

## QC

- ❑ Sterility testing area (USP standard) with material and autoclave pass through.
- ❑ Real-time water Total Organic Carbon (TOC) monitoring using a GE Sievers® TOC analyzer.
- ❑ Real-time water conductivity monitoring to control bioburden.

## PILOT OPERATION

- ❑ State-of-the-art milling technology (Hosokawa Alpine UPZ 160) provides excellent particle size consistency, minimal heat generation, and is easily cleaned.
- ❑ Scalability: Pilot equipment is identical to full scale manufacturing equipment to ensure performance consistency from pilot to production lot sizes.
- ❑ Powder Batch Size Range: 1 kilogram – 10 kilograms.
- ❑ Versatile liquid lot sizes: 40 liters – 200 liters in both PET bottles and bags.



Everything is about to change.

*Focused on your need to eliminate risk, Advanced Bioprocessing sets a new standard in cell culture media manufacturing.*

*Transforming the cell culture media industry.*

**We do that.**



For additional information, take the virtual tour of our facility by visiting us at [bdbiosciences.com/advbio](http://bdbiosciences.com/advbio) or call 877.272.7131 toll free, or 978.901.7236 from outside the U.S.



**United States**  
**BD Biosciences**  
**Advanced Bioprocessing**  
7 Loveton Circle  
Sparks, MD 21152-0999  
Tel 800.638.8663  
[bdbiosciences.com/advbio](http://bdbiosciences.com/advbio)

**Asia Pacific**  
**BD Singapore**  
Tel 65.6861.0633  
Fax 65.6860.1518

**Australia/New Zealand**  
Toll Free: 1800 656 100  
Tel 61.2.8875.7000  
Fax 61.2.8875.7200  
[bd\\_anz@bd.com](mailto:bd_anz@bd.com)

**Europe**  
**BD Biosciences**  
Tel 32.2.400.98.95  
Fax 32.2.401.70.94  
[help.biosciences@europe.bd.com](mailto:help.biosciences@europe.bd.com)

**Canada**  
**BD Biosciences**  
Toll Free 888.259.0187  
Tel 905.542.8028  
Fax 888.229.9918  
[canada@bd.com](mailto:canada@bd.com)

**Japan**  
**Nippon Becton Dickinson**  
Toll Free 81.120.8555.90  
Tel 81.3.6234.5510  
Fax 81.3.6234.5465

*Introducing*  
**BD Biosciences – Advanced Bioprocessing**

**AF<sup>2</sup>™** | **Animal-Free / Antibiotic Free**  
**Cell Culture Media and Supplements**  
**Manufacturing Facility**



Helping all people  
live healthy lives

BD Biosciences – Advanced Bioprocessing is pleased to announce the opening of its stand alone, dedicated, **“ANIMAL-FREE / ANTIBIOTIC-FREE” AF<sup>2</sup>™ FACILITY** for the cGMP production of cell culture media and supplements by October, 2009.

This AF<sup>2</sup> Facility will deliver a new standard for safety and quality for cell culture media that significantly reduces current risks associated with mixed-use plants. Products manufactured in the new plant will be controlled for animal-origin component raw materials to the tertiary level, the most stringent level of control available.

With this new manufacturing capability, BD Biosciences will fully serve the culture media needs of bioprocessors working with mammalian, microbial or stem cell lines.

The BD Biosciences – Advanced Bioprocessing AF<sup>2</sup> Cell Culture Media Manufacturing Facility will deliver high performance cell culture media and supplements with minimal regulatory risk and the most stringent raw material control in the industry.

KEY FEATURE	BENEFIT
Pharma-like Facility Fit and Finish	<ul style="list-style-type: none"> <li>• Environmental Control</li> <li>• Enables Stringent Cleaning of Facility &amp; Equipment</li> </ul>
Industry's Most Stringent AF Policy	<ul style="list-style-type: none"> <li>• Minimizes Risk from AO Components</li> <li>• Simplifies and Accelerates Customer's Regulatory Compliance</li> </ul>
Stand Alone, Fully Dedicated Animal-Free / Antibiotic-Free Facility	Virtually Eliminates Risk of Cross Contamination
Fully Integrated Manufacturing	Provides Customer with Complete Supplemented Media
Fully Scaleable Pilot Capability	<ul style="list-style-type: none"> <li>• Lot-to-lot Consistency</li> <li>• Speed to Market</li> </ul>

## MANUFACTURING FACILITY DETAILS

Pharmaceutical-grade:

- ❑ Complete segregation of all manufacturing areas, including unidirectional product and personnel flow throughout the facility, as well as individual equipment suites with zoned HVAC systems to eliminate cross contamination risk.
- ❑ Modular clean room system, with hardened PVC coated walls and ceilings with cove transitions for ease of cleaning. Full viewing corridors allow complete access to facility, without compromising room integrity.
- ❑ Automated CIP (Clean In Place) and SIP (Sanitize In Place) cleaning process.
- ❑ Robust business continuity systems, including full emergency utility back-up systems and redundant manufacturing infrastructure.
- ❑ cGMP Compliant
- ❑ ISO 9001 Certified Facility

## LIQUID MANUFACTURING

- ❑ Validated to a Sterility Assurance Level of 10<sup>-3</sup>.
- ❑ Highly versatile and fully scaleable lot size capability, from 25 liters to 4000 liters. Flexible packaging suites, with filling capabilities from 1 liter bottles to 200 liters bags. Custom packaging solutions available.
- ❑ Real-time clean room particulate monitoring.

## POWDER MANUFACTURING

- ❑ State-of-the-art milling technologies, including Hosokawa Alpine UPZ Pin Mill, which provides excellent particle size consistency, minimal heat generation and is easily cleaned using a CIP (Clean In Place) system utilizing ultra pure water. Alternative milling technology also available if required.
- ❑ Highly versatile and fully scaleable powder lot size capability from 30 kilograms up to 3000 kilograms.
- ❑ Flexible packaging suites, with filling capabilities from 500 gram to 50 kilogram containers. Custom packaging available upon request.

