## 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<br>(Bayer) |



# **PSCI Auditor Training 2019**

# **Environmental Protection**

Barry Bai 白大明 HSE Manager, External Manufacturing China ELANCO



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





- **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





Pollution **Guardian Environment** Network

Apple wakes up to Chinese pollution concerns

000-6 G Xie Xisoping for Original Dialogue, part of the Guardian Environment Network: Tuesday 4 October 2011 1016 EDT



Chine MCC and Chinese campargers are defined only dynamic CHI, administration of the company's capit drive stock can achieve the Process Proceeds. Structure Medicine 370, 1725

In the face of sustained pressure from Chinese green groups. Apple has finally broken its abance on pollution problems in its supply chain, for the first time

7

#### Auditor Insights | Background Information Review



8

#### 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





### 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

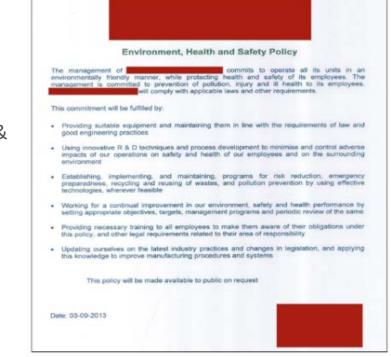
#### Audit Questions Summary – Environmental protection

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



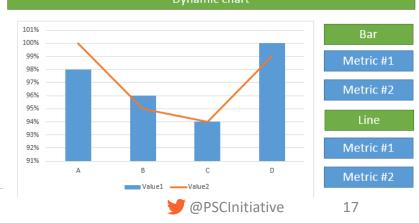
| Gen | General   |   |  |
|-----|---|---|--|
| 31  | Does the facility have written<br>environmental policy, procedures, and<br>practices? | Policy: Yes No<br>Procedure: Yes No<br>Comments:<br>Please provide a copy of the policy and a list of procedure titles. |  |

- 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?



| 32 | <ul> <li>environmental objectives or goals for performance improvement, including metrics and targets?</li> <li>If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years.:</li> <li>Do tracking and reduction programs exist for the following impacts:</li> <li>Energy consumption:</li> <li>Water consumption:</li> <li>Amount of hazardous waste:</li> </ul> |   |  |
|----|---|---|--|
|    |   | Amount of non-hazardous waste:<br>Greenhouse gas emissions:   | Operations Dashboard   |
|    |   | Does the facility publicly report data?<br>Yes No Program description:<br>If yes, where can the information be found: | ilter         Plant Multi Select Filter           lected Date         Previous Day         Goal         Met Goal?         MTD         Previous Year MTD           91%         99%         96%         -5%         93%         90%           100%         97%         98%         2%         97%         95%           90%         92%         97%         -7%         97%         100% |
|    |   | Metric #4   | 1055 1152 1158 🔺 913 1005 1186   |

- 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



\$18,319 🔺 \$19,102

\$15,439

\$19,317

\$18.162

Metric #5

\$19,735

| <br>33 | If the site operates in a water scarce                                   | Yes No NA   |  |
|--------|--|---|--|
|        | region, has the facility developed a long-term strategy for future water | Please explain:   |  |
|        | sourcing and management?   | Is the long-term continuity for future water sourcing and management already covered in the site-based Business Continuity Management plan? |  |
|        |  | Yes No NA<br>Please explain:  |  |
|        |  | Does the facility have an authorisation/permit for water intake from  |  |
|        |  | groundwater, river or a public system? Yes No NA<br>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?

<sup>[1]</sup> 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, <a href="http://www.fao.org/nr/water/topics\_scarcity.html">http://www.fao.org/nr/water/topics\_scarcity.html</a>)



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



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



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



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.

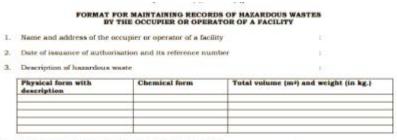
List any vendors or relevant authorities for disposal methods or records that were reviewed.

