

# Prioritization Approaches within Small Molecules

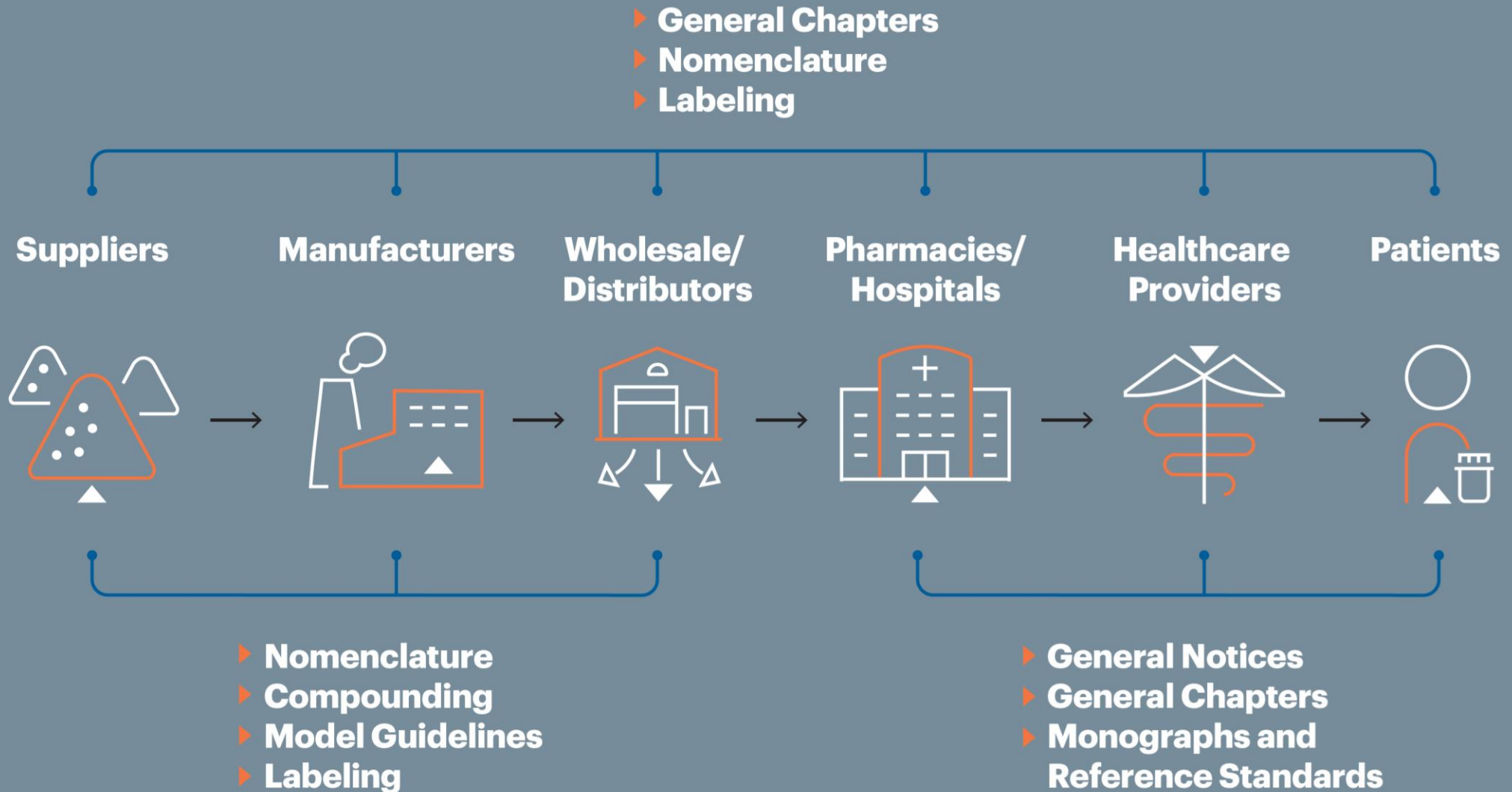
---

Edwin Gump, Ph.D.

