Austrian MJV on Safety Performance Indicators
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We are the leader in serving science

Industry-leading technologies to solve a broad range of complex analytical challenges

- Chromatography and Mass Spectrometry
- Chemical Analysis Instruments
- Electron Microscopy
- Environmental and Process Instruments
- Clinical Assays
- Immunodiagnostics
- Microbiology
- Anatomical Pathology
- Transplant Diagnostics
- Healthcare Market Channel

Extensive portfolio to accelerate life sciences research, discovery and diagnosis

- Biosciences
- Genetic Sciences
- Bioproduction

Leading positions in niche diagnostics segments

Industry-leading offering to increase laboratory productivity

Analytical Instruments

400,000 customers worldwide

Life Sciences Solutions

- Research and Safety Market Channels
- Laboratory Products
- Pharma Services
  - Clinical Trials
  - Small Molecule (API)
  - Biologics
  - Drug Products

Laboratory Products and Services

Specialty Diagnostics

ThermoFisher Scientific
Global Small Molecule API Footprint

Greenville, USA
- Phase I, II & III
- Commercial supply
- Analytical development
- Up to Cat 4

Florence (West), USA
- Phase I & II
- Analytical development
- Up to Cat 3a

Florence (East), USA
- Phase I, II & III
- Commercial supply
- Analytical development
- Up to Cat 3B

Linz, Austria
- Phase I, II & III
- Commercial supply
- Analytical development
- Up to Cat 3a

Regensburg, Germany
- Phase I & II
- Analytical development
- Up to Cat 3a
In Short

- Over €200m revenue

- Key competences in chemical process engineering and large-scale chemical production, operating under strict quality regime (cGMP, ISO)

- Our business segment:
  custom manufacturing of pharma-chemicals – API, intermediates, etc

- Approximately 750 employees incl. temps, thereof approx. 100 in R&D
Process Safety KPIs
We must implement safe processes in production to avoid incidents (health & safety, environment, financial damage, reputation, …..)
Process Safety KPIs

How do we measure our performance?

Safety: OSHA reportable incidents
Process Safety: LOPC (Loss of primary containment)
PSI (Process Safety Incident)
Process Safety KPIs

LOPC classification (reporting to corporate level)

> 1 kg (H300, H310, H330, H350, H360, H370, H440)
> 50 kg (substances with a GHS classification, but not in group 1)
> 500 kg (all other substances)
Process Safety KPIs

A LOPC is an unintended release of material

There are many potential reasons for such releases
  - fixing of flanges, sampling, manual operations, ....
  - overpressure
Process Safety KPIs

A LOPC is a lagging indicator – we are counting the number of events that happened already (easy to count).

This is input for continuous improvement. A requirement of the Safety Management System
Process Safety KPIs

**Leading** activities to prevent LOPCs (leading KPIs)

*fixing of flanges, sampling, manual operations, ....*

Training and education, procedures, checks / documentation on checklists, standardization, contractor management, .......
Process Safety KPIs

**Leading** activities to prevent LOPCs (leading KPIs)

*overpressure*

A liquid is within 2 closed valves and the temperature increases, thermal expansion and some drops may be released at a flange.

Check the position of the valves (manual or technical)
Process Safety KPIs

**Leading** activities to prevent LOPCs (leading KPIs)

*overpressure*

A reactor is connected to nitrogen for blanketing. The inlet valve is not working properly and the pressure inside the reactor is increasing, the safety relieve valve opens and N₂ is released.

Maintenance program
Process Safety KPIs

**Leading** activities to prevent LOPCs (leading KPIs)

*overpressure*

Uncontrolled release of energy by a chemical reaction
Seveso, Italien (10.07.1976, Icmesa): Production of 2,4,5-Trichlorphenole
Bhopal, Indien (03.12.1984, Union Carbide)
Process Safety KPIs

**Leading activity:**

Do *Risk Assessments* (and make sure you have trained people and all information available to describe the scenarios in a realistic way !!!)

Mitigation measures: inherently safer design (scale up), SIL, ....
Process Safety KPIs

Leading activities: We need information about
- intended reaction
- unintended reactions (what happens when ……)
Process Safety KPIs

Exothermic reactions
need cooling to remove the energy

WHAT are the consequences if cooling fails ???
Process Safety KPIs

Runaway Reaction

\[ T_{\text{end}} = \text{MTSR} + \Delta T_{\text{ad}} \text{ (Decomposition)} \]

\[ \text{MTSR} = T_{p} \text{ (Process-/Reactiontemperature)} + \Delta T_{\text{ad}} \text{ (Reaction)} \]
Process Safety KPIs

$T_{\text{process}} \rightarrow \text{MTSR} \rightarrow T_{\text{end,decomposition}}$

The increased temperature generates **increased pressure**
solvent starts boiling $\rightarrow$ vapor pressure
decomposition generates byproducts (CO, CO$_2$, H$_2$O, N$_2$, …)
Process Safety KPIs

Cooling failure $\rightarrow$ $TMR_{ad,\text{process}}$ $\rightarrow$ $TMR_{ad,\text{decomposition}}$

How long does it take until the scenario happens
seconds – minutes – hours – days – months

What time is enough to react and prevent the scenario ??
Process Safety KPIs

**Leading activity:**

Implement **Management of Change** (and make sure Risk Assessments are part of your documented MoC procedure)
Process Safety KPIs

Number of LOPCs
Questions & Answers

Thank you ...!