

Abstract: A wide range of Biologic Facilities design and product Processing are developing at a broad pace. At first glance, these appear to be a wide range of manufacturing platforms addressing the needs for therapeutics to cancer treatments; however trends are emerging. Looking to the future, one can see a common thread leading to Standardization, Automation, Continuous/Semi-Continuous closed process manufacturing Facilities.

The CAGR offers insight to industry market trends.

## FACILITY SOLUTIONS

- Ergonomic Design
- Modularization – Site Coordination
- Standardization
- Regional Supply System
- Sole Source vs Multiple Suppliers
- Lights Out Manufacturing

## 5 YEAR OUTLOOK

- Closed / Functionally Closed System Processing vs Facility Area Classifications
- Continuous Manufacturing
- Modular Design
- Standardized Design & Manufacturing
- Process Improvement to Look for
  - Flow Through Chromatography
  - Continuous TFF
  - Large Leaps in Processing Improvements

## 10 YEAR OUTLOOK

- Bulk Biologic Facilities with Closed / Functionally Closed System Processing
- Shift to Smaller Regional Production Sites
- Digitalization
- Modular Design
- AI Incorporation for Process Control
- Continuous Processing
- Improving Existing Facility Productivity

AE – Analytical Element  
 AEX - Anion Exchange Chromatography  
 AI – Artificial Intelligence  
 AIC – Anti-inhibitor coagulant complex  
 API – Active Pharmaceutical Ingredient  
 ATMP – Advanced Therapy Medicinal Products  
 CAGR – Compound Annual Growth Rate  
 IEC – Ion Exchange Chromatography  
 IP-RP – Ion Pair Reverse Phase Chromatography  
 NMWC – Nominal Molecular Weight Cut Off  
 PPT – Precipitate  
 SEC – Size Exclusion Chromatography  
 SS – Stainless Steel  
 SU – Single Use  
 TFF – Tangential Flow  
 WE – Weight Element

## COMPOUND ANNUAL GROWTH RATE

Category	Market Size (2021-2028)	Period	CAGR
Monoclonal Antibodies (mAbs)	\$126.7 Billion to \$208.6 Billion	(2021 - 2026)	10.50%
Vaccines	\$56.98 Billion to \$153.49 Billion	(2021 - 2028)	14.10%
Plasma Fractionation	\$26.58 Billion to \$40.73 Billion	(2021 - 2028)	6.30%
Advanced Therapy Medicinal Products (ATMP)	\$9.5 Billion to \$21.2 Billion	(2021 - 2028)	13.20%
Global Nanotechnology in Drug Delivery	\$5.2 Billion to \$23.6 Billion	(2021 - 2026)	35.50%
Oligonucleotide Therapeutics	\$2.612 Billion to \$4.949 Billion	(2019 - 2025)	17.30%
Global Microbiome Therapeutics	\$0.376 Billion to \$1.69 Billion	(2019 - 2027)	21.80%
Global Active Pharmaceutical Ingredients	\$67.7 Billion to \$105.8 Billion	(2020 - 2027)	6.60%

**RISK ASSESSMENT**

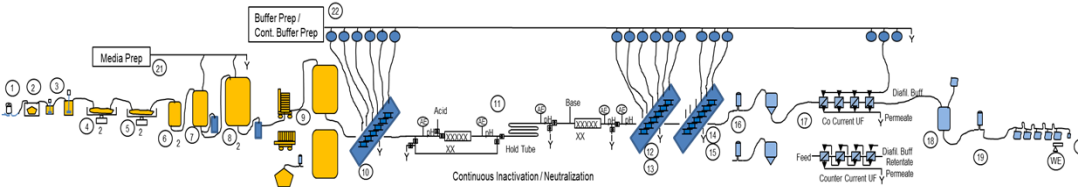
High	Red
Medium	Yellow
Low	Green

- mAb
- Vaccine
- Plasma
- ATMP
- Microbiome
- Oligonucleotides
- Nanotechnology
- API

## SS vs SU DECISION TREE

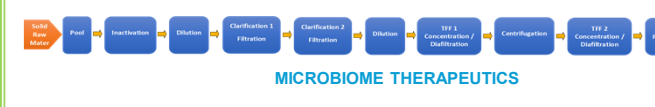
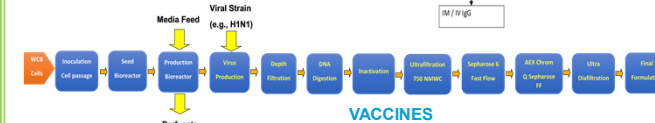
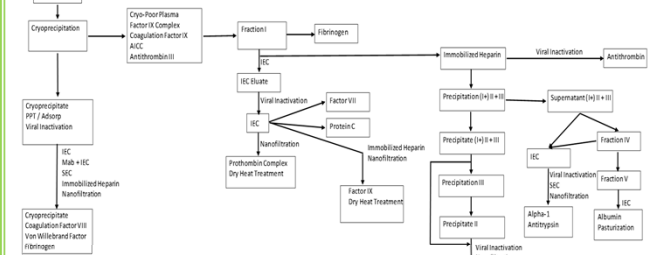


## MONOCLONAL ANTIBODIES (mAbs)

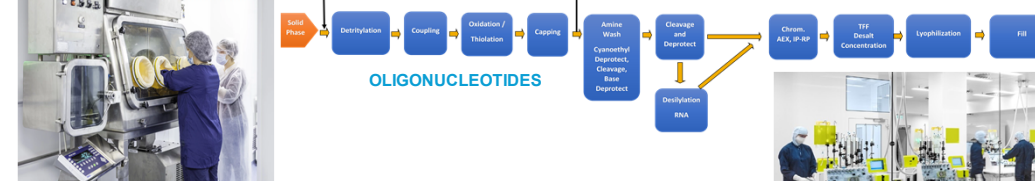


1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	Failure Mode	
																							Operator Error
																							Component Failure
																							Overpressure
																							System Failure
																							Supplier Control

## PLASMA FRACTIONATION



## OLIGONUCLEOTIDES



## ATMP

