

Why more pharma manufacturers
are turning to inline CCIT
to prevent costly losses



GASPOROX

SUMMARY

In recent years, more pharmaceutical manufacturers have reported multi-million-euro losses when container quality issues were detected only after production was completed. These situations often occur because quality control relies on manual deterministic sampling, which only inspects a fraction of containers and provides no real-time feedback.

We are increasingly seeing companies encounter this challenge, delayed detection of container closure defects leading to unnecessary waste, compliance risks, and financial setbacks.

Gasporox inline solutions, including VialArch™ for vials and BottleArch™ for infusion bottles, enable 100% non-destructive, real-time testing directly on the production line. With this technology, deviations are caught immediately, allowing corrective action that prevents large-scale losses while maintaining full compliance with Annex 1 and USP <1207>, adopting non-destructive, 100% real-time container closure integrity testing (CCIT) in-line.

THE INDUSTRY CHALLENGE

Across multiple pharma production sites, similar patterns have emerged:

- Quality issues identified only after batch completion
- Losses in the range of €1M+ per incident
- Reliance on manual deterministic testing that is destructive, time-consuming, and limited in scope
- Risk of compliance breaches with GMP requirements and regulatory guidelines
- High financial and reputational risks from discarded product or recalls

THE GASPOROX SOLUTION

To address these challenges, Gasporox has developed inline headspace analysis systems:

- VialArch™ for injectable vials
- BottleArch™ for infusion bottles

Key features:

- Real-time, non-destructive testing of every container
- Direct inline integration without slowing production
- Automated detection and traceability to enable corrective action
- Compliance with Annex 1 and USP <1207>

RESULTS MANUFACTURERS ACHIEVE WITH INLINE HSA

Pharma companies adopting Gasporox inline CCIT benefit from:

- Prevention of multi-million-euro losses through early defect detection
- Faster batch release through 100% non-destructive testing
- Improved compliance with regulatory requirements
- Greater protection of both patient safety and brand reputation
- Scalable deployment across multiple container types and facilities

KEY TAKEAWAYS

- This is not an isolated issue: multiple pharma manufacturers face the same problem
- Manual deterministic QC leaves blind spots that create costly risks
- Inline CCIT from Gasporox provides immediate corrective action and regulatory compliance
- Both VialArch™ and BottleArch™ offer scalable solutions for different container formats

We are seeing more companies face unnecessary losses due to outdated QC methods. Don't wait until late detection costs you millions, contact Gasporox to explore how inline CCIT can strengthen your production strategy.