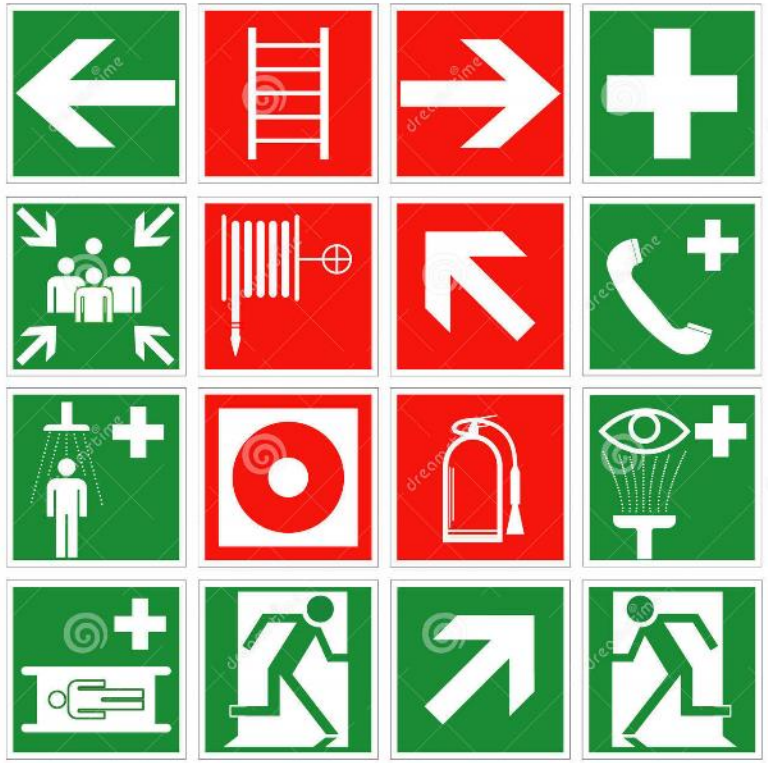
Quantity

- What to look for?
  - Situation during site tour with an excess of hazard signs
- When / how
  - Ask question during site tour if issues are seen
- What good looks like
  - Let to the judgement of the auditor based on experience

Hazard Signage

Emergency signage

- What to look for ?
  - Situation where emergency signage is missing or not appropriate
- When / how
  - During site tour
- What good looks like
  - Compliance with local / national legislation
  - Judgement of the auditor based on experience



Personal Protective Equipment

«Assignment of PPE in the production area is not clear to audit team.»

«Label points out gasmasks and other PPE are mandatory but they are only worn when it is necessary. Also safety glasses were not permanently worn in the production area.»

Some findings from the shared reports...

PPE

According to STOP principle, Personal Protective measures should be the last barrier but it is often used as the first and only one.

PPE

Adequacy of proposed PPE

- What to look for ?
  - Risk assessment defining PPE needs
  - Maintenance of some type of PPE
- When / how
  - During risk assessment review
  - During site tour, when seeing particular PPE in use
- What good looks like
  - PPE are defined based on risk assessment
  - Associate are not overprotected
  - Use of PPE is done correctly

Circulation in/ outside buildings

«One C[...] owned truck at a loading bay was observed not to be secured by safety wedges while being loaded by a fork lift truck [...]»

«It was observed that material was stored all around in the packaging room. There was no reflective strip pasted on the floors to maintain the walkway width»

Some findings from the shared reports...

Circulation in/outside of buildings

Segregation between walkers and traffic

- What to look for ?
  - Crowded areas with a lot of goods movements (not only in warehouses)
- When / how
  - During site tour
- What good looks like
  - Dedicated pathway
  - Markings on the grounds
  - Traffic lights...

Circulation in/outside of buildings

Forklift operations

- What to look for ?
  - Goods movements inside and outside of building
- When / how
  - Concept, SOP can be reviewed during desktop assessment
  - During site tour, good opportunity to observe behaviors
- What good looks like
  - Legal requirements vary but drivers should normally be officially trained

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+55 (11) 94486 6315

PSCI

@PSCInitiative

For more information about the PSCI please contact:

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

info@pscinitiative.org

+55 (11) 94486 6315

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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partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Chemical Process Safety: Which parameters are important to perform a chemical reaction in a safe way?

(Presentation by Dr Stefan Gries, Boehringer Ingelheim Corporate Center)

Speaker : Liu Li (刘立)
EHS&S China, Boehringer Ingelheim

AGENDA 大纲

1. **Session 1**

- **Process safety parameters**
- **Essential information to chemical processes**
- **Critical interactions of material**
- **Exothermic and run-away reaction**
- **Scale up**

2. **Session 2**

- **Runaway reaction**
- **PSCI Questionnaire & Typical Observations**

3. **Audience questions & discussions**

SPEAKER BIO

Mr. Liu Li

- Chemist
- 13 years in Pharam Industry
- 8 years with Boehringer Ingelheim China
- Current position: EHS & S Manager

- Former positions in
  - Medicinal Chemsitry
  - Chemcial Process Research and Development
  - EHS&S

SPEAKER BIO

Dr. Stefan Gries

- Chemist
- More than 25 years with Boehringer Ingelheim
- Current position: Corp. EHS & S
  (occupational health, exposure control, soil and groundwater protection, EHS auditor)
- Former positions in
  - Local EHS (Safety Engineer)
  - Research & Development (Head of pilot plant)
  - Chemical Production (Head of production plant)

TRAINING STRUCTURE

1. **Session 1**
- **Process safety parameters**
- **Essential information to chemical processes**
- **Critical interactions of material**
- **Exothermic and run-away reaction**
- **Scale up**

2. **Session 2**
- **Runaway reaction**
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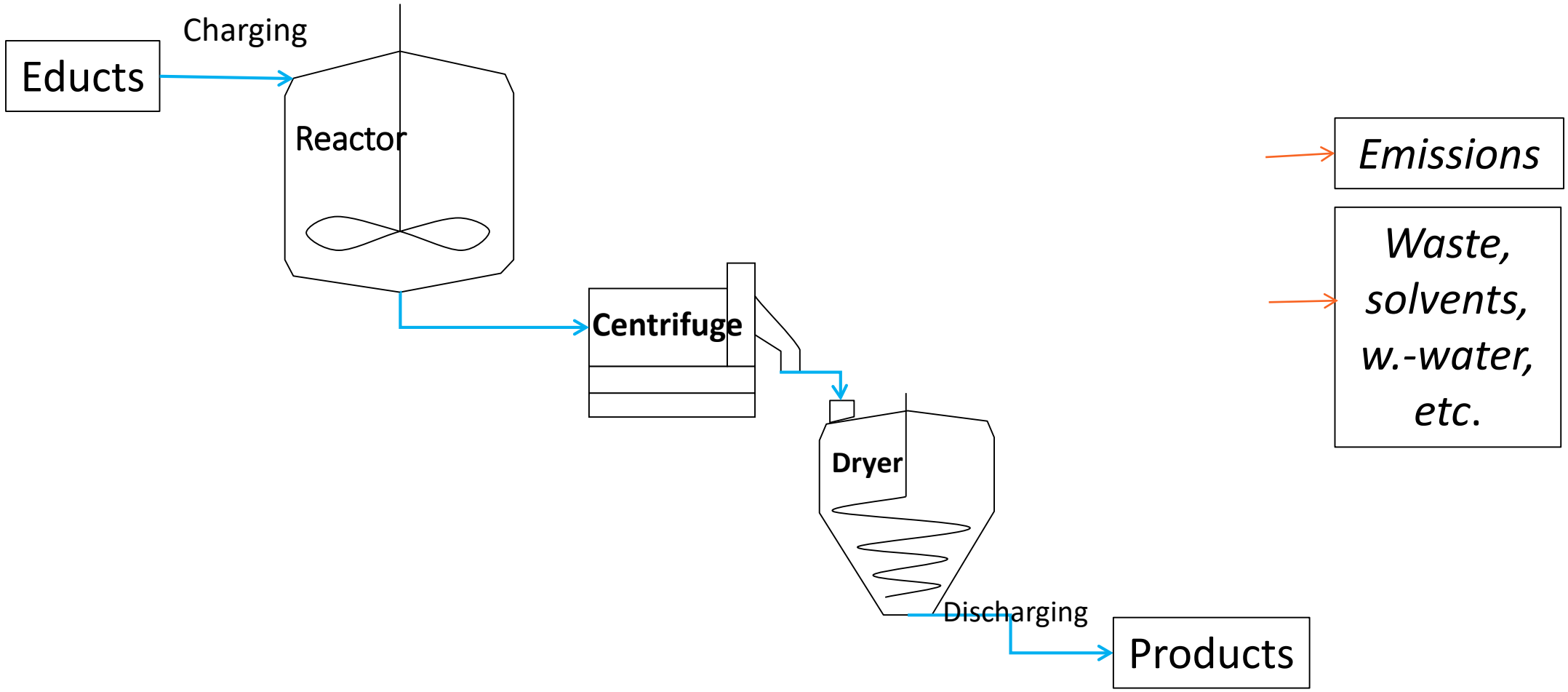
Chemical reaction in a production plant



Which information is necessary for a safe process?

- Knowledge about the used chemicals regarding thermal stability, physical safety parameters and toxicology
  - Educts
  - Products (incl. side products)
  - Reagents
  - Solvents & Auxiliaries
- Knowledge about the chemistry
  - Main reaction and side reactions
  - Waste streams (gas release, liquids and solids)
  - Consecutive reaction, decomposition?
- Reaction type
  - Batch reaction
  - Semi-batch reaction
  - Continuous flow reaction

What is necessary for a safe process?

- Calorimetric data of the chemical reaction
  - Adiabatic temperature rise
  - Gas evolution rate (→ reactor venting sufficiant?)
  - precipitation of solids (→ reduction of heat transfer, stirrer blocking?)
  - Accumulation of reactants, thermal output/time
  - Stability of reaction mixtures, distillation residues, etc.
  - Potential for runaway reaction, abnormal operating conditions
  - If necessary: investigation of the runaway reaction

- Knowledge about critical interaction between the used chemicals and other material
  - Material resistance of reactor & other equipment
  - Possible material contact (e.g. media supply)

What is necessary for a safe process?

- Plant equipment “state of the art”
  - Materials of the equipment = > material tests, corrosive data, etc.
  - Inertisation of equipment
  - Earthing of the equipment, explosion-proof equipment
  - Blow-down system, pressure relief valve, rupture disc,
  - Heating and cooling medium & capacity
  - Safety concept e. g. for electrical shut down

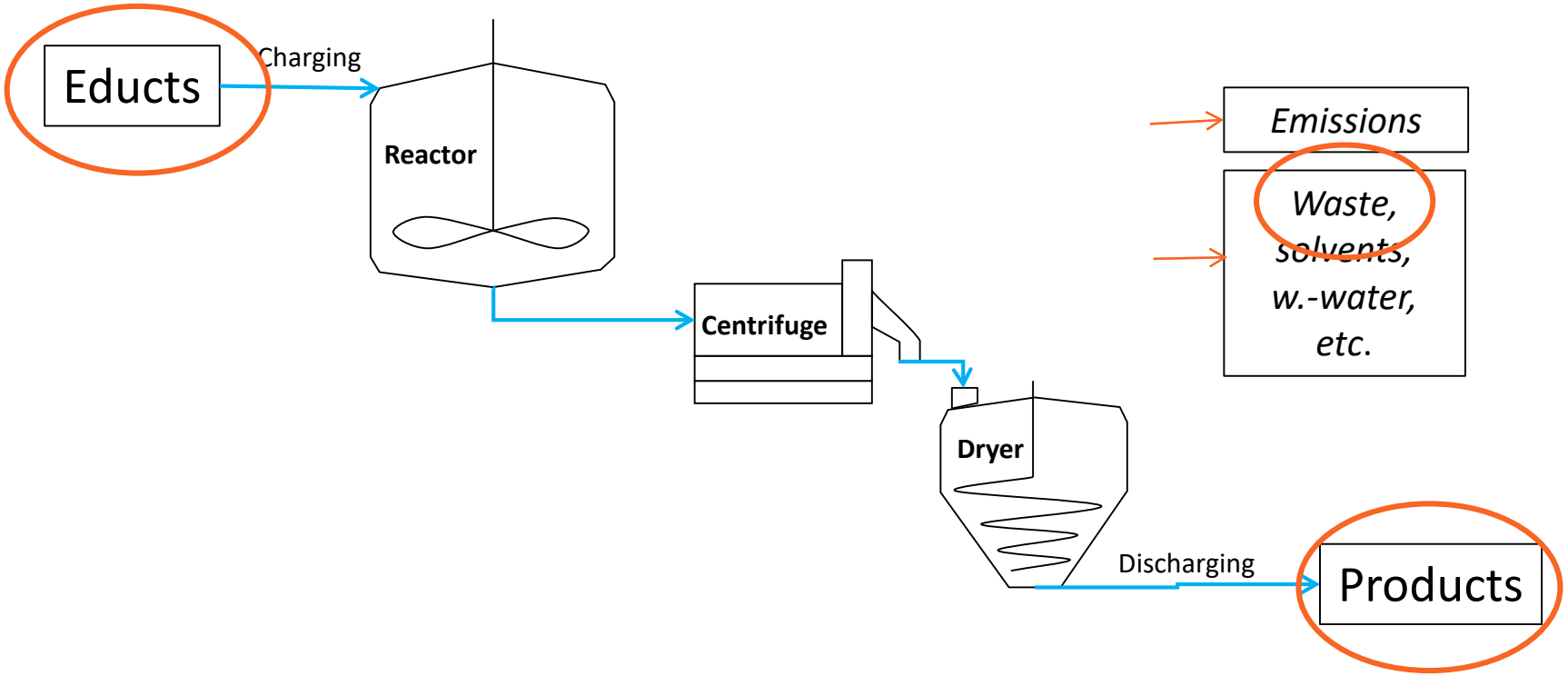
→ Process Hazard Analysis

Examination of the chemical properties and chemical process safety data together with the technical installation of the plant.

A safe chemical process is always an adequate combination of safe substance handling, known chemical process and adapted equipment.

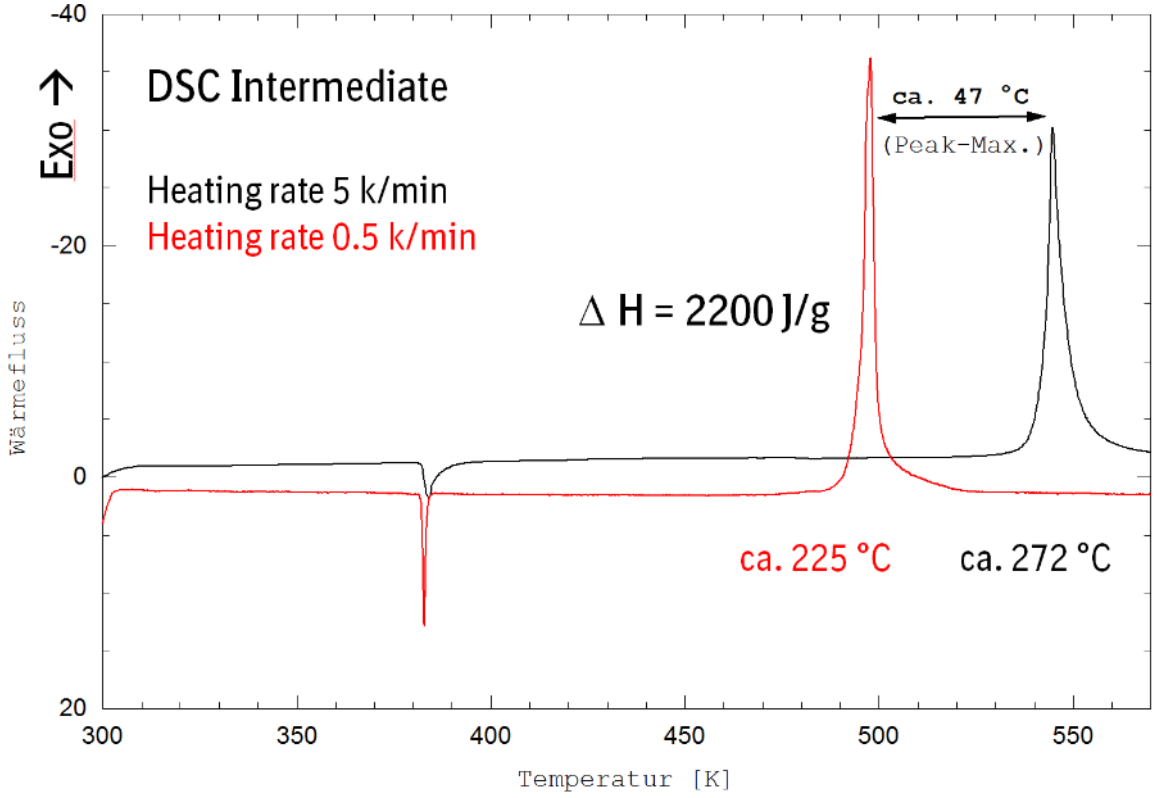
What is necessary for a safe process?

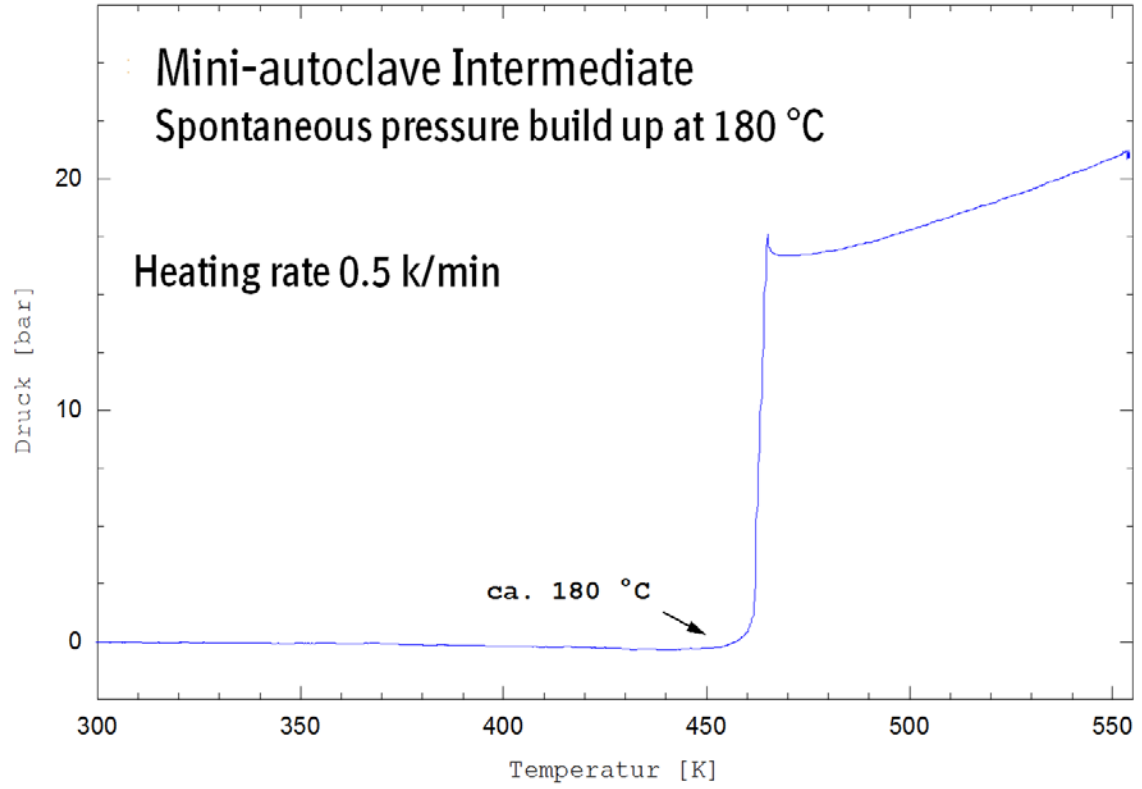
Thermal stability of chemical substances and reaction mixtures



Thermal stability of chemical substances and reaction mixtures

- Thermal stability:
  - Differential Scanning Calorimetry (DSC) or Differential Thermo Analyses (DTA)
- Decomposition test closed vessel (pressure build-up):
  - e.g. in a mini-autoclave





Known hazardous substances

- Typical chemical functions in thermodynamically unstable compounds:

-C≡C-	acetylene and acetylide
$-N_3$	azide and hydrogen azide
$-N{\equiv}N^+$	diazonium salts, triazene, tetrazene
-N=N-	azo compounds
-HN-NH-	hydrazide
>C=N=O	fulminates, oximates
>N-X	halogene nitrogene compounds
$-NO_x$	nitrites, nitrates, nitro- and nitroso compounds
-O-O-	peroxides, peroxy acids, ozonids
$-O-ClO_x$	(per-)chlorate, (hypo-)chlorite

