



Regulatory Convergence: Does a Risk-Based Approach in Developing Regulations Have a Role?

Diane Wurzburger
VP Global Regulatory Intelligence & Policy
GE HealthCare



Framing the Challenge

Fragmented Regulatory Requirements

Different countries have varying regulatory systems causing inefficiencies and delays in medical device approvals.

Resource Constraints in Regulation

Regulatory authorities face challenges managing large volumes of innovative technologies amidst limited resources.

Impact of Advanced Technologies

Emerging AI and digital health solutions raise complexity, requiring regulatory adaptation to maintain safety.

Key Question:

**How can
regulators align
frameworks
without
compromising
patient safety?**



What is Regulatory Convergence?

- **Voluntary alignment of regulatory frameworks** through shared principles and guidance.
- **Does not require identical regulations**
- **Reduces duplications, increases efficiency and maintains safety**
- **Enables reliance pathways, mutual confidence** between regulators

Harmonization

Uniform rules

Convergence

Aligned approaches

Reliance

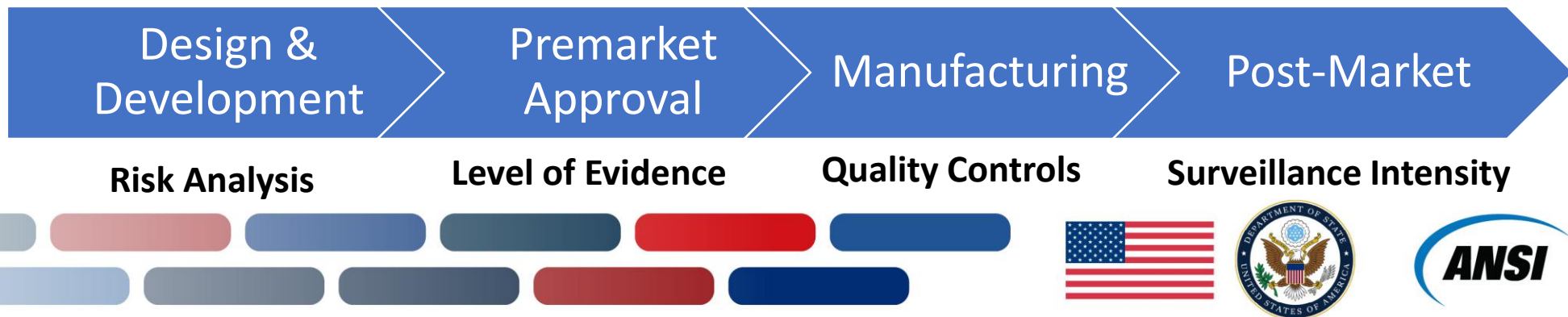
Use of another trusted authority's work



What is a Risk-Based Approach?

- **Regulatory requirements scaled to the level of patient and public health risk**
 - Not all devices pose equal risk
 - Uniform regulation = inefficiency + resource strain
- **Key components include:**
 - Lifecycle – based oversight (pre- and post-market)
 - Comparable device classification
 - Proportionate evidence requirements

Risk-based considerations are embedded end-to-end across the Total Product Lifecycle



