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Technologies innovantes en séparation
industrielle des protéines

Single-Use technologies
INTRODUCTION


Pharma Biot'Expert

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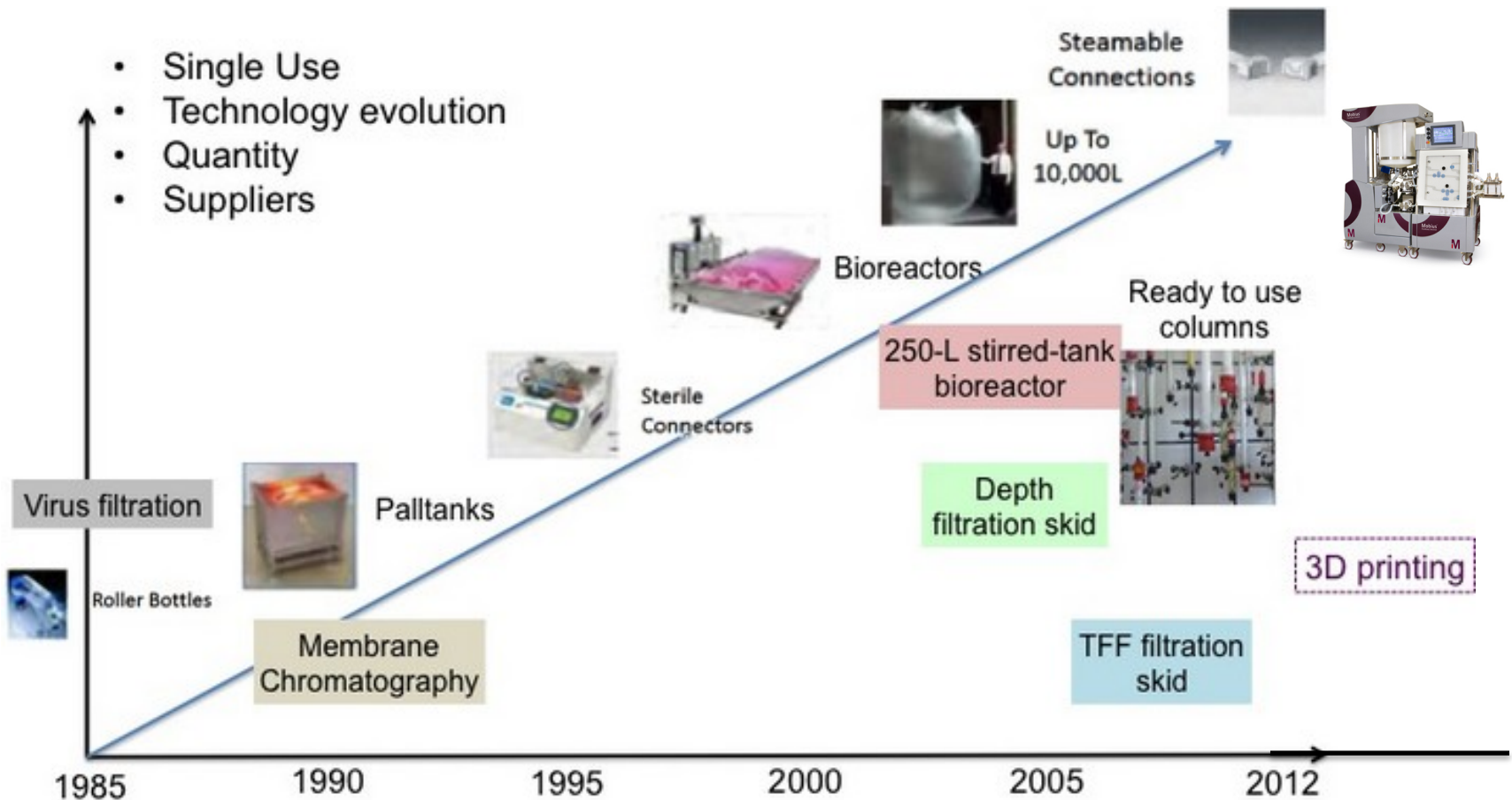
SUMMARY

- Single-Use in Biomanufacturing
- Single-Use historical
- Advantages
- Current limitations
- Future directions for single-use technologies
- Single-Use purification
- An integrated single-use drug substance production process

Single-Use in Biomanufacturing

- **Production facilities until now**
 - relatively inflexible,
 - hard-piped equipment including large stainless steel bioreactors and tanks to hold product intermediates and buffers
- **Technical changes :**
 -  Single-Use technologies across manufacturing process
 - end-to-end single-use manufacturing facility possible

Single use historical



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Advantages

- The flexibility of single-use equipment allows the optimization of the production tool and therefore production costs:
 - ✓ Reducing preparation time, transfer,
 - ✓ Reduction of energy used (autoclaves, SIP), fluids (CIP)
 - ✓ Reducing risk for product cross-contamination in a multiproduct facility
 - ✓ Eliminated of the necessity for cleaning validation
- Production of **multiproduct** possible
- Reduced investment cost for new facilities
- Rapid changeover
- Optimization of manufacturing areas (area used, area classification)

Current limitations

- Leachables and extractables
- Prior investment in fixed equipment
- Scales limited by current 2000 L cell culture bioreactor capacity
- Dependence on supplier supply chain
- High cost of disposables
- Lack of universal standards for vendors
- Solid waste disposal