Known highly reactive substances

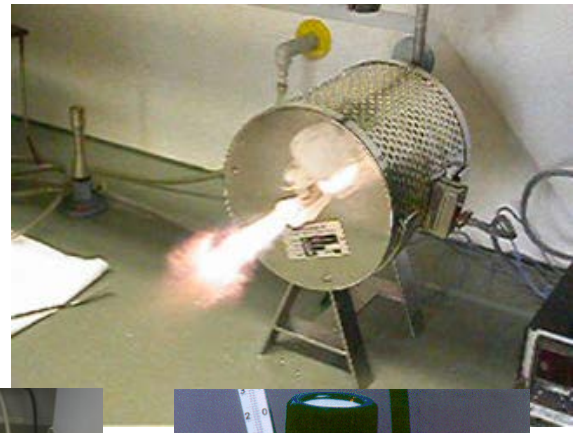
- Typical compounds or chemical functions:

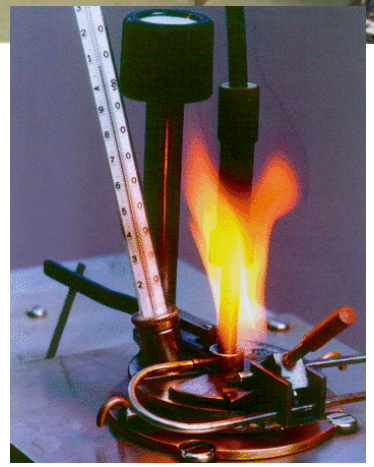
R-Mg-X	Grignard reagents
R-Li	organic lithium compounds
-COCl	acid cloride
-CO-O-OC-	acid anhydride
Na-, K-OR	Sodium-, Potassium alkoholate
$POCl_3$, $SOCL_2$	inorganic anhydride
„H_2SO_4“	conc. acids, lyes
NaH, $LiAlH_4$	hydride
Na, K, Mg, Li …	metals
O_2, H_2	gases
F_2, Cl_2, Br_2	halogen

General handling characteristic of substances

- Additional test for thermal stability
  - Thermogravimetry (TG) or combination TG/DSC; TG/DTA
  - Quasi-adiabatic heat aging in a Dewar flask (or an adiabatic calorimeter)
  - Time Pressure Test

- Flammability of solids or liquids
  - Combustion test
  - Flammability of solids
  - Smoldering temperature; minimum ignition temperature of a dust layer
  - (minimum) dust cloud ignition temperature
  - Ignition temperature of liquids
  - Flash point (of liquids)





General handling characteristic of substances

- Dust explosibility:
  - Dust explosion test
  - Dust explosion characteristics (p_{max}; $(dp/dt)_{max}$; K_{St}; explosion limits
  - Minimum ignition energy (MIE)

- Mechanical sensitivity, further safety characteristics
  - Sensitivity to impact
  - Sensitivity to friction
  - Self-ignition test
  - Conductivity

Details to: Dust stability/explosibility

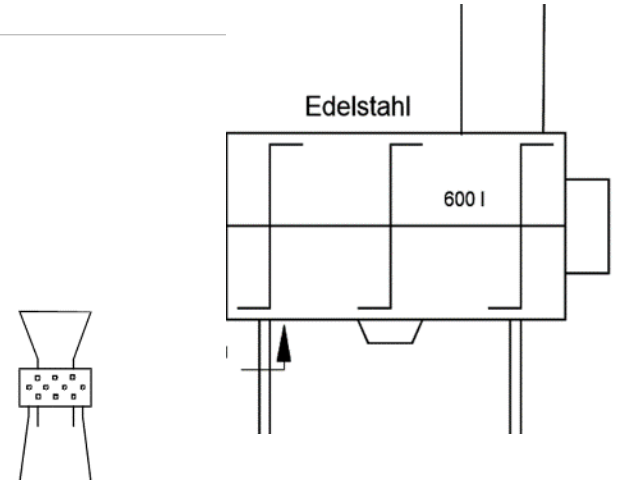
- Mechanical sensitivity: Sensitivity to impact / friction

➢ Important for mechanical actions
(e.g. transport systems, in dryer with agitator, in a pin mill,)
→ maximum temperature & agitation time

- Maximum explosions pressure p_{max}

For most of the organic gases and vapors in mixture with air p_{max} is between 8 bar to 10 bar under initial atmospheric conditions.

➢ Important for e.g. venting pipes/filter units, for mills, dryers („dust containing air“)
→ explosion-resistant design



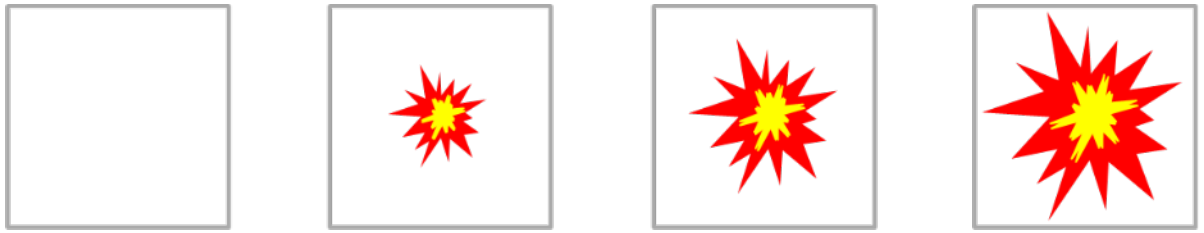
Details to: Flammability of solids or liquids

- Ignition temperature

Auto-ignition temperature (according to EN 14 522)	Temperature class	Maximum surface temperature
> 450 °C	T 1	450 °C
> 300 °C to 450 °C	T 2	300 °C
> 200 °C to 300 °C	T 3	200 °C
> 135 °C to 200 °C	T 4	135 °C
> 100 °C to 135 °C	T 5	100 °C
> 85 °C to 100 °C	T 6	85 °C

Details to: Dust explosibility

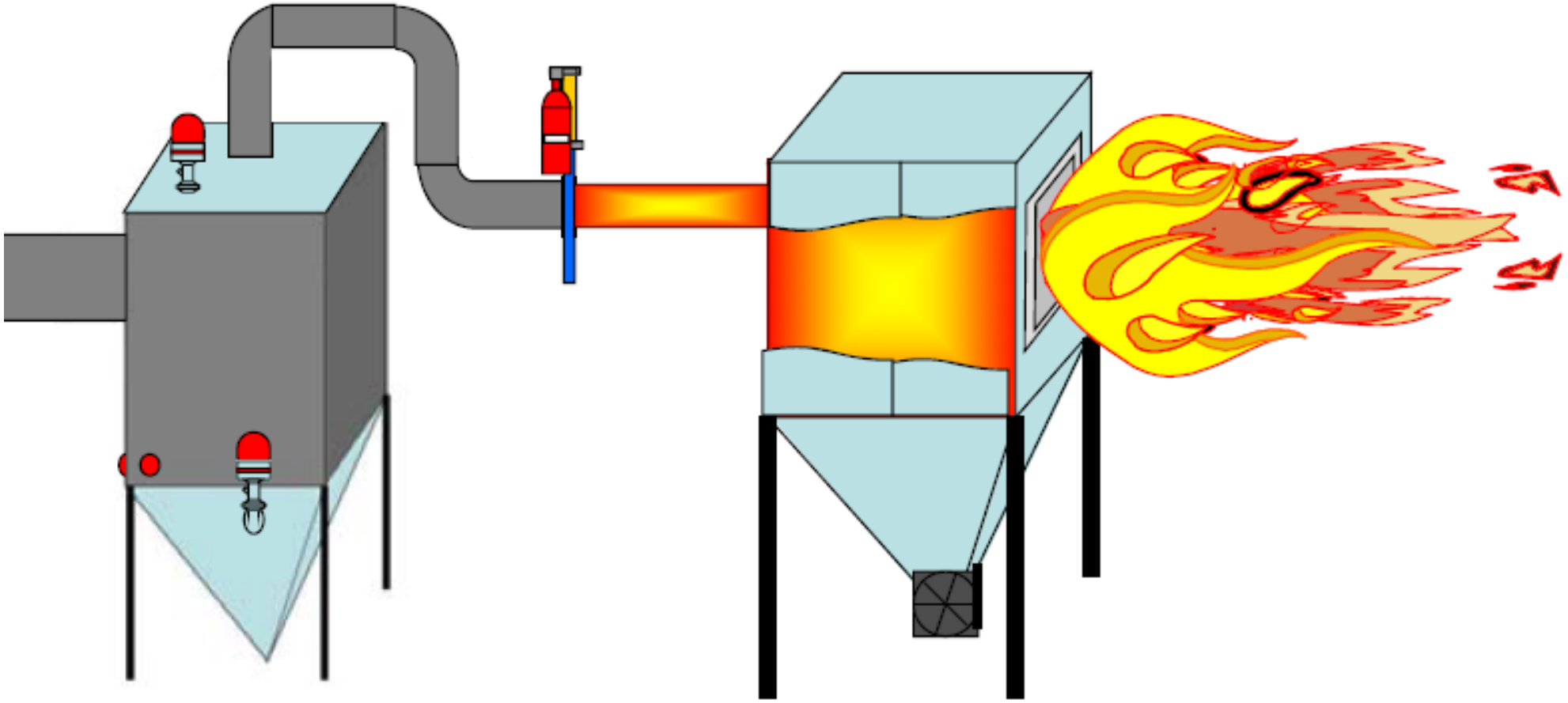
- Maximum explosion pressure rise $(dp/dt)_{max}$ and K_{St}



Dust explosion group	St 0	St 1	St 2	St 3
Kst bar.m.s^{-1}	0	> 0 ≤ 200	> 200 ≤ 300	> 300
Explosion characteristics	no explosion	weak/ moderate	strong	very strong

➢ Important for design of “explosion relief“, “explosion suppression” system

Examples of Process Equipment

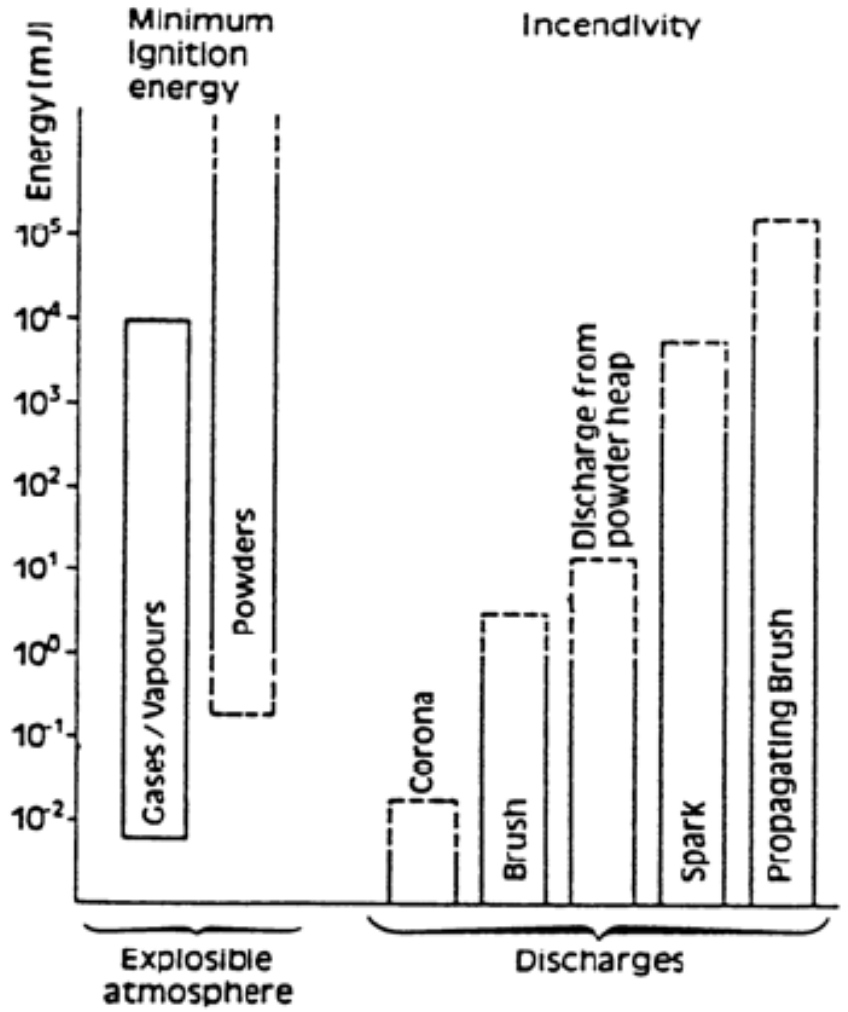


- If the K_{st} is above 300 bar m/s, the valve would not work

Details to: Dust explosibility

- Minimum ignition energy (MIE)

Risk	Substance Name	MIE in air
High risk < 25 mJ	Hydrogen	0.01mJ
	Methanol	0.14 mJ
	n-HeptanE	0.24 mJ
	Acetone	1.15 mJ
	“Normal organic" dust	>10 mJ
	Paracetamol	<10 mJ
Medium risk 25 – 100 mJ	Wheat flour	~50 mJ
	Sugar powder	30-100 mJ
	Coal	30-100 mJ
Low risk >100 mJ	PVC	1500 mJ



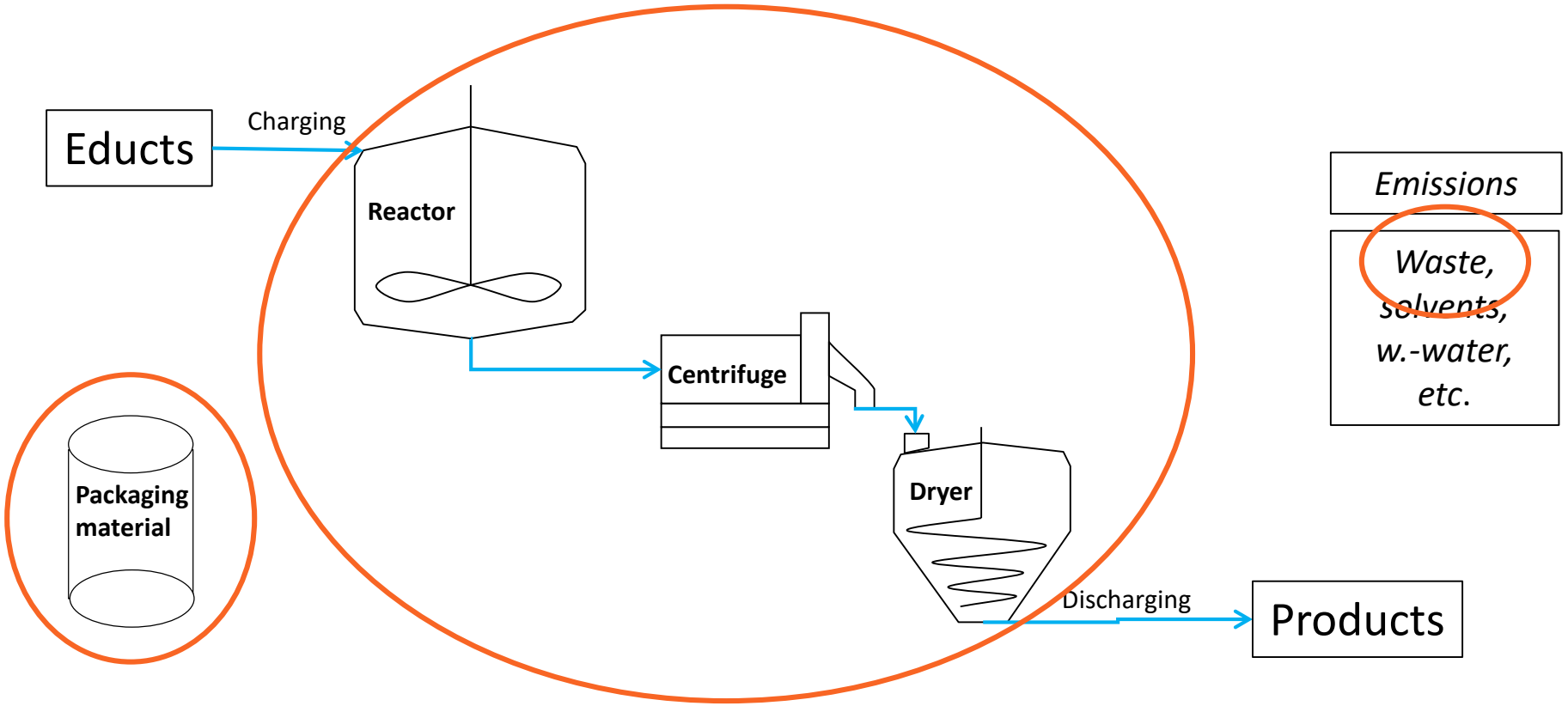
Resulting technical requirements of equipment

Temperatur Class						
Explosion Group	T1 (> 450°C)	T2 (> 300°C)	T3 (> 200°C)	T4 (> 145°C)	T5 (> 100°C)	T6 (> 85°C)
IIA	Acetone Acetic acid Methane Propane Ammonia Benzene Toluene	Fuel Methanol Butan	Hexane Diesel Fuel oil	Acetal-dehyde		
IIB	Hydrogen cyanide	Ethanol Ethane	Hydrogen sulfide			
IIC	Hydrogen					Carbon disulfide

MIE

What is necessary for a safe process?

Critical interaction between the used chemicals and between chemicals and materials



Critical interaction between chemicals and materials

- Incident in a chemical production plant
- Due to an operational error a mixture of thionyl chloride, ethyl acetate and acetyl chloride have to be disposed of. For disposal the worker used the empty thionyl chloride drum. Short time later the drum exploded.

- Result of safety examination in laboratory
- No critical reaction between thionyl chloride, ethyl acetate and acetyl chloride.

- But, the used drum was zinc-coated
  ➔ critical reaction under pressure build-up between ethyl acetate, thionyl chloride and zinc !

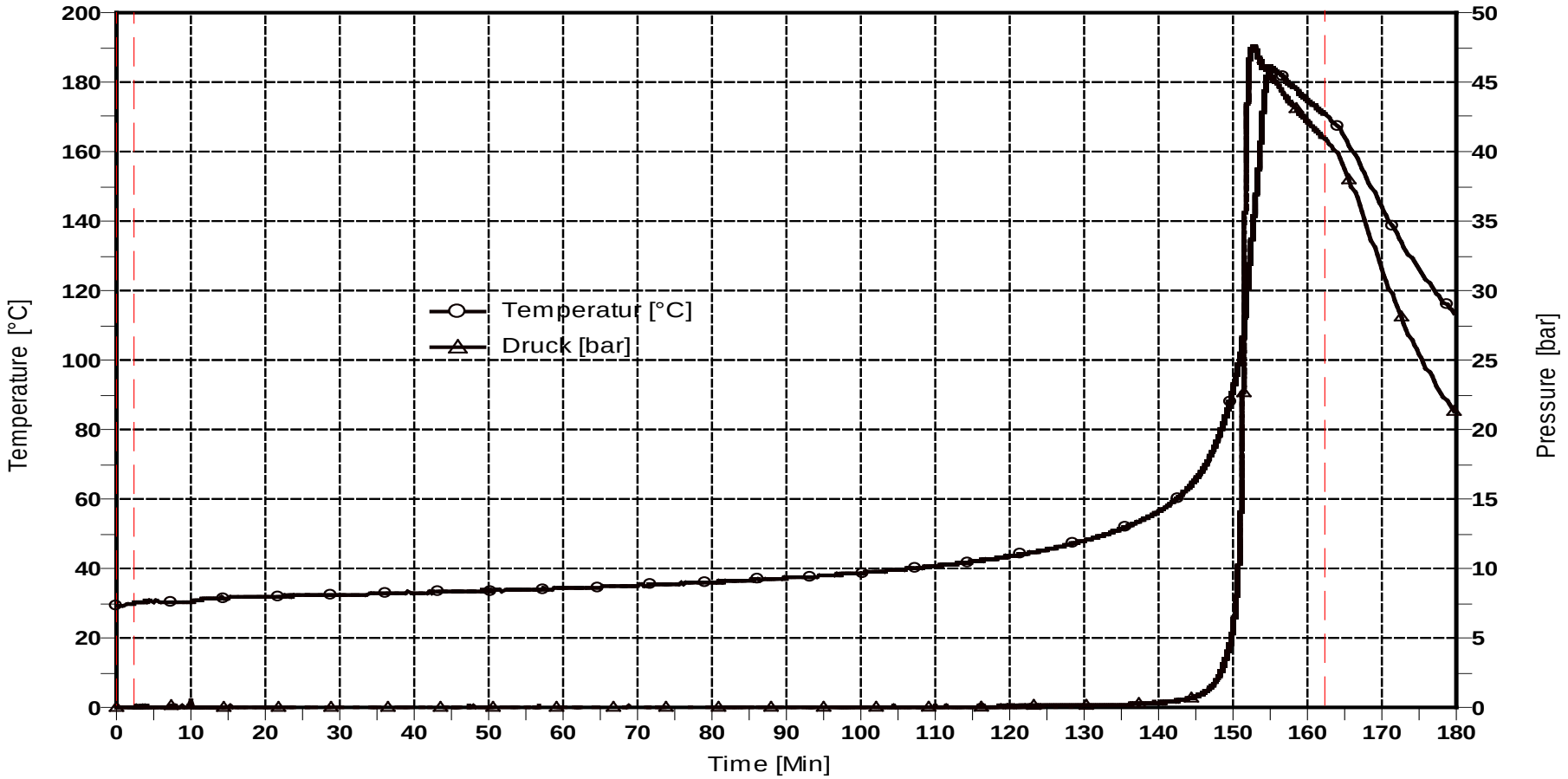
Critical interaction between chemicals and materials

- Incident in a chemical production plant B:
- In a process the excess of $POCl_3$ is distilled off and purged into a 200 l steel drum with a PE-inliner. Approx. 10 h later the drum burst.
- Between the batches the pipes were washed with acetone. Residual quantities of acetone remained in the pipes.

