Bridging Biorisk Management, Cyberbiosecurity, and Regional Collaboration in Southeast Asia

Reflections from the U.S. National Academies Workshop on Biotechnology and Biomanufacturing Safety and Security (Singapore, September 24–25, 2026)

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Executive Summary & Core Takeaways

On September 24-25, 2026, leading scientists, biomanufacturing executives, policy experts, and public health leaders from across Southeast Asia and the United States convened at the Pan Pacific Singapore for the landmark workshop, **Strengthening Southeast Asian Academia and Industry Biotechnology and Biomanufacturing Safety and Security**, hosted by the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM). As Director of the Institute of Environmental Health and Sustainable Development (IEHSD) and a medical doctor specializing in One Health, I had the privilege of representing Vietnam as an invited speaker during the session on *Integrated Biosecurity and Research Security Protections for Biotechnology & Biomanufacturing*.

The primary objective of my presentation and overall engagement was to address a fundamental operational challenge: **How do we translate high-level biosafety and biosecurity policies off paper and embed them seamlessly into daily laboratory bench routines?** Across Southeast Asia, our bioeconomy is expanding rapidly from traditional agricultural biotechnology into advanced synthetic biology, gene editing, industrial biomanufacturing, and mRNA platforms. However, our baseline empirical audits reveal that institutional oversight remains dangerously fragmented. Overcoming this gap requires a unified, process-driven approach anchored in the ISO 35001 biorisk management standard, robust cyberbiosecurity safeguards, non-punitive incident reporting, and sustained regional collaboration.

> **Core Message for Partners & Donors:** *"Effective biorisk management is not an administrative burden or a static checklist - it is an essential operational enabler that protects our researchers, secures biotechnology investments, and safeguards regional health security across Southeast Asia."*

The Evolving Bioeconomy Risk Horizon

Southeast Asia is witnessing unprecedented growth in life sciences innovation. National development strategies - including the **ASEAN Community Vision 2045** and the **2024 ASEAN Leaders' Declaration on Biosafety and Biosecurity** - explicitly mandate the creation of minimum laboratory standards, sustainable human resource capacity, and responsible oversight of high-consequence biological agents. However, the physical and digital risk landscape has evolved beyond legacy frameworks that focused solely on agricultural Genetically Modified Organisms (GMOs):

- **Dual-Use Research of Concern (DURC):** Legitimate scientific inquiry in synthetic biology, metabolic engineering, and viral vector development generates knowledge, techniques, and biological materials that could be accidentally released or maliciously misused if left unmonitored.
- **Cyberbiosecurity Vulnerabilities:** As medical, epidemiological, and genetic data migrate to online cloud databases, digital biological assets - including Whole Genome Sequencing (WGS) data, proprietary strain blueprints, and automated bioreactor control algorithms - become prime targets for cyber theft, ransom, or unauthorized manipulation.
- **One Health Convergence:** Because high-consequence pathogens cross species barriers, effective biosecurity demands seamless, real-time coordination across human health ministries, veterinary services, environmental surveillance networks, and military medical laboratories.

Empirical Reality: What Baseline Audits Reveal

To construct realistic interventions, IEHSD and regional partners conducted extensive empirical assessments across laboratories in Southeast Asia (including baseline audit datasets SAND2025-05544O and SAND2025-05198O). The data highlights four critical operational deficits:

Metric	Survey Finding	Operational Impact & Gap Analysis
36%	**Ad-Hoc / Basic Policies**	36% of surveyed institutions operate on informal, ad-hoc rules without standardized guidelines for handling hazardous biological materials.
61%	**One-Time Orientation**	61% restrict safety training to a single orientation event upon hire, leading to severe protocol decay over time.
71%	**ISO 35001 System Deficit**	71% of standard ISO 35001 biorisk indicators are only partially implemented or entirely missing from institutional operations.
60%	**Biosecurity Risk Deficit**	60% of facilities lack documented biosecurity risk assessments, focusing exclusively on physical biosafety (airflow, gloves) while omitting pathogen tracking.

Key Policy Insight: Traditional national decrees (such as Vietnam's Decree 103) focus heavily on physical facility biosafety criteria (WHO LBM 4th Edition) but completely omit operational biosecurity oversight, pathogen inventory tracking, and incident logging systems. This creates a dangerous illusion of security.

