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PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

High Risk Work Programs

Serious Injuries or Fatality (SIF) / Red Flags

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Bio

- Chemical Engineer,
  PhD in Heterogeneous Catalysis
- Team Leader at Swissi Process Safety (Safety Lab)
- Global HSE & BC Manager
  Novartis Over The Counter
- Head Global Pharma Project Risk and Process Safety Management
  Novartis Pharma
- Currently : Head HSE & BC Third Party Inspection and Compliance, Novartis

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Introduction

Traditional programs like Process Safety Management only indirectly protect employees health and life.

More people targeted programs are required !

Programs are called :

- High Risk Work Programs
- Prevention of Serious Injuries or Fatality (SIF)

Most of the requirements are legal obligation in Europe / USA

2.Confined space entry

3.Work with hazardous energies

5.Working at height

4.Lifting operations

6.High risk contractor and construction work

10. Manual handling

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Agenda

1. **Confined Space Entry** (CSE)
   Working at Heights (WAH)
2. Short Case Study
3. **Working with Hazardous Energies** (WWHE)
   Lifting Operations
   Manual Handling
4. Short Case Study
5. **High Risk Contractors**
6. Short Case Study

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Confined Space Entry

This is an operation that takes often place although common thinking is that it's only related to entering in small vessels.

Typical activities :

- Manual charging of reactors
- Visual inspection
- Cleaning of equipment
- Inspection and maintenance

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Confined Space Entry - Risks

- Asphyxing atmosphere
- Moving parts
  (hazardous energies)
- Exposure to chemicals
- Injuries / accident
- Difficulties during rescue

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Confined Space Entry - Criteria

- No harmonized definition between companies, authorities, experts
- Usually related to a dimension (volume, length), difficulty of access, potential hazardous atmosphere / energies present
- Need to make sense, be consistent with other programs
- Need to be enforced !

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Confined Space Entry – Program Elements

- Definition of Confined Space
- Inventory of Confined Space
- Permit system
- Atmosphere monitoring
- Planning of rescue operations
- Maintenance of equipment (oxygen monitoring, rescue equipment,...)

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Work at heights

- All operations that are above ground ; where a fall is possible.
- Access to remote places (inspections, reparations, cleaning, maintenance)
- Access to roofs
- Access to underground or excavated areas

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Work at heights - Risks

- Fall
- Fall of objects
- Impact due to moving parts (scissor lift, MEWP)
- Failure of equipment (Lack of maintenance of the ladder, platform,...)

Work at heights - Criteria

- Definition of height
  - 0 meter
  - 1.8 – 2 meters

Mobile Elevated Work Platform (MEWP)

Scissor lift

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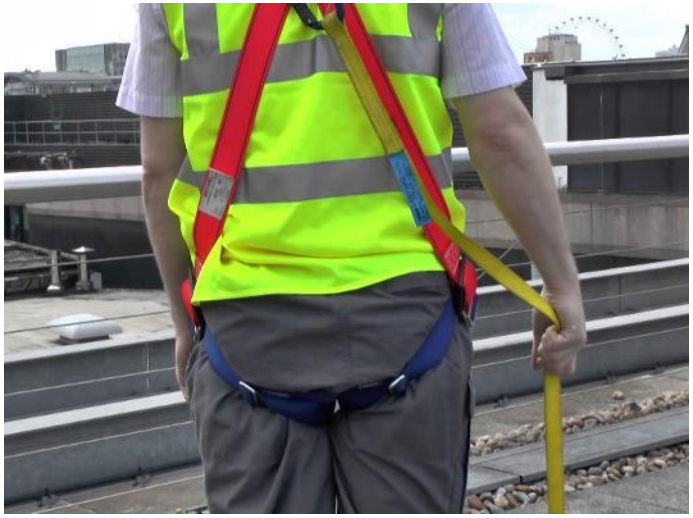
Work at heights – Program Elements

- Definition
- Risk assessment
- PPE – Fall protection system
- Rescue
- Permit system
- Maintenance program
- Safety perimeter during operation



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Working at Heights

- What is right ?
- What is wrong ?

- What are doing when you see such a situation during the audit ?

- Which documents are you checking after the visit ?

- What will be the finding(s) ?

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Confined Space Entry

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Some wrong behaviors...

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Working with hazardous Energies

- Any work done on an equipment that can release energy and harm people
- Working on a packaging line that is switched on by someone else
- Retained energy like compressed air, spring...
- Work on electrical equipment

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Working with hazardous Energies - Risks

- Injuries due to moving parts
- Injuries due to electricity

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Working with hazardous Energies - Criteria

Hazardous energies are

- Moving or rotating machine parts
- Pressure or steam systems
- Hazardous materials
  (e.g., chemicals, solvents, toxic gases, asphyxiants gases etc.)
- Gravity & stored energy
  (e.g., springs, potential energy which would cause equipment to move or rotate, explosion suppression systems, etc.)
- Electricity
  (mains and stored e.g., capacitors)
- Pneumatic valves
- Extreme temperatures
- Ionizing and non-ionizing energy sources
  (e.g., nuclear, x-ray, lasers, UV, etc.)