Why risk-based regulation supports convergence

Common language



Risk principles make regulatory expectations easier to compare

Predictable controls



Similar risk levels lead to similar evidence & review expectations

Efficient resource use



Regulators focus effort where risk is highest

Foundation for reliance

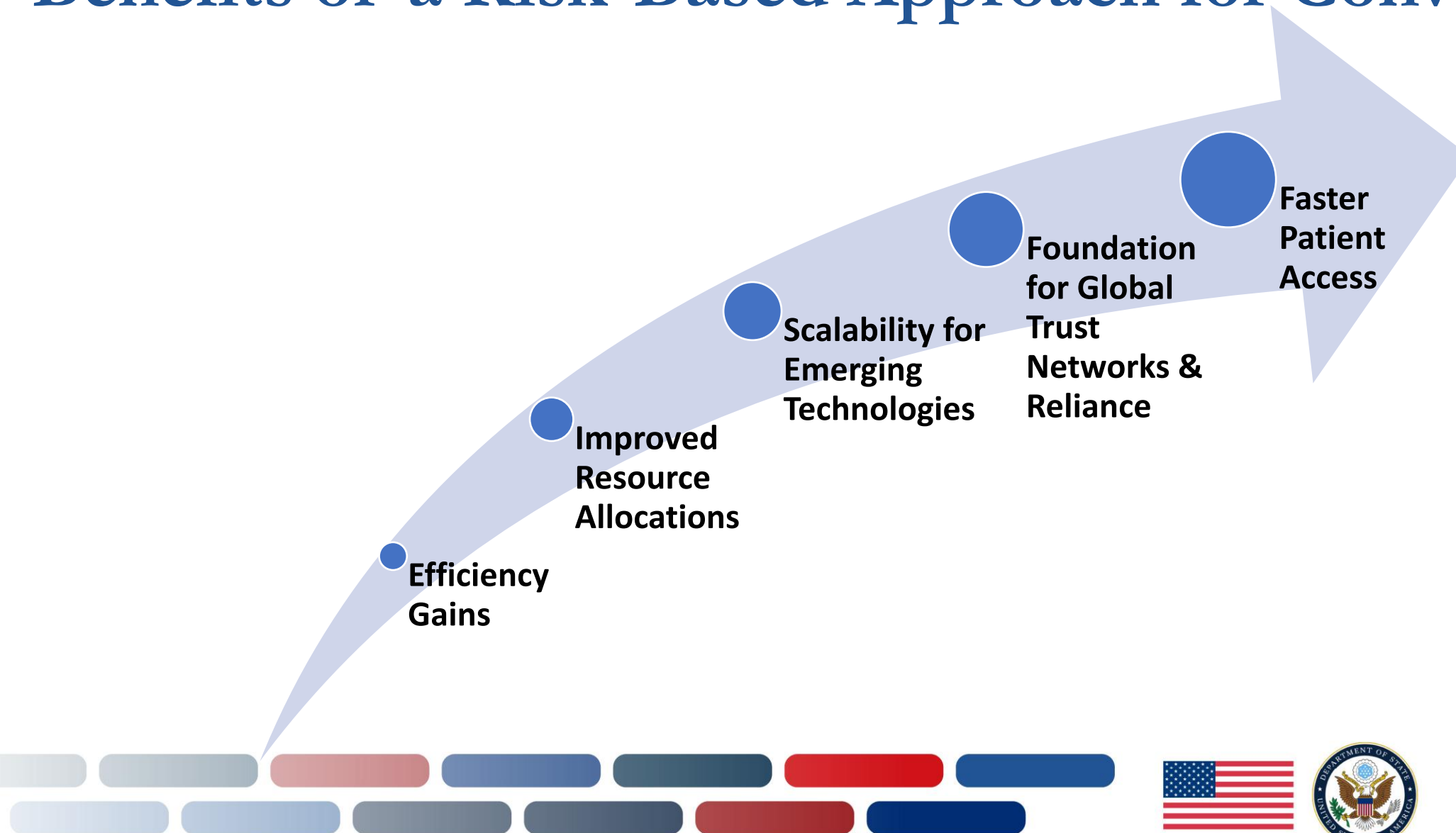


It becomes easier to understand whether another authority's review is sufficient

Risk-based regulation provides a bridge between regulatory convergence and regulatory reliance