- Result of safety examination in laboratory:
- Retarded critical reaction between acetone and $POCl_3$.

Critical interaction between chemicals and materials

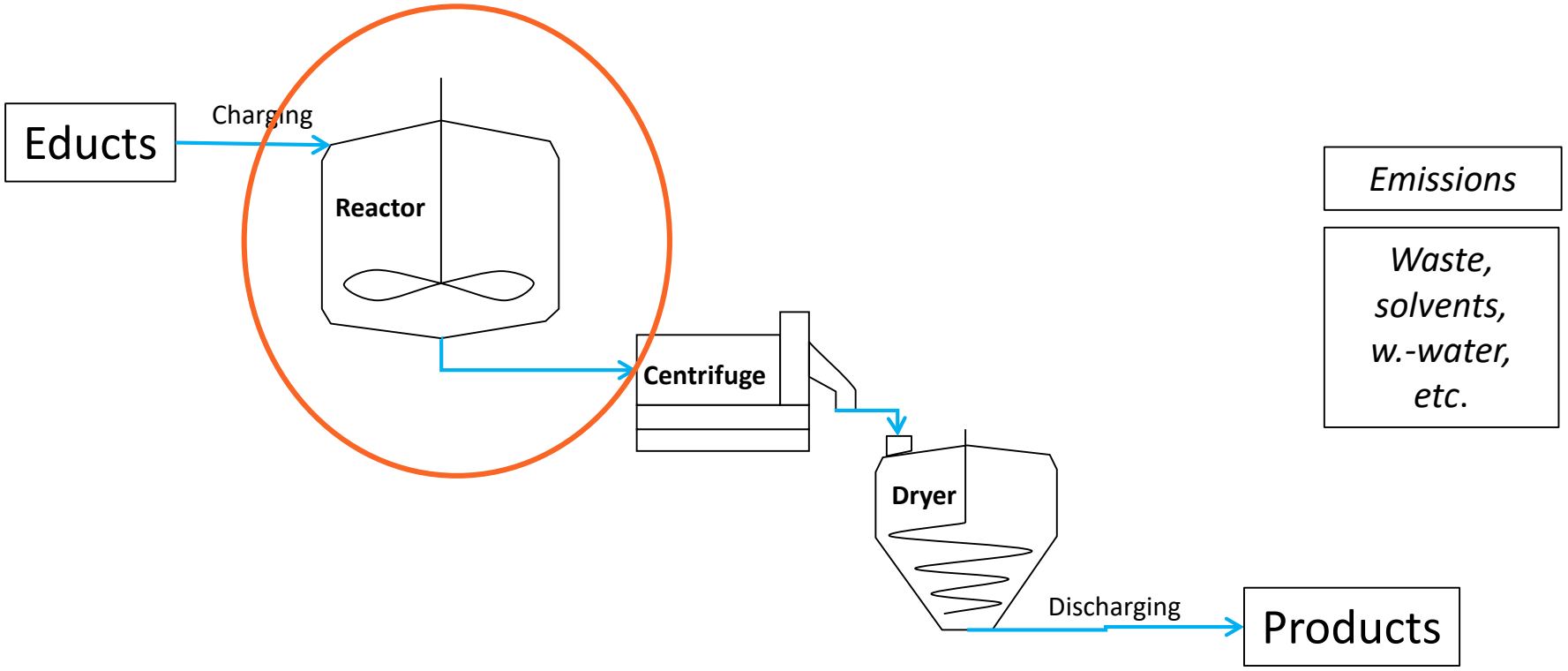
- Reaction experiment
- closed cell test, $POCl_3$ overlay with ca. 5.8 weight-% acetone



What is necessary for a safe process?

Chemistry – chemical reaction

Calorimetric measurements for chemical reactions



Chemistry – chemical reaction

- The chemical reaction should be known, including side reactions and consecutive reaction. The chemical reaction can depend on the reaction temperature or the working procedure.
- Mass balance of the whole reaction is very useful
- Side products can have a big influence on process safety
- Are decomposition reactions known?
- Waste streams can contain highly reactive compounds or unstable substances (e. g. slow gas generation leading to a pressure build up in waste containers)

Working procedure for chemical reaction

- Batch reaction:

All reagents are charged to the reactor.
Then the content is heated to the reaction temperature.

- The accumulation of reaction partners is at the beginning 100 %.
- For an exothermic reaction, if the cooling capacity is not sufficient, an uncontrolled temperature rise occurs and a run away reaction is possible.
- Batch reactions should only be applied with endothermic or very slow reaction with smooth exothermic behavior.

What is in general the best temperature for running a exothermic batch reaction?

The lowest possible reaction temperature is in general the safest temperature!

Working procedure for chemical reaction

- Semi-batch reaction

One reaction compound (including solvent) is charged to the reactor.
The other compound is added over a defined time at the reaction temperature.

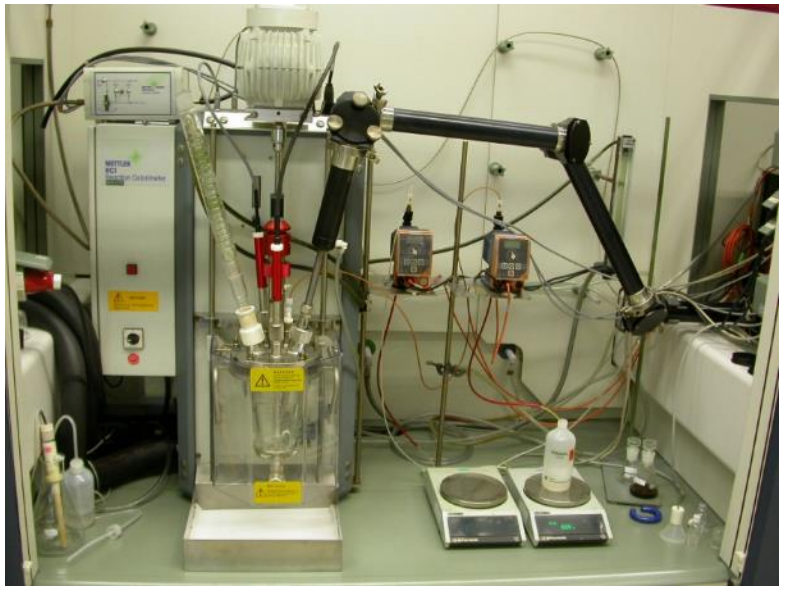
- The accumulation of reaction partners is at the beginning 0 %.
  Across the whole addition time the accumulation should be small.
- Always add the reactive compound.
  (Adding a catalyst or a compound in a huge excess is not a semi-batch process!)
- A stop of the addition stops further heat generation (if low accumulation).

What is in general the best temperature for running a exothermic semi-batch reaction?

The highest possible temperature is the best! -> fast reaction -> less accumulation

Chemical reaction parameters, calorimetric measurements

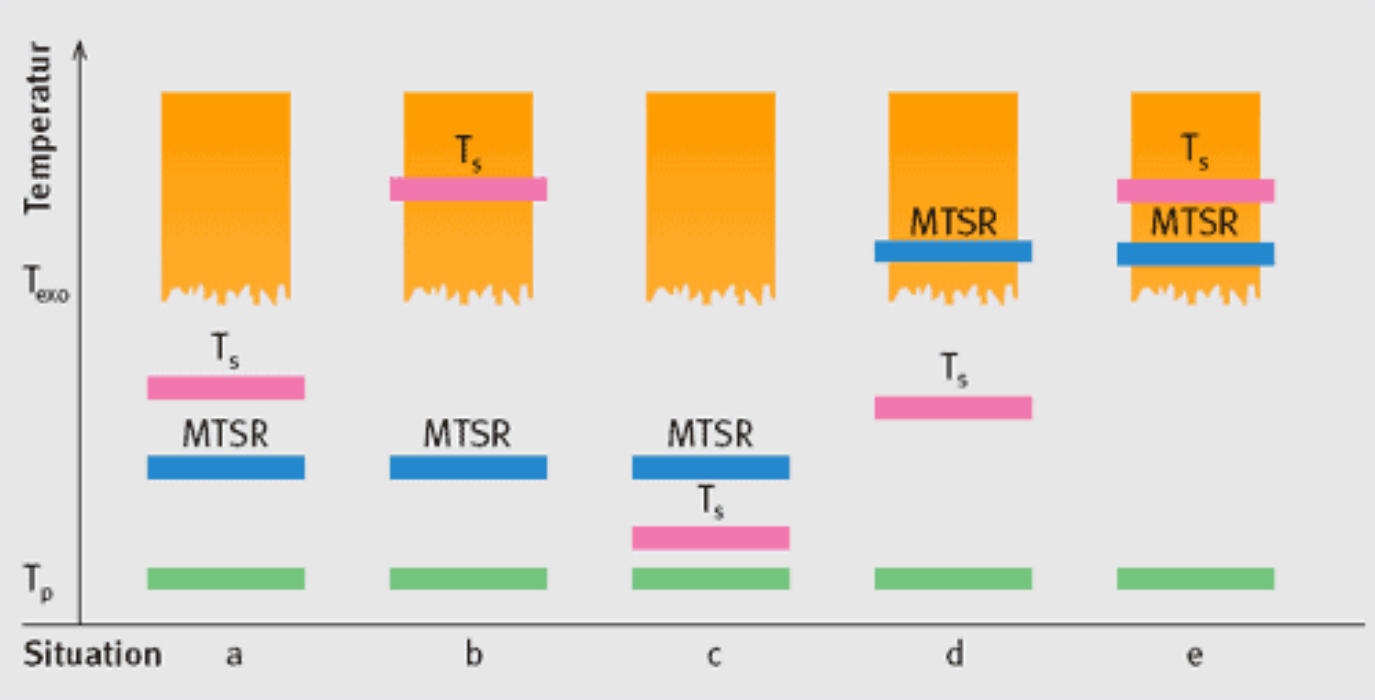
- Safety investigation of reaction under process like conditions:
- Reaction calorimeter (e.g. Mettler RC1) with dosing, gas measurement etc.



- Determination of:
- Heat of reaction ΔH_R [J/g] or [J/mol]
- Heat capacity c_p [J/g K]
- Adiabatic temperature rise ΔT_{ad} [K] or [°C]
- Degree of accumulation [%]
- Gas release [l/min]

- Adiabatic investigation of abnormal operating conditions:
- Determination of thermal stability under adiabatic conditions (no heat exchange, like DTA)

Thermal hazard potential of chemical reactions



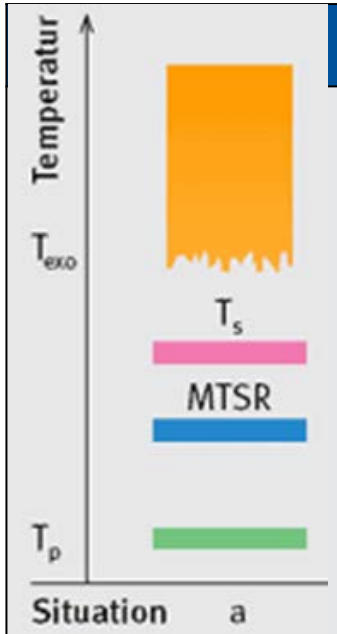
T_p : process temperature at the start of the deviation

MTSR: maximum temperature of the synthesis reaction; $MTSR = T_p + \Delta T_{ad} \cdot \alpha_{accu}$

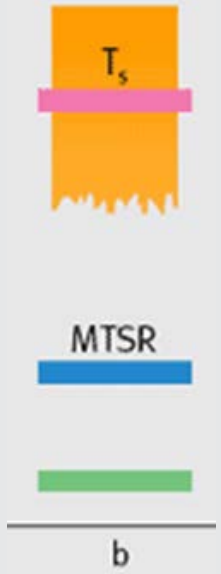
T_{exo}: the maximum temperature at which a substance or reaction mixture can just be handled safely

T_s: (=T_b) the boiling point in an open system

Thermal hazard potential of chemical reactions

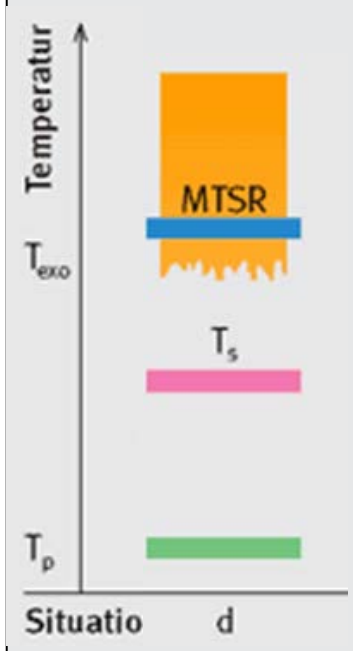


Description - criticality
The boiling point of the mixture and the maximum reaction temperature stay below T_{exo}. Such processes may be regarded as inherently safe with respect to the process deviation evaluated.

Case	Description - criticality
	Absence of the boiling point barrier, but maximum reaction temperature below T_{exo}. The process may be regarded as safe.

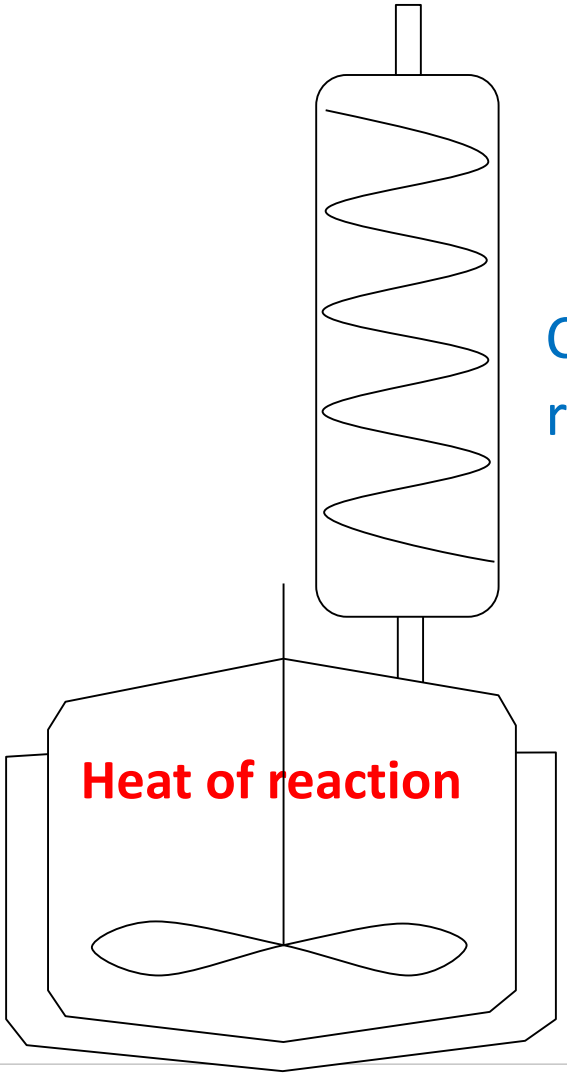
Case	Description - criticality
	The boiling point with its latent heat of evaporation may be considered as a safety barrier (adquate condenser!) In a closed system, the reactor must be designed for the maximum expected overpressure or be equipped with a pressure relief device. It would be better to reduce the accumulation so that the boiling point could not be reached.

Thermal hazard potential of chemical reactions

Case	Description - criticality
	It must be evaluated if the evaporation capacity provides sufficient safety. If not, additional organizational or technical measures have to be implemented. If the operation is performed in a closed system, the temperature corresponding to the relief valve's set pressure may not be too high.

Case	Description - criticality
	This case must be rated as problematic. In case of a (simple) cooling failure, the reaction can pass over the safe temperature range. Plant and/or process modifications should be evaluated in such situations.

Temperature control of chemical reaction



Cooling by
reflux condension

Cooling jacket

Heat balance of exothermic reactions

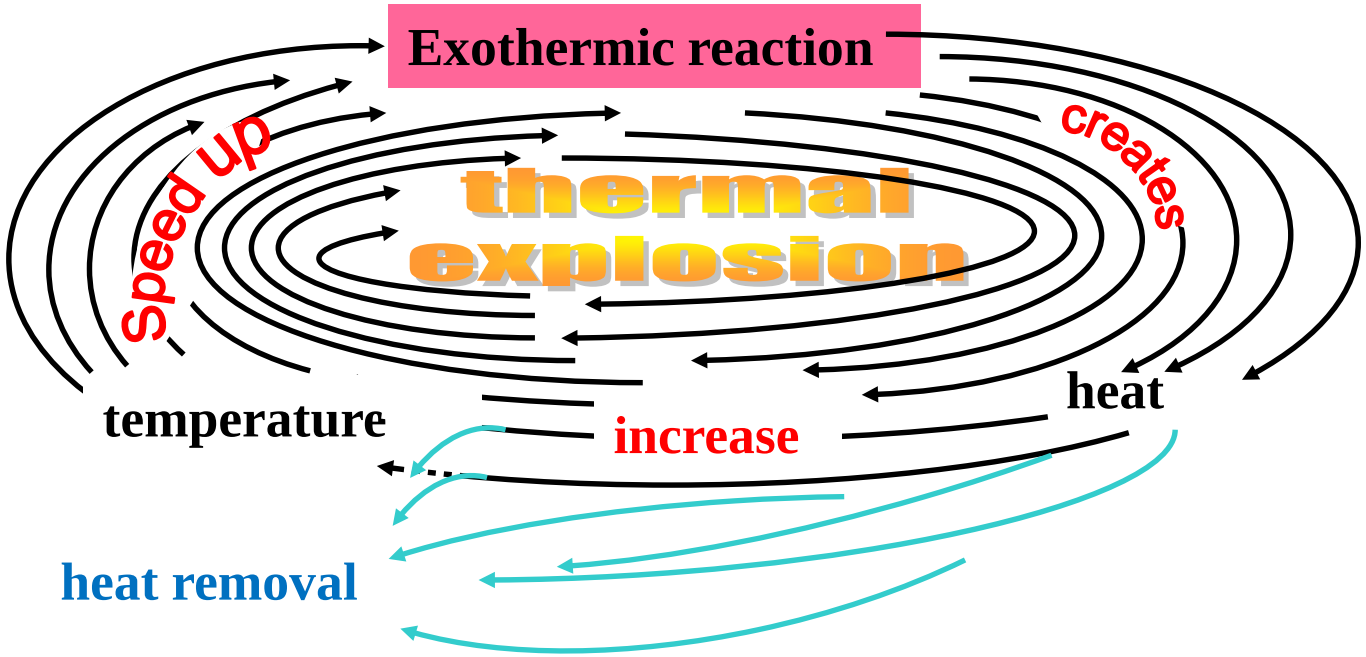
heat production

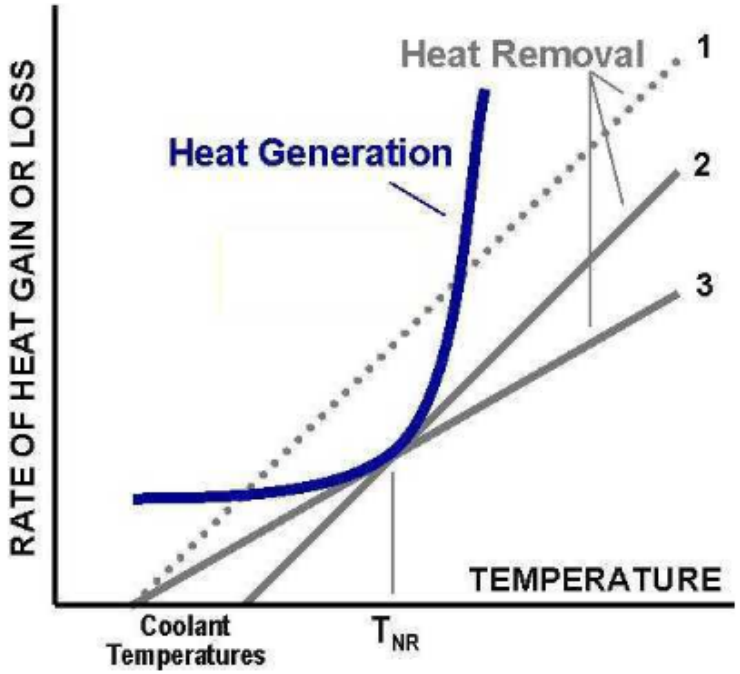
heat removal

Increased heat production	Decreased heat removal
• Additional energy supply (e.g. heating, stirring, pumping) • Higher concentration of reactants (e. g. missing solvent) • Presence of a catalyst (e.g. rust, nonferrous metals) • Initiation of other exothermic processes (e.g. side reaction, decomposition)	• Loss of cooling (e.g. pump failure, solvent evaporated) • Degrade heat transfer (e.g. fouling, adhesion) • Increase of viscosity (e.g. higher degree of polymerization) • Inadequate mixing (e.g. pump failure, solvent evaporated, stirrer failure)

Exothermic and run-away reaction

- An exothermic reaction produces heat which leads to an increase of the reaction temperature if the cooling capacity is not sufficient.
- A runaway reaction is an exothermic chemical process, which leads to uncontrollable reaction conditions due to an uncontrolled rise of the reaction speed.

