*Subsection:*

# Pharmapack 2026

# Pharmapack 2026

*International Pharmaceutical Industry Journal speaks with Informa Markets' Silvia Forroova on what to expect at Pharmapack 2026*

**What major trends will Pharmapack 2026 be putting in the spotlight this year?**

Pharmapack 2026 is focusing on six key themes that address the pharmaceutical packaging industry's most pressing challenges. Sustainability and ESG initiatives take centre stage as companies shift from basic compliance to implementing genuine circular economy principles. The event will also highlight CDMO partnering strategies, reflecting the pharmaceutical industry's growing reliance on outsourced manufacturing – a trend that's accelerated significantly in recent years.

Artificial intelligence integration represents another major focus area, as AI is revolutionising everything from design processes to quality control and production methodologies. The event will showcase advanced packaging technologies, particularly smart packaging solutions and connected health innovations that improve patient engagement and safety. Device innovation, especially next-generation drug delivery systems, will feature prominently alongside comprehensive coverage of regulatory compliance challenges as companies navigate an increasingly complex global regulatory landscape.

This comprehensive approach reflects Pharmapack's unique positioning as the gathering place for "Europe's pharma packaging's most influential minds."

**What new themes or innovations are you expecting to draw the strongest interest from attendees?**

The intersection of sustainability and technology is generating fantastic excitement among attendees this year. Biopolymer innovations are leading the charge, with companies demonstrating plant-based packaging alternatives that maintain the rigorous protection standards pharmaceutical products require. Smart packaging integration is another major attraction, featuring IoT sensors, NFC/RFID tags, and QR codes that enhance product safety and provide unprecedented supply chain transparency.

Circular packaging design concepts are capturing significant attention, particularly initiatives focused on device circularity and innovative approaches to incorporating recycled content. AI-powered quality control systems that offer real-time monitoring capabilities for blister packs and vials are drawing substantial interest from manufacturers looking to boost both efficiency and compliance. Perhaps most exciting are connected health solutions that transform packaging from passive containers into active interfaces that support patient adherence and engagement.

**How will Pharmapack 2026 highlight progress in sustainability and reduced plastic use?**

Pharmapack 2026 has created a comprehensive sustainability framework through multiple dedicated channels. The event features a dedicated Sustainability Centre that showcases partnerships with organisations like the Alliance to Zero and includes PDA Innovation workshops, providing attendees with practical implementation strategies. Circular economy showcases will demonstrate how pharmaceutical companies are fundamentally rethinking packaging lifecycles, moving away from traditional linear models toward regenerative approaches.

Material innovation displays will highlight breakthrough alternatives that maintain pharmaceutical safety standards while dramatically reducing environmental impact. The event directly addresses the new EU Packaging and Packaging Waste Regulation (PPWR) that entered into force on February 12, 2025, providing crucial guidance on compliance with requirements for recycled content, environmental labelling, and extended producer responsibility that will be enforced starting August 12, 2026. Industry collaboration models will showcase how initiatives like the CPHI Sustainability Collective are driving cross-industry progress, demonstrating that meaningful sustainability advances require coordinated efforts across the entire pharmaceutical value chain.

**Where do you think the industry still faces the biggest obstacles in reducing environmental impact?**

The pharmaceutical industry faces several persistent and complex challenges in reducing environmental impact. Regulatory complexity represents perhaps the most significant hurdle, as companies must balance ambitious environmental goals with stringent pharmaceutical safety requirements across multiple jurisdictions. This challenge becomes even more complex when considering that pharmaceutical packaging must maintain product integrity, sterility, and stability.

Cost pressures create another substantial barrier, as sustainable materials frequently carry premium pricing that challenges traditional procurement models and margin expectations. Supply chain integration difficulties compound these challenges – coordinating sustainability initiatives across complex global manufacturing networks requires unprecedented collaboration and standardisation. Technical limitations persist in ensuring sustainable materials meet pharmaceutical stability and protection requirements, particularly for sensitive biologics and temperature-controlled products. The absence of unified industry standards for sustainable packaging assessment and implementation creates additional complexity, making it difficult for companies to benchmark progress and ensure consistent approaches across different markets and regulatory environments.

**What regulatory or manufacturing discussion topics do you expect to be widely discussed?**

The regulatory landscape is experiencing unprecedented change, creating numerous focal points for discussion at Pharmapack 2026. The new EU Packaging and Packaging Waste Regulation requirements for recycled content, environmental labelling, and extended producer responsibility will dominate conversations, particularly as the August 12, 2026 enforcement deadline approaches and companies scramble to ensure compliance.

Global harmonisation challenges will feature prominently, as manufacturers struggle to manage different regulatory requirements across markets while maintaining cost-effective operations. Sustainability compliance preparation for packaging waste reduction mandates and circular economy regulations will be extensively discussed, particularly as companies seek practical strategies for meeting environmental targets

without compromising pharmaceutical safety standards. Manufacturing discussions will focus on integrating these diverse regulatory requirements while maintaining operational efficiency and cost control in an increasingly complex compliance environment.

**How will the event address the rising need for stronger anti-counterfeiting measures?**

The anti-counterfeiting packaging market's explosive growth – reaching approximately $199 billion in 2025 and projected to reach $352 billion by 2030 – reflects the urgency driving Pharmapack 2026's comprehensive approach to security innovations. The event will showcase advanced authentication technologies including RFID and blockchain-enabled QR codes that provide robust product verification capabilities while remaining user-friendly for healthcare providers and patients. Supply chain transparency solutions using real-time tracking systems, serialisation, and advanced barcoding will be extensively featured, particularly those supporting regulatory requirements like the US Drug Supply Chain Security Act. Digital integration showcasing IoT-enabled packaging that provides continuous monitoring capabilities will demonstrate how modern anti-counterfeiting measures extend beyond static security features to dynamic, real-time protection systems. The event will emphasise practical implementation strategies that balance security effectiveness with operational efficiency and cost considerations.

**What kinds of security or traceability innovations do you expect visitors to encounter this year?**

Visitors will encounter cutting-edge technologies that represent the next generation of pharmaceutical security and traceability. Blockchain integration solutions providing immutable supply chain records will be prominently featured, demonstrating how distributed ledger technology can create tamper-proof audit trails from manufacturing through patient delivery.

Temperature and moisture indicators providing real-time environmental monitoring for sensitive products will demonstrate how traceability extends beyond location tracking to comprehensive condition monitoring. Enhanced serialisation advances meeting global regulatory requirements will show how track-and-trace capabilities are evolving to provide more granular, real-time visibility throughout the supply chain. Connected packaging featuring IoT sensors that provide continuous product status updates will illustrate how packaging is transforming from a passive container into an active participant in supply chain security. These innovations collectively address both regulatory compliance requirements and the growing need for supply chain resilience.

**How is the sector adapting packaging solutions to meet increasingly complex logistics demands?**

The pharmaceutical packaging sector is undergoing fundamental transformation to address sophisticated supply chain requirements driven by globalisation, regulatory complexity, and evolving therapeutic modalities. Cold chain optimisation represents a critical adaptation area, with advanced temperature-controlled packaging solutions specifically designed for biologics and vaccines that require precise temperature maintenance throughout extended distribution networks. The pharmaceutical cold chain packaging market's projected growth from $20.6 billion in 2025 to $83 billion by 2035 reflects the massive scale of this challenge.

