

THE PHARMA SAFETY PARADOX

**Highly controlled.
Invisible risk.**

The pharmaceutical industry is one of Europe's most strategic sectors. But behind scientific innovation, strict procedures and advanced technologies, human factors still influence safety, quality, compliance and operational performance every day.



The industry at a glance:



Pharmaceutical operations include:

API manufacturing

Active pharmaceutical ingredients, chemical synthesis, biological processing.

Formulation & filling

Mixing, sterile processing, aseptic filling, dosage preparation.

Packaging & labelling

Serialization, inspection, labelling, traceability.

Quality control

Testing, validation, laboratory analysis, inspections.

Logistics & distribution

Cold chain management, warehousing, transportation.



Many of the conditions that influence risk remain hidden until something goes wrong.

Risks in pharmaceutical environments³:



Biological

- Bacteria
- Viruses
- Contamination
- Pathogens



Chemical

- Toxic substances
- Vapours
- Powders
- Solvents



Ergonomic

- Repetitive tasks
- Manual handling
- Musculoskeletal disorders



Human factors

- Fatigue
- Rushing
- Frustration
- Complacency



Other exposures

- Cross-contamination
- Temperature excursions
- Pressure
- Sterility failures



584,371

Workplace accidents in the EU caused by slips, trips & falls.⁴

One of the most common workplace accident types in Europe.

Workplace accidents highlights:

29.2%

wounds and superficial injuries⁵

26.8%

sprains, strains & dislocations⁵

MSDS

musculoskeletal disorders remain the most widespread occupational health problem in the EU⁵

In pharmaceutical environments, risks can be increased by:

- Sterile cleaning procedures
- Repetitive movement
- Shift work
- PPE restrictions
- Fatigue
- Production pressure

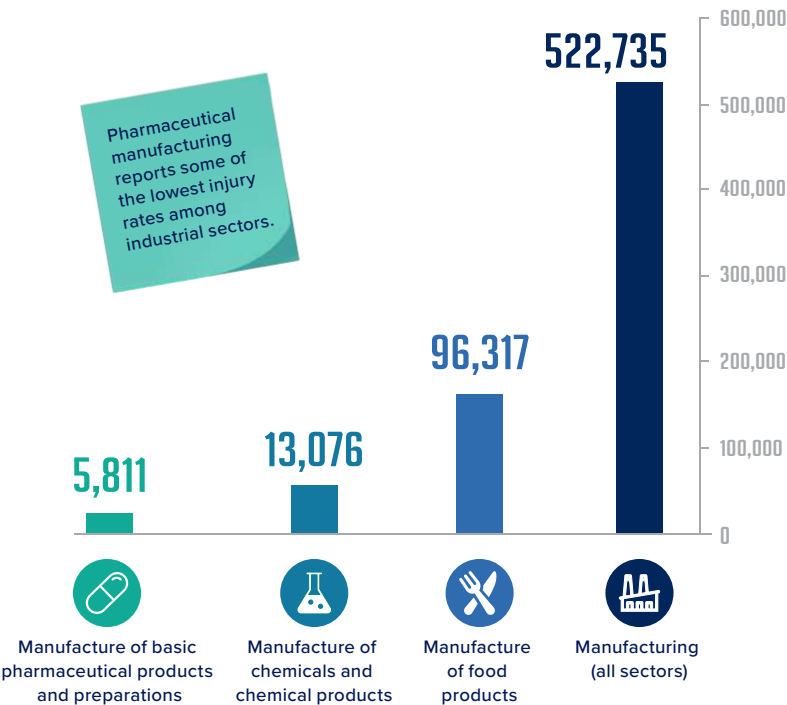
REPORTED INCIDENTS in Pharma

Lower volume,
but exposure varies.

Pharmaceutical manufacturing reports some of the lowest injury rates among industrial sectors.

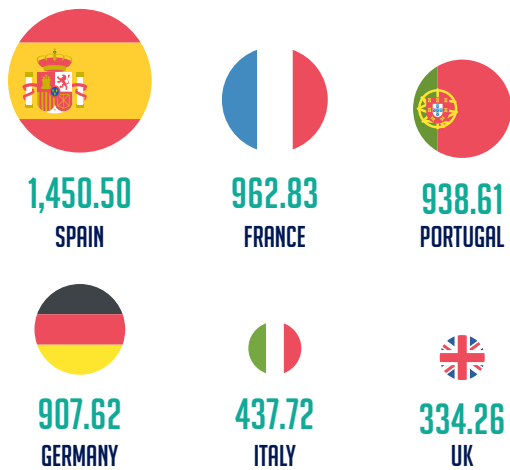
Reported workplace accidents by industry

Annual non-fatal workplace accidents reported under ESAW methodology (2023)⁶



Pharmaceutical accident incidence rates by country (2023)

Incidence rate (non-fatal accidents per 100,000 workers)⁶



Rates vary across Europe

Differences may reflect variations in reporting methodologies, operational activities, workforce structure and national reporting systems.

The cost of deviations & incidents

221
CONFIRMED QUALITY
DEFECTS IN 2024
Out of 395 quality defect notifications received by EMA.⁷

€22K – €48K
AVERAGE DEVIATION COST⁹

7.7
DAYS
Average length of domestic inspections +3 days for international.⁸

UP TO
€880K
Product loss impact.⁹

Leverkusen industrial explosion (2021)



A single explosion at a chemical processing and waste incineration facility in Leverkusen, Germany, demonstrates how one event can have devastating human, operational, environmental and financial consequences.

