



Changes in the Regulatory Environment Surrounding the Asian Region and Responses – Collaboration with PMDA

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Key Measures

1. Promote Regulatory Convergence and Harmonization
2. Leverage Digital Transformation and Regulatory Innovation
3. Enhance Clinical Trial Capabilities and Collaboration
4. Capacity Building and Regulatory training
5. Accelerate Development of Advanced Therapies
6. Focus on Regional Supply Chain Resilience
7. Foster Public-Private Partnerships
8. Strengthen Pharmacovigilance and Post-Market Surveillance
9. Encourage Sustainable and Value-Based Healthcare Models



1. Promote Regulatory Convergence and Harmonization

- Adopt Common Standards
- Mutual Recognition Agreements (MRAs)



2. Leverage Digital Transformation and Regulatory Innovation

- Digital Submissions and AI-Driven Review Processes
- Regulatory Sandboxes for Emerging Technologies



3. Enhance Clinical Trial Capabilities and Collaboration

- Regional Clinical Trial Networks
- Adopt Adaptive Trial Designs



4. Capacity Building and Regulatory Training

- Knowledge Sharing Initiatives
- Regional Centers of Excellence



5. Accelerate Development of Advanced Therapies

- Joint Advanced Therapy Pathways
- Incentivize Biologics and Regenerative Medicine



6. Focus on Regional Supply Chain Resilience

- Strengthen Supply Chain Networks
- Digital Supply Chain Management



7. Foster Public-Private Partnerships

- Collaborative Research Initiatives
- Innovation Incubators



8. Strengthen Pharmacovigilance and Post-Market Surveillance

- Harmonized Regional Pharmacovigilance Systems
- Real-Time Monitoring Technologies



9. Encourage Sustainable and Value-Based Healthcare Models

- Value-Based Pricing Models
- Green Manufacturing Initiatives



Thank you