Vice President - Small Molecules  
Global Standards and Science Division



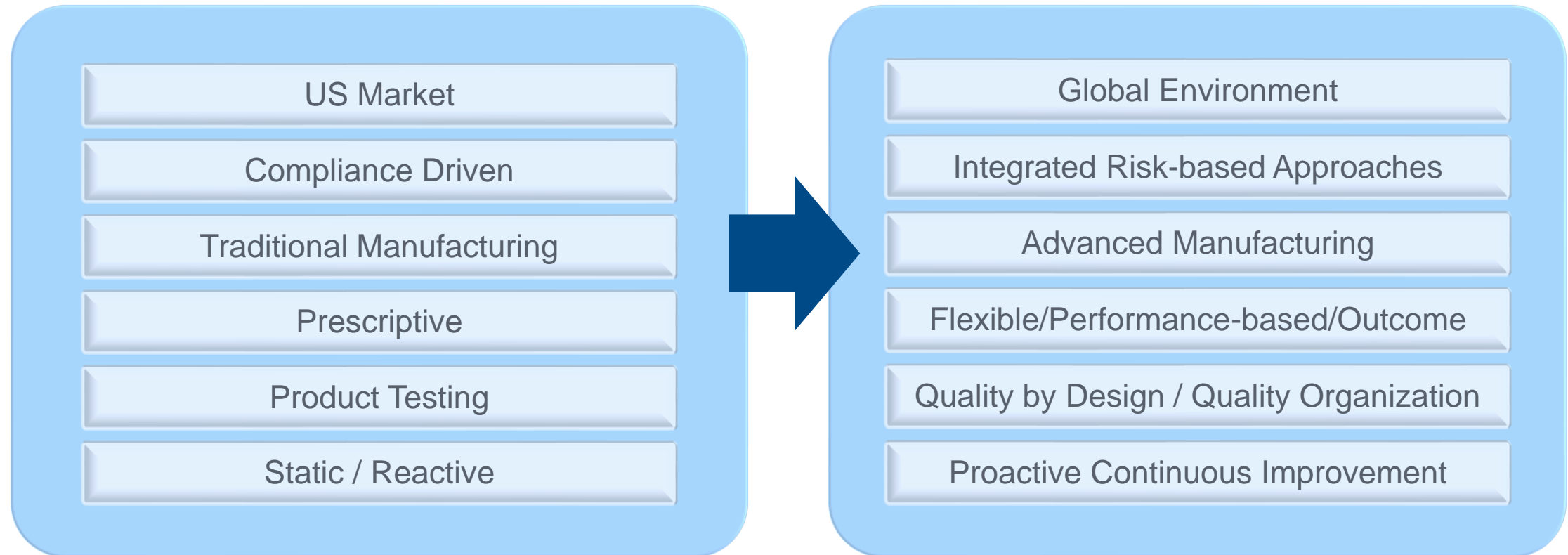
# More than 9,000 USP Standards provide quality benchmarks across the supply chain



# Quality Paradigm Shifts Directly Impacting Standards




Proactively and collaboratively identify paradigm shifts and drive discussions of solutions to ensure quality products are supported through relevant standards.