Translating ISO 35001 into Practical Laboratory Controls

To bridge this gap, institutions must transition from static regulations to a continuous, process-driven biorisk management system using **ISO 35001**. This requires operationalizing four core domains:

1. **Material Accountability & Storage:** Replacing informal paper logbooks with digital pathogen tracking software, verifiable access logs, sample transfer confirmation protocols, and dual-lock cold storage units for high-consequence agents.
2. **Access & Physical Security:** Implementing biometric access controls, background checks for staff entering BSL-2/BSL-3 containment zones, visitor logging, and physical perimeter safeguards.
3. **Waste & Containment Management:** Establishing agent-specific chemical and thermal inactivation Standard Operating Procedures (SOPs), validated autoclave cycles, and emergency spill response protocols to ensure zero environmental release.
4. **Incident Logging & Non-Punitive Culture:** Establishing mandatory, non-punitive near-miss reporting systems. When a laboratory technician accidentally drops a vial or suffers a minor glove tear, they must feel psychologically safe to report the incident immediately without fear of termination or public embarrassment.

Vietnam's Strategic Action Plan & Regional Alignment

In Vietnam, IEHSD works alongside national ministries to implement a comprehensive Strategic Action Plan that aligns physical laboratory safety with digital biosecurity:

- **Governance & Data Classification:** Enforcing the national Cybersecurity Law and Decree 13/2023 by establishing a strict **Three-Tier Biological Data Classification System** (Public, Restricted, Confidential) to regulate genomic transfers and industrial bioprocess documentation.
- **Facility & Supply Chain Screening:** Mandating dual-use risk screening for large-scale bioreactors and automated DNA synthesizers, while enforcing 'Know Your Customer' (KYC) verification protocols on sales of sensitive biological strains and precursor reagents.
- **Cyberbiosecurity & Industrial Automation:** Securing Supervisory Control and Data Acquisition (SCADA) and Programmable Logic Controller (PLC) systems in biomanufacturing facilities, while conducting routine data breach simulation exercises.
- **Adopting Singapore's DURC Governance Model:** Moving away from rigid, outdated lists of regulated pathogens to adopt Singapore's **Consequence-Based Risk Classification** framework, evaluating whether experiments could inadvertently enhance pathogen toxicity, transmissibility, or immune evasion.

Empowering the Workforce: Scaling Peer-Led Education

Equipment, biometric locks, and written manuals are ineffective without trained, vigilant personnel. Baseline audits indicate that **80% of institutional implementers cite staff resistance to changing established habits** as their primary barrier, while **70% cite severe budget constraints**.

To overcome these human barriers, IEHSD and the Vietnam One Health University Network (VOHUN) successfully demonstrated the power of the **Peer-Led Master Trainer Model**:

- **30 Master Trainers → 110+ Local Practitioners:** 30 TDP-certified Vietnamese Master Trainers designed and facilitated 6 Advanced Trainer Workshops across Vietnam, training over 110 local practitioners across 62 medical, veterinary, and academic institutions.
- **29 Certified Advanced Assessors:** Established a qualified cohort of regional assessors capable of conducting institutional ISO 35001 gap analyses using standardized 500-question audit tools.

- **Targeting Peripheral & Provincial Laboratories:** Expanding continuous refresher training beyond top national institutes to reach provincial diagnostic and university laboratories, which face a 55% compliance gap compared to central facilities.

A Strategic Call to Action for Donors, Industry, and Regional Partners

The Singapore workshop demonstrated that technical solutions exist, but scaling them across Southeast Asia requires sustained international partnership, target funding, and institutional leadership. IEHSD calls upon international donors, industry partners, and regional bodies to support four strategic priorities:

1. Operationalize the ASEAN Biosafety Network	Activate the regional platform mandated by the 2024 ASEAN Leaders' Declaration to harmonize laboratory guidelines, facilitate technical exchanges, and establish standardized biorisk audit metrics.
2. Harmonize High-Risk Biobanking	Support the ASEAN Biobank Feasibility Study (led by the Philippines and Singapore) to consolidate fragmented pathogen storage, eliminating security vulnerabilities across high-consequence sample repositories.
3. Scale One Health University Networks	Provide dedicated grant support to SEAOHUN and VOHUN to integrate biorisk management, cyberbiosecurity, and dual-use bioethics into undergraduate and postgraduate medical, veterinary, and biotechnology degree curricula.
4. Launch Institutional Twinning & Seed Grants	Establish country-level twinning programs paired with small seed grants ($5,000–$15,000) to mentor provincial laboratories through ISO 35001 implementation, digital inventory adoption, and local trainer coaching.

Conclusion: The Institute of Environmental Health and Sustainable Development remains fully committed to leading these efforts in Vietnam and across the ASEAN region. By uniting physical biosafety, cyberbiosecurity data protection, workforce empowerment, and executive leadership, we can ensure that biotechnology and biomanufacturing serve as powerful engines of sustainable development and health security.

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