Predictive logistics powered by AI-driven systems are optimising packaging selection for specific shipping conditions, weather patterns, and route characteristics, ensuring optimal protection while minimising costs. Sustainability integration has become non-negotiable, with packaging solutions that reduce environmental impact without compromising protection standards. Regulatory compliance packaging that simplifies adherence across multiple jurisdictions is increasingly important as companies seek to streamline global distribution while meeting diverse regulatory requirements efficiently.

**How do you see manufacturers balancing cost pressures with the push for innovation and efficiency?**

Manufacturers are adopting increasingly sophisticated strategic approaches to balance competing pressures for cost control and innovation investment. Phased implementation strategies enable gradual adoption of sustainable and innovative technologies, spreading costs over time while managing financial impact and operational risk.

Efficiency optimisation through AI and automation is providing pathways to reduce operational costs while simultaneously improving quality and compliance outcomes. Value demonstration has become crucial, with companies developing sophisticated methodologies to quantify sustainability benefits, risk reduction, and brand differentiation value. The key insight is that innovative packaging solutions provide long-term value through risk mitigation, regulatory compliance, operational efficiency, and competitive differentiation that often outweighs initial cost premiums.

**How is AI shaping the way exhibitors approach design, quality control and production?**

Artificial intelligence is fundamentally transforming pharmaceutical packaging operations across all major functional areas. In design optimisation, AI algorithms are creating packaging solutions that simultaneously balance protection requirements, sustainability objectives, and cost constraints through sophisticated modelling. These systems can rapidly iterate through thousands of design variations to identify optimal solutions for specific product and distribution requirements.

Process optimisation using machine learning is identifying efficiency improvements in packaging operations that reduce waste, improve throughput, and enhance consistency. Supply chain intelligence driven by AI is optimising logistics, reducing costs, and improving reliability through predictive analytics that anticipate and mitigate potential disruptions. The integration of AI is enabling pharmaceutical companies to achieve precision, efficiency, and quality control while supporting sustainability objectives and regulatory compliance requirements simultaneously.

**Silvia Forroova**

Silvia Forroova is the Director of Partnerships & Sustainability for the CPHI portfolio at Informa Markets. With over 15 years of experience in global events, she specializes in strategic partnerships for pharmaceutical supply chain, packaging, and drug delivery industries. Silvia leads sustainability initiatives across the CPHI portfolio of events, developing strategies that drive positive environmental impact for trade shows and the wider pharmaceutical industry. She is also a co-founder of the Sustainability Collective, fostering collaboration for sustainable innovation.

# Navigating AI-Driven Pharmaceutical Visual Inspection

**The pharmaceutical industry continues to grapple with quality control issues. Traditional inspection methods are failing to meet the demands of modern production, with high-profile contamination incidents like stainless steel particles in Moderna vaccines exposing critical vulnerabilities.[1] Manual inspection remains prone to human error, whilst conventional automated systems can only detect what they've been programmed to find. As regulatory scrutiny intensifies and production complexity increases, manufacturers need a solution. AI automated technology represents a sophisticated evolution in visual inspection that addresses fundamental limitations of both manual and traditional automated approaches. Promising to transform pharmaceutical quality assurance, artificial intelligence-driven inspection offers the capability to achieve zero-defect production whilst maintaining commercial viability.**

## The Regulatory Imperative

Regulatory bodies, including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and Medicines and Healthcare products Regulatory Agency (MHRA), are progressively expecting manufacturers to demonstrate robust quality control capabilities that extend beyond traditional compliance measures.

Current Good Manufacturing Practice (cGMP) incorporates strict contamination control protocols designed to prevent foreign particles from compromising pharmaceutical products, with enforcement becoming increasingly stringent across global markets.

The FDA's Guidance for Industry on the Inspection of Injectable Products for Visible Particulates requires that all medicinal products intended for parenteral administration be visually inspected for particulate matter, and that any container showing visible particulates must be rejected.[2] In addition, the United States Pharmacopoeia guidance on visible particulates in injections establishes regulatory requirements for visual inspection of parenteral products, enforcing demonstration through 100% visual inspection that batches are "essentially free of visible particulates" before release.[3] These regulations underscore the critical importance of comprehensive inspection capabilities in pharmaceutical manufacturing.

Currently, no AI-specific regulations are in place, though the EU has drafted GMP Annex 22 (Artificial Intelligence) and Annex 11 (Computerised systems), which are under review. A key regulatory principle emerging from these drafts is that for critical GMP applications, only static or deterministic models are permitted, whilst dynamic or continually learning models are not acceptable for critical GMP uses.[4,5]

This regulatory framework means AI models must be locked and static when deployed in inspection machines for production, with self-learning capabilities reserved for development and future releases rather than automatic onsite production model updates.

Given that AI-specific regulations remain in draft stages, AI-based inspection machines are currently governed by the same regulatory framework as traditional inspection machines. The EU policy on automated visual inspection (AVI) states: "where automated methods of inspection are used, the process should be validated to detect known defects (which may impact product quality or safety) and be equal to, or better than, manual inspection methods".[6]

Many AI automated inspection systems support the various compliance frameworks by creating comprehensive audit trails that satisfy regulatory documentation requirements, providing manufacturers with defensible quality assurance processes.

## Technological Advancement and Capabilities

AI automated technology represents a sophisticated evolution in visual inspection that addresses fundamental limitations of both manual and traditional automated approaches. Manual inspection remains subject to human error, fatigue, and inconsistency, whilst traditional automated inspection can only identify defects for which it has been explicitly programmed.[7] AI automated technology offers significant advantages, including novel defect detection capabilities and continuously improving detection through self-learning algorithms, fundamentally changing the inspection paradigm.

AI-based inspection machines achieve substantially reduced false negative rates, decreasing the percentage of acceptable products incorrectly rejected from 10–20% to approximately 2%.[8] This dramatic improvement in accuracy translates directly to significant cost savings and reduced waste. Additionally, AI technology can analyse sequences of images as video content, gaining insights from motion patterns and multi-angle views of suspected defects to inform final good or bad determinations, providing a more comprehensive assessment than static image analysis.

The operational mechanism of AI automated inspection involves training deep neural network models with extensive datasets comprising images of acceptable products, which are labelled good, alongside images of defective products, labelled bad, with defect areas indicated.

Comprehensive training typically utilises one million acceptable images and 2.5 million defective images. Acceptable images include perfectly good products as well as images containing expected distractions such as bubbles, scale marks, and engraved logos.

Defective images encompass typical contamination types within pharmaceutical products, including glass, particles, and metal contaminants, though the range of defect types need not be exhaustive. Following training, models learn to recognise features of acceptable products with expected distractions, contrasted against defective products.

During deployment, inspection machines capture multiple images of each product, feeding these to the model for good or bad determinations. Models render 'good' judgments when all features contained in images match those expected from acceptable products. While 'bad' judgements

are made when either of two criteria are met: certain features align with defect patterns from training, or certain features do not conform to the acceptable product feature profile, even when not directly matched to a specific defect type.

This second criterion operates on a 'fail safe' principle, ensuring potentially problematic products are flagged for further evaluation. Inspection machines also assess capping defects, container cosmetic defects, and fill level control, each utilising separately trained deep neural network models following essentially identical methodologies.

