

HPAPI CONTAINMENT EXCELLENCE: Q&A



At Ajinomoto Bio-Pharma Services, HPAPI containment is approached as an integrated lifecycle capability rather than as a stand-alone safety feature.

Safe and compliant HPAPI manufacturing is a system that aligns safety, quality and operational performance from early development through commercial supply. This approach is built on in-house toxicological assessment, OEB-based risk classification, engineered containment, closed processing, facility-integrated controls, trained execution and performance verification under representative operating conditions.

Together, these elements support reliable HPAPI manufacturing while protecting personnel, product quality and ultimately patient safety.

Integrated lifecycle containment

At Aji Bio-Pharma Services containment is managed as an end-to-end strategy spanning early development, scale-up, commercial manufacturing, cleaning, changeover, maintenance, warehousing, QC and waste handling.

Scientifically grounded and verified

At Aji Bio-Pharma Services we do our own in-house toxicological assessment, OEB classification, containment performance target setting, and in-house SMEPAC-based verification under actual process conditions with EHS oversight.

Operationally pragmatic by design

At Aji Bio-Pharma Services, closed processing is embedded throughout our containment strategy, supported by engineered controls, facility segregation, standardized procedures, training, simulations and formal analytical verification during cleaning and line clearance.

Q1.

Why is containment so critical in HPAPI manufacturing?

High potency APIs require a fundamentally different manufacturing approach because their elevated potency is associated with stringent toxicological thresholds, frequently resulting in occupational exposure limits in the low microgram-per-cubic-meter range or below.

The risk profile of HPAPIs extends beyond operator exposure alone. Even trace residues can represent a critical cross-contamination hazard that may compromise product quality and ultimately patient safety.

For that reason, conventional handling approaches are presented as no longer sufficient for these compounds. Instead, safe and compliant HPAPI manufacturing is described as a fully integrated containment strategy that protects personnel, product quality and patient safety across all operational phases and throughout the full product lifecycle.

For Aji Bio-Pharma Services these are enablers of manufacturing reliability. By embedding a scientifically grounded and risk-based containment strategy early in the project, the organization can reduce late-stage redesign, deviations and avoidable operational constraints.



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Q2.

What does a robust containment strategy look like in practice?

The starting point is a strong scientific foundation. At project initiation, APIs and relevant intermediates undergo a comprehensive in-house toxicological assessment. The resulting data are used to assign the appropriate occupational exposure band and corresponding containment performance target, and to derive health-based exposure limits.

From there, the containment strategy is built according to the hierarchy of controls, with engineering controls prioritized over operational measures. **ABPS' containment strategy** highlights primary containment solutions such as closed sampling and dispensing systems, high-containment isolators, barrier technologies, closed material transfer systems, contained discharge technologies and contained analytical sample preparation.

Process design is also treated as a form of primary containment. Closed processing is supported by in-situ operations, process analytical technology for in-line monitoring and telescoping to maintain closed transfer between process steps.

Even with strong source containment, residual risk remains. That is why ABPS' containment strategy also focusses on facility-integrated secondary containment through local exhaust ventilation, HVAC-based segregation, pressure cascades, HEPA filtration, directional airflow, dedicated HPAPI areas and controlled personnel and material flows. Together with procedures, training and task-specific PPE, these measures form a layered system designed for reliable execution under GMP conditions.

Q3.

How is containment performance sustained over time?

Engineered containment solutions alone do not guarantee effective exposure control. Their performance must be demonstrated under representative operating conditions.

Containment performance is therefore verified using the standardized SMEPAC methodology, enabling quantitative evaluation of airborne particulate emissions and surface contamination against predefined targets. At Aji Bio-Pharma Services SMEPAC-based verification is conducted in-house under EHS oversight and under actual process conditions, including operator interaction.

A key differentiator is that this verification is embedded in a lifecycle approach. Cleaning and changeover activities are explicitly included, recognizing that exposure and cross-contamination risks can increase during equipment opening, disassembly or manual access. These activities are managed through validated compound-specific cleaning procedures, analytical verification, MACO-based assessment and formal line-clearance before subsequent operations are released.

The human factor is treated as equally important. This is a continuous effort based on comprehensive training, hands-on simulations, controlled access, gowning and de-gowning procedures, spill response and decontamination protocols, as well as a broader culture of safety, learning, incident reporting and continuous improvement. Together, these elements support sustained containment performance over time.





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