CCSI™

Contamination Control Society, India

THE CCSI CLEANROOM CHRONICLE

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Chairman's Foreword: Engineering Certainty in an Age of Exposure

Compliance is a failing strategy if it only lives on paper. With the strict enforcement of global benchmarks such as EU GMP Annex 1, a controlled environment is either an unbroken chain of engineering certainty or an unmitigated operational risk.

Purity is an uncompromising, daily manufacturing discipline. At the Contamination Control Society, India (CCSI), our objective goes beyond checking a box; our mandate is to anchor true knowledge sovereignty within India's engineering ecosystem.

"We do not build cleanrooms to satisfy regulators; we build them to protect the integrity of our products, our data, and our collective industrial future."

As the sole Indian national member body of the ICCCS in Switzerland, we translate global technical intelligence directly to your shop floor. This edition of The Cleanroom Chronicle serves as your tactical roadmap—covering modern barrier transformations, field leak protocols, and our Q3 technical calendar, featuring the new Bangalore Chapter tracks.

Don't treat this as casual reading. Take these updates to your validation tracks, challenge your teams, and let us collectively drive Indian manufacturing to its world-class peak.

📝 **Call for Technical Papers & Advertising**

To advance this vision, CCSI is expanding its repository. We invite origiTechnical write-ups, case studies, and blog posts from practising professionals. Submit your field-verified insights to ccsindiasecretariat@gmail.com for review for publication.

Advertising slots are now also available on our website and in our newsletter. For enquiries, please contact the CCSI Secretariat.

Thank you for your unwavering commitment to engineering excellence.

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🏛 SECTION 1: NATIONAL VISION & GLOBAL ANCHORS

Editorial: Purity as a Core Strategic Asset

As precision manufacturing becomes the absolute bedrock of India's industrial trajectory, the integrity of our controlled environments cannot remain static. From the delicate assembly lines of electric vehicle (EV) battery packs to the zero-tolerance corridors of sterile pharmaceuticals, biotechnology, aerospace, and defence, contamination control is no longer a downstream validation checkbox. It is an upstream engineering disciplinene.

As the premier authority for cleanroom standards in India, CCSI is aggressively expanding its operational and educational footprint. Our mission is to ensure that our domestic technical community possesses the collective knowledge sovereignty required to compete, comply, and lead on the global stage.

Global Integration: CCSI & ICCCS Switzerland ICCCS

CCSI serves as the official **Indian National Body** representing the country as a full member of the **International Confederation of Contamination Control Societies (ICCCS)**, headquartered in Switzerland. This prestigious global alliance positions CCSI as the sole authorised custodian of international contamination-control credentials in India

The Gold Standard: Joint CCSI & ICCCS Global Certifications

Through this platform, we are uniquely empowered to conduct the **four official ICCCS training courses** domestically:

- **Accredited Faculty:** All specialised technical tracks are developed and delivered exclusively by ICCCS-accredited **trainers**, matching international validation baselines step-for-step.
- **Five-Year Global Passport:** Successful candidates receive an official **joint certificate issued directly by CCSI & ICCCS**. This credential has absolute global validity across international regulatory jurisdictions for 5 years from the date of issuance.

SECTION 2: REGIONAL FOOTPRINT & TRAINING RETROSPECTIVES

Strategic Footprint: CCSI Launches Bangalore Chapter

To better serve India's high-tech industrial corridors, CCSI officially inaugurated its **Bangalore Chapter** on **May 22, 2026**, during an exclusive technical evening at the Hotel Pai Viceroy. The launch marks a monumental milestone in building a localised technical caucus for southern India's thriving biopharma, semiconductor, and medical-device hubs.

The executive board—led by **Chairman Sarfraz Panjwani, Secretary Mr Santsaran Advani, Treasurer Ismail Mulla, and Board Member Sunil Lachhwani**—welcomed a diverse delegation of regional validation engineers, HVAC contractors, and plant heads, setting a collaborative tone for the chapter's upcoming technical calendar. Following this successful launch, the chapter immediately rolled out its structured educational series to train the next generation of industry professionals.

The inaugural event and its subsequent sessions featured high-calibre technical presentations:

- **Mr Pankaj Shah (Chairman Emeritus, CCSI)** delivered a comprehensive overview of the historical evolution of Indian cleanroom practices, highlighting the critical shift from qualitative monitoring to quantitative risk assessment.
- **Santsaran Advani (Secretary, CCSI)** unpacked the mechanics of the revitalised CCSI operational framework, outlining how the society will influence national technical committees.
- **Mr Jayadev Kenchappa (Cleanroom Expert & Bangalore Chapter Mentor)** provided a masterclass on navigating daily operational discrepancies on the shop floor.