**Economic Benefits and Performance Metrics**

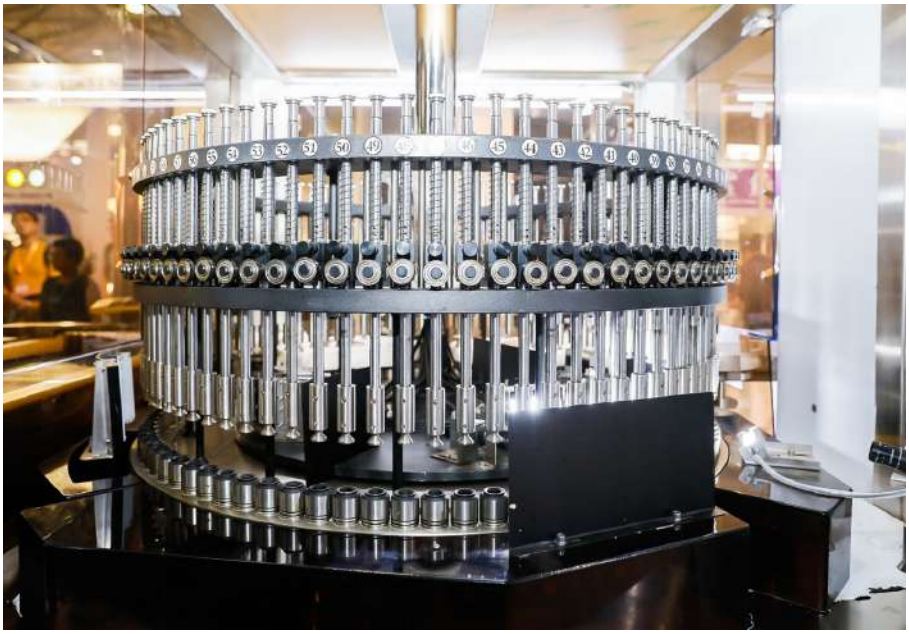
AI automated inspection has the potential to deliver substantial cost-saving benefits through reduced labour costs, minimised waste, and avoidance of recall expenses. Implementing more sophisticated visual inspection technology can reduce regulatory compliance costs, prevent reputational damage from quality issues, and avoid loss of market opportunities. The most significant cost saving derives from waste reduction, with false rejection rates decreasing from approximately 15% to 2%, saving 13% of final products that would otherwise be unnecessarily discarded.[9]

Performance evaluation of inspection systems relies on two primary metrics: false negative rates (miss rates) and false positive rates (false rejections). False negative rates measure the percentage of defective products not rejected by the inspection process, whilst false positive rates measure the percentage of acceptable products mistakenly rejected. Probability of Detection (PoD) or detection rate represents the inverse of false negative rates, calculated as (1 – false negative percentage).

According to the United States Pharmacopeia, visual inspection is a probabilistic process rather than an absolute one, with detection likelihood influenced by particle size, shape, colour, density, and reflectivity. The human eye has a theoretical resolution limit of ~11 µm, though practical resolving power is closer to 85–100 µm. Under controlled conditions, manual inspection demonstrates a PoD only slightly above 0% for 50 µm particles, rising to about 40% for 100 µm single-seeded spherical particles (polystyrene beads), approximately 70% for 150 µm particles, and exceeding 90% for 200 µm and larger particles.[10]

For glass-based containers, where delamination or breakage makes glass particles a major contamination risk, differences in detection performance between methods are pronounced. Studies show that manual inspection detects only about 40% of units containing a single glass particle sized between 50–400 µm, missing the majority. By comparison, traditional automated inspection systems typically detect around 90%, while AI-based vision systems can achieve up to 98.5% detection, corresponding to a missed fraction of only 1.5%.[11] These performance improvements represent a substantial enhancement in safety and quality assurance for sterile products.

For plastic-based containers, where foreign matter is harder to distinguish due to transparency and refractive similarity, performance disparities are even more pronounced. Manual inspection achieves about 25% PoD for a single plastic particle, increasing to ~45% when five 400 µm particles are present. Traditional automated systems show limited capability, achieving ~65% detection, whereas AI-based inspection systems report ~95% PoD. Regarding false rejection rates, conventional machine vision is often confounded by bubbles and cosmetic features, resulting in 10–20% false rejections, compared with ~2% for AI-based systems, a performance level comparable to human inspection.[11]



**Implementation Challenges and Solutions**

Transitioning from manual or automated visual inspection to AI automated inspection presents specific challenges that manufacturers must navigate carefully. One significant challenge involves setting explicit parameters for acceptance thresholds, which differs markedly from manual inspection, where acceptance thresholds are often verbally communicated and relatively vague. Pharmaceutical companies frequently encounter varied opinions on machine threshold settings among different departments, including quality control, production, and financial teams. Achieving consensus on numerical threshold levels can prove challenging during initial implementation phases, requiring careful change management and stakeholder alignment.

Successful implementation requires comprehensive validation processes that demonstrate equivalence or superiority to existing methods. Companies must establish robust training protocols for personnel operating new systems, develop standard operating procedures that accommodate AI-driven processes, and ensure integration with existing quality management systems. Additionally, manufacturers must address data governance requirements, including proper dataset curation, bias management, and comprehensive documentation of model development and validation processes.

**Future Technological Developments**

Visual inspection technologies continue evolving towards improved performance and broader applicability. Current development focuses on creating more generic computer vision neural network models, similar to trends in large language models. Present approaches require training different models for different container formats and, in some cases, different drug solutions. Given similarities between acceptable and

defective samples and recent algorithmic developments, efforts are underway to combine and fuse different models into unified general inspection models. This consolidation saves customers effort in switching between models and reduces potential operational risks, whilst significantly alleviating machine manufacturers from numerous calibration iterations.

Depth of field limitations in camera imaging have constrained inspection capabilities for decades, particularly when detecting small particles within relatively large containers such as 30ml vials. Leveraging AI model predictive capabilities, algorithms are being developed to forecast particle trajectories in three-dimensional space based on the first 20% of image sequences. These predictions enable real-time liquid lens control to adjust camera focus planes according to predicted particle trajectories. This approach overcomes shallow depth of field limitations and obtains significantly sharper images of suspected particles. In doing so, false negative rates could be cut from 2% to 0.2%, and probability detection rates improved from 99% to 99.8%.[12]

Advanced AI techniques also enable enhanced defect classification and characterisation, providing manufacturers with more detailed information about contamination sources and patterns. Machine learning algorithms can identify trends in defect occurrence, supporting predictive maintenance programmes and process optimisation initiatives. These capabilities extend AI benefits beyond immediate inspection to broader manufacturing intelligence applications.

**Strategic Implementation Considerations**

Successful transition to AI-driven pharmaceutical visual inspection requires strategic planning that encompasses technical, regulatory, and organisational dimensions. Manufacturers must assess their current quality control infrastructure, identify specific improvement opportunities, and develop phased implementation approaches that minimise operational disruption. Regulatory considerations should inform technology selection and validation strategies, ensuring compliance with evolving requirements whilst positioning organisations for future regulatory developments.

