ThermoFisher SCIENTIFIC

Austrian MJV on Safety Performance Indicators

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Patheon
part of Thermo Fisher Scientific

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

Analytical Instruments

Extensive portfolio to accelerate life sciences research, discovery and diagnosis

Life Sciences Solutions

- Biosciences
- Genetic Sciences
- Bioproduction

- Clinical Assays
- Immunodiagnostics
- Microbiology
- Anatomical Pathology
- Transplant Diagnostics
- Healthcare Market Channel

Specialty Diagnostics

Leading positions in niche diagnostics segments

Laboratory Products and Services

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

Industry-leading offering to increase laboratory productivity

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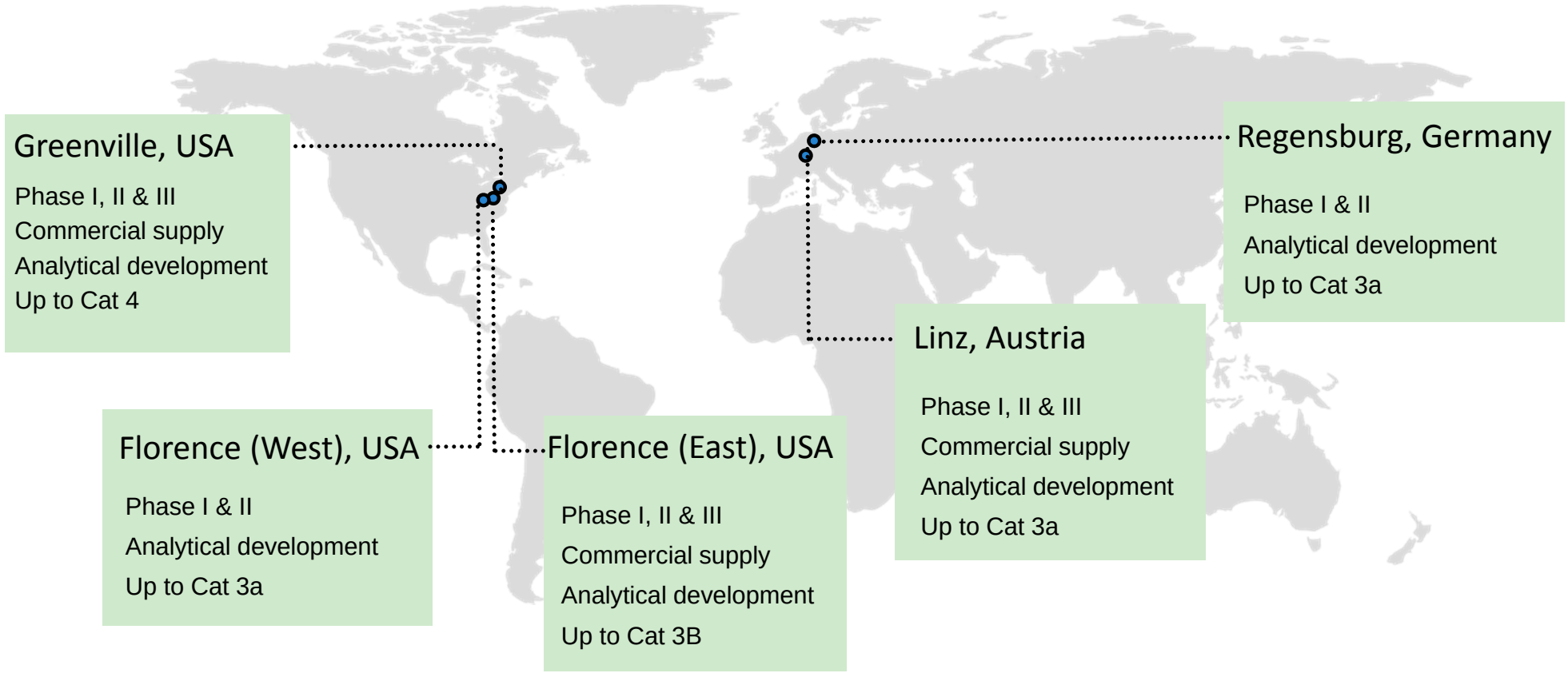
Global Small Molecule API Footprint



Greenville, USA

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

Regensburg, Germany

Phase I & II
Analytical development
Up to Cat 3a

Linz, Austria

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

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

Infrastructure | Site Overview

MPU B700

Quality B8

R&D B70

MPU B52

Pilot MPU B30

High Shelf Storage B55/56

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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

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 performace ?