# Ensuring standards have impact

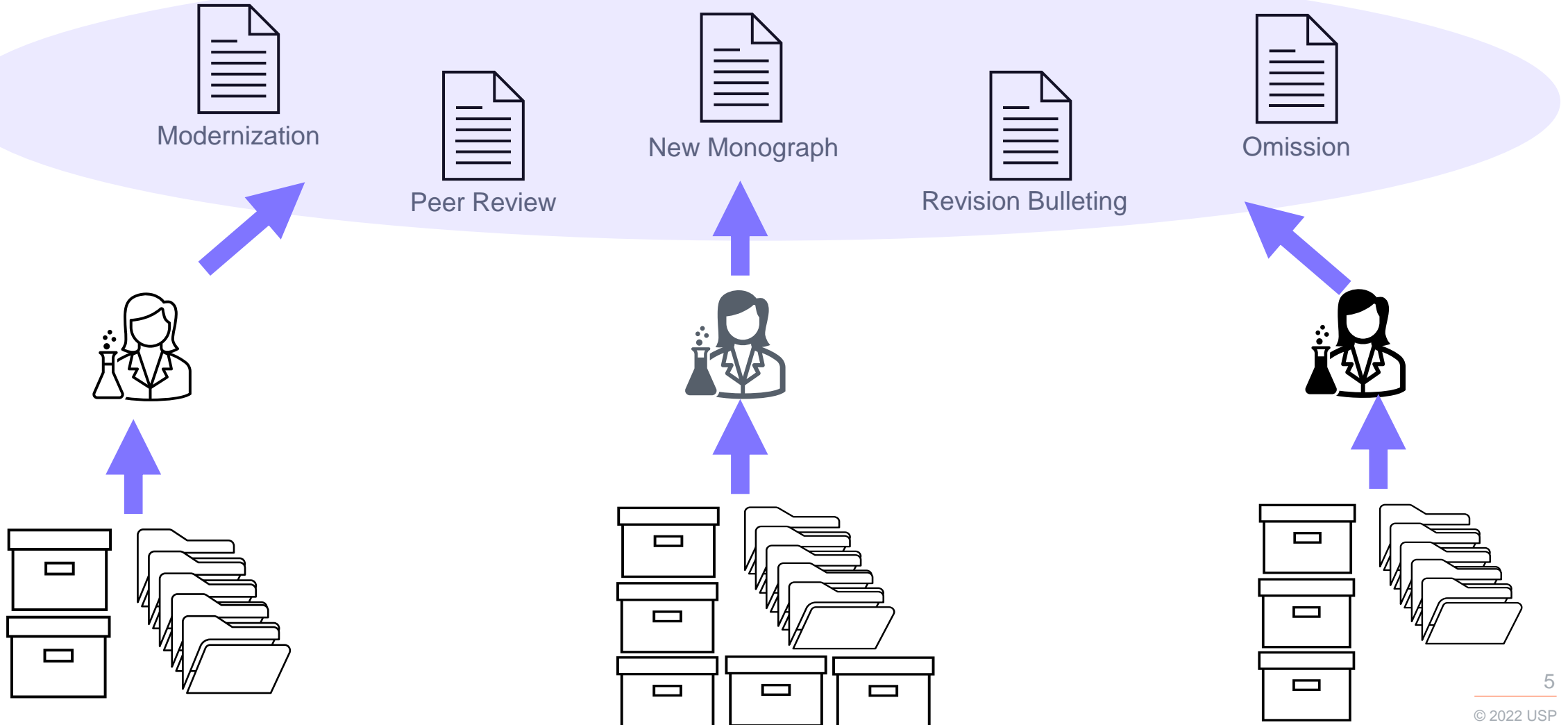


- 
- A group of nine diverse children of various ethnicities and ages are standing in a line, smiling and laughing. They are dressed in casual clothing like t-shirts, sweaters, and jeans. The background is a dark, out-of-focus indoor setting.
- ▶ To date, our standards impact 2 billion people globally – but our commitment to empower a healthier tomorrow doesn't stop there.
  - ▶ As medicines come to market and public health issues emerge, new standards must be created to address public need.
  - ▶ Standards evolve to keep pace with industry changes and to respond to public health challenges.