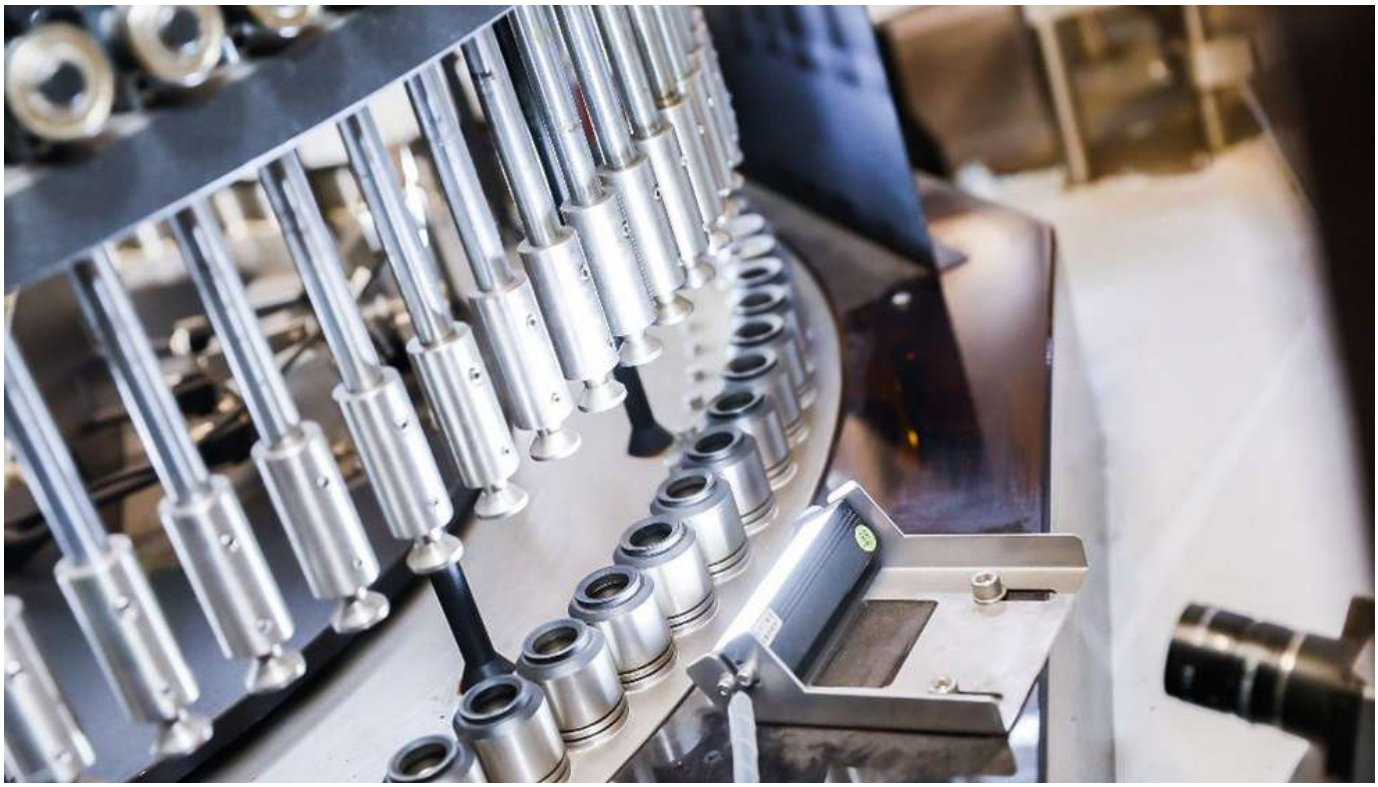
Training and change management programmes are essential for successful implementation, as staff must understand new technologies and adapt established working practices. Quality assurance professionals require training in AI system validation and ongoing monitoring, whilst production personnel need familiarity with automated system operations and exception handling procedures. Management support and clear communication about implementation benefits help ensure organisational buy-in and successful technology adoption.

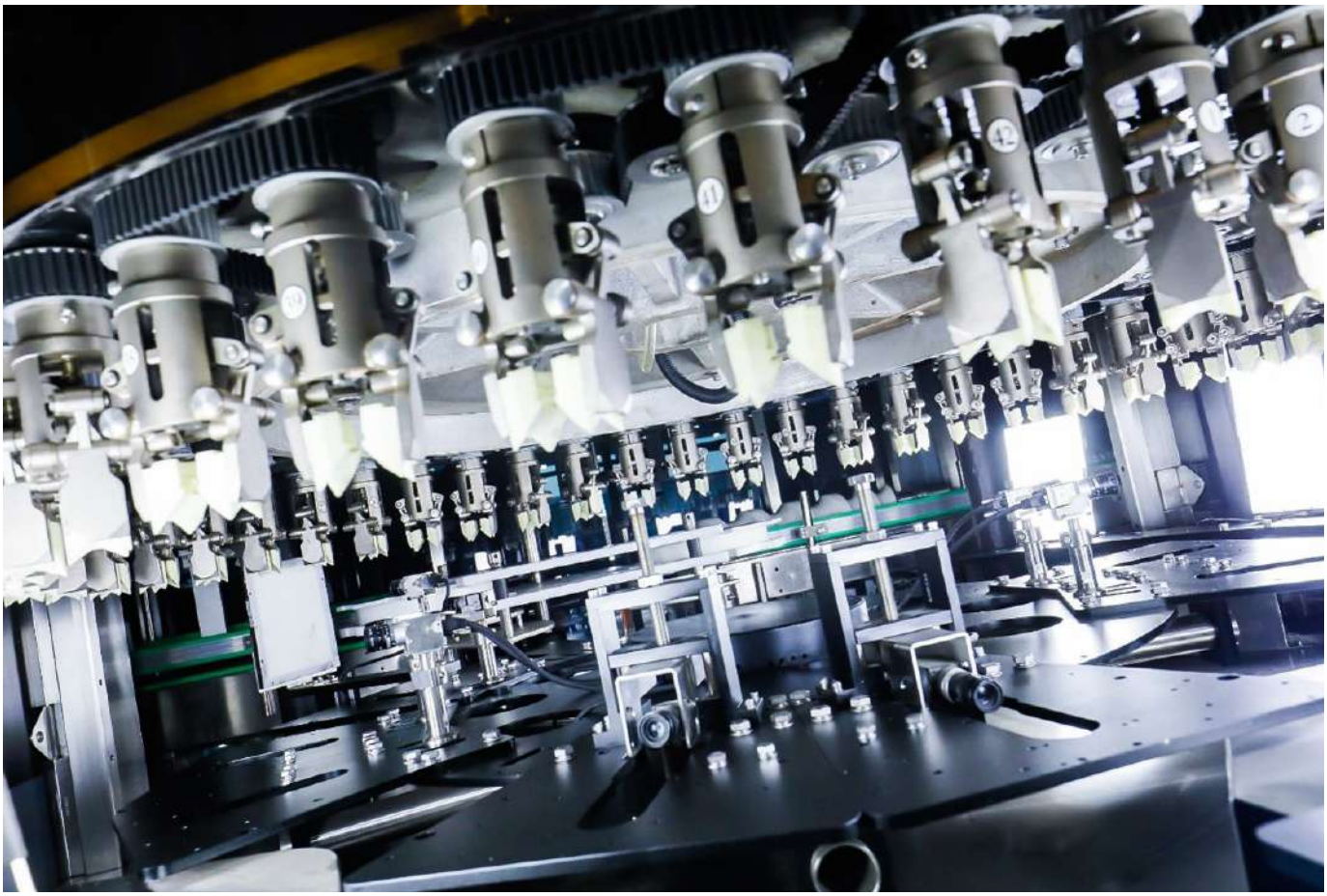
When it comes to financial considerations, decision-makers should evaluate not only initial capital costs but also ongoing operational benefits, including reduced waste, improved compliance, and enhanced product quality. Total cost of ownership analyses should incorporate labour savings, reduced recall risks, and competitive advantages from superior quality control capabilities.