Working with hazardous Energies Program Elements

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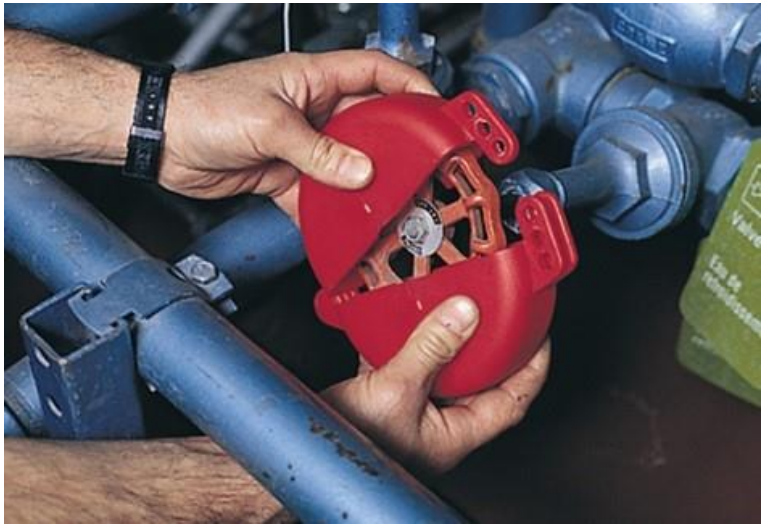
- Definition
- Permit system
- Lock-out tools
- Tag-out tools
- Procedure for special cases
- Possibility of locking out
  (can be checked during visit also if there is no LOTO currently taking place)



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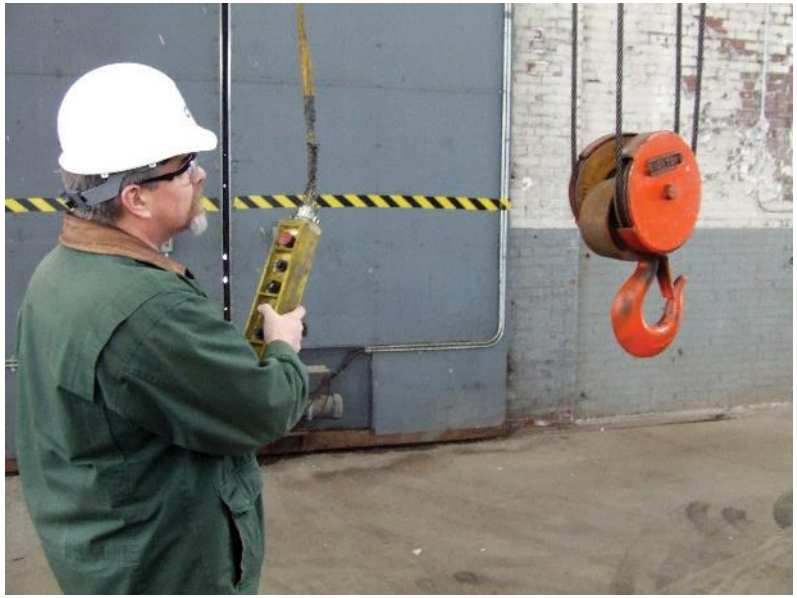
Lifting Operations

- Moving goods and materials using dedicated equipment
- Lifting of equipment for maintenance or repairs



Lifting Operations - Risks

- Fall of transported goods
- Failure of lifting equipment
- Injury of persons nearby
- Damage to nearby installation (→ chain reaction)

Lifting Operations– Program Elements

- Task assessment
- Equipment clearly and visibly labeled with appropriate information
- Inspection of the equipment prior to use
- Respect of limitations
- Maintenance program

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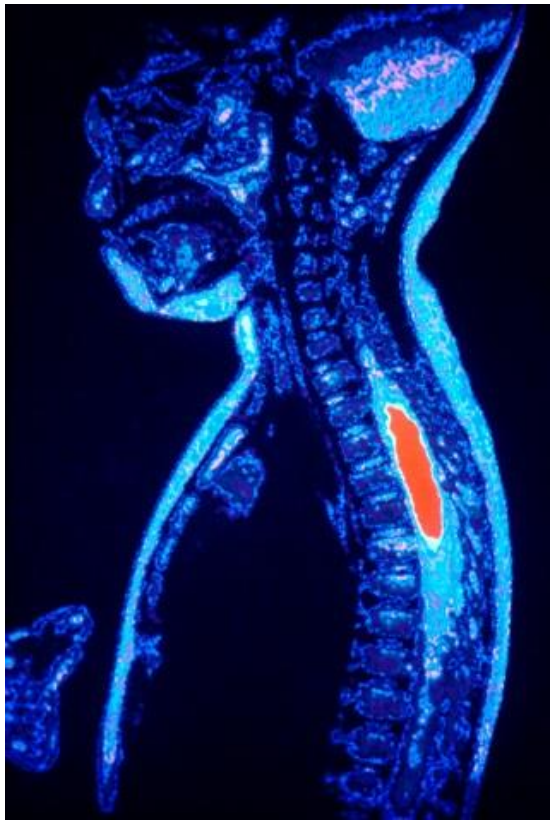
Manual Handling

