

imMEDIATE

ADVANTAGE™ Fact Sheet



Fast-tracked **risk mitigation 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
- Stability and shipping study testing service support for cGMP products

Seamless scale-up – removing variables from your process transfers:

1. Manufacturing technology

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

Risk Mitigation

Manufacturing Variables Removed, Consistency Improved

2. Quality

- All equipment, scales, hoods, pH meters, osmometers and pipettes in imMEDIATE ADVANTAGE are maintained, calibrated and certified on a routine basis. Equipment is calibrated 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 bi-annually.

Risk Mitigation

Performance Variables Removed, Experimental Data Accuracy Improved

3. Packaging

The same high-quality plastic bottles and flexible media bags are used in both cGMP and imMEDIATE ADVANTAGE product packaging.

- Full product description
- Product code
- Date of manufacture
- Storage recommendations
- A unique, traceable lot number

Risk Mitigation

Shipping and Storage Variables Removed, Operational Efficiency Improved

4. Raw materials

100% of components utilized in imMEDIATE ADVANTAGE manufacturing are the same as those used in SAFC Biosciences™ cGMP manufacturing and meet Quality Assurance 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.

Risk Mitigation

Sourcing Variables Removed, Supply Chain Improved

imMEDIAtе

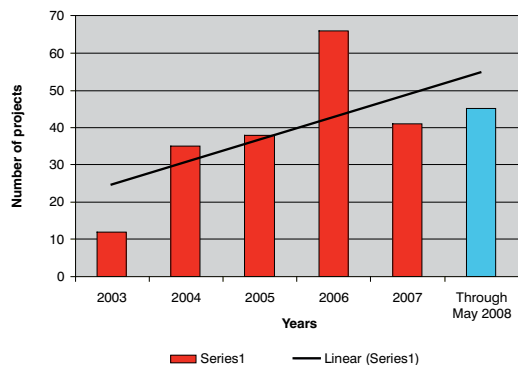
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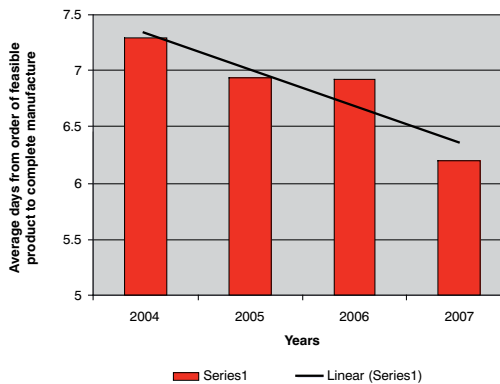
Speed, Consistency and Confidence

A history of supplier excellence

Projects scaled-up from imMEDIAtе ADVANTAGE to cGMP



Global imMEDIAtе ADVANTAGE lead times



- Over a decade of experience with imMEDIAtе ADVANTAGE product scale-up
- Over 500 products have been transferred from imMEDIAtе ADVANTAGE to cGMP large scale manufacture since the beginning of the imMEDIAtе ADVANTAGE program
- Over 10 million liters of dry powder cGMP media in 2007 came from products transferred from imMEDIAtе ADVANTAGE prototyping
- Over 4,300 unique product numbers have been generated in support of application-specific requirements in imMEDIAtе ADVANTAGE

- Over 1500 orders in 2007 with less than a 0.5% defect rate
- Over 75 projects since 2006 have been multi-department feasibility tested for scale-up
- Over 300 raw materials are stocked and managed through imMEDIAtе ADVANTAGE
- 6.2 working days was the average lead time to manufacture in 2007 for imMEDIAtе ADVANTAGE

Chart 1

The number of successful liquid media, dry powder media, buffers, concentrates and feeds that have been successfully scaled up from prototype to large-scale manufacture.

Chart 2

imMEDIAtе ADVANTAGE continues to work with customers to meet milestones faster.



Flexibility and responsiveness are only of value if they allow customers to reach their goals sooner. By providing seamless scale-up manufacturing technologies and superior raw material supply chain management, SAFC Biosciences provides assurance that milestones will be met throughout the commercialization process.