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 N_2 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

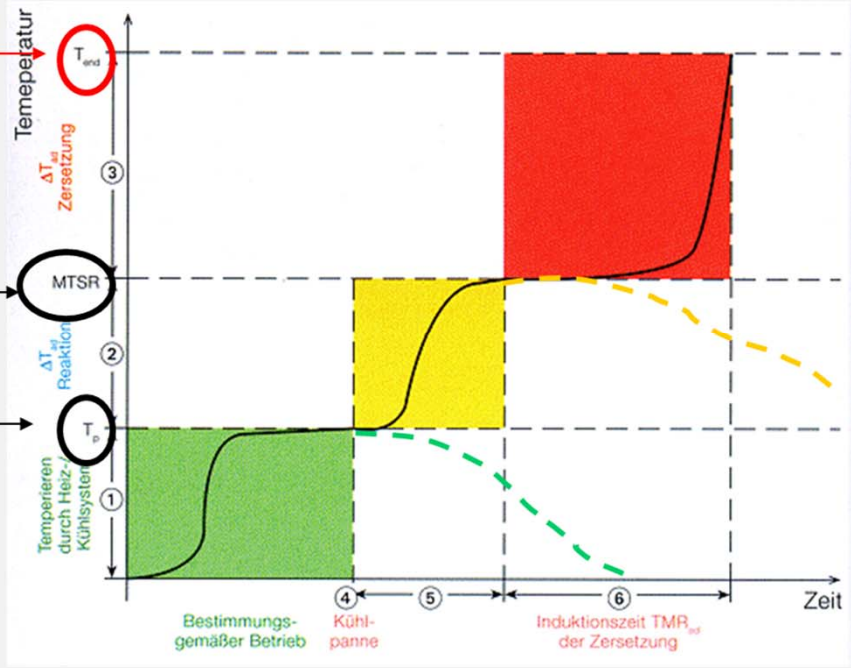
need cooling to remove the energy

WHAT are the consequences if cooling fails ???

Runaway Reaction

T_{end} = MTSR + ΔT_{ad} (Decomposition)

MTSR =
T_p (Proces-/Reactiontemperature)
+ ΔT_{ad} (Reaction)



Process Safety KPIs

$T_{process}$ → MTSR → $T_{end,decomposition}$

The increased temperature generates **increased pressure**

solvent starts boiling → vapor pressure

decomposition generates byproducts (CO, CO_2, H_2O, N_2, …)

Process Safety KPIs

Cooling failure → $TMR_{ad,process}$ → $TMR_{ad,decomposition}$

How long does it take until the scenario happens

seconds – minutes – hours – days – months

What time is enough to react and prevent the scenario ??

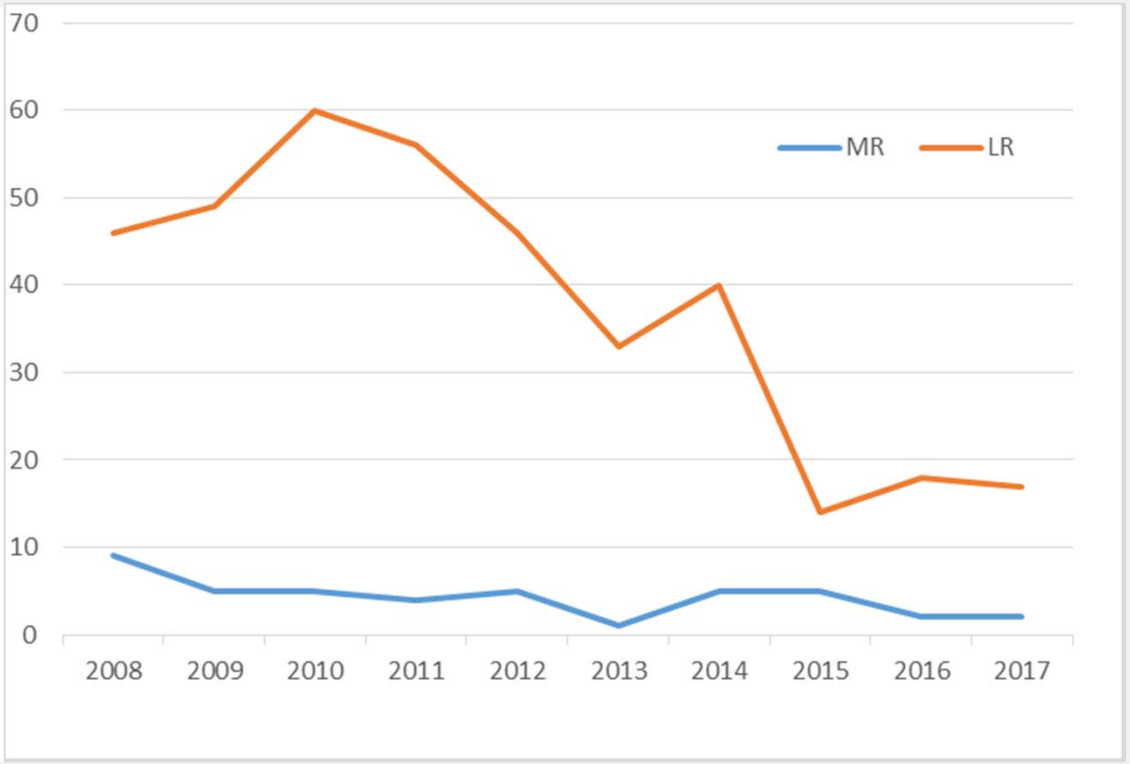
Process Safety KPIs

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

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