# What are we changing and why?



## The old ways – portfolios and everyone does everything



# Changing the way that we work



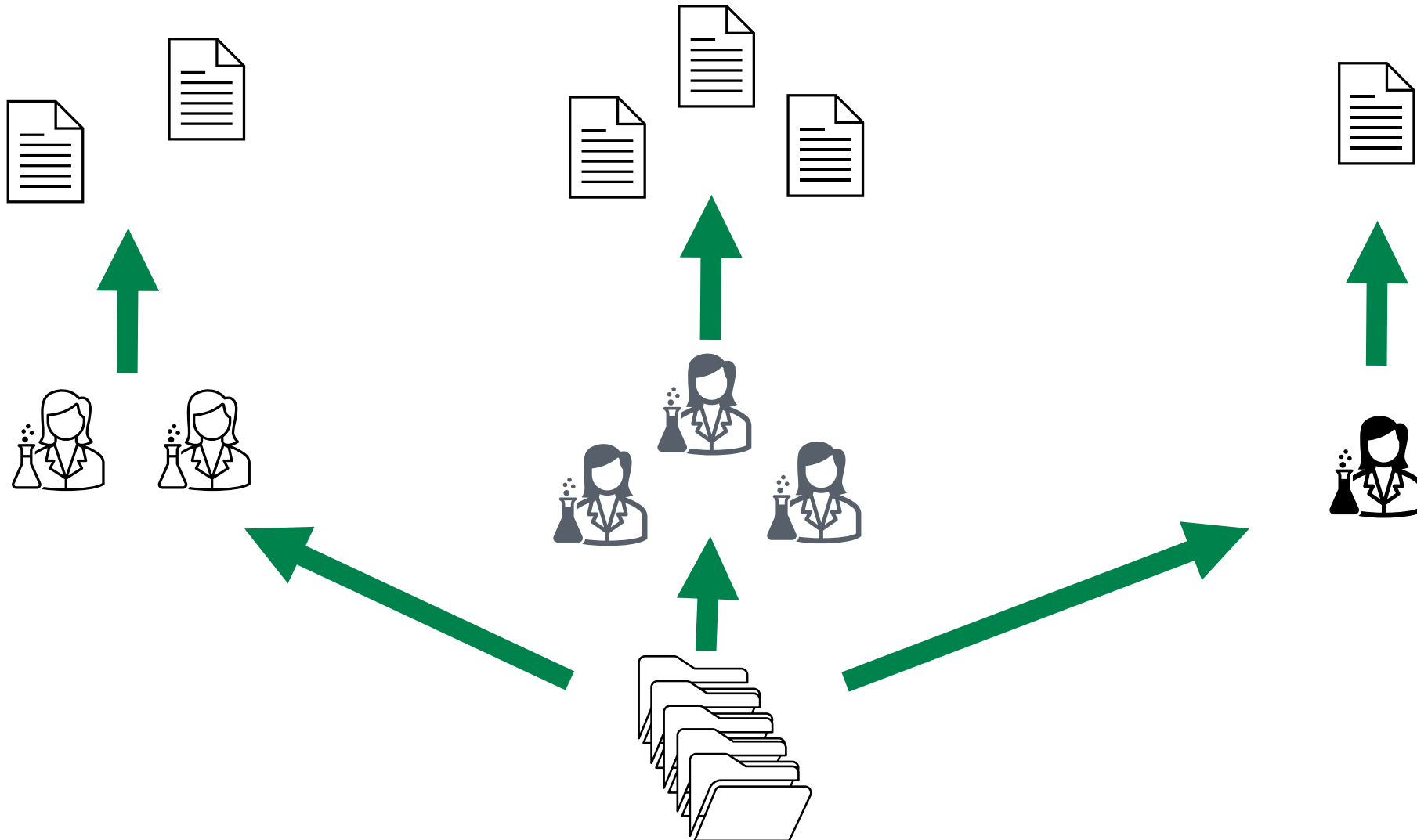
## The path forward

- ▶ Elimination of documentary scientist portfolios
- ▶ Centralized distribution of work
  - More strategic and balanced distribution
  - Assignment ensures available capacity and attuned expertise
- ▶ Focus available resources on high impact, high value, work
  - Not working towards a number
- ▶ Establish more focused, specialized roles, for scientist efficiency, e.g.
  - Small Molecules Centralized Review Team
  - Small Molecules Accelerated Case Team

# The New Way



## Centralized distribution, with focused roles



## Priority

**Assess, acquire, and produce standards that align with key priority design principles**

### ▶ Production Plan

#### – Operational Priority

- Standards development work USP is obligated to process promptly, must be addressed quickly for regulatory compliance, avoid drug shortages, etc. Completion by required timelines must be assured.
- e.g. accelerated revisions

#### – Strategic Production

- Standard development work that USP chooses to pursue; priority determination ensures capacity supports the most impactful standards



# How Work Will be Assigned



## Assignment by four factors

- Case Prioritization
  - Identify and work on items most important to Small Molecules
- Case Requirements
  - What special expertise/experience does this case require to be efficiently executed?
- Staff Capacity
  - Visibility into individual capacity based on level of experience and complexities in case load
- Staff Capability
  - Documented skills inventory



# Collaboration drives standards development



## Engagement around knowledge is an essential thread



# Thank You



**The standard of trust**