

## Klaritex Inc. Releases New Report on 10 Cleanroom Trends Reshaping North America and Their Impact on Eye Protection

President & CEO Atif Sarfraz highlights key regulatory, operational, and humanfactors shifts that are redefining cleanroom goggles in North America

BURLINGTON, ONTARIO, CANADA, December 5, 2025 /EINPresswire.com/ -- Klaritex Inc., a North America-based supplier focused on cleanroom eyewear, has released a new analysis titled "10 Cleanroom Trends Reshaping North America (and What They Mean for Eye Protection)." The new report outlines 10 Major trends of how evolving regulatory expectations, sustainability pressures, and production demands in pharma, biotech, and semiconductors are reshaping requirements for cleanroom goggles.



The cleanroom today is far more than a HEPA-filtered environment. It is a tightly regulated, data-driven operational space where procurement, QA, and EHS teams face critical questions: Which standards matter most? How do we balance sustainability with sterility assurance?

Under the leadership of President & CEO Atif Sarfraz, Klaritex Inc. tracks global regulatory updates, cleanroom standards, and human-factors research so that its eyewear performs not only in validation data, but in real production environments across North America.

"Cleanrooms are experiencing fundamental shifts in how contamination control is understood and implemented," said Atif Sarfraz, President & CEO of Klaritex Inc. "Annex 1, smarter monitoring, sustainability requirements, and the expansion of advanced manufacturing are reshaping expectations for PPE. Eye protection now needs to be auditable, traceable,

comfortable during long shifts, and aligned with the realities of modern cleanroom behavior."



# 1. Annex 1 and the Contamination Control Strategy (CCS)

The 2022 revision of EU GMP Annex 1 introduced a formal Contamination Control Strategy (CCS) that integrates facility design, monitoring, personnel behavior, and control of microorganisms,



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particles, and pyrogens. Even plants not shipping to the EU are feeling the effects as multinational sponsors harmonize expectations. Cleanroom goggles now require audit-ready documentation, including test reports, material declarations, and clear change-control histories.

2. ISO 14644 Remains Foundational. But Monitoring Has Evolved

ISO 14644-1 continues to define air cleanliness

classifications, but monitoring has become more rigorous. Plants are reviewing data more frequently and investing in smarter sampling strategies. Fogging, poor seals, and frequent adjustments now factor directly into contamination-control risk.

#### 3. Human-Factors Design as a Compliance Tool

of Klaritex Inc.

Guidance from organizations such as the Canadian Centre for Occupational Health and Safety reinforces that PPE must be selected for hazard protection and prolonged wearability. Operator discomfort often results in loosened straps, goggles being lifted to clear fog, or modifications that undermine their design.

Anti-fog performance, adaptive seals, and ergonomic strap systems now play a central role in contamination avoidance.

Klaritex places significant emphasis on long-shift comfort in cleanroom conditions—allowing operators to wear goggles without constant adjustment and reducing compliance interventions.

## 4. Z87.1+ Markings and Impact/Splash Protection

In North America, ANSI Z87.1+ is the primary standard governing eye and face protection. Markings such as Z87.1+ (high-impact protection) and D3 (droplet and splash protection) are essential indicators for matching PPE to specific hazards. Cleanroom buyers increasingly require

full compliance to these markings and documented test results.

#### 5. Sustainability as a Procurement Driver

Sustainability is now central to PPE decision-making. Life-cycle comparisons show advantages for reusable systems under certain conditions, but the decision between disposable and reusable options must weigh contamination risk, process flow, and local constraints. Goggles designed for multiple uses—or with replaceable components—support sustainability goals while protecting CCS outcomes.

### 6. North American SupplyChain Resilience

Global disruptions have highlighted the risks of long, fragile supply chains. Cleanroom operators are prioritizing:

Regional molding and assembly

On-shore or near-shore warehousing

**Dual-sourcing strategies** 

Industry coverage has emphasized these themes in conversations with leaders such as Atif Sarfraz. Lead time and continuity of supply now matter as much as unit cost.

## 7. Digital Traceability and Audit-Ready Documentation

CCS-driven environments demand instant access to documentation. QA teams increasingly expect lot-level traceability via RFID, QR, or barcodes, along with immediate download of certificates of conformity, Z87.1 test reports, fog-performance data, material compatibility information, and change-control summaries.

Klaritex is aligning its documentation model with Annex-1-style expectations so cleanroom teams can integrate eyewear data directly into validation and QA workflows.

## 8. Biopharma and ATMP Growth Increase Aseptic Discipline Requirements

The expansion of sterile injectables, biologics, and ATMP manufacturing has intensified focus on aseptic behavior. Annex 1 stresses personnel gowning discipline, environmental and process monitoring, and clear differentiation between Grade A/B and support zones.

In this environment, the best goggles are those operators never feel the need to touch—reducing the risk of contamination from re-seating or fog clearing. Low-profile frames that integrate under hoods and visors support aseptic discipline.

#### 9. Semiconductors and Advanced Packaging Elevate Optical Requirements

North American semiconductor and advanced packaging facilities require ISO 1–7 conditions and tight gowning protocols. These environments rely on extreme optical precision for inspection and assembly. Clarity, distortion control, and color fidelity are critical eyewear attributes alongside impact and splash protection.

10. Thought Leadership Influences Specifications

Buyers increasingly depend on practical, vendor-neutral guidance to interpret standards and build better specifications. Publications such as Cleanroom Technology regularly provide technical insights. The Cleanroom goggles in North America market report featuring Atif Sarfraz highlights three recurring themes:

Comfort as a compliance driver

Sustainability across the PPE lifecycle

The importance of supply-chain resilience

According to Klaritex, the best suppliers support cleanroom teams with URS development, training content, and CCS documentation, not just product shipments.

A Structured Checklist for Cleanroom Goggle Buyers

The report encourages buyers to evaluate cleanroom goggles against criteria such as:

Standards & markings (ANSI Z87.1+, EN ISO 16321-1, CSA Z94.3; D3 splash protection)

Anti-fog performance & comfort, preferably with third-party field validation

Cleanroom compatibility, including particle shedding and disinfectant resistance

Traceability, via RFID, QR or barcodes

Sustainability, through reusable designs or packaging reduction

Supply resilience, including manufacturing and warehouse locations

Klaritex Inc.'s Approach to Meeting These Trends

Klaritex designs and supplies cleanroom goggles aligned with the industry's evolving needs:

Human-centred engineering for long-duration comfort

Standards-driven performance aligned with ANSI Z87.1+, EN ISO 16321-1, and CSA Z94.3

Audit-ready documentation compatible with CCS frameworks

North American supply strategies for continuity and reduced lead-time risk

Sustainability-minded design, from materials to packaging

"Our goal is straightforward," Sarfraz said. "We aim to be the most reliable and technically credible <u>supplier of cleanroom goggles</u> in North America, and a long-term partner for teams that take contamination control seriously."

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