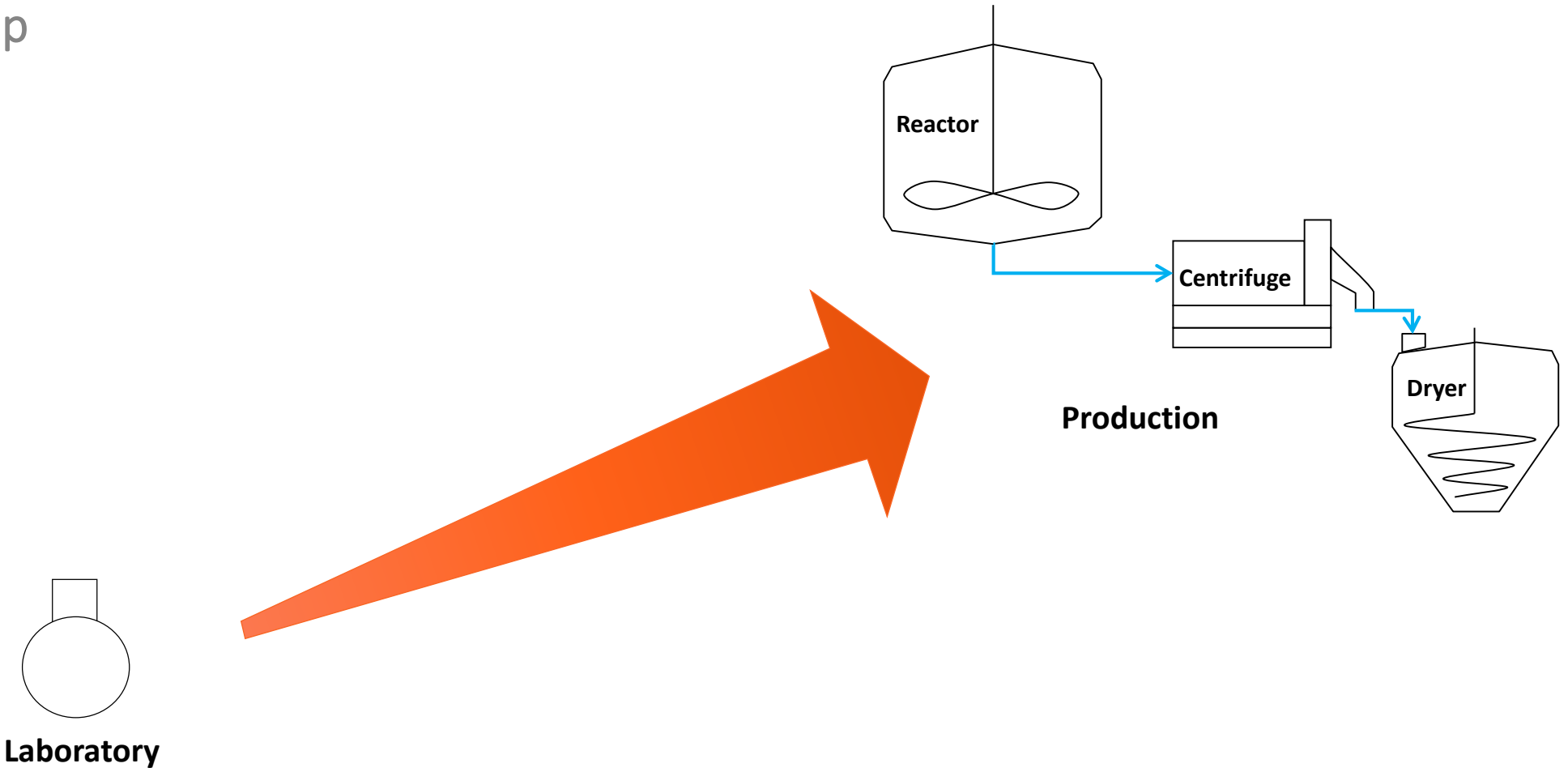




Exothermic reaction and run-away reaction

What is necessary for a safe process?

Scale up



Scale up laboratory → (pilot) plant

- Example of a heat balance change during the scale up

- From laboratory (1 l) to pilot plant (1 m^3).
- Dosing controlled reaction
- Exothermic reaction
- Reaction heat of 360 kJ kg^{-1} (= 0,1 kWh kg^{-1})
- Density of reaction mass is 1 g cm^{-3}
- Reaction temperature 80 °C
- Filling degree is 100 %
- Heat transmission of both apparatus are 500 W m^{-2} K^{-1}
- Effective temperature difference for cooling is 30 K

Scale up – laboratory – (pilot) plant

	Laboratory	Pilot or production plant
Reactor size	1 l	1 m^3
Cooling surface	0,046 m^2	4,4 m^2
Specific cooling power	15 kW m^{-2} (= 500 W m^{-2} K^{-1} * 30 K)	
Cooling power	**0,69 kW** (= 15 kW m^{-2} * 0,046 m^2)	**66 kW** (= 15 kW m^{-2} * 4,4 m^2)
Reaction power with 3 h dosing time	0,03 kW (= 0,1 kWh kg^{-1} * 1 kg /3h) *heating required*	33 kW (= 0,1 kWh kg^{-1} * 1000 kg /3h) cooling sufficient
Reaction power with 2 h dosing time	0,05 kW (= 0,1 kWh kg^{-1} * 1 kg /2h) *no cooling required*	50 kW (= 0,1 kWh kg^{-1} * 1000 kg /2h) cooling sufficient
Reaction power with 1 h dosing time	0,1 kW (= 0,1 kWh kg^{-1} * 1 kg /2h) cooling sufficient	**100 kW** (= 0,1 kWh kg^{-1} * 1000 kg /1h) **cooling insufficient**

Factor 1000

Factor ~100

Factor ~100

Expectation of an EHS auditor

R&D → scale up → production

Amounts of substances	Location	Working documents	Guidance documents
miligrams to grams	Research & Development Laboratory	- Lab documentation - First observations to process safety	- Policy „Safe Research & Development“ - Lab safety SOPs
grams to kilograms	Transfer from tab to kilolab / pilot plant	- Basic safety report - Transfer report	- Regulation to „Basic safety examinations“ - Transfer protokoll
kilograms	kilolab / pilot plant	- Batch records - Safety assessments - Process safety examinations	- Guidelines for safety examinations - SOPs to substance handling etc.

Expectation of an EHS auditor

R&D → scale up → production

Amounts of substances	Location	Working documents	Guidance documents
kilograms to tons	Transfer from pilot plant to production	- Transfer report - Risk assessment - Technical measures	- Transfer protokoll - SOP „Risk assessement/ HAZOP“
kilograms to tons	Production plant	- Batch records - Change Control documents - Maintenance of technical installation	- SOP „ CC“ - SOPs „Maintanance“
kilograms to tons	Transfer to other plants	- Transfer report - Risk assessment - Technical measures	- Transfer protokoll

Usefull Links/ Infos

- https://www.bgrci.de/fachwissen-portal/topic-list/hazardous-substances/
- https://downloadcenter.bgrci.de/resource/downloadcenter/downloads/R003e_Gesamtdokument.pdf

Accident Prevention & Insurance Association - data sheets
[BG-Merkblätter R 001-007]

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Auditor Training 2019

Runaway Reaction Explosion

(taken from a presentation by Lamy Bao)

PSCI Questionnaire &observations

(Presentation from Dr. Stefan Gries Boehringer Ingelheim Corporate Center, Corp. EHS&S)

Speaker: Mr. Li Liu Boehringer Ingelheim Corporate China. EHS&S

TRAINING STRUCTURE

1. Session 1
- Process safety parameters
- Essential information to chemical processes
- Critical interactions of material
- Exothermic and run-away reaction
- Scale up

2. Session 2
- Runaway reaction
- PSCI Questionnaire & Typical Observations

3. Audience questions & discussions

Investigation Report - Explosion in T-2 Labs

- **Location: Jacksonville, Florida (USA)**
- **Incident: Explosion in Reactor due to runaway reaction**
- **4 employees killed, 32 injured (including 28 from surrounding community**
- **Explosion force: Equivalent to 1,400 lbs of TNT (≈ 635 kg TNT)**
- **Causes:**
  - **Company did not recognize the worst credible scenario**
  - **No redundancy in cooling system**
  - **Inadequate pressure relief device**

Reaction Hazards - Historical Data of Incidents

(Ref. Book: Chemical Reaction hazards by John Barton)

Following data was collected for 189 industrial incidents in UK involving thermal runaway reactions:

- **134 incidents were classified by processes, key ones are:**
  - **Polymerization (condensation): 64 (48%)**
  - **Nitration: 15 (11 %)**
  - **Sulphonation: 13 (10%)**
  - **Hydrolysis: 10 (7%)**
  - **Raw Materials Quality: 15 (11%)**
  - **Others: 13%**
- **34 incidents were caused because there was no study done for reaction hazards**

Reaction Hazards – Incidents by Causes

(Ref: Book: Chemical Reaction hazards by John Barton)

- **35 incidents were caused by mischarging of reactants or catalysts (29%)**
- **32 incidents were caused by temperature control (27%)**
- **25 incidents were caused by maintenance (21%)**
- **17 incidents were caused by agitation (14%)**
- **11 incidents were caused by human error (9%)**

PSCI Questionnaire and Typical observations

Audit Questions Summary – Process Safety

Topic	Question summary
Process Safety	76: Top 3 most hazardous process activities conducted at this facility 77: Process hazard assessment 78: Evaluated the impact of its operation on the community Evaluated the impact from the activities of neighboring businesses 79: Risk assessment for explosion of flammable liquids, vapors, powders, and gases 80: Preventive maintenance of safety relevant equipment. 81: Handling compressed gases safely 82: Bulk chemical handling procedures 83: Safety measures around direct fire equipment (e.g. boiler, incinerators, ovens etc.)

Process Safety - Typical Observations

77	Does the facility perform Process Hazard Assessment (PHA)? *Aim is to identify processes or operations that could present significant risks in case of deviation (exothermic reactions, use of flammable, combustible or toxic materials, processes involving extreme temperatures or pressures).*	… • Collection of process information (process safety data, design information, operating parameters, and equipment specifications) • Hazard evaluations capturing significant risks during process development, preliminary engineering, and upon completion of process design? • Sizing of pressure vessels and relief devices according to appropriate codes and standards? • Flammable storage areas separate from production and well managed?

No safety data for any chemical reaction are available (example: heat of reaction, adiabatic temperature rise, decomposition temperature,…)
The auditee has made some improvement to collect process safety data and to conduct PHA for high sophisticated chemical reaction (nitration, oxidization, hydrogenation etc.) running at site. Nevertheless the interpretation of this data and the transfer into safety measures for the production is not always reliable.
Basic safety data for chemical processes are available from the Development report. However data are archived and in case of changes these data are not any more reconsidered, since there is no systematic approach in place to cover chemical safety data in a change control system.

Process Safety - Typical Observations

Most of the vent pipes coming from safety valves or rupture disks have at least 3 ninety degree angles. Therefore there is no evidence about the pressure profile inside the venting pipe. This leads to back pressure build up in case of activation with a certain risk for pipe bursting.
The reactor where the bromination takes place misses a safety valve or rupture disc respectively. Furthermore the adiabatic reaction heat is not known.
The explosion vent of the fluid bed dryer in the Bromhexine clean rooms is venting into the cleanroom.
In the chemical production building, the venting pipes of the safety valves end close to the floor in the production room. Taking into consideration the highly hazardous nature of the ingredients (e.g. Oleum, CO, SO_3) this may lead to fatal accidents in case of a pressure relief.

Process Safety - Typical Observations

79	Does the facility perform risk assessment related to the explosion of flammable liquids, vapors, powders, and gases in processing operations (including storage, transfer and charging)? Does it include the following steps?	• Assessment of the hazards (Minimum Ignition Energy, Kst classification rating, Impact sensitivity etc.) of the handled combustible dusts and powders • Hazardous area classification (zones according EU-ATEX and Classes according to US-NFPA) … • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, … • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals. • Assessment of the hazards due to mechanical ignition sources? • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, and wet areas? • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals. • Assessment of the hazards due to mechanical ignition sources?

Process Safety - Typical Observations

Safety data like MIE, St Class etc. are available for most of the finished products (API). No data is available for isolated intermediates. Hence it could not be proven if the Fluid Bed Drying of intermediates can be done safely.
The company has not assessed the hazards (Minimum Ignition Energy, K_{st} classification rating, Impact sensitivity etc.) associated with combustible dusts and powders being handled in various operations at site.
At the installations in the production area stainless steel clamps were installed instead of using copper wires for grounding and bounding. No evidence was provided showing that this type of bounding grounding is as safe and effective as copper wires.

Process Safety - Typical Observations

The Customer product is received in packaging, treated in anti-static agents and the specifications for the finished product require it to be packaged in liners that are treated with anti-static agents. However, the material handled in the intermediate steps is not treated with anti-static agents. Site personnel assume that the minimum ignition energy is low enough to warrant this type of packaging if the incoming and finished product are packaged in anti-static treated liners.
There is no gas detector near the ethanol recovery device at VB1 workshop, no O2 detector at centrifuges which used N2.
In the production plant, grounding points and grounded piping are installed. A detailed SOP for working in Ex-zones is available and trained. But an instruction, how to ground mobile equipment (e.g. solvent drums) is not included in this SOP.
An Ex light in the hydrogenation room was labeled as “Ex ed IIB T4”, which was not the proper type for hydrogen environment.

Process Safety - Typical Observations

80	Describe how the facility ensures preventive maintenance of safety relevant equipment.	• Pressure safety relief valves/rupture disks • Bonding/earthing systems • Mass transfer systems (e.g. piping systems) • Pressurized vessels • Explosion prevention system (e.g., prevention of static electrical discharge) • Is there emergency power supply for relevant equipment?

Anti-static bridge connection of pipes for transporting flammable chemicals is very rusty in Building A-6.
Most of the P+IDs presented during the audit where not up to date. Furthermore the guidelines of ISO14617 regarding the symbols are not followed. P+IDs should always be up to date, showing the "as build" situation to avoid any risk due to mistaken identity of any component of an equipment.

Process Safety - Typical Observations

81	Does the facility provide a means for handling compressed gases safely that includes:	Inspection and approval before acceptance of delivery? Storage in a segregated area designed for compressed gases? Separation or barriers to manage compatibility issues? Gas classification labeling? Regulator, hose and flexible connection inspections?

PSCI Questionnaire

82	Has the facility developed and implemented bulk chemical handling procedures that include:	Not applicable Specific unloading and loading procedures? Identification sampling before unloading? Hose inspection? Fire protection? Spill control measures (dike or bund area)?

Storage of Oxalyl Chloride is done under “normal” conditions (Hyderabad room temperature in the warehouse).
As of the “Tech Pack” information, the storage temperature should not exceed -10°C.
Even if there are some newer SDS available that storage at middle European room temperature range (max. 25°C) might be sufficient, the company could not show evidence that the change of storage conditions was assessed.

The bulk unloading process needs improvement. The unloading area is asphalt but no defined retaining volume in case of any spillage is provided.

Process Safety - Typical Observations

83	What are the safety measures around direct fire equipment (e. g. boiler, incinerators, ovens etc.)? *Consider gas accumulation, steam overpressure...*	

In the Building B, Water For Injection (WFI) system, the clean steam generator operates at 65 psig with a safety relief valve venting directly to the room. In the case of activation, 155°C steam would be released and fill the room.

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+55 (11) 94486 6315

PSCI

@PSCInitiative

For more information about the PSCI please contact:

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

info@pscinitiative.org

+55 (11) 94486 6315

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.

carnstone
partners ltd

DAY 1 AGENDA

08:00 – 08:30	Registration, coffee/tea	
08:30 – 08:45	Welcome	Birgit Skuballa (Bayer)/ Maggie Zhang (Carnstone)
08:45 – 09:30	Introduction to PSCI Audit updates	Birgit Skuballa (Bayer)
09:30 – 10:45	General Safety	Birgit Skuballa (Bayer)
10:45 – 11:00	BREAK	
11:00 – 12:30	Process Safety 1	Li Liu (Boehringer Ingelheim)
12:30 – 13:30	LUNCH	
13:30 – 14:30	Process Safety 2	Li Liu (Boehringer Ingelheim)
14:30 – 15:30	General Environment	Daming Bai (Elanco)
15:30 – 15:45	BREAK	
15:45 – 17:00	PIE/AMR	Ken Sun (GSK)
17:00 – 17:30	EXAM Part 1	

DAY 2 AGENDA

08:00 – 08:30	Registration, coffee/tea	
08:30 – 10:30	Occupational Health and Industrial Hygiene	Wenjia Xu (J&J)
10:30 – 10:45	BREAK	
10:45 – 12:30	Emergency Preparedness and Response	Daniel Rehm (Elanco)
12:30 – 13:30	LUNCH	
13:30 – 15:00	High Risk work and red flags for dangerous working	Catherine Zhang (Bayer)
15:00 – 15:15	BREAK	
15:15 – 15:45	EXAM Part 2	
15:45 – 16:00	Training wrap up	Birgit Isabelle Skuballa (Bayer)

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Auditor Training 2019

Environmental Protection

Barry Bai 白大明
HSE Manager, External Manufacturing China
ELANCO

Bio 个人简介

Company Role: HSE manager, ELANCO External Manufacturing
Tasks: Provide HSE support and oversight for external partners

2013-Present ELANCO
2005-2013 The Chemical company (CYTEC, 3M and BASF)

Master in Environment Engineering
Bachelor in Safety Engineering

Barry Bai 白大明
Bai_da_ming@elanco.com

AGENDA 大纲

1. **Auditor insights**
2. **Audit overview – SAQ/Audit tool questions review with auditor guidance**
3. **Deep dive – Pharmaceuticals in the Environment**
4. **Example audit findings**
5. **Audience questions**

1. AUDITOR INSIGHTS

Auditor Insights | Preparation for the Site Visit

Preparation is Key

- Supplier website & SAQ
- Internet
- Google satellite imagery

Auditor Insights | Background Information Review

Auditor Insights | Background Information Review

Auditor Insights | Opening Meeting

- Overview presentation – supplier
- Site tour expectations – be specific
- Documents
- Permission to photograph
- Neighbors

Auditor Insights | Tour of the Facility Exterior

First Impressions Count !!!

Auditor Insights | Tour of the Facility Exterior

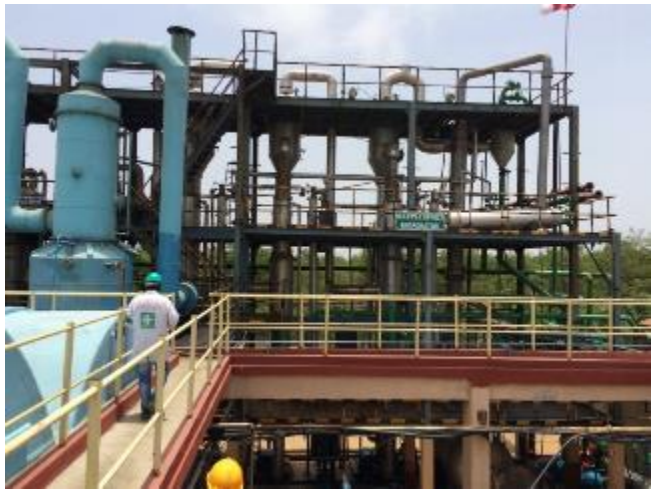
Particularly look for the following:

- Surface water
- Storm drains
- General housekeeping
- Excavations for construction
- Storage or placement of waste materials exterior to the facility
- Evidence of releases
- Visible emissions from air emission sources
- Significant dead vegetation (not seasonal)

Auditor Insights | Tour of the Facility Interior

Interior Tour should include:

- Boilers and Diesel Generators
- Fuel storage areas
- Wastewater collection and treatment systems
- Stormwater collection and discharge systems
- Waste storage areas



Auditor Insights | Tour of the Facility Interior

Interior Tour should also include:

- Process areas
- Water extraction wells
- Potable water delivery and storage systems
- Deep wells or borings for waste or wastewater disposal
- Underground storage tanks
- Air pollution control equipment for boilers and process emissions
- Solvent storage and recovery
- Incinerators

2. AUDIT OVERVIEW

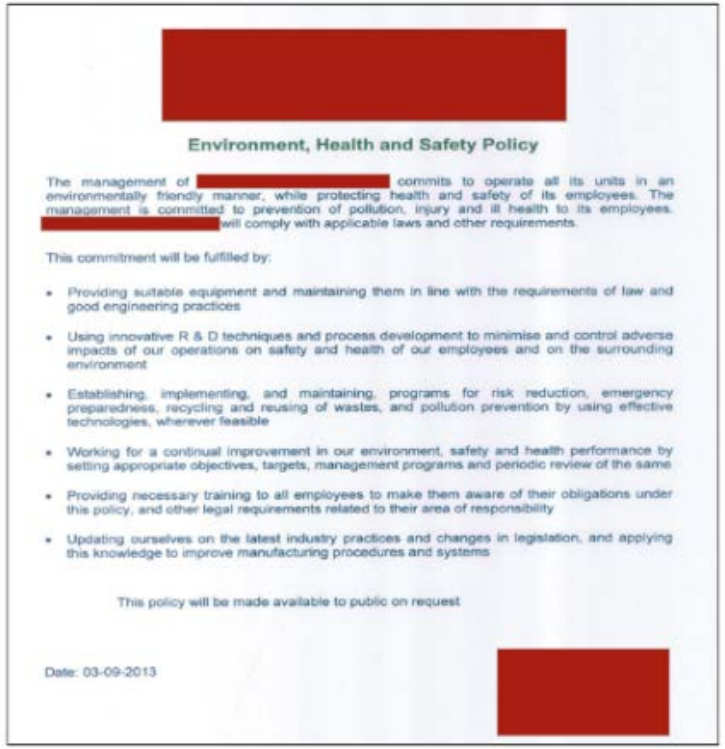
Audit Questions Summary – Environmental protection

Topic	Question summary
General	• Written environmental policy, procedures, and practices • Environmental objectives or goals for performance improvement, including metrics and targets • If in a water scarce region, is there a water strategy
Chemical registrations	• Is the site affected by any chemical registration program (REACH etc.)
Environmental Authorizations	• Environmental permits or authorization
Waste and Emissions	• Process to manage third-party waste treatment and disposal • Waste disposal methods & locations (explain as applicable) • Process wastewater management • Types of air emissions • Hazardous chemicals (including APIs) management program • Storm water management practices
Spills and releases	• Hazardous materials transportation • Soil, surface water or groundwater contamination • Potential environmental risks from hazardous substances

Audit Overview

General		
31	Does the facility have written environmental policy, procedures, and practices?	Policy: Yes No Procedure: Yes No Comments: Please provide a copy of the policy and a list of procedure titles.