€150 – 400M+
DAMAGES, CLEANUP AND DOWNTIME

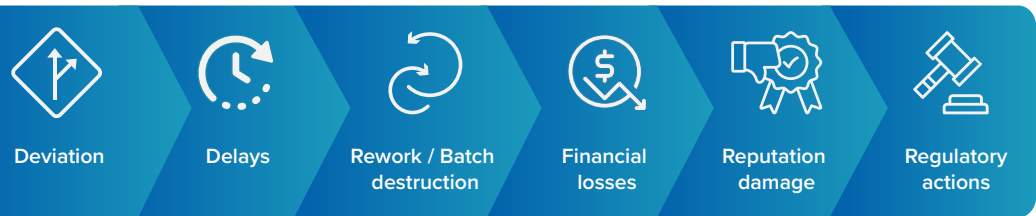
7
FATALITIES

31
INJURIES

Lower incident volume does not always mean lower exposure to risk.

Operational complexity, hazardous substances and human factors still influence outcomes every day.

Small errors can escalate quickly



Despite relatively low incident frequency in highly regulated industries, **a single event can still have catastrophic consequences.**

What's beneath the SURFACE?

Invisible human factors drive
visible consequences.

Highly controlled environments can still
produce deviations, incidents and losses.



80%+

OF PROCESS DEVIATIONS ARE
ATTRIBUTED TO "HUMAN ERROR"*

Human error is often the final label. **Not the root cause.**

*UK Data based on the latest comparable incidence metric in 2018.⁹

WHAT WE SEE

(Visible consequences)



Incidents



Deviations



Recalls



Investigations



Contamination
events



Product loss
& waste



Low injury
rates (TRIR)

WHAT WE DON'T SEE

(Hidden human conditions)



Staffing issues

Rushing

Cognitive overload

Frustration

Production pressure

Normalization

Interruptions

Complacency

Distractions

Time pressure

Fatigue

Everyday conditions below the surface fuel the risk we don't see.

HUMAN FACTORS. REAL IMPACT. EVERY DAY.

Operational risk is shaped by human performance.
Awareness, habits and work conditions determine outcomes.

Transient operations create **disproportionate risk**

<10%

OF OPERATING TIME IS SPENT
IN TRANSIENT OPERATIONS



50%+

OF PROCESS SAFETY INCIDENTS
OCCUR DURING THOSE OPERATIONS¹⁰

Non-routine work
increases complexity.
Complexity
increases the
likelihood of
critical errors.

Transient operations include:



Startups



Shutdowns



Cleaning
cycles



Changeovers



Maintenance



Troubleshooting



Contractor
interventions

Fatigue & Performance

17 HOURS AWAKE

can impair cognitive
performance similarly to alcohol¹¹

HIGHEST ERROR PROBABILITY

occurs between

2AM – 5AM

ROTATING SHIFTS, FATIGUE & DELIVERY PRESSURE

increase exposure to

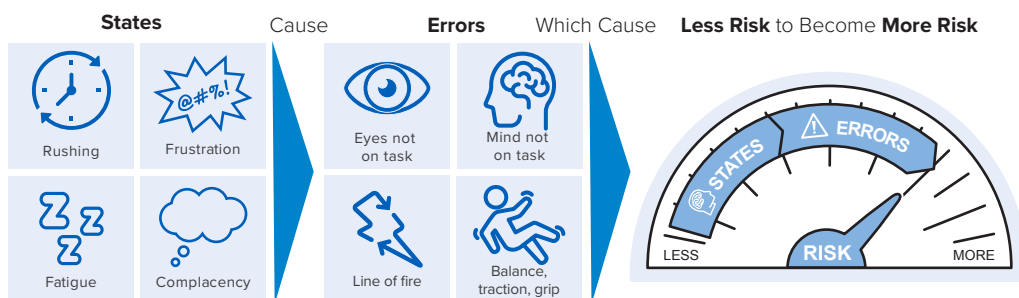
CRITICAL ERRORS

Human performance
directly influences:

- Product quality
- Worker safety
- Compliance
- Business continuity
- Patient trust

THE PATHWAY TO CRITICAL ERRORS

It's the everyday human states that
contribute to critical errors and increase
exposure to risk.



Human factors are **not random**.

Fatigue, rushing, frustration and complacency are manageable human conditions, not isolated incidents.



When people learn to recognise human
factors they can **reduce the errors,
incidents and operational risks**
they contribute to.

SAFESTART WORKS WITH

14 MULTINATIONAL
pharmaceutical companies

 **SAFESTART**® global.safestart.com

SCHEDULE A PRESENTATION



Sources:

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- 3 - Taveau, J. (13/08/2020). Understanding pharmaceutical manufacturing safety hazards + risk assessments.
- 4 - Osha Europe (28/02/2022). Slips, trips and falls.
- 5 - Eurostat (2025). Accidents at work-statistics on causes and circumstances.

- 6 - Eurostat (2024). ESAW (Accidents at work by economic activity) EMA.
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- 8 - MQEG Inspections topic team (10/06/2025). Annual regulatory GMP/GDP inspection survey 2024 data.
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