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



4. Description of storage and treatment of hazardous waste

| Date | Method of storage of hazardous<br>wastes | Date | Method of treatment of hazardous wastes |
|------|--|------|---|
|      |  | -    |   |
|      |  | -    |   |

#### Schedule I (See rules 3 (1))

| S.No. | Processes  | Hazardous Waste *   |
|-------|--|---|
| 20.   | Production or industrial use of<br>synthetic dyes, dye-intermediates<br>and pigments   | 20.1 Process waste sludge/residues containing acid or other<br>toxic metals or organic complexes<br>20.2 Dust from air filtration system  |
| 27.   | Production of organo-silicone<br>Compounda   | 27.1 process residues   |
| 28.   | Production/formulation of<br>drugs/pharmaceucicals &<br>health care product  | 20.1 Process Residues and wastes     20.2 Spens catalysel spent catabas     20.3 Off specification products     20.4 Date-expired, discarded and off-specification     drags/medicines     20.5 Spens organic solvents  |
| 33.   | Disposal of barrels containers used<br>for handling of hazardous wastes<br>chemicals   | <ul> <li>33.1 Chemical-containing residue arising from<br/>decontamination.</li> <li>33.2 Blodge from treatment of waste water arising out of<br/>cleaning/disposal of barrels/containers</li> <li>33.3 Discarded containers/barrels/liners contaminated<br/>with hazardous wastes/chemicals</li> </ul> |
| 34,   | Purification and treatment of<br>exhaust air, water & waste water<br>from the processes in this achedule<br>and common industrial effluent<br>treatment<br>plants (CETP's) | 34.1     Flore gass cleaning residue       34.2     Spenti ion exchange residue       34.3     Chemical sludge from waste water treatment       34.4     Oi and grease skinming residues       34.5     Chromium sludge from cooling water  |
| 35.   | Partification process for organic<br>compounds/solvents  | 35.1 Filters and filter material which have organic liquids in<br>them, e.g. miseral oil, synthetic oil and organic<br>chlorine compounds<br>35.2 Speni catalysi<br>35.3 Speni catalysi   |
| 36.   | Haundous want treatment<br>processes, e.g. incineration,<br>distillation, separation and<br>concentration techniques   | <ul> <li>36.1 Shudge from wet scrubbers</li> <li>36.2 Ash from incineration of hasardous waste, flue gas cleaning residues</li> <li>36.3 Spent acid from batteries</li> <li>36.4 Distillation residues from contaminated organic advents</li> </ul>   |

- 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



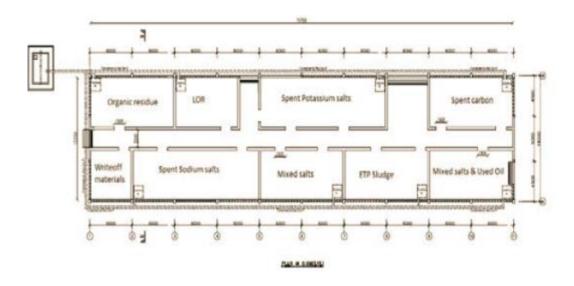




# More on Hazardous Waste Management Storage and Handling

#### **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





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 pretreatment):
- 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



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

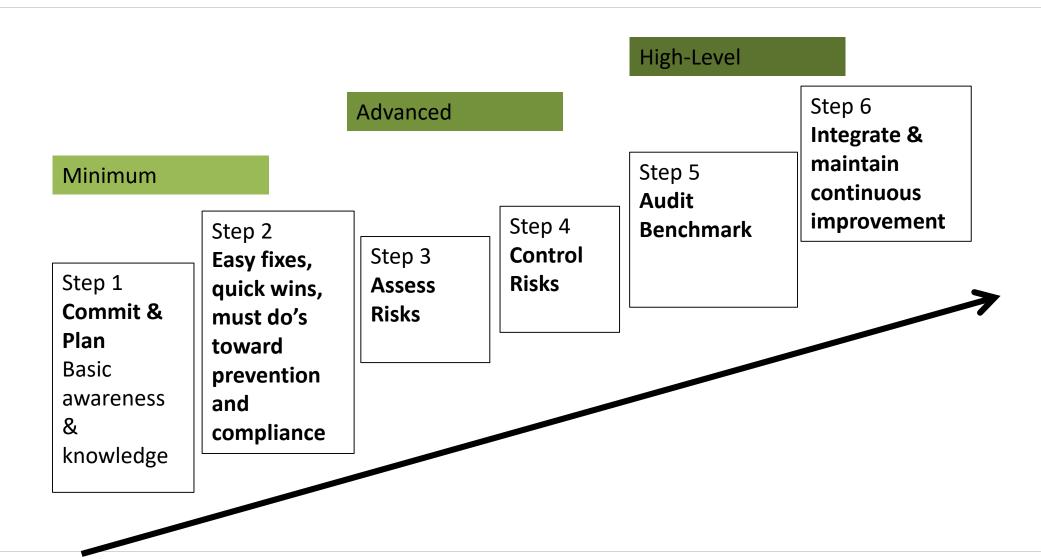
- Treatment volume Evidence of overspill
- Inspect Final Discharge Point
  - Where does it discharge to-standing waterbody, sewer, river, sea
  - Can you go to see the discharge point
  - What does the effluent look/smell like
    - Strong solvent odour
    - Visible contamination
- Permitted Volumes 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