Futures directions for single-use technologies

- Market share ~ 20% (3- 5 years)
- Modular cleanrooms + Single-Use = Modular facility
- Manufacturing capacity : 2000 L → 5000 L
- Manufacturers introduce at some stage of process Single Use equipment →
 - ~ 90% : Disposable filters and tubing
 - ~ 77% : Disposable bioreactors
 - ~ 58% : Disposable membrane adsorbers



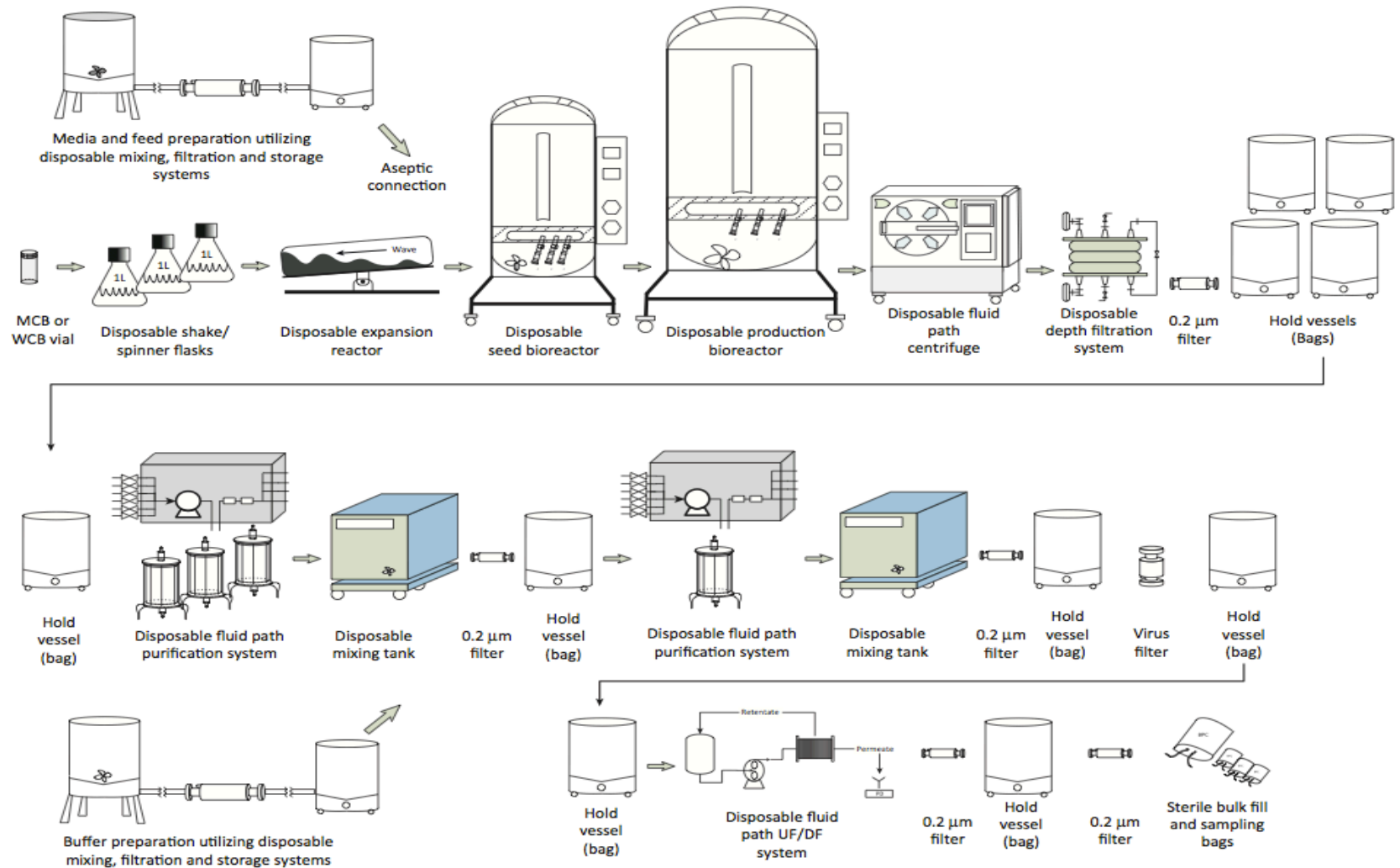
Conclusion

The growth of single-use manufacturing technologies are anticipated to reduce biopharmaceutical manufacturing costs thus aiding the launch of biosimilars, facilitating clinical entry for a wider range of innovative products and an expansion of biomanufacturing activities closer to markets for products manufactured in these facilities. For these reasons, the feeling is that these technologies have the potential to significantly alter the biopharmaceutical landscape in the years to come.

Single-Use in purification

- **Introduction**
 - ✓ Cell-culture technology development → more productive/efficient protein production
 - ✓ Protein purification becomes a bottleneck because of regulatory needs and diversity of proteins
- **Issues with current chromatography systems**
 - High capital costs
 - High operating costs
 - Long process time
 - “These issues are particularly noticeable in clinical manufacturing, where expensive resins such as Protein A are only used to 10% of their useful lives,”
 - Technology gap compared with cell-culture technology
- **Promising technology**
 - Continuous chromatography

An integrated single-use drug substance production process



Merci de votre attention



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