- Ask for the supplier's environmental, health and safety policy.
- How are people trained in it?
- Are procedures in place for environmental activities?
- Do the operating procedures include environmental aspects?
- Is there clear evidence that the procedures are followed?
- During personnel interviews, are they familiar with the environmental policy, procedures & practices?



[redacted]

Environment, Health and Safety Policy

The management of [redacted] commits to operate all its units in an environmentally friendly manner, while protecting health and safety of its employees. The management is committed to prevention of pollution, injury and ill health to its employees. [redacted] will comply with applicable laws and other requirements.

This commitment will be fulfilled by:

- Providing suitable equipment and maintaining them in line with the requirements of law and good engineering practices
- Using innovative R & D techniques and process development to minimise and control adverse impacts of our operations on safety and health of our employees and on the surrounding environment
- Establishing, implementing, and maintaining, programs for risk reduction, emergency preparedness, recycling and reusing of wastes, and pollution prevention by using effective technologies, wherever feasible
- Working for a continual improvement in our environment, safety and health performance by setting appropriate objectives, targets, management programs and periodic review of the same
- Providing necessary training to all employees to make them aware of their obligations under this policy, and other legal requirements related to their area of responsibility
- Updating ourselves on the latest industry practices and changes in legislation, and applying this knowledge to improve manufacturing procedures and systems

This policy will be made available to public on request

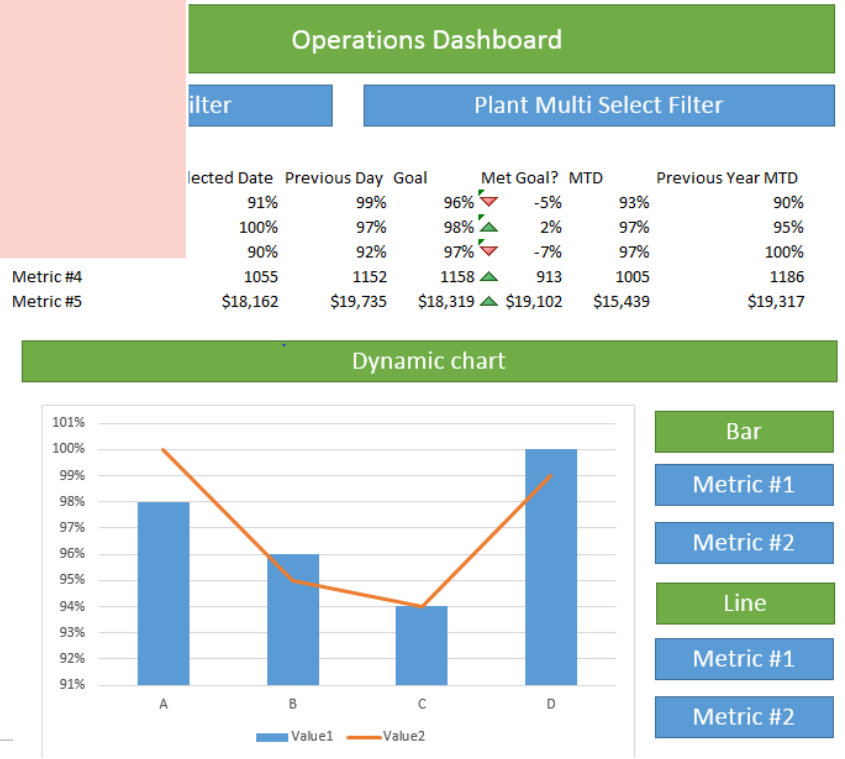
Date: 03-09-2013

[redacted]

Audit Overview

32	Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?	Yes No If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years.: Do tracking and reduction programs exist for the following impacts: Energy consumption: Water consumption: Amount of hazardous waste: Amount of non-hazardous waste: Greenhouse gas emissions: Does the facility publicly report data? Yes No Program description: If yes, where can the information be found:

- Does the facility have clear environmental goals?
- Are they set locally or at the corporate level?
- Is there clear support for achieving the goals?
- Review the methods that facility has in place to measure key environmental impacts



Audit Overview

33	If the site operates in a water scarce region, has the facility developed a long-term strategy for future water sourcing and management?	Yes No NA Please explain: Is the long-term continuity for future water sourcing and management already covered in the site-based Business Continuity Management plan? Yes No NA Please explain: Does the facility have an authorisation/permit for water intake from groundwater, river or a public system? Yes No NA Please explain: Does this authorisation/permit have any requirements that will restrict or stop your ability to obtain water? Yes No NA Please explain:

- Describe any fresh water availability, access or infrastructure issues the site may be facing locally or regionally.
- Is the water withdrawal from groundwater from a renewable/sustainable source (not depleting the groundwater source)?
- If the site is reliant on a municipal water system, does the site know if the municipality will be unable to capture and distribute adequate supplies of water due to infrastructure development issues or lack of institutional capacity to maintain and manage them appropriately?

[1] Water scarcity is defined by the UN Food and Agriculture Organization as: (i) scarcity **in availability** of fresh water of acceptable quality with respect to aggregated demand, in the simple case of physical water shortage; (ii) scarcity **in access** to water services, because of the failure of institutions in place to ensure reliable supply of water to users; (iii) scarcity due to the **lack of adequate infrastructure**, irrespective of the level of water resources, due to financial constraints. In the last two cases, countries may have a relatively high level of water resources endowment but are unable to capture and distribute them because of limited financial resources for infrastructure development or lack of institutional capacity to maintain and manage them appropriately. (UN FAO, http://www.fao.org/nr/water/topics_scarcity.html)

Audit Overview

Chemical Registrations		
34	Is the site affected by a chemical registration program such as EU REACH (Registration, Evaluation; Assessment, Authorization and Restriction of Chemicals), China REACH, or TSCA (Toxic Substances Control Act) which requires registration or authorization to import or use a specific compound?	Yes No NA If yes, please identify the program: In case of yes, do you have a process in place to comply with the regulation? Yes No NA Which materials are applicable? • Finished Products produced in the site • Raw materials used for finished products • Other
35	Do you send materials to a region where REACH or similar regulations apply?	Yes No If yes, how do you ensure compliance in this region and what is your role in this case?

Audit Overview

Environmental Authorizations		
36	Does the facility have the required environmental permits or authorizations?	Yes No NA If yes, please list the permit type, the name of the permit, and the expiry date: NOTE: Please have all required environmental permits, licenses, information registrations and restrictions available for review including supporting compliance documentation.

Describe the permits and list the permit # or name, confirm expiry date and compliance conditions, if there were any non-compliances within last 3 years. Also add which data was reviewed for permits, for example, waste water sampling results for flow, BOD, pH, etc.

Confirm that all commercially manufactured products are endorsed in the site permits/permit applications.
For R&D suppliers in China, EIA permit at pilot scale does not need to specifically list the products.

What mechanisms does the site use to track compliance against the permit or authorisation conditions?

List all reportable and non-reportable non-compliance with permits (and parameters) within last 3 years.
Review compliance history via web search
Review compliance history with the site during the visit including:
Status of authorisations | Any notices of violation | Any fines or penalties for non-compliance | Any spills or unplanned releases

Describe any permits specifically regulate Active Pharmaceutical Ingredients (especially antibiotics)? For example, wastewater limits, waste disposal requirements).

If site handles antibiotics, indicate the applicability of any permit conditions for managing or controlling waste streams, wastewater or biosolids/biomass from that contain APIs.

Audit Overview

Waste and Emissions		
37	Does the facility have a process to select and manage third-party waste treatment and disposal facilities and service providers?	Yes No NA What records or documentations of waste disposal are maintained: Please provide specific details on land filling of waste (categories and volumes):

Check records/supporting documents such as manifests or shipping records, supplier selection procedure, contracts, audits of waste vendors, etc.
Indicate any non-compliance(s) for the site or contracted waste management supplier.
Describe assurances that waste disposal contractors possess authorizations /certifications from regulatory authorities to manage specific waste streams in accordance with local regulations and that containment and monitoring programs are in place.
Describe selection process review for the use of third-party waste facility or provider. Does it include considerations for staffing and API residual management?
Are the third-party waste treatment vendors used by the facility approved by regulatory authorities? How does the site know that they have valid Environmental permits?
How are third-party waste vendors reviewed periodically for their HSE performance/compliance?
How are waste manifest/transfer record systems followed and maintained for disposal of wastes as per applicable regulations?

More on Waste Management Disposal

- Waste must be disposed at authorized disposal facilities.
- Confirm locations of disposal
- Tracking system for waste shipments and shipment records retention
- Review hazardous waste manifests

More on Waste Management Vendor Considerations

- Does the facility audit their waste vendors?
- Do they have the right authorisations?
- Determine frequency, audit protocols, auditor qualification
- What is described in the contract?

Audit Overview

38	Does the facility use any of the following waste disposal methods & locations (explain as applicable)? Include explanation of how hazardous, including API containing waste (e.g. antibiotics), biohazardous, fermentation biomass, non-hazardous waste is disposed of.

Onsite vs. offsite disposal
Methods: Incineration (energy recovery?), landfill (hermetically sealed?), deep well, land application, other/reuse/recycling

Describe any criteria prescribed, established or referred to for determining the disposal pathway and whether compliance can be demonstrated

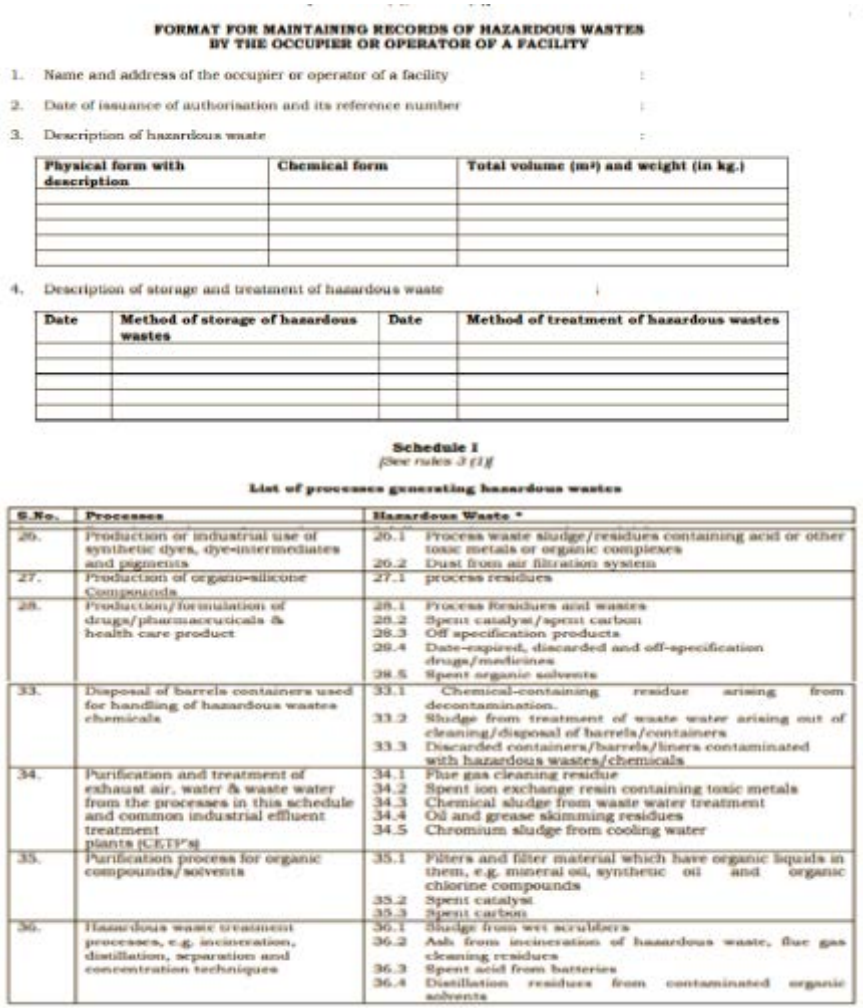
Comment on the appropriateness of waste disposal via methods reportedly used with focus on high risk disposal such as land application, deep well injection, or landfill of hazardous waste. Review in detail treated wastewater and/or sludge/fermentation biomass applied to land for irrigation and/or fertilizing purposes that might include API residual.

List any vendors or relevant authorities for disposal methods or records that were reviewed.

Does this disposal method cover any of the following?

- Branded materials
- API/drug product residuals
- Biosolids, biomass or sludge containing API
- Are environmental impacts from API residuals considered?

More on Waste Management Identification, Characterization, and Inventory



FORMAT FOR MAINTAINING RECORDS OF HAZARDOUS WASTES BY THE OCCUPIER OR OPERATOR OF A FACILITY

1. Name and address of the occupier or operator of a facility :
2. Date of issuance of authorisation and its reference number :
3. Description of hazardous waste :

Physical form with description	Chemical form	Total volume (m³) and weight (in kg.)

4. Description of storage and treatment of hazardous waste :

Date	Method of storage of hazardous wastes	Date	Method of treatment of hazardous wastes

Schedule I

[See rules 3 (1)]

List of processes generating hazardous wastes

S.No.	Processes	Hazardous Waste *	
26.	Production of industrial use of synthetic dyes, dye-intermediates and pigments	26.1 26.2	Process waste sludge/residues containing acid or other toxic metals or organic complexes Dust from air filtration system
27.	Production of organo-silicone Compounds	27.1	process residues
28.	Production/formulation of drugs/pharmaceuticals & health care product	28.1 28.2 28.3 28.4 28.5	Process Residues and wastes Spent catalyst/spent carbon Off specification products Date-expired, discarded and off-specification drugs/medicines Spent organic solvents
33.	Disposal of barrels containers used for handling of hazardous wastes chemicals	33.1 33.2 33.3	Chemical-containing residue arising from decontamination. Sludge from treatment of waste water arising out of cleaning/disposal of barrels/containers Discarded containers/barrels/liners contaminated with hazardous wastes/chemicals
34.	Purification and treatment of exhaust air, water & waste water from the processes in this schedule and common industrial effluent treatment plants (CETP's)	34.1 34.2 34.3 34.4 34.5	Flue gas cleaning residue Spent ion exchange resin containing toxic metals Chemical sludge from waste water treatment Oil and grease skimming residues Chromium sludge from cooling water
35.	Purification process for organic compounds/solvents	35.1 35.2 35.3	Filters and filter material which have organic liquids in them, e.g. mineral oil, synthetic oil and organic chlorine compounds Spent catalyst Spent carbon
36.	Hazardous waste treatment processes, e.g. incineration, distillation, separation and concentration techniques	36.1 36.2 36.3 36.4	Sludge from wet scrubbers Ash from incineration of hazardous waste, flue gas cleaning residues Spent acid from batteries Distillation residues from contaminated organic solvents

- The site should have a documented process to identify and properly characterize all of its waste streams
- An inventory of wastes generated should be available on site
- The inventory should include at a minimum:
  - Point of Generation (process generating the waste)
  - Hazardous characteristics and classification (corrosive, flammable, radioactive, etc.)
  - Annual Generation Rate

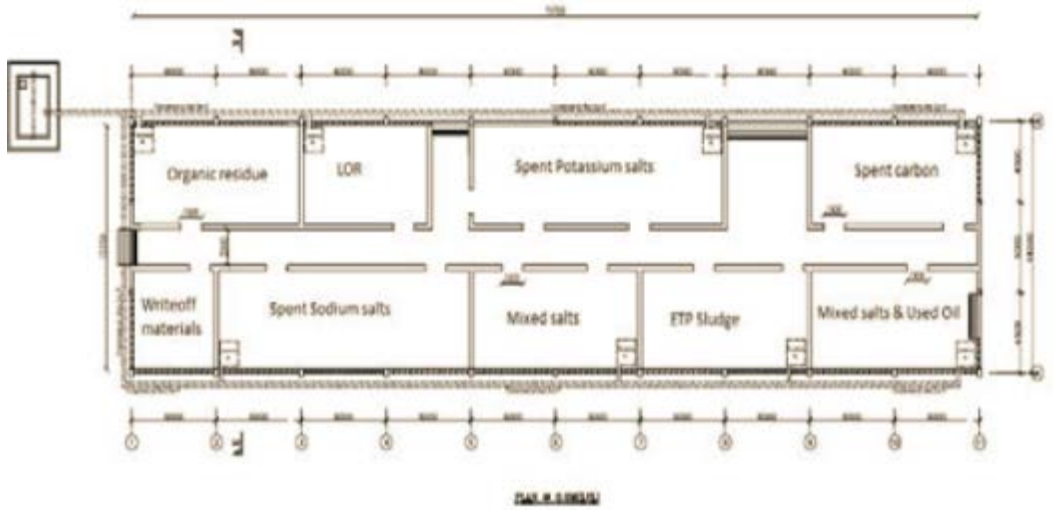
More on Hazardous Waste Management Storage and Handling

- Waste storage areas should be secured and managed
- Located indoors or in covered
- Impervious floors with secondary containment
- Storage areas clean and free of debris and accumulated liquids
- Sufficient aisle space

More on Hazardous Waste Management Storage and Handling

Review the following:

- Inspection program
- Separate storage for incompatible wastes
- Suitable emergency response equipment in place
- Suitable PPE available for personnel managing waste
- Proper security and signage



More on Waste Management Bio-Medical Waste

- Confirm with the site if they generate biohazardous wastes (e.g., microbiological testing wastes)
- Review storage and handling methods
- Must be managed appropriately while on site
- Segregated from other hazardous wastes
- Confirm disposal method and location
- Incinerated at an approved location

Audit Overview

39	Indicate which methods are used to manage process wastewater from this facility.	Check all that apply to treatment and disposal of wastewater: • Pretreatment of process water Yes No Please describe method(s) (example – hydrolysis with caustic or heat pre-treatment): • On-site wastewater treatment: Yes No Please describe: Does the facility collect, store, and analyze samples? Wastewater? Yes No Sludge? Yes No • Discharge to an offsite treatment facility: Yes No Please describe off-site treatment method (example - biological treatment followed by activated carbon filter): • Discharge to a settling/retention pond: Yes No Please describe: • Discharge to surface water (e.g., river, lake, ocean): Yes No Please describe: • Collection and transfer to an off-site wastewater management facility/company: Yes No Please describe: • Other, e.g. Zero liquid discharge, wastewater for irrigation, evaporation via cooling tower, incineration; deep well injection: Yes No Please describe: Are environmental impacts of API considered in disposal of: • Wastewater? Yes No • Sludge/biomass? Yes No

Audit Overview

Are wastewater discharges or practices in line with the permits issued by local agencies?

Describe how wastewater is managed (dedicated and sufficient staff, documented procedures, condition of facility). If an off-site wastewater treatment plant is used, describe selection/oversight by supplier in Question 50.

Assure that samples are collected, stored, and analyzed with results reported in accordance with local regulatory requirements.

Describe the wastewater treatment flow and treatment methods/treatment technologies used and surface water that receives wastewater effluent from the site. (Include all on-site plant discharges and any off-site treatment plant and the waterbody that receives the discharge).

Describe condition of monitoring equipment and effectiveness of controls. Water/wastewater monitoring devices and treatment systems are in good operating condition and appropriately maintained (e.g., in accordance with manufacturer's recommendations).

Describe best practices used by the site (treatment, capture, and containment or practices especially for highly potent API) to prevent or reduce API discharges in wastewater. Are these controls manually operated or proceduralized?

Describe how APIs are quantified in wastewater: mass balance, sampling with sufficiently sensitive method, etc. Describe risk assessment process and oversight such as procedure available, all APIs accounted for, toxicological info available, competent professional provides oversight, recommendations are incorporated, etc.

