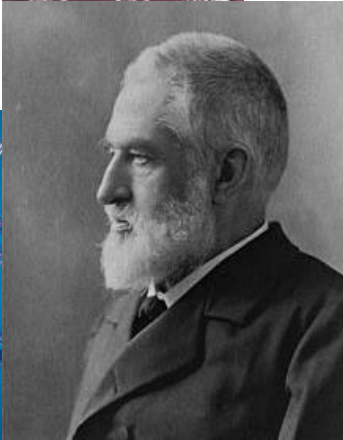
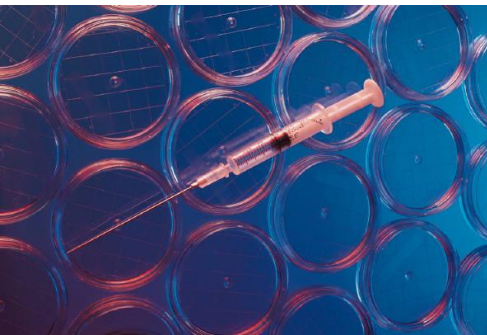
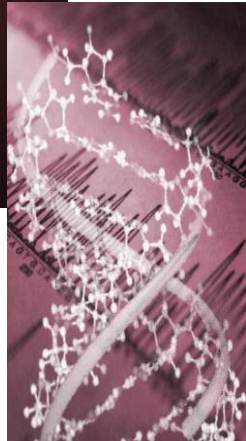


Pyramids, Puddings, Fingerprints, and Frogs: Looking Back on 20 years of Platform Development

Jeffrey C. Baker, Ph.D.

CASSS Well Characterized Biological Products
Washington, DC

January 26, 2023



In The Beginning excellence in process development and innovative manufacturing were critical strategic capabilities

- it was considered a business differentiator for investors
- it was considered a capacity intensifier and risk mitigator for low-volume, high potency products, especially in multiproduct sites.
- it increased likelihood of technical success at green site plants
- it enabled data driven explanation of regulatory commitments or CAPA events with regulatory authorities.
- it enabled recruiting and retention of top technical talent in the molecular life sciences for the development and manufacturing workforce where pain of failure was perceived to be quite high.

- “...on board and up to speed, enhancing shareholder value by shedding capital and headcount to boost return on net assets in cross functionally aligned but nevertheless individually accountable matrix organizations where patient centered, risk based decisions are the North Star and alignment of message and systemic anticipation and mitigation of relevant risks allow us to fully realize the potential of diverse workforces empowered by shared operational values in fungible work environments.”
- Ground rules and swim lanes
- Deliverables and more swim lanes
- Roadmaps and Gantt Charts (with POCs and SMEs in their swim lanes)
- Critical Success Factors
- Lean and Leaner, W.I.N. (What's Important Now), SMART Goals
- **Milestone based thinking, workforce specialization, and a tyranny of timelines**





In 2022 CDER approved

- 22 novel small molecule drugs.
- 15 novel protein therapeutics
- 7 biosimilar therapeutic proteins (351(k))