**Conclusion**

The pharmaceutical industry stands at a defining moment. The leap from manual inspection to AI systems achieves much higher accuracy, representing more than a technological advancement as it embodies a turning point in how we safeguard human health. Manufacturers embracing this transformation are not merely upgrading equipment; they are positioning themselves as leaders in an industry where precision directly translates to lives protected and trust earned.

Whilst manual and traditional methods have likely reached their performance ceiling, AI-driven inspection continues evolving with algorithmic breakthroughs. Future developments could promise detection rates approaching 99.8%, transforming today's ambitious goals into tomorrow's minimum standards. The technology transcends business metrics, becoming an instrument of global health protection where every contaminated





vial prevented represents a patient safeguarded.

As regulatory frameworks become increasingly stringent and market dynamics continue evolving, AI-driven visual inspection transitions from emerging technology to essential infrastructure. Forward-thinking manufacturers implementing these systems today establish competitive advantages that will prove increasingly difficult to replicate. In a regulatory environment where quality assurance capabilities determine market access and operational sustainability, AI-driven inspection represents a fundamental component of future pharmaceutical manufacturing excellence.

## REFERENCES


1. Chooi, W.H. et al. (2022) Vaccine contamination: Causes and control, Vaccine. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC8860342/ (Accessed: 20 August 2025).
2. (2021) Inspection of Injectable Products for Visible Particulates – Guidance for Industry. Available at: https://www.fda.gov/media/154868/download (Accessed: 20 August 2025).
3. (2014) The United States Pharmacopeia. Chapter 790. Available at: https://doi.usp.org/USPNF/USPNF_M7197_01_01.html (Accessed: 21 August 2025).
4. (2025) Annex 22: Artificial Intelligence. Available at: https://health.ec.europa.eu/document/download/5f38a92d-bb8e-4264-8898-ea076e926db6_en?filename=mp_vol4_chap4_annex22_consultation_guideline_en.pdf (Accessed: 20 August 2025).
5. (2011) Annex 11: Computerised Systems. Available at: https://health.ec.europa.eu/system/files/2016-11/annex11_01-2011_en_0.pdf (Accessed: 20 August 2025).
6. (2022) Annex 1: Manufacture of Sterile Medicinal Products. Available e05af55b-38e9-42bf-8495-194bbf0b9262_en (Accessed: 21 August 2025)
7. (2020) Vision Inspection Using Machine Learning/Artificial Intelligence. Pharmaceutical Engineering (November–December 2020). Available at: https://ispe.org/pharmaceutical-engineering/november-december-2020/vision-inspection-using-machine (Accessed: 20 August 2025).
8. Xin Weisheng (2025) Internal research on AI-driven visual inspection performance compared to traditional visual inspection machines. Unpublished internal data.
9. Xin Weisheng (2025) Internal research on AI-driven visual inspection performance compared to traditional visual inspection machines. Unpublished internal data.
10. Cherris, R. (2016) Visual Inspections of Injections – NGVF Masterclass Slides. PDA/PharmOut. Available at: https://www.pharmout.net/wp-content/uploads/2018/02/NGVF-2016-Visual-Inspections-of-Injection.pdf (Accessed: 21 August 2025).
11. Mazaheri, M. et al. (2024) 'Monitoring of Visible Particles in Parenteral Products by Manual Visual Inspection – Reassessing Size Threshold and Other Particle Characteristics that Define Particle Visibility', Journal of Pharmaceutical Sciences. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0022354923004112 (Accessed: 28 August 2025)
12. Xin Weisheng (2025) Company prediction on future AI visual inspection detection rates. Unpublished internal estimate.



**Yuting Shao**

Yuting Shao, Director of Xin Weisheng, is a passionate serial entrepreneur with over 11 years of experience delivering customised solutions to international pharmaceutical clients. She is the Director of Xin Weisheng, a global leader in pharmaceutical machinery, specialising in aseptic processing lines, AI-driven visual inspection systems, and high-speed packaging solutions. Yuting holds a BA (Hons) in Economics from the University of Cambridge and an MBA from Judge Business School, University of Cambridge.

**Email: yuting@shxws.net**

# Moisture Control in Pharmaceutical Packaging:

## *Comparing Silica Gel, Molecular Sieve, and Equilibrium Technologies*

**Moisture is one of the most prevalent risks to pharmaceutical stability. From oral solid dosage (OSD) forms such as tablets and capsules to inhalation devices, fluctuations in humidity can compromise drug quality, alter dissolution profiles, and shorten shelf life. Excess moisture can catalyze hydrolytic degradation or polymorphic changes, while overly dry conditions may cause excipients and gelatin capsules to lose mechanical integrity.**

**Traditionally, packaging has relied on desiccants such as silica gel and molecular sieve to mitigate moisture ingress. These technologies remain widely used and effective in many applications. However, their inherent adsorption behaviours – either too gradual or too aggressive – do not always align with the specific needs of modern drug products. This has prompted interest in engineered equilibrium systems designed to maintain a target relative humidity (RH) rather than simply reducing it as far as possible.**

**This article reviews the strengths and limitations of silica gel and molecular sieve, and explores the role of equilibrium humidity stabilisers, such as EQIUS®, in balancing product stability with packaging efficiency.**

### Silica Gel: Versatile and Economical Moisture Control

Silica gel, composed of amorphous silicon dioxide, has long been favoured in pharmaceutical packaging. Its internal network of pores adsorbs water vapor through capillary condensation, allowing it to function across a broad RH range.

#### Advantages of Silica Gel

- **Cost-Effective and Scalable:** widely available, suitable for high-volume packaging with options to further moderate costs through bulk purchasing or optimised usage.
- **Versatile formats:** available as packets, canisters, capsules, or washers, adaptable to different packaging designs.

#### Limitations of Silica Gel

- **Limited efficiency at low RH:** struggles to achieve or maintain ultra-low humidity levels required by highly hygroscopic APIs or the amount of silicagel required to achieve low RH is very important.
- **Potential overdrying:** in certain cases, may reduce RH below optimal thresholds, causing gelatin capsule brittleness or tablet friability and can stress sensitive dosage form.

Silica gel remains a practical solution for many products where moderate moisture control suffices, but may fall short when precise or low-RH environments are essential.

### Molecular Sieve: Targeting Low RH with High Capacity

Molecular sieve, typically a crystalline aluminosilicate (zeolite), offers a sharper tool for moisture control. Its uniform pore sizes selectively adsorb water molecules, enabling aggressive uptake even at very low ambient humidity.