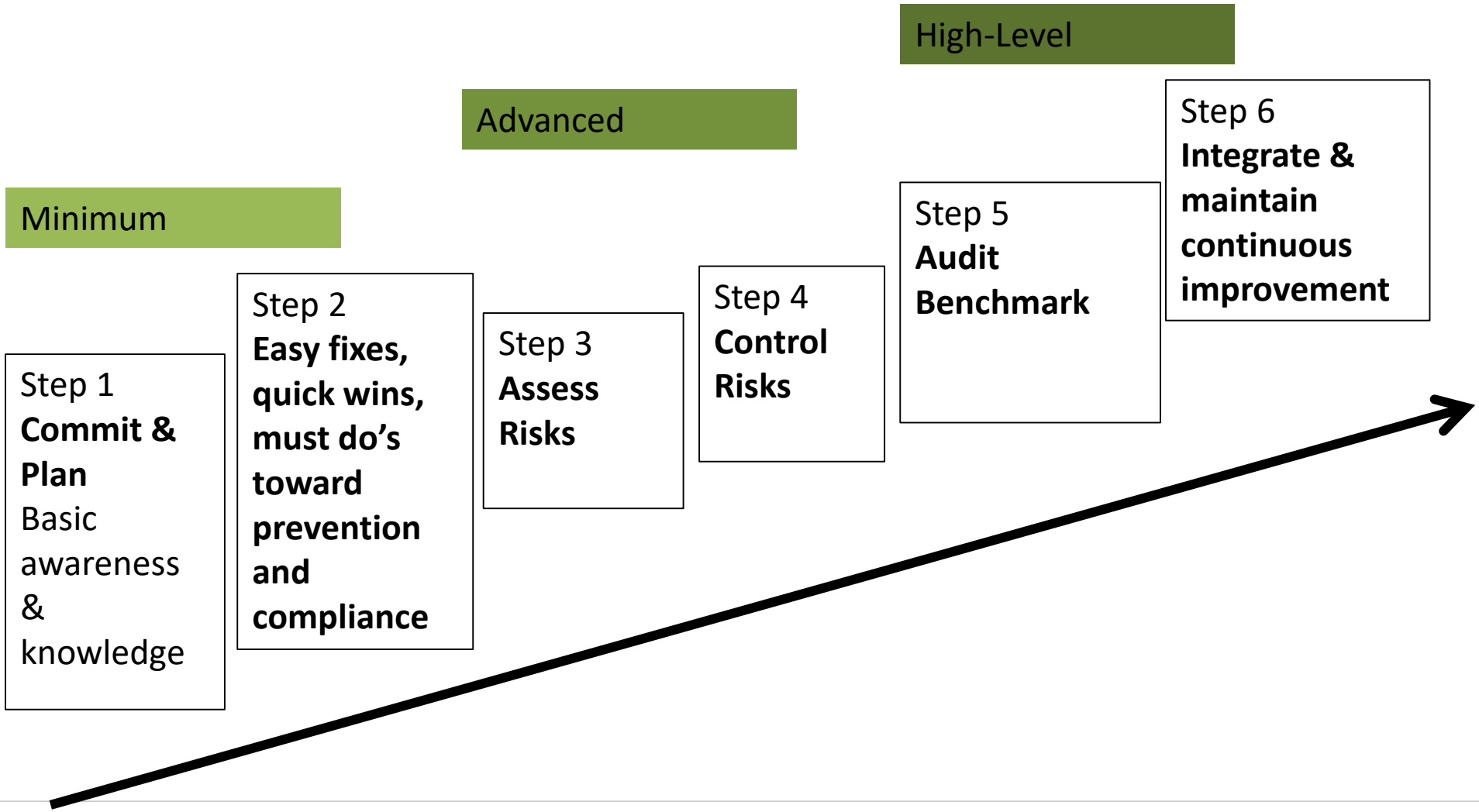
Review qualification for persons managing API emissions (i.e. knowledge of regulatory requirements and quantification of APIs in treated waste water)

More on Wastewater Treatment

- Treatment volume - Evidence of overspill
- Inspect Final Discharge Point
  - Where does it discharge to-standing waterbody, sewer, river, sea
  - Can you go to see the discharge point
  - What does the effluent look/smell like
    - Strong solvent odour
    - Visible contamination
- Permitted Volumes vs Daily Flows
  - What are they limited to
  - Compliance history
  - Specific parameters
- Treatment Capability
  - Do the know what the treatment type is

More on Wastewater Treatment

Wastewater Maturity Ladder



Audit Overview

40	Indicate which of the following types of air emissions are generated at the facility. Describe the types of pollution control activities if used.	Emission Type	Generated?
		Volatile organic chemicals	Yes No NA
		Corrosive vapors (e.g. acid, caustic)	Yes No NA
		Particulates or dusts	Yes No NA
		Ozone depleting substances	Yes No NA
		Combustion by-products	Yes No NA
		Other Pollutants (e.g., GHG, cyanides, sulfides, ammonias, bromines, phosgene)	Yes No NA

Are the air emissions/air quality monitored periodically as per local regulations?

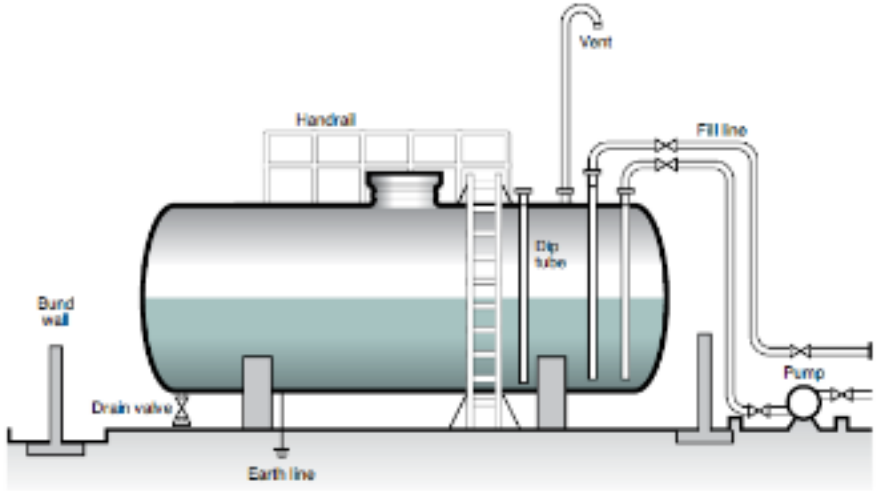
Are the monitoring reports maintained?
Were there any limit exceedances?

Is the air/emission monitoring carried out internally or a third-party?

Are third-party external labs approved for carrying out the tests?

More on Air emissions : Controls of Storage tanks

- Management and control of emissions from storage tanks
- Determine what controls are in place
- Look for controls (and emergency plans) in place for storage of bulk quantities of volatile toxic or highly flammable compounds
- Review Authorisations



More on Air emissions : Process emissions control

- Determine what controls are in place on process equipment
- Determine if the operating parameters and maintenance of the air pollution control equipment is understood and in place
- Review the Authorisation for any specific requirements for vent controls on process equipment

Requirements may include:
- Specific Limits on emissions
- Ambient air quality sampling and limits
- General conditions

More on Air emissions : Odor controls

- Note any odors on your interior and exterior tour
- Review odor control systems in place with facility staff
- Confirm operation and maintenance are adequate to prevent nuisance odors
- Confirm operation is in compliance with the Authorisation

Audit Overview

41	Has the facility developed and implemented a hazardous chemicals (including APIs) management program that includes development and maintenance of a current inventory of all hazardous chemicals (including APIs) used, manufactured or stored on-site, including those for production, maintenance, utilities, and laboratory purposes?	Yes No Please explain and list site hazardous substances:

Audit Overview

42	Has the facility established good storm water management practices?	Yes No Describe how the facility manages storm water and avoid contamination How has the retention volume been calculated? Does it take into account specific factors like rain, environmental hazards of substance stored/handled. Yes No Describe shortly any arrangements that are in place to treat / dispose of the water that would have been collected. Does the facility have a system for controlling and collecting water from fire-fighting to prevent off-site impacts? Yes No Please describe

Is there a dedicated storm water network inside the plant? Describe how the retention volume is calculated and if it takes into account specific factors like rain or environmental hazards of substance stored/handled. Briefly describe any arrangements that are in place to treat / dispose of the water that would have been collected.
If there is no dedicated network, how is storm water collected, measured/analyzed and discharged?

Are there documented programs to manage storm water and storm water contamination control?

Audit Overview

Spills and Releases		
43	Does the facility transport any hazardous materials that are subject to a regulatory authority that specifies transportation requirements? (including but not limited to the International Air Transportation Association (IATA), International Civil Aviation Organisation (ICAO), International Maritime Dangerous Goods (IMDG) Code, ADR (formally, the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)), U.S. Department of Transportation (DOT).	Yes No Describe how the facility manages the transportation of hazardous materials and dangerous goods

Audit Overview

44	Does the facility or immediate surroundings external to the site have any known soil, surface water or groundwater contamination?	Yes No If yes, please provide a brief description of how this is being managed and whether it impacts surroundings of the site (e.g., neighboring facilities, companies), adjacent natural habitats:

Is any soil, surface water or groundwater testing carried out periodically?
Is it required by local regulations?
Are records maintained?

Audit Overview

45	Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products and APIs, as follows:	Are there spill containment systems for hazardous substances (including petroleum products and APIs)? Yes No NA Please explain:

Drum storage, above ground tanks, in ground tanks

Secondary containment 110% volume of largest container/tank ?
Leak detection & overfill protection for tanks ?

Spill containment integrity is inspected, documented and maintained in satisfactory condition to prevent the discharge of waste materials into the environment.

Solid wastes are stored, protected from the elements and in a manner to prevent discharge as the result of rain/storm water runoff.

Are waste containers in good condition, compatible with the material being stored and maintained closed except during filling and emptying?

Are protocols or procedures for reporting leaks, spills and other abnormalities related to API waste handling in place and being followed?

Are potential emergency scenarios arising from storage of hazardous substances (including APIs) identified in the site Emergency Response Plan? Are controls and responses and detailed in the Emergency plan?

Have unpermitted releases been reported to the proper authorities and remedial measures instituted to prevent reoccurrence and address impacts associated with said release?

More on Material Storage Containers & Tanks

- Review storage of drummed and bagged materials
- Assess if warehouses are properly managed and have containment for potential releases
- Look for poor material storage practices
- Review the requirements of the Authorisation

- Look for appropriate maintenance on tanks
- Do the tanks have overflow and overfill protection?
- Fire detection and suppression
- Check for appropriate containment
- Review tank truck loading and unloading practices

More on Material Storage Underground Storage Tanks

- Where are they?
- Review construction and containment methods
- Review methods used to determine leaks
- Review tank truck loading and unloading practices

Audit Overview

46	Are tank truck, railcar, and other bulk transportation unit loading and unloading areas for hazardous substances provided with containment equivalent to at least 110% of the largest transportation unit handled in that area, or for compartmentalized transportation units, equivalent to at least 110% of the single largest compartment?	Yes No NA Please explain:

4. EXAMPLE AUDIT FINDINGS

- Paint a picture for reviewers in the report as if they have never been to the site
- Be specific where possible to provide context of scope of issue, impact to supply chain, depth of problem
- Accurate without overstating or understating issue

Case 1

Q39: Indicate which methods are used to manage process wastewater from this facility.

Real PSCI audit finding

The site has no evidence about the effectiveness of the private waste water treatment works.

What kinds of wastes are sent to the private waste water treatment works?
Is the site required to use this private waste water treatment works?
Does the site characterize waste water sent offsite?

Case 1 – Model finding

The site sends production wastewater to a private wastewater treatment plant via hired tanker truck daily.

The private wastewater treatment plant is the common local plant the site (and rest of industrial park) is required to use. The site characterizes the wastewater going offsite so quantity of API in discharge is known. The site has requested/been refused/not yet received information on treatment capability and effectiveness of the private wastewater treatment plant.

Case 2

Q45: Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products as APIs, as follows: …
Does the site have protocols or procedures for storing and handling drums, providing containment for drums and managing spills from drums?

Real PSCI audit finding

Some hazardous wastes (empty chemical containers) stored in the open air.

Case 2 – Model finding

Approximately 40 empty 55 gallon metal drums (previously containing hazardous chemicals) were stored on loading dock of Building 16 with no protection from the elements.

Exercise 1

Q45: Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products as APIs, as follows: … Does the site utilize Secondary containment in the form of double walled tank and piping or an external vault with a capacity equivalent to 110% of the largest tank or vessel in the containment area?

Real PSCI audit finding

Containment at tank farm is not adequate.

What kind of containment – double wall, vault…

What is the deficiency? Too small, breach, not compatible with material stored, doesn't exist…

How would you improve this finding?

Instructions

1. Use the audit finding sheet provided to write up the finding.
2. **Add details from your experience** not mentioned in the bad finding example.
3. You have 5 minutes (or less time if everyone is finished)
4. Afterwards we will discuss your answers

Exercise 1 - Sample finding

Tank farm storing solvents has concrete pad and berm surrounding tanks but 3 breaches have been cut into concrete to accommodate rain water removal, compromising the integrity of the berm.

Exercise 2

Practice writing audit finding:

Write an audit finding based on the below gathered information:

- These drums were stored at the backyard of a site that manufactures API intermediates
- 3 out of 5 drums were empty, 2 were half-full (content unknown, strong odor of organic solvents noticed)
- The site also handles hazardous materials

Exercise 2 - Sample finding

Behind the waste storage building, 5 rusty drums were stored directly on the soil without any further labeling or protection against the environment.

Three out of five drums were empty, two were half-full with an unknown content, a strong odor of organic solvents was noticed.

Furthermore other trash including other glass pieces, plastic boxes as well as cleaning equipment was found nearby these drums.

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+55 (11) 94486 6315

PSCI

@PSCInitiative

For more information about the PSCI please contact:

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

info@pscinitiative.org

+55 (11) 94486 6315

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.

carnstone
partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Pharmaceuticals in the Environment

Ken Sun

EHS&S Lead - Third Party

GSK

AGENDA

Pharmaceuticals in the Environment

Introduction

Risk assessment

PSCI tool

Mitigation strategy & example

Bio

Ken Sun

EHS&S Lead -Third Party, GSK

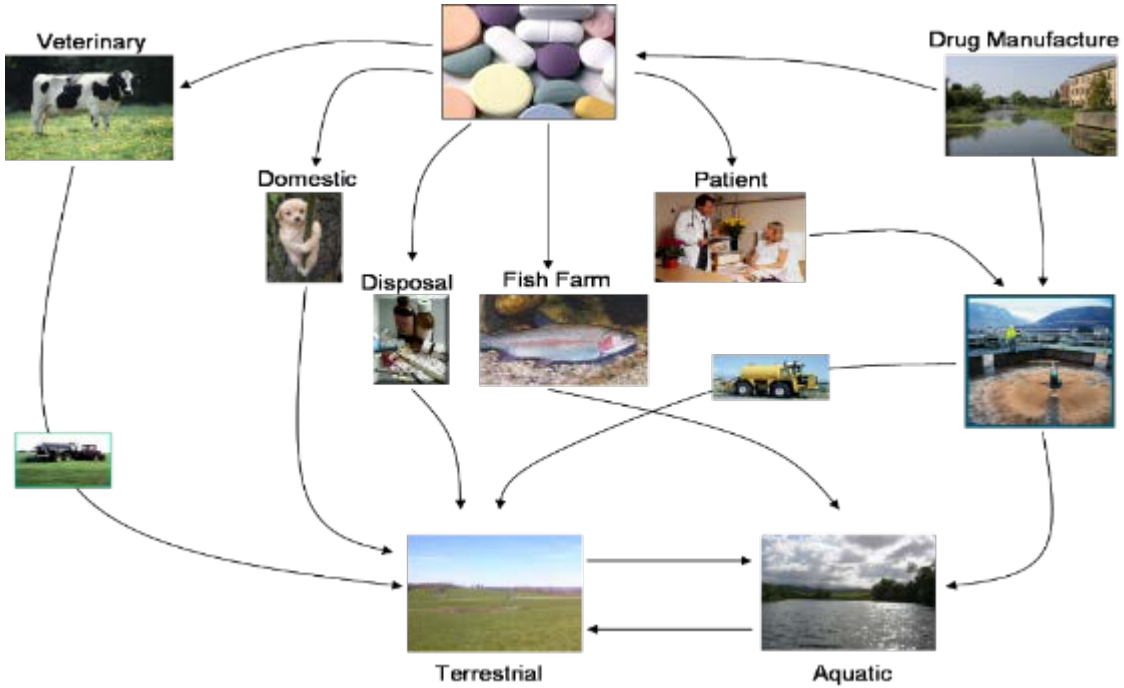
- Over 20 years multi-national pharmaceutical experience, covering whole site life cycle, from Green field site location selection & construction to site transition/close.
- Experienced for various roles, including mechanical engineer, Production Supervisor, Industry Facilitator, Project Regulatory Manager, Site Risk Champion, Site Transition Manager, Production Operation manager and Value Stream Head, EHS Manager and China Region EHS Lead
- Certified Safety Engineer. Mechanical & Electrical Bachelor degree. Quality management Master degree. Six-Sigma blackbelt

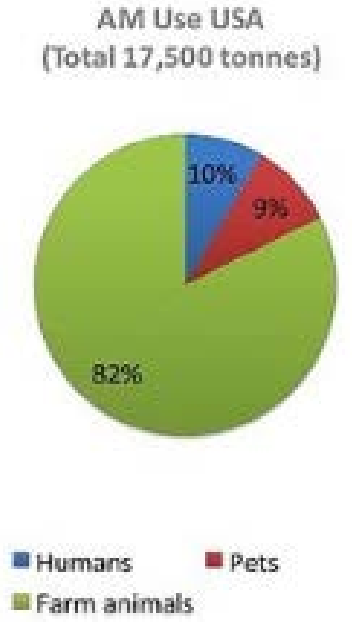
Contact information

Email; ken.d.sun@gsk.com
Mobile +86 13958096331

PIE Introduction

Sources of Pharmaceuticals in Surface Waters



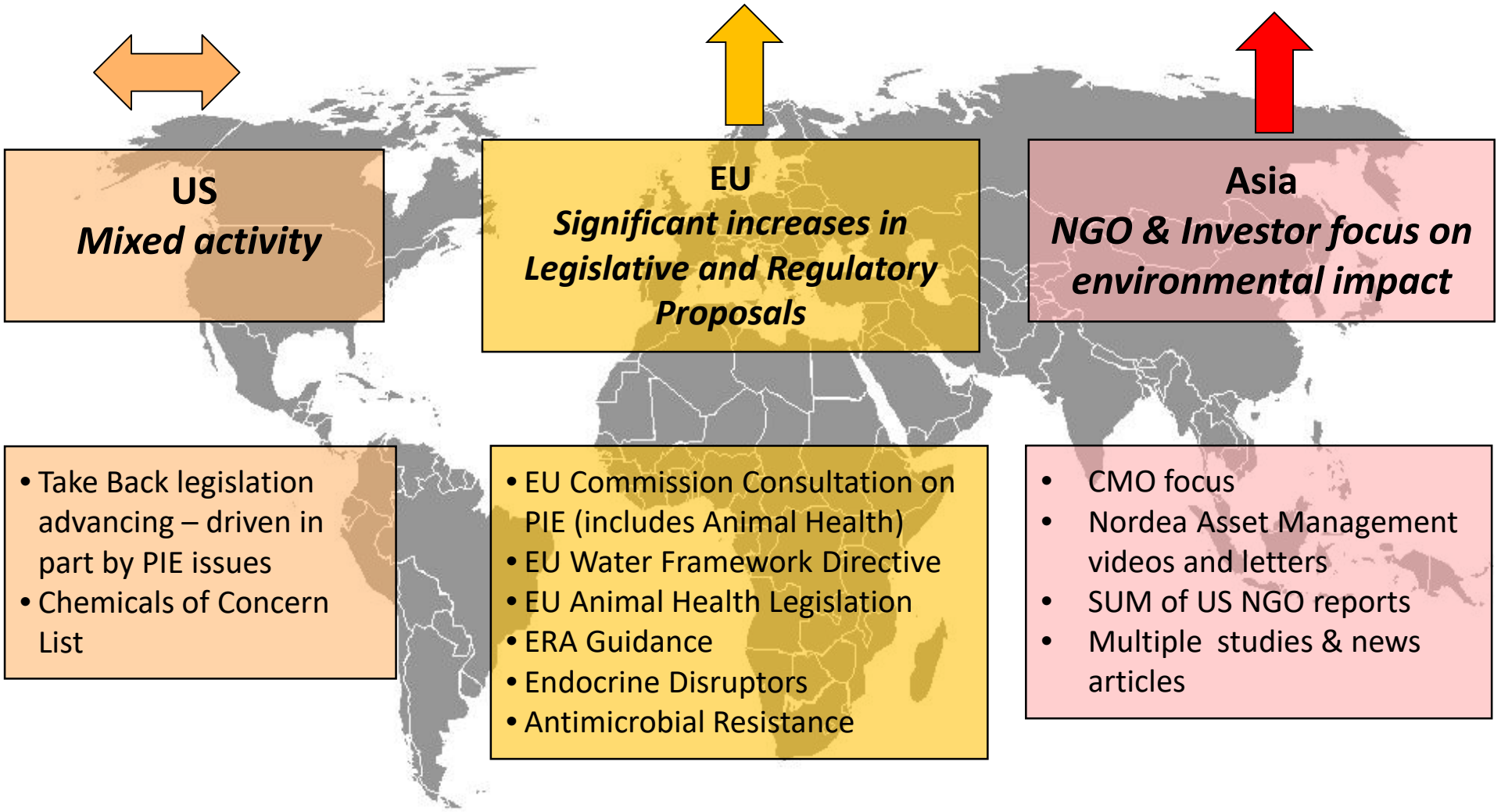


- Largest use of antibiotics globally is in animal production and human health. This is the largest source (98%) of antibiotics in the environment

- Manufacturing emissions to the environment are estimated <2% by mass.