Tech Talk on Basic Concepts of Cleanrooms (By CCSI Bangalore Chapter)

CCSI Bangalore Chapter organised a Tech Talk on Basic Concepts of Cleanroom by Mr Jayadev Kenchappa, Cleanroom Expert & Consultant, on 25th June 2026 at The Institution of Engineers, Karnataka Centre, Bangalore, at 6.30 PM

The presentation provided a comprehensive introduction to cleanroom technology, covering the basic principles and practical aspects required for designing, operating, and maintaining cleanroom facilities.

The presentation, attended by 62 industry professionals, was highly interactive and well received, especially by young engineers and professionals entering the cleanroom industry.

The program was sponsored by Steriventa and supported by ISHRAE and ASHRAE, Bangalore Chapters.

Snapshots From the Archive: Past CCSI Training Initiatives

A foundational pillar of CCSI's mission is translating abstract ISO standards into practical shop-floor competencies. Our past hands-on training workshops have continuously bridged this gap for hundreds of technical professionals across India.

Past programs emphasise tactile, physical practice—ranging from sterile material-transfer mechanics to zero-contamination component handling under the watchful eyes of certified instructors (*Figure 3*). By simulating high-pressure line interventions in a controlled learning environment, operators develop the default physical muscle memory necessary to minimise human-borne particle shedding before entering live clean zones.

SECTION 3: RECENT GLOBAL TRENDS IN CONTAMINATION CONTROL

The Demise of "Paper Compliance": Live CCS Execution

Data compiled from recent global regulatory inspections at sterile manufacturing facilities reveal a stark reality: 30% to 35% of critical GMP observations are directly tied **to fragmented contamination control systems.** Regulators have fundamentally shifted their approach. They are no longer evaluating thick, static binders filled with isolated, historical Standard Operating Procedures (SOPs). Instead, inspectors are demanding real-time shop-floor evidence that your **Contamination Control Strategy (CCS)** operates as a live, interconnected ecosystem across every single shift.

The Major Technical Paradigm Shifts

1. **Mandatory Barrier Technology:** Under the fully enforced **EU GMP Annex 1 and PIC/S global baseline**, the implementation of Restricted Access Barrier Systems (RABS) and complete isolators (as seen in *Figure 4*) has transitioned from an advanced premium option to an outright regulatory expectation. If your core manufacturing process requires direct human intervention within critical Grade A zones, your engineering team must now explicitly justify why barrier technology cannot be deployed.

2. **Continuous Environmental Monitoring:** Moving to a periodic, interval-based sampling approach in critical zones is no longer acceptable. Modern cleanroom architecture demands continuous monitoring of viable and non-viable airborne particulates during active operations, supported by automated data integrity paths that prevent the manipulation, omission, or deletion of trending excursions.

3. **Realism in Airflow Visualisation (Smoke Studies):** "Perfect world" smoke studies have become an audit liability. Regulatory inspectors are actively flagging airflow visualisation videos that show only cleanrooms in static, undisturbed states. Modern expectations demand that smoke studies capture actual, worst-case operational simulations. Your visualisation portfolios must document active human interventions, rapid physical movements, component transfer steps, and equipment changeovers to successfully demonstrate that air sweeps predictably away from critical processing surfaces.

🛠 SECTION 4: TECHNICAL FOCUS — FIELD LEAK VERIFICATION

Technical Protocol: Executing an Actionable Cleanroom Leak Test

To maintain standard compliance across your facilities, your technical teams should treat the validation cycle as a systematic, highly repeatable sequence:

1. **Establish Upstream Concentration (Prerequisite):** Introduce the challenge aerosol (e.g., polyalphaolefin) into the air handling system upstream of the HEPA filters. Ensure uniform distribution across the ductwork, verifying a stable upstream concentration of 10 to 100 micrograms per litre.
2. **Scan the Filter Face and Frame (Execution):** Position the photometer or discrete particle counter probe approximately 2.5 centimetres (1 inch) from the filter media face. Scan the entire face with overlapping strokes at a maximum speed of 5 centimetres per second.

3. **Inspect the Perimeter Seal (Critical Boundary):** Slowly traverse the entire perimeter gasket seal and

the mechanical joint between the filter frame and the housing structure. Frame leaks account for greater than 60% of validation failures and must be isolated from face media leaks.
4. **Quantify and Remediate (Evaluation):** Define a leak as any sustained reading greater than 0.01% of the upstream challenge concentration. If a leak is identified, evaluate if it falls within repairable limits (less than 0.5% of the total filter area) or requires immediate filter replacement.