#### Advantages of Molecular Sieve

- **Strong low-RH performance:** effective in maintaining near-zero humidity, essential for APIs that degrade under even slight moisture exposure.

#### Limitations of Molecular Sieve

- **Risk of overdrying:** extreme adsorption can reduce humidity below the stability window for certain formulations, leading to capsule brittleness or altered drug release profiles.

Molecular sieve is therefore particularly useful for highly moisture-sensitive products, diagnostics, or biologics, but requires careful evaluation to avoid overdrying effects.

### Beyond Traditional Desiccants: The Role of Equilibrium Systems

While silica gel and molecular sieve provide broad moisture protection, their limitations underscore a key challenge: not all products benefit from an environment that is simply "as dry as possible." For many OSD forms and inhalation devices, stability depends on maintaining RH within a defined window rather than at extremes.

Equilibrium humidity stabilisers, such as EQIUS®, represent a different approach. Instead of adsorbing moisture indefinitely, these systems are engineered to buffer the internal package environment to a target RH – for example, 25–45% RH.

#### Working Principle of Equilibrium Systems

Equilibrium stabilisers are composed of materials conditioned to a specific RH. Once sealed within packaging, they act as a buffer – adsorbing or releasing moisture to maintain the defined equilibrium. This differs from conventional desiccants, which only adsorb.

Such stabilisation is valuable when product performance depends on avoiding overdrying. For instance, gelatin capsules may become brittle below ~30% RH, while tablets require strong moisture protection to prevent degradation or loss of efficacy.

#### Applications in OSD Packaging

- **Capsules:** Hard gelatin capsules are vulnerable to brittleness or cracking under excessively dry conditions. Equilibrium stabilisers help maintain capsule flexibility and integrity over time.
- **Tablets:** By controlling RH within the package, degradation pathways such as hydrolysis or polymorphic transitions can be minimised, supporting consistent dissolution and bioavailability.

#### Applications in Inhalation Devices

- **Dry powder inhalers (DPIs):** Powder flowability and aerosolisation efficiency depend strongly on moisture. Equilibrium stabilisers maintain consistent RH, safeguarding dose delivery.
- **Medical devices and biosurgery products:** Where device performance or sterility is influenced by environmental moisture, equilibrium solutions provide a controlled microclimate without extremes.

NIPRO

# LYOPHILIZATION VIALS

enhanced with NIPRO's proprietary VIALEX™ treatment

## Proven To Significantly Reduce Lyophilization Fogging

Up to 98% reduction in critical fogging events

•

Validated under demanding freeze-drying conditions and test solutions

•

Latest 2025 tests conducted by external lyophilization experts confirm the results

NIPRO | Nipro PharmaPackaging International
Blokhuisstraat 42, 2800, Mechelen, Belgium | pharmapackaging@nipro-group.com | www.nipro-group.com

Nipro Corporation
www.nipro.co.jp

| Feature | Silica Gel | Molecular Sieve | Equilibrium Stabiliser |
|---|---|---|---|
| RH range effectiveness | Low to medium | Very low RH | Targeted RH (e.g. 25–45%) |
| Risk of overdrying | Possible | High | None |
| Format flexibility | High | High | High |
| Suitability for capsules | Variable | Risk of brittleness | Maintains integrity |
| Customisation potential | Limited | Limited | High |

*Comparative Overview*

**Regulatory and Industry Considerations**
Moisture control strategies are increasingly guided by regulatory frameworks and quality standards. The USP <671> permeation test provides a benchmark for evaluating moisture barrier performance of pharmaceutical containers, while ICH Q1A stability testing underscores the need to simulate climatic conditions across global markets.

In this context, equilibrium technologies offer advantages in demonstrating compliance and predicting long-term stability. By maintaining a consistent internal RH, packaging systems can meet regulatory expectations for reproducibility and patient safety.

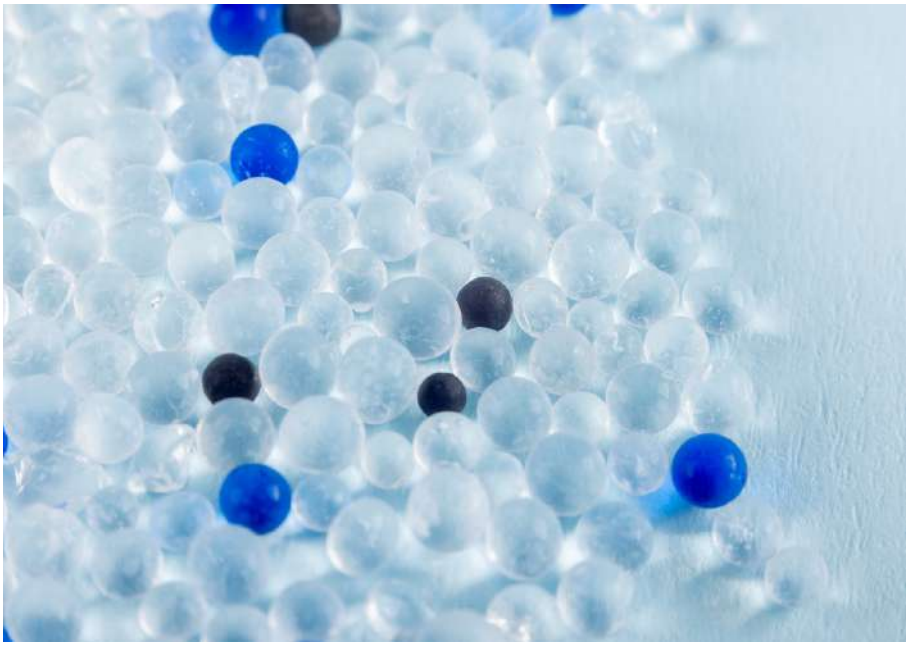
**Strategic Implications for Packaging Science**
From a broader industry perspective, equilibrium stabilisers illustrate the evolution of packaging from passive barriers to active environmental management systems. Rather than only protecting against moisture ingress, packaging can now actively regulate internal conditions to align with product needs – including avoiding excessively low humidity, which can be as detrimental as high humidity for certain sensitive products.

This shift supports a more holistic view of pharmaceutical stability, in which dosage form, excipients, packaging, and storage interact dynamically. For companies, it also provides a means of differentiating products by ensuring consistent performance across varied climates and distribution chains.

**Conclusion**
Silica gel and molecular sieve remain essential in pharmaceutical packaging, offering reliable moisture control for a wide range of products. However, both technologies have limitations silica gel may not provide sufficient low-RH protection, while molecular sieve risks overdrying and higher costs.

Equilibrium humidity stabilisers, like EQIUS, go beyond traditional solutions by actively maintaining the precise RH level each product requires – unlike other desiccants that simply dehydrate. This tailored approach ensures optimal stability for oral solid dosage (OSD), capsule, and inhalation applications, protecting therapeutic integrity with unmatched precision.

As pharmaceutical formulations become more complex and global distribution grows, moisture control strategies will continue to evolve. Equilibrium systems mark a game-changing shift in packaging technology – from passive protection to adaptive, adaptive moisture management – ensuring medicines stay safe, effective, and reliable throughout their lifecycle.