HOWEVER this is a high profile area for pressure groups, media, NGOs etc

Global Perspective



US
Mixed activity

- Take Back legislation advancing – driven in part by PIE issues
- Chemicals of Concern List

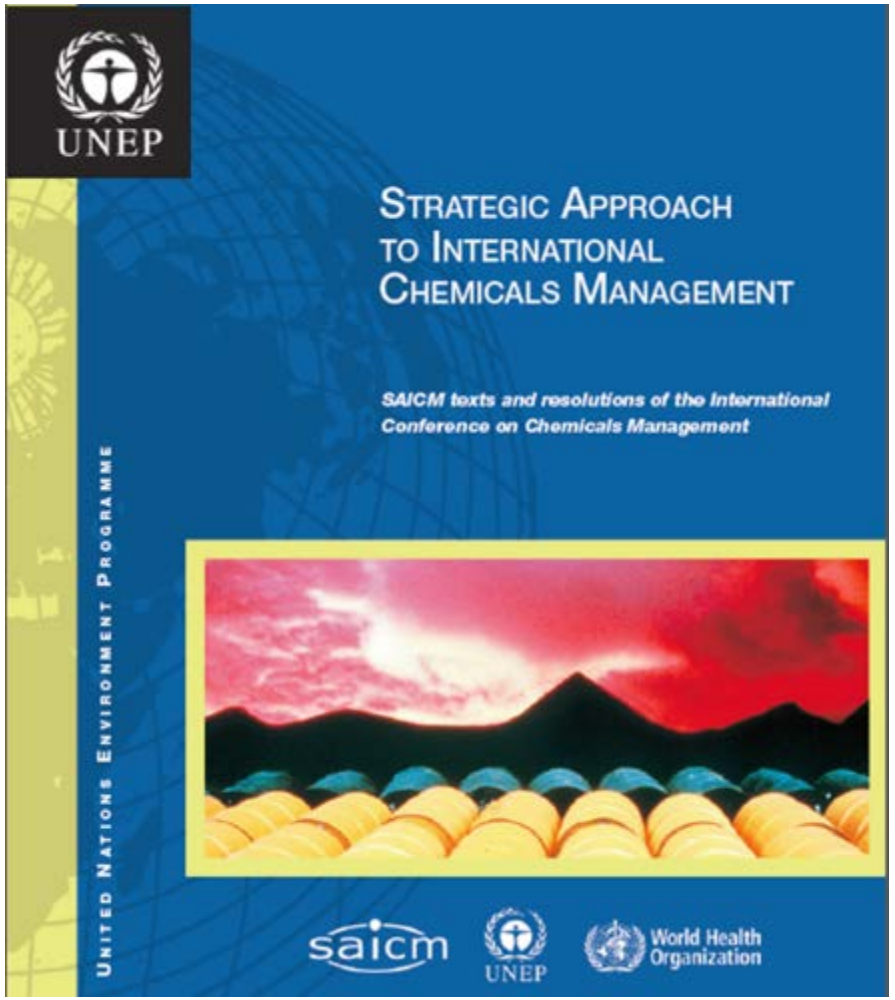
EU
Significant increases in Legislative and Regulatory Proposals

- EU Commission Consultation on PIE (includes Animal Health)
- EU Water Framework Directive
- EU Animal Health Legislation
- ERA Guidance
- Endocrine Disruptors
- Antimicrobial Resistance

Asia
NGO & Investor focus on environmental impact

- CMO focus
- Nordea Asset Management videos and letters
- SUM of US NGO reports
- Multiple studies & news articles

Stakeholders voicing their concerns



At its first session, held in Dubai, United Arab Emirates, from 4 to 6 February 2006, the International Conference on Chemicals Management adopted the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy. The Conference also recommended the use and further development of the Global Plan of Action as a working tool and guidance document. Together these three documents constitute the Strategic Approach to International Chemicals Management.

Emerging Policy Issues:

- Lead in Paint
- Chemicals in Products
- Endocrine Disrupting Chemicals
- Hazardous substances in electrical and electronic products
- Nanotechnology and manufactured nanomaterials
- Environmentally Persistent Pharmaceutical Products*

*Added October, 2015

Drug Resistance Research

- Harvard Medical School and Technion Institute of Technology demonstrate how bacteria move as they become immune to antibiotics, supported by grants from the NIH and European Health Council*

- Cinematic Approach to Drug Resistance
- **https://www.youtube.com/watch?feature=player_embedded&v=plVk4NVIUh8**

*A Cinematic Approach to Drug Resistance", Harvard Gazette, September 8, 2016

Drug Resistance Research

Global Response on AMR

- WHO Health Assembly 2015
- UK-One Health Report
- UK- O'Neil Report 2016
- UN General Assembly 2016
- International Federation of Pharmaceutical Manufacturer's and Associations 2016-Davos Declaration

Reduce Environmental pollution

ESTABLISH MINIMUM STANDARDS TARGETING THE EMISSION OF MANUFACTURING WASTE CONTAINING APIs

ENCOURAGE THE PHARMACEUTICAL INDUSTRY TO DRIVE HIGHER STANDARDS THROUGHOUT THEIR SUPPLY CHAINS

Review on Antimicrobial Resistance

Tackling drug-resistant infections globally

O'Neill Final Report - 2016

World Health Organization

GLOBAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE

SIGNATORY COMPANIES

Allergan (NYSE: AGN)
AstraZeneca (NYSE: AZN)
Cipla (NSE: CIPLA)
DSM Sinochem Pharmaceuticals (Euronext: DSM)
F. Hoffman-La Roche Ltd., Switzerland (VTX: ROG)
GSK (NYSE: GSK)
Johnson & Johnson (NYSE: JNJ)
Merck & Co., Inc., Kenilworth, New Jersey, U.S.A. (NYSE: MRK)
Novartis (NYSE: NVS)
Pfizer (NYSE: PFE)
Sanofi (EURONEXT:SAN, NYSE: SNY)
Shionogi & Co., Ltd. (TYO: 4507)
Wockhardt (NSE: WOCKPHARMA)

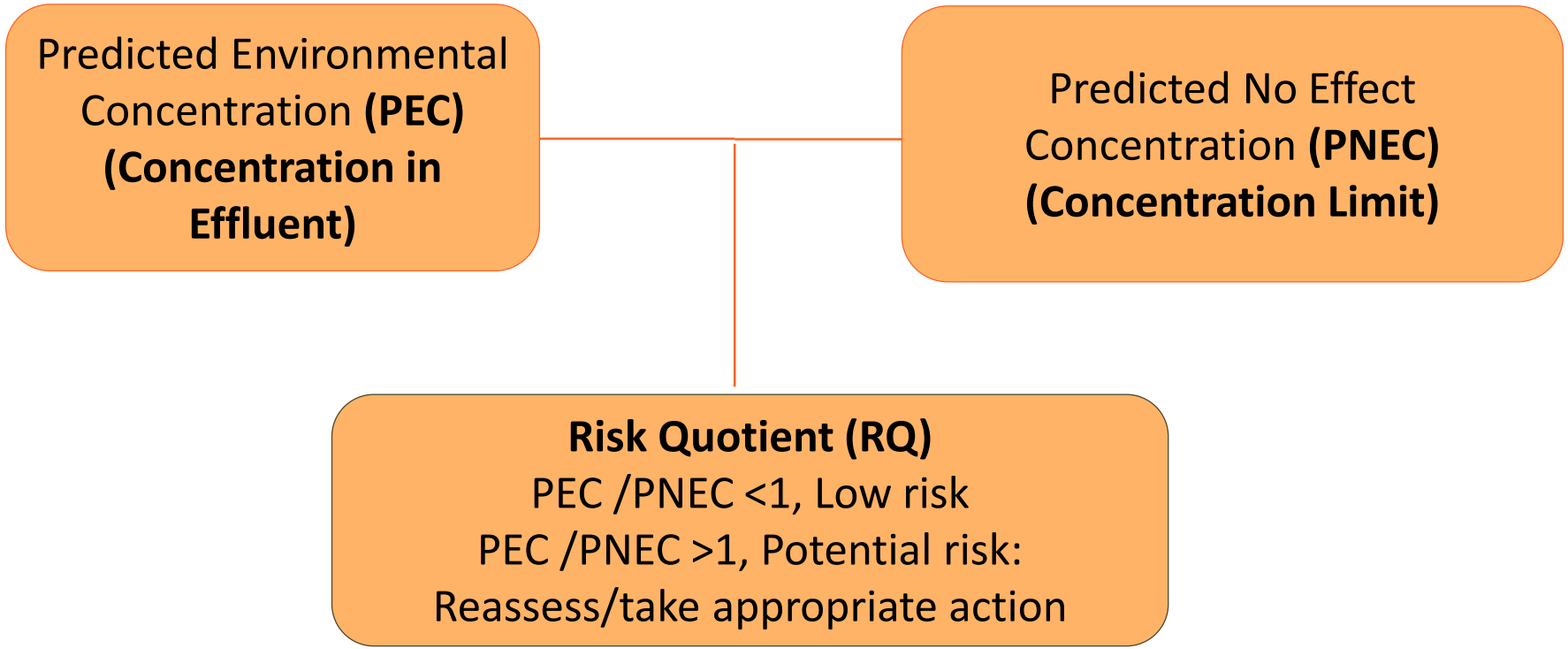
PIE Risk assessment

Pre Assessment Information

- What information can you gather in advance:
  - What APIs do they handle
  - Safety Data Sheets (SDS)-Example
  - Is there any guidance available for the limit to water (PNEC)
  - Where is the nearest water body-receiving water
  - Flow rates of receiving water bodies

API Environmental Risk Assessment

- Good management practices may not eliminate all API released to water
- Site responsibility is to know whether the amount released could have a potential impact on the environment
- Environmental Risk Assessment requires data and professional judgment



PEC Data Collection & Analysis

- Review batch records to determine API losses
- Estimate API losses (account for batch and cleaning cycles)
- Estimate treatment plant removal efficiency using the API chemical and physical properties, literature, or assume 0%
- Get wastewater and receiving water flows

Examples

On-Site

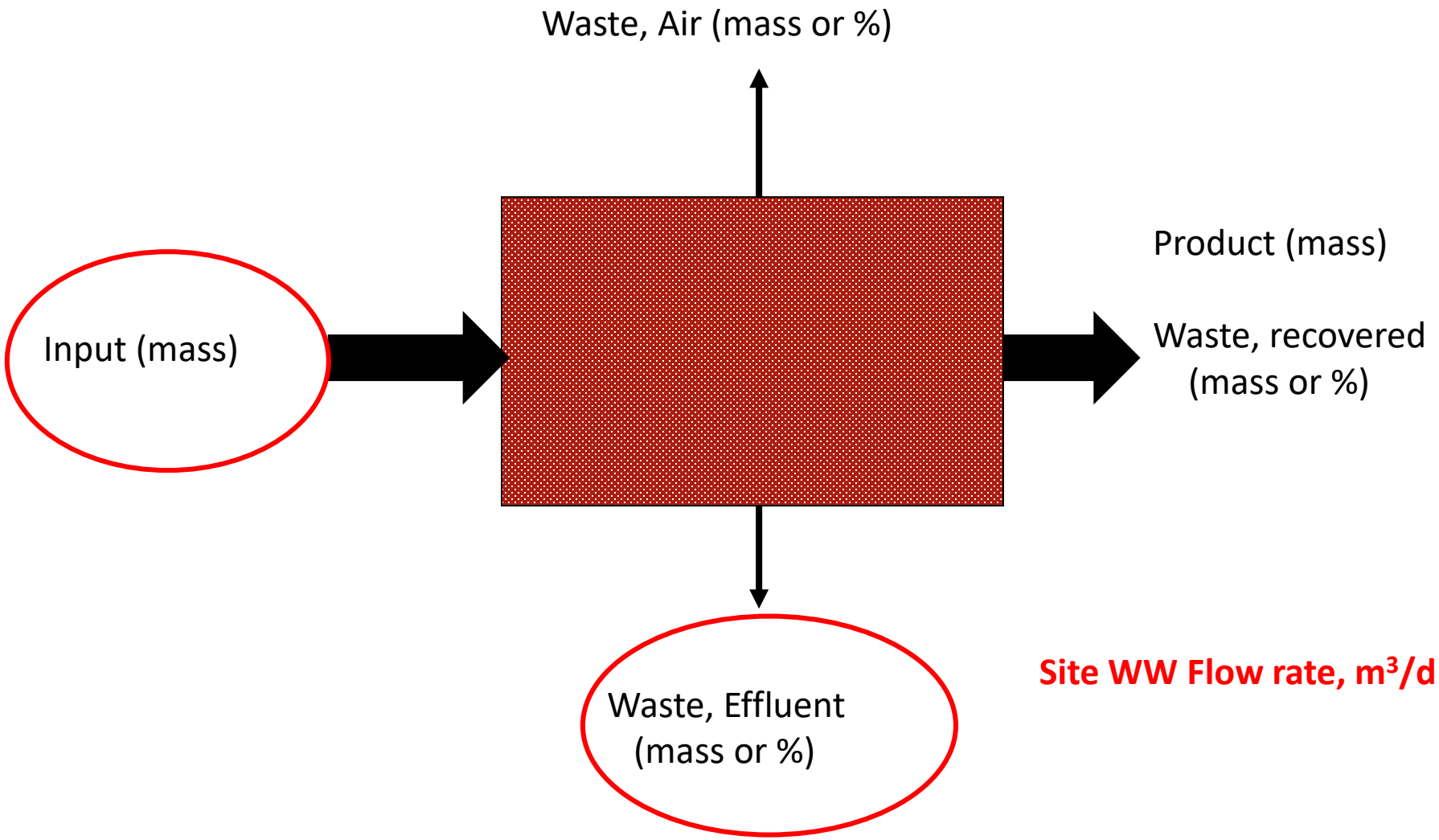
batch records	wastewater POG[1]
product yield	wastewater flows
batch/year	WWTP unit ops
cleaning cycles	API analyses[2]

Off-Site

POTW flow
POTW unit ops
receiving water flow

1 POG = Point of Generation
2 API analysis of wastewater, solvent waste, solid waste, etc.

API Mass Balance



API Mass Balance Loss - Example

Using mass balance values

1. Must be representative of the process
2. Consider control chart for calculated losses

Date of Manufacture	Item Code	# of vials filled	Amount of API in vials (kg), (calculated)	Amount of API not in vials (kg), (calculated)	Daily sum of amount not in vials
04-JAN-2011 14:13:03	000000000000	15767	18.037448	0.095552	0.216272
04-JAN-2011 14:18:08	000000000000	15745	18.01228	0.12072	
11-JAN-2011 14:12:12	000000000000	15740	18.00656	0.12644	0.332416
11-JAN-2011 14:09:54	000000000000	15765	18.03516	0.09784	
11-JAN-2011 14:24:55	000000000000	15756	18.024864	0.108136	
18-JAN-2011 10:52:49	000000000000	15723	17.987112	0.145888	0.283768
18-JAN-2011 10:46:36	000000000000	15730	17.99512	0.13788	
25-JAN-2011 16:24:28	000000000000	15534	17.770896	0.362104	0.491976
25-JAN-2011 16:22:15	000000000000	15737	18.003128	0.129872	
	Avg Number of vials filled	Avg Amount of API in vials (kg)	Avg Amount of API not in vials (kg)	Worst Case API in Wastewater (kg)	Limit API in Wastewater (kg/day)
	15721.89	17.99	0.15	0.29	0.65
				Cumulative Daily Worst Case (kg)	
				0.49	

Calculating the Risk Quotient

$$\text{Risk Quotient (RQ)} = \frac{\text{PEC}}{\text{PNEC}} = \text{<1 or >1?}$$

Risk Quotient		
Less than (<) 1	Indicates that the expected concentration is lower than the concentration indicating low/no potential environmental risk	
Greater than (>) 1	Indicates that the expected concentration exceeds the no-effect concentration indicating the potential for risk	

Permits

- Most discharge permits will address established parameters, e.g., control of pH, biological oxygen demand, chemical oxygen demand, etc.
- Some discharge permits include periodic general toxicity testing, i.e., whole effluent toxicity
- Most discharge permits will NOT directly address active pharmaceutical ingredients (APIs) but DO include a 'general duty' clause, i.e., "No toxics in toxic amounts".

Guidance

SETAC PRESS

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Hazard/Risk Assessment

A RISK-BASED APPROACH TO MANAGING ACTIVE PHARMACEUTICAL INGREDIENTS IN MANUFACTURING EFFLUENT

DANIEL J. CALDWELL,*† BIRGIT MERTENS,‡ KELLY KAPPLER,§ THOMAS SENAC,‖ ROMAIN JOURNEL,‖ PETER WILSON,# ROGER D. MEYERHOFF,†† NEIL J. PARKE,†† FRANK MASTROCCO,‡‡ BENGT MATTSON,§§ RICHARD MURRAY-SMITH,‖‖ DAVID G. DOLAN,## JÖRG OLIVER STRAUB,††† MICHAEL WIEDEMANN,‡‡‡ ANDREAS HARTMANN,§§§ and DOUGLAS S. FINAN,###

†Johnson & Johnson, New Brunswick, NJ, USA
‡Janssen Pharmaceutical Companies of Johnson & Johnson, Beerse, Belgium
§Johnson & Johnson Consumer Group of Companies, Skillman, New Jersey, USA
‖Sanofi, Paris, France
#Sanofi Bridgewater, New Jersey, USA
††Eli Lilly, Indianapolis, Indiana, USA
‡‡Pfizer, New York, New York, USA
§§LIF, Swedish Association of the Pharmaceutical Industry, Stockholm, Sweden

Caldwell et al Paper

PNEC Resources

Webinar series:

Part 1

Part 2

Part 3

Part 4

PSCI tool

Audit Overview | Wastewater question

39	Indicate which methods are used to manage process wastewater from this facility.	Check all that apply to treatment and disposal of wastewater: • Pretreatment of process water Yes No Please describe method(s) (example – hydrolysis with caustic or heat pre-treatment): • On-site wastewater treatment: Yes No Please describe: Does the facility collect, store, and analyze samples? Wastewater? Yes No Sludge? Yes No • Discharge to an offsite treatment facility: Yes No Please describe off-site treatment method (example - biological treatment followed by activated carbon filter): • Discharge to a settling/retention pond: Yes No Please describe: • Discharge to surface water (e.g., river, lake, ocean): Yes No Please describe: • Collection and transfer to an off-site wastewater management facility/company: Yes No Please describe: • Other, e.g. Zero liquid discharge, wastewater for irrigation, evaporation via cooling tower, incineration; deep well injection: Yes No Please describe: Are environmental impacts of API considered in disposal of: • Wastewater? Yes No • Sludge/biomass? Yes No

Audit Overview | Auditor guidance for wastewater

Are wastewater discharges or practices in line with the permits issued by local agencies?

Describe how wastewater is managed (dedicated and sufficient staff, documented procedures, condition of facility). If an off-site wastewater treatment plant is used, describe selection/oversight by supplier in Question 50.

Assure that samples are collected, stored, and analyzed with results reported in accordance with local regulatory requirements.

Describe the wastewater treatment flow and treatment methods/treatment technologies used and surface water that receives wastewater effluent from the site. (Include all on-site plant discharges and any off-site treatment plant and the waterbody that receives the discharge).

Describe condition of monitoring equipment and effectiveness of controls. Water/wastewater monitoring devices and treatment systems are in good operating condition and appropriately maintained (e.g., in accordance with manufacturer's recommendations).

Describe best practices used by the site (treatment, capture, and containment or practices especially for highly potent API) to prevent or reduce API discharges in wastewater. Are these controls manually operated or proceduralized?

Describe how APIs are quantified in wastewater: mass balance, sampling with sufficiently sensitive method, etc. Describe risk assessment process and oversight such as procedure available, all APIs accounted for, toxicological info available, competent professional provides oversight, recommendations are incorporated, etc.

