

Feel confident with **tailored solutions** for process development through manufacturing

imMEDIate ADVANTAGE™ (non-cGMP manufacture)

Fast, flexible and personalized manufacturing services for media formulations, buffers, concentrates and feeds. Every client has direct access to dedicated staff with extensive expertise in chemistry media formulation to support the completion of your milestones:

- Quick-turnaround custom orders manufactured within 10 business days or fewer
- Customized non-cGMP liquid and dry powder media, concentrate and buffer formulations in small volumes
- Operates collaboratively across all functional areas to provide a solution that meets the complexity of biopharmaceutical scale-up and technology transfer
- Automated barcoding system to reduce the variability in manual systems



Seamless scale-up – Removing variables from your process transfers

Manufacturing Technology

Remove Variables, Improve Consistency

SAFC uses the same dry powder media milling technology and liquid media manufacturing technology from non-cGMP quick-turnaround orders to large-scale cGMP manufacturing.

Powder Formulations

- Classical, serum-free, protein-free, and chemically defined media formulations and reagents used in various biologic and vaccine expression systems
- Buffers formulated for various downstream processes
- Pin mill platform process - small-scale, non-cGMP products transferable seamlessly to large-scale production
- Product quantities ranging from 500 g to 5 kg

Liquid Formulations

- Classical, serum-free, protein-free, and chemically defined media formulations and reagents used in various biologic and vaccine expression systems
- Buffers formulated for various downstream processes
- Product volumes ranging from 1L to 200L packaged in bottle or standard bags

Quality

Remove Performance Variables, Improve Experimental Data Accuracy

- SAFC maintains and certifies all equipment, scales, hoods, pH meters, osmometers and pipettes in imMEDIate ADVANTAGE on a routine basis, with calibration on a daily basis
- Standard operating procedures and batch records are required for all imMEDIate ADVANTAGE manufacturing processes and finished products
- Separate reviewer for each lot produced
- Certificate of compliance testing is available for all lots of imMEDIate ADVANTAGE products
- imMEDIate ADVANTAGE is audited annually

Raw Materials

Remove Sourcing Variables, Improve Supply Chain Consistency

100% of components utilized in imMEDIate ADVANTAGE manufacturing are the same as those used in SAFC cGMP manufacturing and meet Quality Assurance (QA) release.

- imMEDIate ADVANTAGE will facilitate unique requests that call for components currently not cGMP sourced for prototyping purposes or not (QA) released to meet timeline goals



Clinical Pipeline and imMEDIATE ADVANTAGE™ phase map

Pre-clinical early stage	Pre-clinical late stage (24 mo. total)	Phase 1 (12 mo.)	Phase 2 (12-24 mo.)	Phase 3 (3-5 yrs.)	Commercial launch	Second generation/Improved process	
High-throughput screening of molecules						Expression system optimized	
<ul style="list-style-type: none"> Media and feed selection Media and concentrate simplification Raw material selection 						Media/feed selection through highput screening of a media library, RM selection, media and concentrate simplification and feasibility	
Expression system defined						Process improvements	
<ul style="list-style-type: none"> Media and feed selection Media and concentrate simplification Downstream buffer identification 						Custom media, feed, buffer screening	
Pilot-scale production parameters						Address inconsistencies, optimize or change manufacturing process	
<ul style="list-style-type: none"> Media and feed selection Media and concentrate simplification Raw material selection Analytical parameter testing 						Portfolio of capabilities supported through	
Develop small-scale model (3L - 300L)							
<ul style="list-style-type: none"> Media and feed selection Media and concentrate simplification 	<ul style="list-style-type: none"> Raw material selection 						
	Develop and optimize purification process for large-scale manufacturing						
	<ul style="list-style-type: none"> Custom buffer media selection Concentrate simplification 						
	Identify production feed and media and optimization of process						
	<ul style="list-style-type: none"> Media and feed selection Media and concentrate simplification Raw material selection Analytical testing 						
	Complete "shake down/engineering" runs to test the manufacturing process & equipment throughout PD						
	<ul style="list-style-type: none"> Media and concentrate simplification Raw material selection 			<ul style="list-style-type: none"> Analytical testing 			
	PD delivers production process to MFG & MFG begins scale-up/feasibility						
	<ul style="list-style-type: none"> Media and feed selection Media and concentrate simplification 			<ul style="list-style-type: none"> Raw material selection 			
				Complete final media/feed stability studies			
				<ul style="list-style-type: none"> Analytical testing Stability studies 			
Order notification	Risk assessment	Feasibility determination	cGMP batch record creation	Quality review	Planning	Production	
Seamless Scale-up							

Contact us for imMEDIATE ADVANTAGE support and information:

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Legend

Solid colors represent customer responsibility or task. Light colors represent SAFC capability (product/service) to support the task.

Colors represent key value drivers for specific customer tasks.

Reliability

Performance

Efficiency

Speed