**Elisa Le Floch**

Elisa Le Floch, Global Product Manager, Colorcon, has over 14 years of experience in active pharmaceutical packaging. At Colorcon, she is responsible for developing and deploying functional packaging solutions focused on improving drug stability and protection. Her expertise lies in controlling the drug microenvironment (moisture and oxygen), supporting pharmaceutical, nutraceutical and diagnostic applications. She leverages her background in pharmacy to maintain a practical, medicine-focused approach, always linked to real product use and patient safety.

**Valère Logel**

Valère Logel, Global Head of Innovation, Colorcon Functional Packaging, is a leading topic expert in the field of preservation packaging. With over 15 years of experience, he has led the development and market introduction of innovative packaging solutions for moisture control, oxygen adsorption and multi-layer polymer barriers.


pci
PHARMA SERVICES
pci.com
Your world leading CDMO.
Advanced Drug Delivery
and Drug Device Combination
Products.
talkfuture@pci.com
PCI stands at the forefront of innovation. As a trusted partner, our unparalleled expertise in sterile fill-finish, final assembly, and packaging of advanced drug delivery and drug device combination products positions us as leaders in delivering patient centric therapies.
Our clinical to commercial solutions include:
• Sterile Fill-Finish and Lyophilization
• Packaging Design, Sustainability Assessment and Performance Testing
• Final Assembly and Packaging of:
– Vials & Syringes
– Prefilled Syringes
– Needle Safety Devices
– Autoinjectors
– Pens
– On-Body Devices
Together, delivering life changing therapies | Let's talk future™

# Clinical and Commercial Packaging:
## *Delivering the Next Generation of Pharmaceutical Therapies*

**The global pharmaceutical packaging sector is entering a decisive phase of transformation. As pipelines fill with targeted therapies, biologics, and complex drug-device combinations, the role of packaging is expanding well beyond protection and compliance. It now encompasses agility, patient usability, sustainability, and digital traceability – all under mounting regulatory and cost pressures.**

According to Grand View Research, the global pharmaceutical packaging market was valued at USD 139 billion in 2023 and is projected to reach USD 265 billion by 2030 – a CAGR of 9.7%. The contract packaging segment alone is expected to double within a decade, reflecting pharma's growing reliance on outsourcing partners for specialised expertise.

This expansion is matched by complexity. Accelerated development timelines, smaller patient populations, and diverse global markets are reshaping packaging operations from a linear process into a strategic discipline. Whether for oral solid dose (OSD) forms or injectables and drug-device combinations, the common denominator is the need for integrated, flexible, and compliant packaging solutions that can adapt quickly to scientific and commercial realities.

**Agility and Late-Stage Customisation in Oral Solid Dose Packaging**

Traditional packaging strategies were built around scale: long production runs, stable SKUs, and predictable demand. That model is increasingly unfit for purpose in a world of precision medicines and regionalised launches. A more adaptive framework – often referred to as Late-Stage Customisation (LSC) – is now emerging as an industry best practice.

LSC allows manufacturers and CDMOs to postpone the final printing, labelling, or configuration of packaging until demand is clearer or regional destinations are confirmed. Digital printing technologies make this possible: rather than producing large volumes of pre-printed components, companies can maintain a neutral "brite stock" and add variable data, artwork, and language versions at the final stage. It is important to establish the highest common denominator of the core component – whether that is a nude blister, an assembled device, or another base configuration – so manufacturers can still capitalise on larger-volume runs for that shared element while applying appropriately scaled, flexible techniques for market-specific or even named-patient customisation.

This approach tackles what engineers sometimes call the "trumpet syndrome" – where complexity widens downstream as multiple SKUs, languages, and regulatory variants accumulate. Late-stage flexibility narrows that funnel.

The benefits extend across the product lifecycle:

- **Reduced waste and inventory –** fewer obsolete printed components and more efficient warehouse utilisation.
- **Accelerated speed-to-market –** particularly for drugs with short shelf lives or limited stability data.
- **Enhanced compliance –** real-time adaptation to regulatory or language changes.
- **Improved working capital –** less money tied up in pre-configured packaging stock.

LSC can be implemented at several levels, from simple on-demand printing purchased from suppliers to fully integrated in-house systems that print everything from lidding foil to patient inserts. The choice depends on a company's investment appetite and throughput needs.

For clinical programmes – where protocols evolve and batch sizes remain small – on-demand labelling offers critical agility. For commercial production, integrated digital printing and serialisation capabilities ensure consistency and traceability across markets. Increasingly, automation, AI-driven forecasting, and even blockchain-based traceability are being layered on top to enhance responsiveness and oversight.

In short, agility is replacing volume as the defining measure of efficiency. For OSD products, late-stage customisation has become one of the most effective levers to achieve that flexibility without compromising quality or compliance.

**High-Potent Packaging: Safety, Containment, and Control**

The industry's pivot toward highly potent active pharmaceutical ingredients (HPAPIs) – particularly in oncology and other targeted therapies – has redefined packaging operations. These compounds, often requiring occupational exposure limits in the low nanogram range, demand facilities

that combine containment precision with manufacturing and packaging efficiency.

Modern high-potent packaging suites exemplify this evolution. Built around stringent airflow management, segregated zones, and dedicated HVAC systems with up to 20 air changes per hour, they maintain negative-pressure environments that prevent cross-contamination. Many facilities now perform SMEPAC testing (using surrogate materials to model particulate behaviour) to validate containment performance before any commercial run.

Automated inspection systems play an equally vital role. High-potent blister and bottling lines integrate multiple verification layers – infrared and electromagnetic sensors for tablet counting, vision systems to confirm label accuracy, and in-line serialisation to comply with the EU Falsified Medicines Directive and U.S. DSCSA.

Even the materials used in such environments are specialised: low-roughness stainless-steel surfaces (Ra ≤ 0.8 µm) that resist product adhesion and enable manual or semi-automated cleaning; wall panels and flooring engineered for smooth, easy decontamination; and sealed dust extraction systems designed for micro-particulate capture.

The design philosophy is one of containment through flow: unidirectional personnel and material movement, airlocks separating primary and secondary packaging zones, and "de-boxing rooms" to remove cardboard before entry. These controls, once confined to manufacturing, now extend seamlessly into packaging.

The commercial driver is clear. The rise of small-batch, high-value therapies means packaging lines must handle frequent changeovers without compromising safety. Achieving that balance – throughput with containment – represents the cutting edge of modern pharmaceutical packaging engineering.

**Injectable and Drug-Device Combination Packaging**

If OSD packaging is evolving toward agility, injectable and drug-device combination products (DDCPs) embody complexity. The market for self-injection devices alone is expected to reach USD 97 billion by 2031 – driven by biologics, chronic disease management, and the shift toward home-based care.

Packaging for these products sits at the intersection of sterility assurance, mechanical precision, and patient usability. Components must protect sensitive formulations from oxygen, moisture, and light while integrating seamlessly with delivery devices such as prefilled syringes, autoinjectors, or on-body injectors.

Best-in-class CDMOs now offer end-to-end solutions encompassing:

- Device assembly and functional testing – ensuring correct alignment, torque, and activation forces.

- Labelling and serialisation – maintaining full traceability through global supply chains.
- Cold-chain management – with validated environments from 2 °C down to –196 °C for cell and gene therapies.
- Kitting and final packaging – combining multiple components (device, instructions, ancillaries) into a single, compliant unit.

