Innovation in Biomanufacturing: Challenges and Opportunities Short Talk

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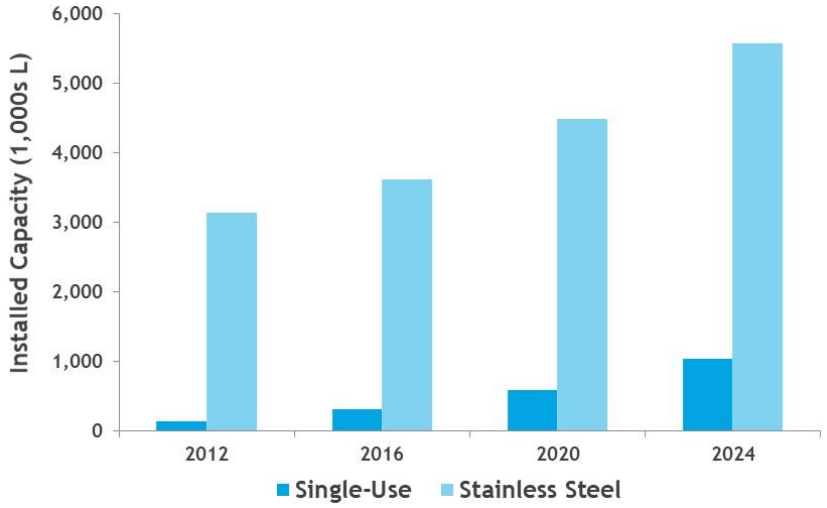
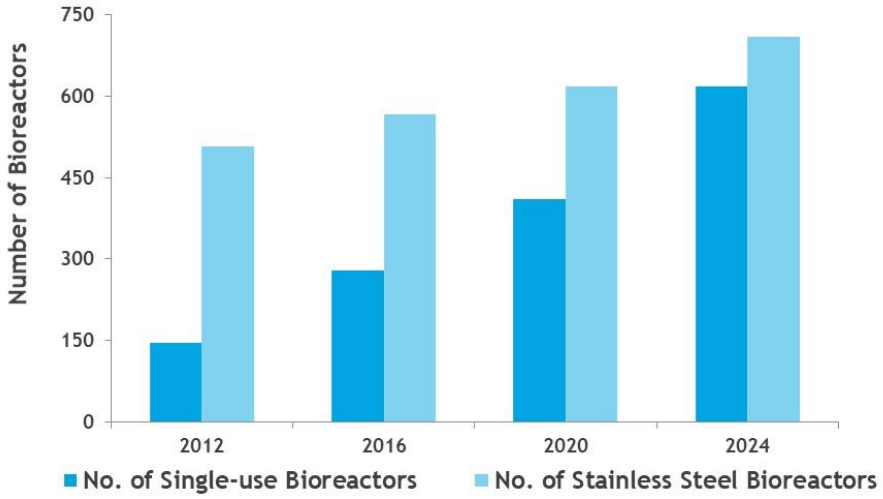
Perspective is based on experience

Personal experience and thoughts on Innovation in Biomanufacturing

- Career in bioprocessing with experience in participating in/leading introduction of new technologies to the industry, including:
  - Protein A (yes, this was a new technology once!)
  - Pre-packed chromatography column technology (BioFlash -> Opus)
  - Single-use technologies
  - Novel affinity ligand discovery and development (Dyax/Wyeth TN8.2 collaboration)
  - Continuous countercurrent chromatography (Tarpon BioSMB; 4D Bioprocess -> Resilience)
- Current focus as part of Resilience is leveraging innovation to develop evolved platforms for production of biologics
- Overall conclusions include:
  - Introduction of new technologies to our industry is possible but challenging.
  - Benefit needs to be consistent with the level of effort.
  - Timelines for adoption of innovation are long compared to other industries

One example: Adoption of single-use bioreactor (SUB) technology





- Timeline
  - 1999 – Single-use bioreactor (SUB) technology for suspension cell culture introduced [Wave]
  - 2006 – First CSTR-type SUBs introduced
  - 2011 – First 2,000L SUB introduced
  - 2014 - First FDA approval of biopharmaceutical manufactured in production SUB

- Adoption trend continuing 20 yrs post introduction
  - Average Single-Use Bioreactor (SUB) installed base growth rate over period: 12.8% pa (No.) and 18.2% pa (Vol.)
  - Average SS Bioreactor installed base growth rate over period: 2.8% pa (No.) and 4.9% pa (Vol.)

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Sources: Data/graph derived from BDO's BPTG bioTRAK® database: https://www.bdo.com/industries/life-sciences/bioprocess-technology

Innovation Challenges and Opportunities

- The biopharmaceutical industry has an established track record of adopting new technologies and approaches, but we are very conservative. Why?
  - **Risk.**
    - Penalties for delays and setbacks in pharmaceutical development programs are severe
    - Significant costs and perceived risks in our highly regulated industry – nobody wants to "go first"
  - **No "good time"** to implement new technologies – obstacles exist at all stages of development
  - **Lack of proactive investment.** Relatively little investment is dedicated for new technology development and implementation
  - **Benefits underappreciated.** We often focus primarily on *cost* and *timeline* benefits only, while underappreciating the potential to add *value* to our programs and products.
  - **IP uncertainty.** Freedom to operate is paramount to ability to supply.
- There are many opportunities to improve our ability to innovate. Strategies include:
  - Consortia to enable pre-competitive industrial collaboration in innovation
  - Regulatory engagement to provide mechanisms for feedback to innovators
  - Standards and guidance documents to provide common understanding and vocabulary
  - Proactive investment by industry in new technologies to enable readiness

Thank you!
Questions welcome…

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