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

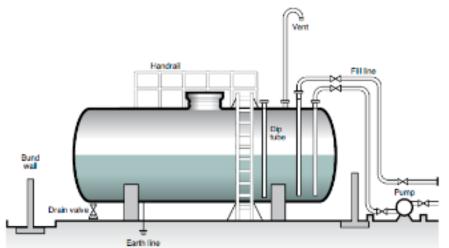
Are third-party external labs approved for carrying out the tests?



#### 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







| 41 | Has the facility developed and implemented a hazardous chemicals (including APIs)   | Yes No   |
|----|---|--|
|    | 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 | Please explain and list site hazardous substances: |
|    | for production, maintenance, utilities, and laboratory purposes?  |  |



| 10 |   |   |  |
|----|---|---|--|
| 42 | Has the facility established good storm | Yes No  |  |
|    | water management practices?             | 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?



#### 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

44

Does the facility or immediate surroundings external to the site have any known soil, surface water or groundwater contamination?

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?

Yes No



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

## 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







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



### 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



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?



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.

Quantity?

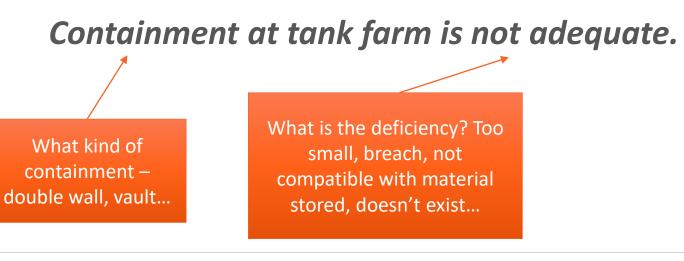
On concrete pad, on soil, etc? Approximately 40 empty 55 gallon metal drums (previously containing hazardous chemicals) were stored on loading dock of Building 16 with no protection from the elements.



### 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**



### How would you improve this finding?

#### Instructions

- 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.

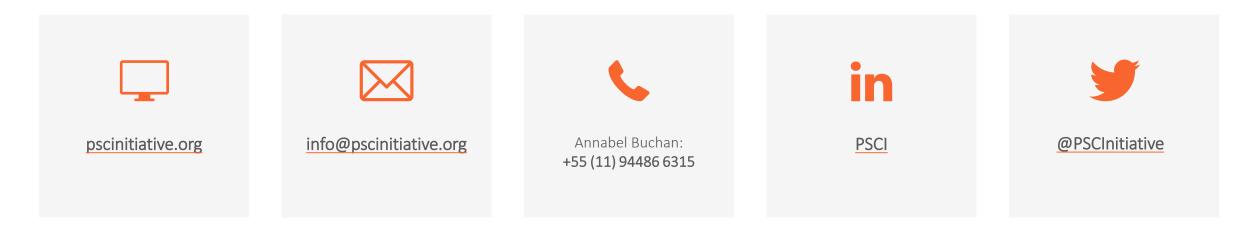
Furthermore other trash including other glass pieces, plastic boxes as well as cleaning equipment was found nearby these drums.







## CONTACT



#### 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.