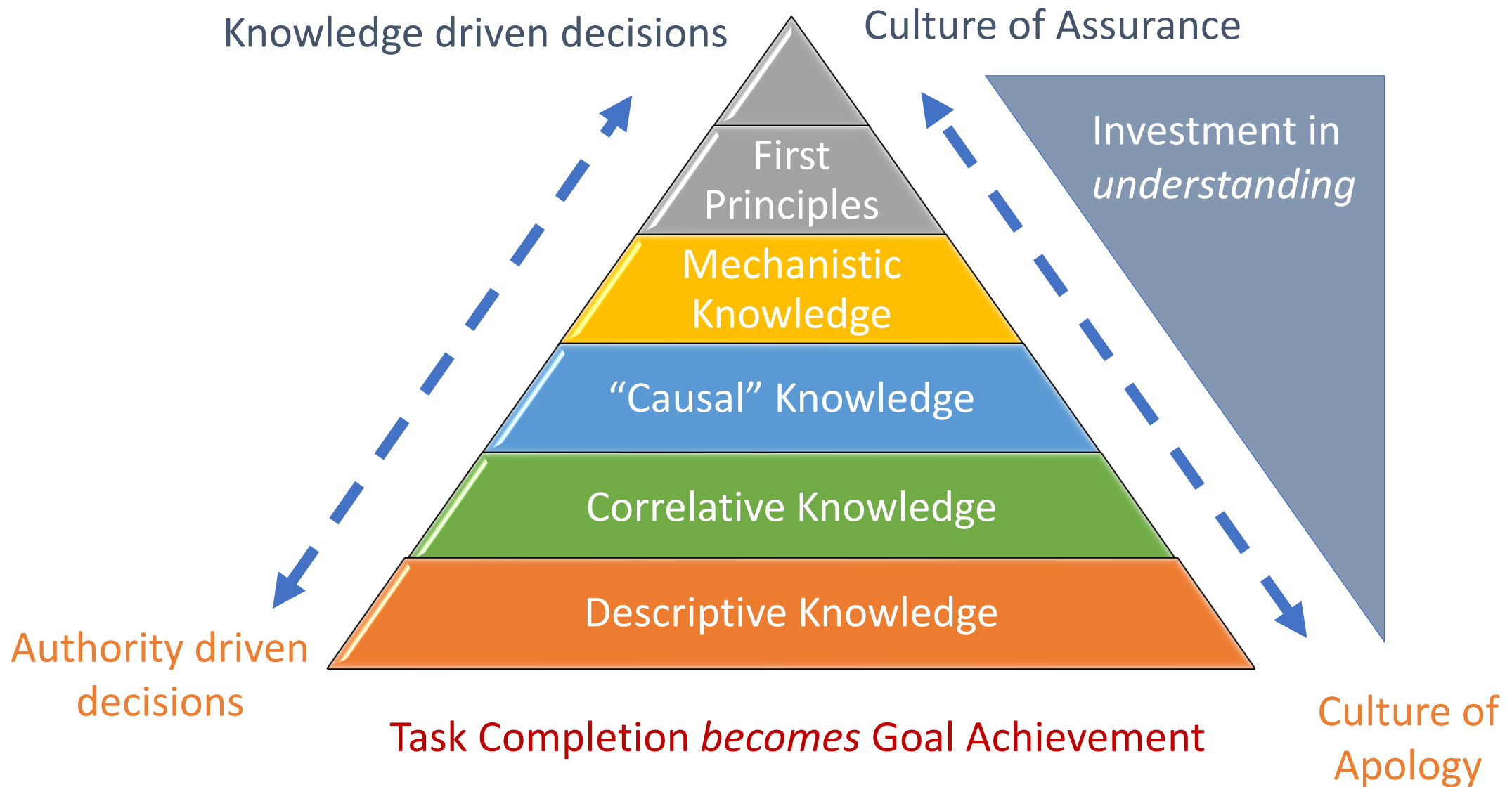
In 2022 CBER approved

- 2 vaccines (one live, one mRNA)
- 5 gene therapies
- 1 fecal microbial suspension



Why am I a little concerned?

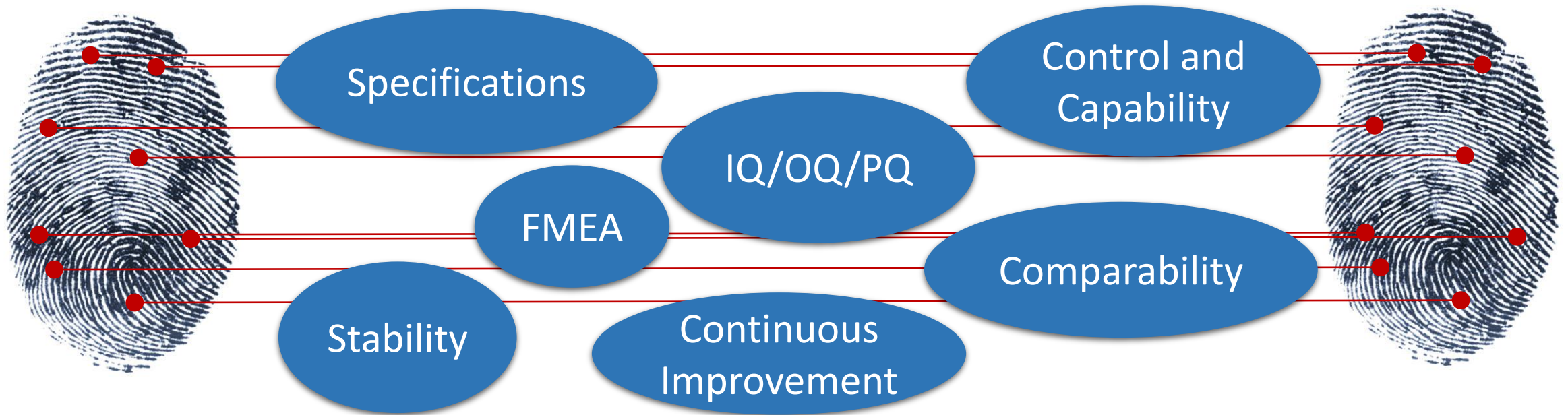
- The focus on speed is rapidly building (fully acceptable) barracks in the basement.



Why am I a little concerned?

- Effects of Speed rather than Velocity
- The Myth of Fingerprints

Fingerprints all over the biotech space



The Myth of Fingerprints: Identity, Difference, and Awareness

“Courtroom testimony and reports stating or even those implying that fingerprints collected from a crime scene belong to a single person are indefensible and lack scientific foundation”.

Report on Latent Fingerprint Examination (2017) , AAAS Scientific Responsibility, Human Rights, and Law Program.
This AAAS study aligns with previously published reports by the National Research Council (2009), National Institute of Standards and Technology (2012), and the President’s Council of Advisors on Science and Technology (2016).

“Fingerprint examiners are presently ill-equipped to reason their conclusions as they are accustomed to regarding their conclusions as a matter of certainty and seldom challenged.

The Fingerprint Inquiry Report of Scotland (2011), Crown Copyright

Why am I a little concerned?

- Effects of Speed rather than Velocity
- The Myth of Fingerprints
- The Pilot Plant Problem



Why am I a little concerned?

- Effects of Speed Superseding Velocity
- The Myth of Fingerprints
- The Pilot Plant Problem
- “The Pudding Problem”



“Metaphors comprise the conceptual spectacles through which we view the world.” -- Immanuel Kant

“Science must begin with myth and with the criticism of myths.”
-- Karl Popper, *Conjectures and Refutations*, 1963