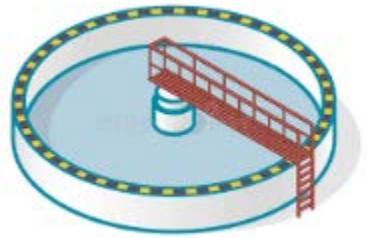
Review qualification for persons managing API emissions (i.e. knowledge of regulatory requirements and quantification of APIs in treated waste water)

PIE mitigation Strategy & Examples

Strategy

Type of mitigation strategy depends on local specs :

- Waste water flow on site/WWTP configutation
- Type & number of 'problematic' APIs



At source mitigation

- Targeted waste stream with highest API load
- Single API mitigation
- GMP consideration (inside plant)
- $

Pre-treatment

- Treat multiple waste streams, multiple API mitigation
- Avoid full flow of Waste Water treatment
- No GMP (outside plant)
- $$

End of pipe treatment

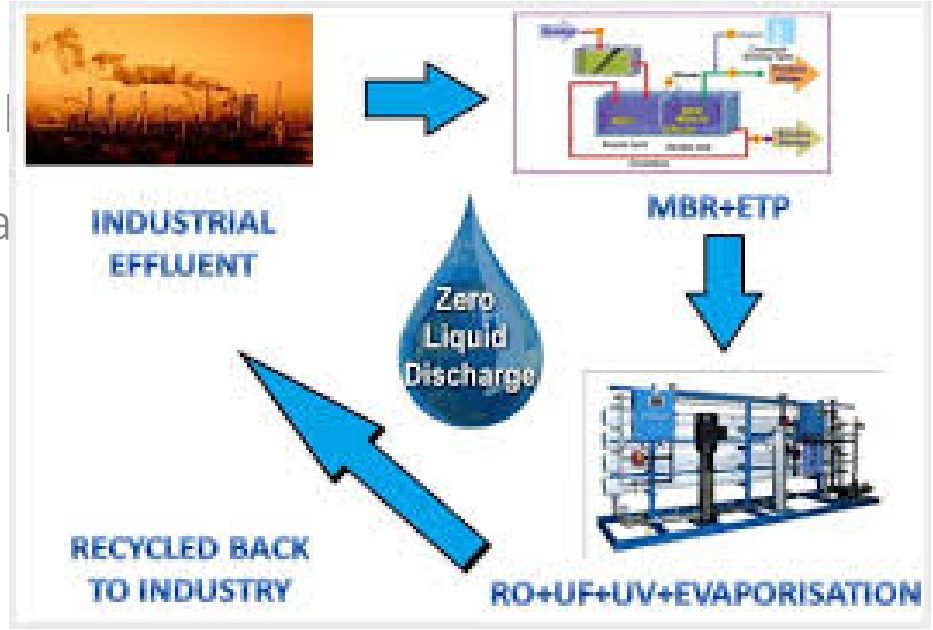
- 'Polishing' step after WWTP
- 'All inclusive'
- No GMP (outside plant)
- $$$

EXAMPLE
Zero Liquid Discharge

- Zero Discharge-Reuse of treated effluent

- Check the mass balance volumes-
  - e.g. is the daily amount of effluent the same as the input to the cooling towers
  - is the volume far greater than irrigation use

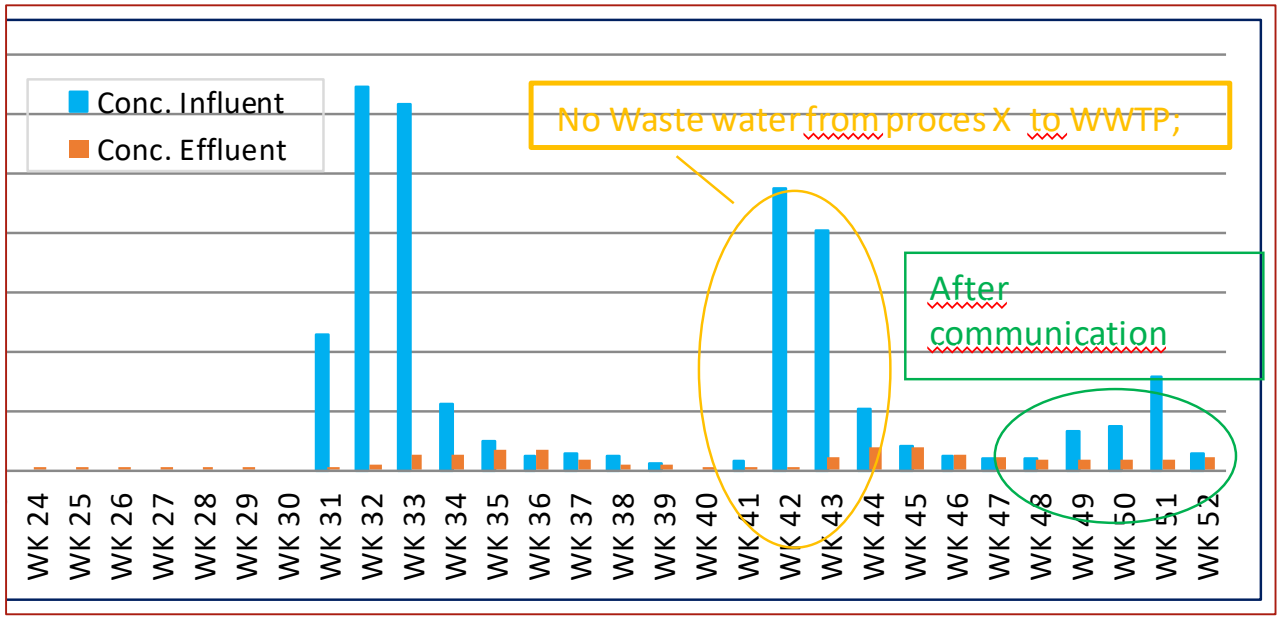
- ZLD Doesn't always equal 'zero risk'. Ground dispersion may resul in:
  - Dermal/inhalation exposure to applicator and/or recreationa users
  - Edible vegetation and/or groundwater users
  - Terrestrial organisms
  - Mist inhalation from opened cooling uses



Zero Liquid Discharge

EXAMPLE
At source mitigation @ API chemcial manufacturing plant

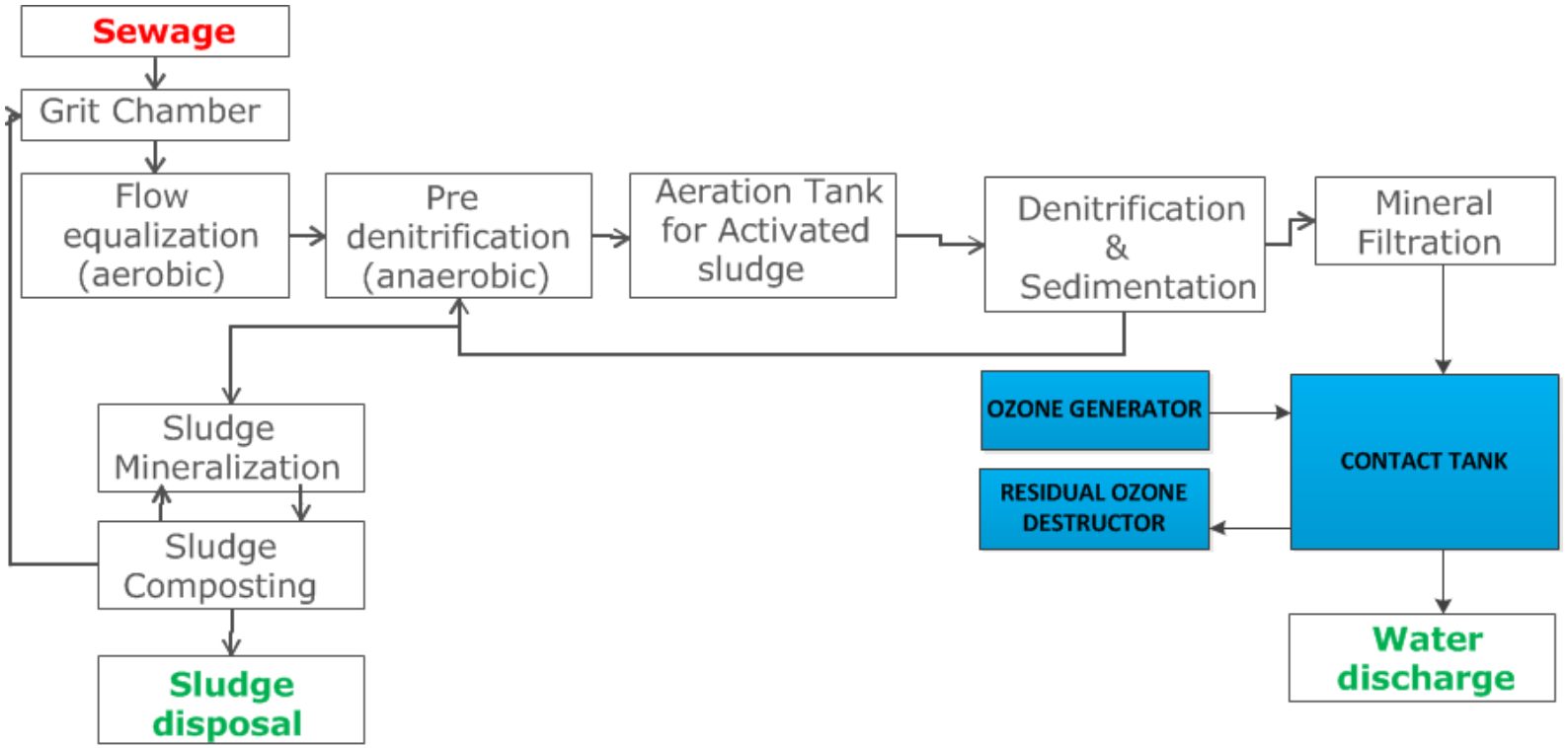
- Discard process wastewater with ‘problematic compound X’ to incineration instead of WWTP
- Investigation with procesmanager → during emptying of centrifuge, some product falls on floor and is flushed to sewer → include good practice in SOP to avoid flushing residual powders in sewer



EXAMPLE
Pre treatment @ API chemcial manufacturing plant : mobile equipment to treat process streams

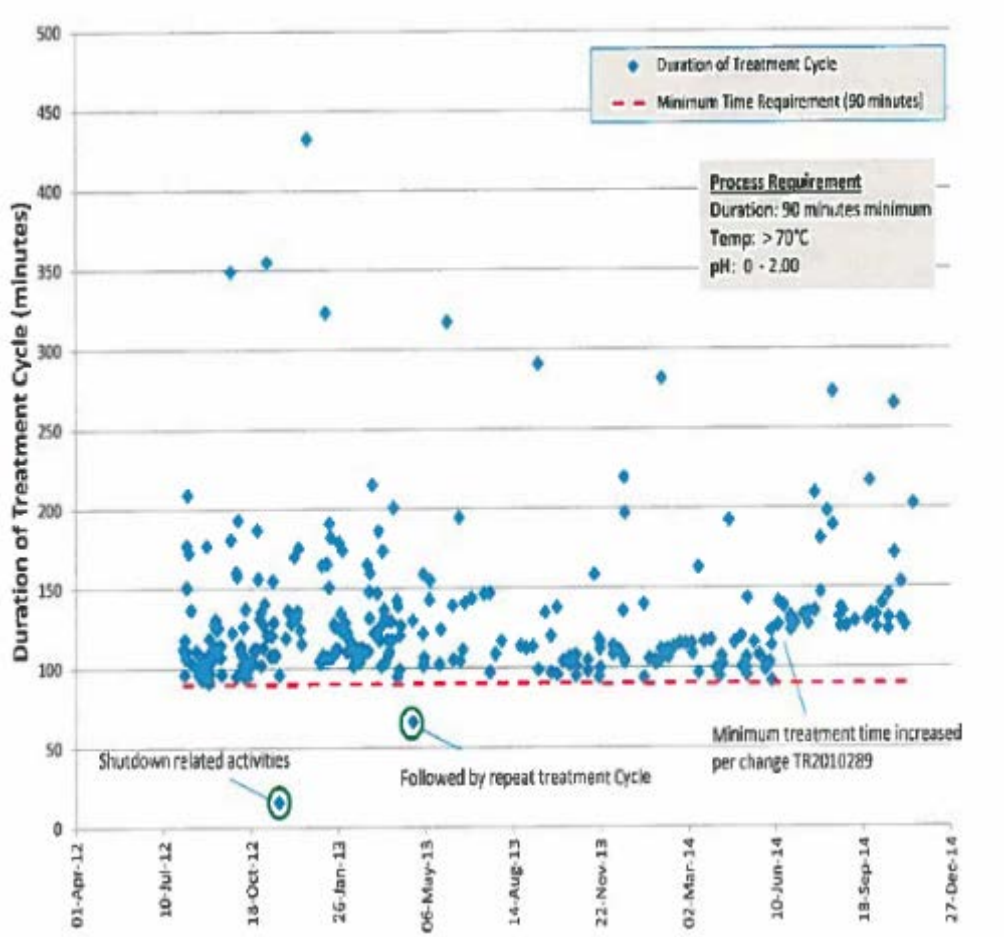
- Remove API from production wastewaters with modular technology (advanced oxidation/adsorption/etc.)
- Pre-treated water can furter be treated in on site water treatment plant
- Equipment can be trucked to other locations (other plants e.g.)

EXAMPLE
End of pipe MBR + ozone treatment @ fill&finish Pharma plant



EXAMPLE
On-site Treatment Removal Performance of API

- Batch wastewater Fill/Finish API collection and treatment system
- Performance testing of acid plus high temperature treatment showed 95% API destruction
- Process requirements
  - Temperature >70°C
  - pH 0 – 2.00 s.u.
  - ≥ 90 minutes

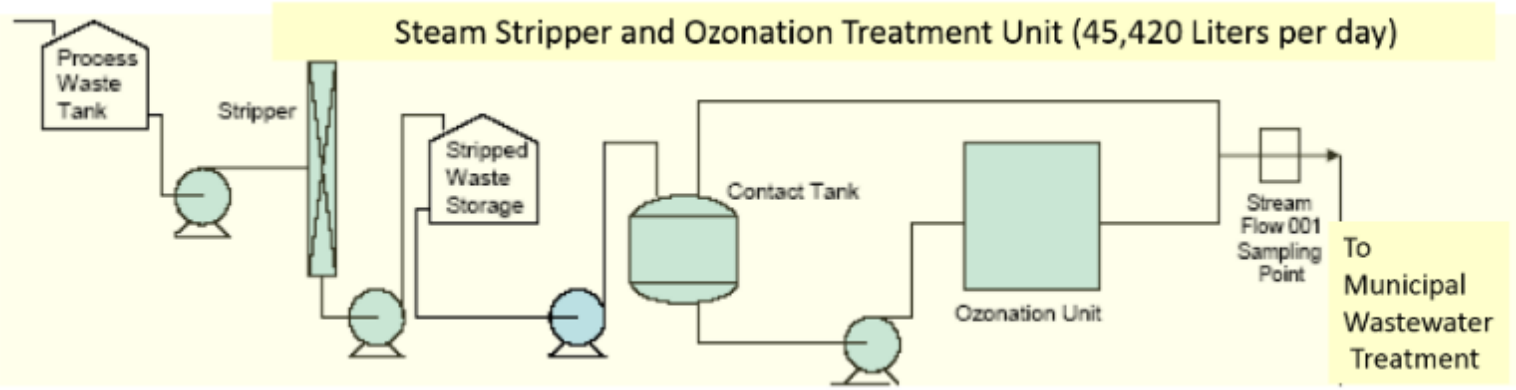


EXAMPLE Audit Questions to Consider:

1. Is appropriate staffing provided to manage and implement programs to control emissions of active ingredients?
2. What are the business area's written qualifications for persons performing and reviewing environmental calculations.
3. How were the process requirements for temperature plus time and pH determined? How does the site ensure that the wastewater content has not changed to impact treatability?
4. Is the treatment system manually operated systems
5. Are other physical barriers (plugged floor drains) in place and do all API containing wastewaters go to this treatment system?
6. Are appropriate systems in place to control the loss of active ingredient to wastewater from production (i.e. to ensure we do not have treatment breakthrough)?

EXAMPLE
On-site Treatment and Control of API Discharge

- 2 Bulk chemically synthesized APIs manufactured at this site
  - Product A – All waste streams collected for off-site incineration -system cannot physically discharge to the wastewater sewer system
  - Product B - Batch Wastewater Collection and Treatment System



EXAMPLE Audit Questions/Actions to Consider:

For Product A

1. Field verify that system is not physically connected to the sewer system
2. Verify that wastewater is sent to an incineration system

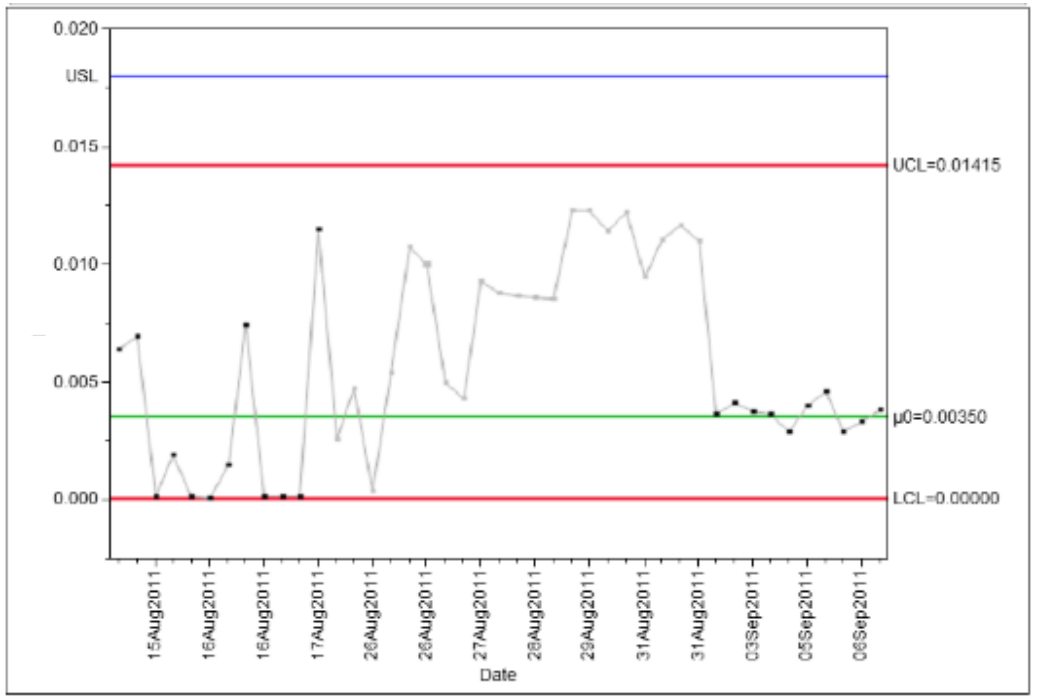
For Product B

1. Review the treatment design studies to verify the assumptions that went into designing the treatment system
2. What are the critical process variables for the ozonation system used to ensure that it routinely achieves API removal credit
3. Verify that the assumptions used for using the municipal treatment system are adequate (i.e. size, treatment provided, location of discharge)

EXAMPLE
On-site Treatment and Control of API Discharge

- Large Scale Batch Ozonation
- Greater than 93% API destruction
- Batch processing

Risk Quotient at site final discharge – PNEC $_{acute}$	Risk Quotient at site final discharge – PNEC $_{chronic}$
< 0.211	<0.762



EXAMPLE Audit Questions/Actions to Consider:

1. What were the PNEC values used in these calculations? Were the PNEC values developed by the site or provided by another source? Check the source and background values behind setting the PNEC values.
2. Is appropriate staffing provided to manage and implement programs to control emissions of active ingredients?
3. What are the business area's written qualifications for persons performing and reviewing environmental calculations and running the treatment system.
4. How were the process requirements for ozonation system (ozone concentration and reaction time) determined? How does the site ensure that the wastewater content is not changed to impact treatability?
5. Is the treatment system manually operated?
6. Are other physical barriers (plugged floor drains) in place and do all API containing wastewaters go to this ?

EXAMPLE
Results of Refined PEC Estimates

CASE EXAMPLE Assumptions:

Maximum API loss rate: 0.5 kg/day API
Municipal discharge flow rate: 10,000 m^3/day
River low flow rate: 20,000 m^3/day
Fraction of river allowed for mixing: 0.5
Drinking water Intake flow: 100,000 m^3/day

PEC at Point of Application	PEC – No Removal	PEC – After On-Site Treatment	PEC – After On-site and Municipal Removal
PEC_{acute}	50 ug/L	2.5 ug/L	1.4 ug/L
$PEC_{chronic}$	25 ug/L	1.25 ug/L	0.7 ug/L
$PEC_{drinking\ water}$	0.02 ug/L	0.001 ug/L	0.0006 ug/L

EXAMPLE Audit Questions/Actions to Consider:

1. What were the PNEC values used in these calculations? Were the NEC values developed by the site or provided by another source? Check the source and background values behind setting the PNEC values.
2. Is appropriate staffing provided to manage and implement programs to control emissions of active ingredients?
3. What are the business area's written qualifications for persons performing and reviewing environmental calculations.
4. How were the process requirements for temperature plus time and pH determined? How does the site ensure that the wastewater content is not changed to impact treatability?
5. Is the treatment system a manually operated system?
6. Are other physical barriers (plugged floor drains) in place and do all API containing wastewaters go to this ?

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+55 (11) 94486 6315

PSCI

@PSCInitiative

For more information about the PSCI please contact:

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

info@pscinitiative.org

+55 (11) 94486 6315

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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