Equally important is human factors engineering. Regulatory authorities increasingly expect usability studies to demonstrate that patients – including those with dexterity or vision impairments – can safely and effectively administer therapy. Packaging design therefore influences not only logistics and safety but also regulatory approval.

The manufacturing infrastructure supporting these capabilities is changing rapidly. Device assembly lines are now modular and scalable, running from small pilot operations (a few units per minute) to fully automated commercial systems (hundreds of units per minute). Serialisation and aggregation are integrated from the outset, allowing serialised data to flow through manufacturing execution systems and enterprise resource planning platforms.

These operational advances are transforming injectables packaging from a linear finishing step into a precision manufacturing discipline in its own right – one that unites engineering, patient experience, and data integrity.

**Balancing Sustainability with Safety and Performance**

Perhaps no challenge is more pressing – or more difficult – than embedding sustainability into pharmaceutical packaging. The market for sustainable pharma packaging is projected to grow from USD 99 billion in 2024 to nearly USD 377 billion by 2034, at a CAGR of over 14 %.

However, implementing environmentally responsible materials within a highly regulated, safety-critical industry is far from straightforward. For oral solid doses, transitioning to recyclable or bio-based films and cartons is feasible; for injection devices, it is considerably harder. Materials must maintain barrier properties, chemical compatibility, and sterility – without compromising device function or patient safety.

To address this, packaging engineers are turning to life-cycle assessment (LCA)


tools to quantify environmental impact and identify "hotspots" for improvement across materials, transport, and disposal. Even small interventions can deliver significant results: resizing or reconfiguring secondary packs can cut packaging volume by up to 30 %, reduce cold-chain footprint, and save hundreds of thousands of litres of water or fuel annually.

Paper-based or bio-derived alternatives, certified under ISCC+ mass-balance standards, are beginning to replace petroleum plastics in certain device trays and cartons. Hybrid approaches – for instance, downgauged thermoplastics reinforced with renewable fillers – maintain strength and barrier properties while lowering carbon impact.

But sustainability extends beyond materials. It encompasses process efficiency (shorter print runs, less overstock), logistics optimisation (regional packaging to reduce transport), and circular design (easier separation of recyclable components). In this respect, digital printing and late-stage customisation directly support environmental goals by reducing waste and obsolescence.

Ultimately, sustainable packaging is less about a single innovation than a systems approach – one that unites materials science, engineering, usability, and data to deliver measurable carbon and cost reductions without compromising quality.

**Integration and Lifecycle Thinking**

A defining trend across the industry is the integration of clinical and commercial packaging operations. Historically, clinical supply and commercial manufacturing existed in separate silos; today, the ability to scale seamlessly from early-phase studies to market launch is a critical differentiator.

Integrated CDMOs have begun designing packaging networks that can:

- Support both small-batch and large-scale production within the same validated framework.
- Transition from clinical randomisation and blinding to commercial serialisation without re-validation.
- Employ common packaging materials and components across phases to streamline qualification.
- Combine packaging data with manufacturing execution and ERP systems for full product traceability.

This "bench-to-shelf" philosophy improves not only efficiency but also quality governance. It minimises handovers, reduces transport risk for high-value or temperature-sensitive products, and enables rapid response to regulatory changes.

In practice, the integration of manufacturing, packaging, and distribution is reinforced by digitalisation. Real-time data capture, predictive maintenance, and AI-driven forecasting are reshaping how packaging lines are scheduled and optimised. The future lies in connected packaging ecosystems that unite material suppliers, manufacturers, and distributors through shared digital standards.

**Toward Packaging as a Strategic Discipline**

Across oral solids, injectables, and combination products, several principles now define best practice in pharmaceutical packaging:

1. Agility over scale-smaller, more flexible runs beat monolithic production in a fragmented global market.
2. Containment by design-high-potent

Quality time for better care

TERUMO
MEDICAL CARE SOLUTIONS

PHARMACEUTICAL

# PLAJEX™ Ready-to-Fill Polymer Syringe for Biotech Formulations

**Precisely engineered for today's challenging biotech formulations**

- Durable COP syringe*
- Ready-to-fill format
- Tight dimensional tolerance*
- Rigid needle shield

- Device compatibility
- Silicone oil-free solution*
- Tapered needle
- Meets compendial requirements and ISO*


A simple formula for biotech success

PM-08754

handling must extend seamlessly into packaging.
3. Integration across the lifecycle-clinical and commercial packaging should operate as a continuum.
4. Sustainability with accountability-measurable LCAs, recyclable materials, and process efficiency will become baseline expectations.
5. Patient-centric functionality-usability, labelling clarity, and device ergonomics must guide packaging decisions.
6. Digital traceability-serialisation and data integration are now central to compliance and supply-chain resilience.

Packaging, once a finishing step, is now a strategic enabler – shaping how effectively therapies reach patients, how sustainably they are produced, and how rapidly companies can adapt to change.

**Conclusion: The New Front Line of Therapeutic Delivery**

The coming decade will see pharmaceutical packaging evolve from logistics to leadership-becoming the interface where science, regulation, and sustainability converge. CDMOs and pharma manufacturers that treat packaging as an innovation platform rather than a constraint will gain decisive advantage.

Late-stage customisation is redefining responsiveness; high-potent containment sets new safety benchmarks; device and combination product packaging blends engineering with empathy; and sustainability reframes the industry's environmental footprint.

The most successful organisations will integrate these disciplines – not as isolated capabilities, but as elements of a holistic, digitally connected value chain from molecule to market. In that future, packaging is not the last step in drug delivery. It is the first signal that innovation has reached the patient – safely, efficiently, and responsibly.

**REFERENCES**


1. https://www.grandviewresearch.com/horizon/outlook/pharmaceutical-packaging-market-size/global
2. https://www.precedenceresearch.com/pharmaceutical-contract-packaging-market
3. https://www.precedenceresearch.com/sustainable-pharmaceutical-packaging-market



**Paul Smallman**

Paul Smallman is a senior technical leader at PCI Pharma Services, bringing over 30 years of expertise in pharmaceutical packaging and drug delivery systems. At PCI, Paul plays a key role in delivering innovative technical solutions across the entire drug product lifecycle – from stability studies and clinical trial supplies to full-scale commercial launch. He leads cross-functional technical teams to ensure the successful design, development, and implementation of packaging formats and processes that meet the unique needs of each client. Partnering with a wide range of small, mid-size, and large biopharmaceutical companies, Paul has a proven track record of directing complex projects from concept to commercialisation, helping to bring life-changing treatments to patients around the world.

PHARMAPACK
by informa

PARIS
21–22 JAN 2026

# Pack your bags for Paris, unpack the future of pharma.

Explore the event

COLD CHAIN®
TECHNOLOGIES

# LET'S GO FURTHER

## Introducing the new **CCT Tower Elite**

Reusable, Universal, 1600L

- Universal configuration
- Modular temperature solution
- Reusable with leasing options
- Easy and space-efficient conditioning
- Robust and Reliable solution to ship high-value products
- International & Domestic. All mode of transport
- No Pharma corridor, manual intervention or TCV vehicles required
- Qualified to ISTA 7D methodology and ASTM D4169 transit tested
- System hibernate and recharges when placed into refrigeration during shipment


Learn More

COLDCHAINTECH.COM