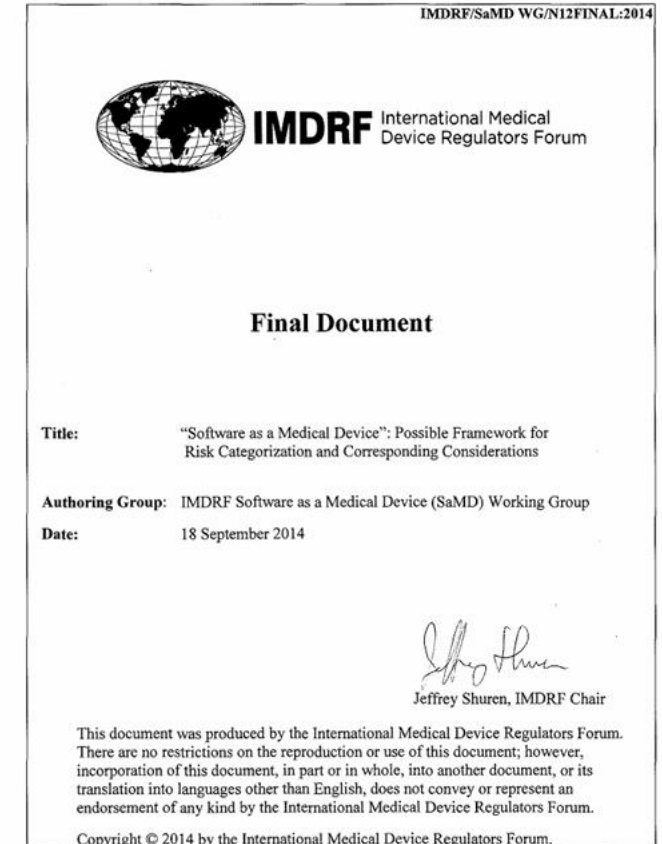


Benefits of a Risk-Based Approach for Convergence

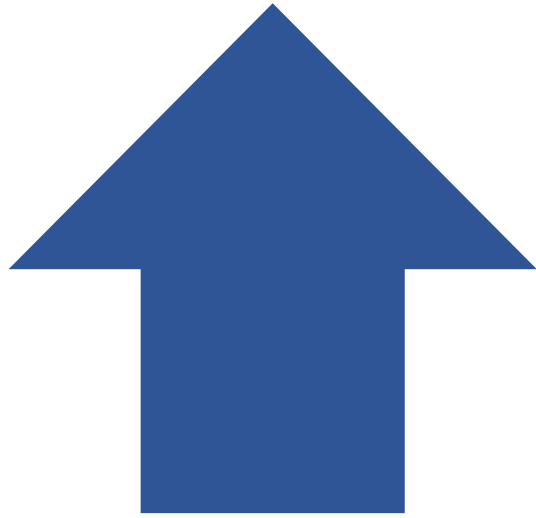


Case Example: Software as a Medical Device

- **IMDRF risk framework categorizes software into 4 risk levels (I-IV)**
 - Based on:
 - Clinical impact (inform → treat)
 - Condition severity
 - Strong example of convergence that is widely adopted across regions



When Risk-Based Regulation Goes Wrong

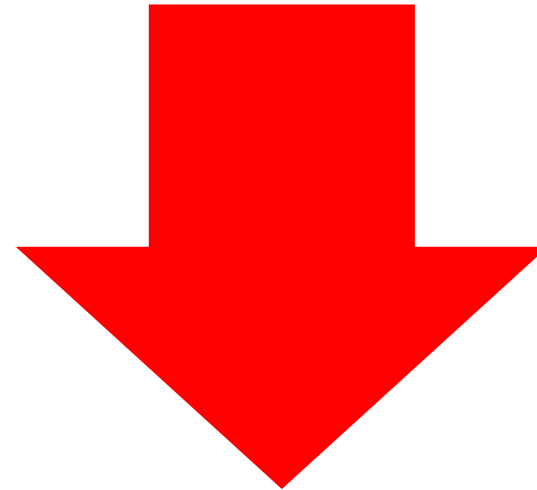


Over-regulation

- High-risk controls applied to low-risk products
- Delays timely access
- Creates unnecessary burden
- Blocks innovation

- Low-risk controls applied to high-risk products
- Weakens public health protection
- Undermines confidence

Under-regulation



What is the Future Direction?

- **Increased use of Reliance Models and shared assessments**
- **Greater adoption of IMDRF guidance**
- **Greater alignment in**
 - Post-market surveillance
 - Change management (eg, PCCP)
- **Risk-based models evolving for innovations**
 - AI/ML lifecycle regulation



Key Take Aways

- **Risk-based regulation is the foundation of modern device regulation and is already a global common principle**
- **It enables convergence without requiring full harmonization**
 - ✓ **Proportionate oversight**
 - ✓ **Efficient resource use**
 - ✓ **Trust and cross-regulator alignment**
 - ✓ **Faster patient access**

Without risk-based thinking → convergence is not scalable



Thank you!