SECTION 5: UPCOMING TECHNICAL CALENDAR – Q3 2026

Advance your facility's compliance, lower your operational overhead, and secure internationally recognised credentials by registering for our upcoming third-quarter tracks.

Event Type	Program Title & Technical Focus	Schedule & Location
Technical Webinar	**Chapter Formation (Hyderabad)** Inauguration of CCSI Hyderabad	**11th July 2026** Time: 6:30 PM Hotel Manohar Begumpet, Hyderabad
Technical Webinar	**Energy Management in Cleanrooms** Strategies for optimising HVAC power consumption and thermal load management without compromising pressure cascades or air change rates.	**31st July 2026** Time: 4:00 PM IST Platform: Digital Stream
Technical Webinar	**Cleanrooms for Data Centres** Controlling airborne macro-particles and corrosive micro-gases to protect high-density server architecture. Focuses on preventing corrosion of copper and silver filaments, humidity transitions, and particulate management under specialised ISO 14644-1 parameters.	**21st August 2026** Time: 4:00 PM IST Platform: Digital Stream
International Masterclass	**HEPA Filters Testing & Standards** An intensive, internationally accepted training program combining rigorous theoretical models with **hands-on practical sessions** inside an operational factory.	**28th & 29th August 2026** Location: Mumbai / Factory Location

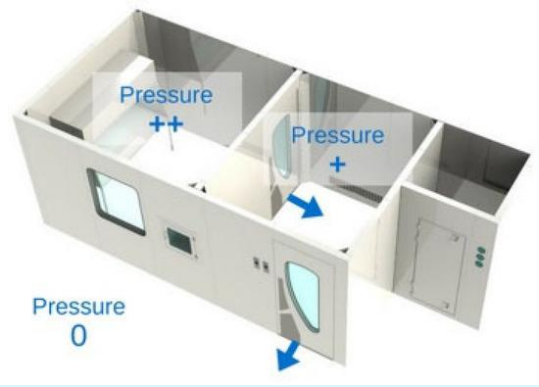
⚠ **Registration Notice:** Due to the hands-on nature of the factory floor testing modules, spaces for the August Masterclass are strictly capped to maintain optimal trainer-to-student ratios. **Get in touch with the CCSI Secretariat immediately** to lock in your registration.

SECTION 6: OPERATIONAL EXCELLENCE & PARTNER MEDIA

Audit-Ready Checklist: Shop Floor Baseline Evaluation

Before your next external regulatory audit window opens, bring your engineering, validation, and quality assurance teams together to evaluate your live operational controls against this baseline:

- [ ] **Interlocking Dynamics:** Are the physical interlocks on your Grade A and B pass-through hatches functioning perfectly, ensuring that entry and exit doors can never be breached simultaneously?
- [ ] **Pressure Differential Stability:** Do your adjacent cleanroom zones maintain a continuous minimum differential pressure of **10 Pascals** as a live, monitored guidance value?



- [ ] **Human Factors Alignment:** Have your gowning and glove management protocols drifted over time? Are your operators trained to explain the scientific *"why" behind their movements rather than simply memorising step-by-step instructions*?
- [ ] **Vector and Material Tracking:** Is your raw

  material transfer sequence completely separated from personnel airlocks, or do you have a strictly enforced, time-based operational segregation protocol in place?

Join the Caucus: CCSI Membership Tiers

The Contamination Control Society, India, is a high-level technical caucus engineered for the architects of purity. We invite validation engineers, cleanroom designers, HVAC specialists, quality directors, manufacturing leaders, and other professionals interested in this field to align with our mission formally.

Membership Category	Structure Details
Professional Tier	Entrance Fee: **WAIVED** (Introductory Offer) Annual Subscription: ₹500/- *(Billed as a minimum 3-year term: ₹1,500 + GST)*
Life Membership	One-time Structural Investment: **₹15,000/- + GST** ProProvides permanent voting rights and lifetime access to global training networks.

Media & Industry Placement Opportunity

Interested in advertising with us? Get in touch with the CCSI secretariat now. Engage directly with hundreds of cleanroom architects, validation engineers, facility heads, and technical decision-makers across India's premium high-tech manufacturing sectors.

Connect with the Secretariat for Registrations, Corporate Partnerships, & Advertising Opportunities:

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