- Lifting, transport of equipment
- Lifting, transport of chemicals (bags, drums...)
- Repetitive tasks involving body movements

Manual Handling - Risks

- (Back) injury
- Short term absence
- Long term absence



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Manual Handling - Criteria

- Lifting heavy objects
- Pulling, pushing or pressing with high force
- Repetitive or sustained lifting, pulling, pushing or pressing
- Awkward body positions or bad postures – either repetitive or for prolonged periods
- Exposure of whole or part of body to sustained vibration
- Driving a vehicle with significant vibration
- Manual handling of loads that are difficult to hold (e.g. slippery), or unstable / unbalanced

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Manual Handling – Program Elements

- Risk assessment
- Management of Change (inclusion of this hazard in the triggering list)

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Working at Heights

- What is right ?
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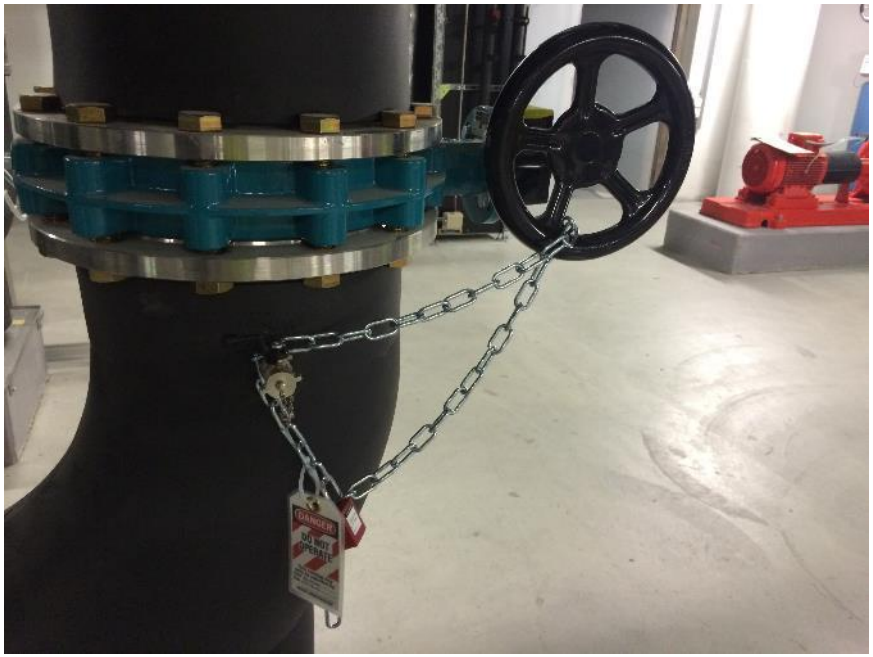
Challenging situation

During your visit, no operation like entry in a Confined Space Entry or Working at Heights take place...

What do you do to get an idea of the efficiency of their programs?

Is that a proper Lock-out ?



If you see this...

What is your conclusion ?

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High Risk Contractors - Purpose

- Works that are not routine (= complex and high risk) are usually realised by specialised, external companies
- Includes Construction workers
- Trend in Europe/USA to have also routine work being done by external companies

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High Risk Contractors - Risks

- Activity in itself
- Contractors lacking training / experience
- Not familiar with the facility
- Discrepancy between industry and «local» way of working
- Impact on adjacent / remote operations

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High Risk Contractors - Criteria

Contractors performing high risk activities → definition, see f.ex. SIF activities

Resident contractors vs. one time contractors

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High Risk Contractors – Program Elements

- Pre-selection of contractors
- On-boarding orientation (know the site)
- Need to use the Permit to Work system
- PPE / approved tools
- Checks during works
- Assessment of performance

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Short Case Study

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Short Case Study

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Short Case Study

Besides usual risks of getting injured (trips, falls...) :

Important fire load

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Programs

When you review those programs...

- Make sure that the program makes sense
- Make sure that what is written in a SOP is implemented
- Look for proofs of efficiency of those programs
- Look for consistency of those programs
- Look for interdependency

Conclusion

Those High Risk Work or SIF Programs are very important.

They might be seen as low priority because they impact only one person at a time...

but those operations takes place several time a day therefore ***they make a difference*** !