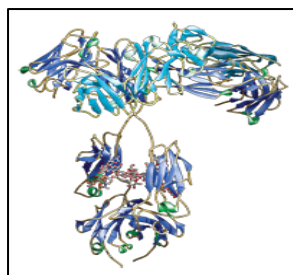




# Worcester, MA Biologics



Biologics



APIs



Finished Goods



High  
Potency

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# Worcester Capabilities

	Asia					Europe			Latin America			North America					
	Shanghai China	Goa India	Cimanggis Indonesia	Katsuyama Japan	Karachi Pakistan	Ludwigshafen Germany	Silgo Ireland	Campoverde Italy	Buenos Aires Argentina	Rio de Janeiro Brazil	Tlalpan Mexico	Abbott Park Illinois, USA	North Chicago Illinois, USA	Worcester Massachusetts, USA	Wyandotte Michigan, USA	Barceloneta Puerto Rico	Jayuya Puerto Rico
<b>Active Pharmaceutical Ingredient</b>																	
Chemical							*	*					*		*	*	
Fermentation													*				
Biologic														*			
High Potency							*								*		
<b>Manufacturing / Dosage Product</b>																	
Tablets	*	*	*	*	*	*	*	*	*	*	*	*				*	*
Massing Granulation (High Sheer)	*	*	*	*	*	*	*	*	*	*	*	*				*	*
Massing Granulation (Low Sheer)			*	*	*	*			*	*	*	*					*
Massing Granulation (Single Pot)	*						*	*	*								
Drying Granulation (Fluid Bed)	*	*	*	*	*			*	*	*	*	*					
Compressing Granulation (Roller Compactors)						*		*									
Capsules				*		*	*		*	*	*	*				*	
Particle Coating					*					*	*	*				*	*
Direct Compression (Dry Blend)				*	*	*	*	*	*	*	*	*				*	*
Micro-tablets						*											
Meltrex (melt-extrusion)						*										*	
Liquids						*		*								*	
Syrups / Suspensions		*	*	*	*			*	*	*	*	*					
Ointments / Creams				*	*					*							
High Potency				*	*		*										*
<b>Product Packaging / Printing</b>																	
Blisters	*	*	*	*	*	*		*	*	*	*	*				*	*
Blister Foils / Foil			*		*			*	*		*	*					*
Bottles	*			*	*	*		*	*	*	*	*				*	*
Sachets			*	*	*			*									
Sticks								*									
Wallets				*	*							*				*	
Suppositories				*						*							
Syringe Packaging				* tubes	* tubes					* tubes		*					



# Worcester Facility

- Located in Worcester, Massachusetts, the Abbott Bioresearch Center (“ABC”) has been manufacturing biologics for over 15 years
- The manufacturing plant utilizes approximately half of the 400,000 square foot facility, with approximately 400 employees dedicated to biologics manufacturing
- ABC manufactures a portfolio of development products for Abbott and third party clients, and continues to produce HUMIRA as a backup to our plant in Puerto Rico
- Licensed by regulators worldwide





## Why Abbott

Our expert staff, proven operational systems and state-of-the-art facilities, give you access to

- Flexibility and experience
- Proven regulatory track record



# Strengths

Flexibility and Experience.

21 years experience handling > 28 different biologics

Support for whatever pieces your project needs, from cell line development to product launches

Non-GMP operations at 3L, 300L, 500L and 3,000L scales

cGMP operations at 500L, 3,000L and 6,000L scales



# Strengths

## Proven Regulatory Track Record

- Type V DMF filed with the FDA
- 4 GMP compliance certificates from German Health Authorities
- More than 20 INDs, CTX, IMPD, CTAs filed/product in patients
- Licensed for commercial production of HUMIRA™ & Recothrom™
- Proven inspection record

Regulatory Agency	Inspection Type	Inspection Date	Approval Date
US FDA	Pre-Approval Inspection (PAI)	September 2002	December 2002
EMEA	Pre-Approval Inspection (PAI)	November 2002	Sep 2003/Mar 2004
EMEA	Recertification for Multi-use/General GMP	May 2004	N/A
Health Canada	On-Site Evaluation Inspection	May 2004	September 2004
US FDA	Biennial Inspection (General GMP)	December 2004	N/A
Mexico MOH	Inspection for Reduced Testing Permit	May 2006	June 2006
Korea FDA	Pre-Approval Inspection (PAI)	June 2006	July 2006
Health Canada	SNDS for Multi-use	N/A	April 2007
US FDA	Biennial Inspection (General GMP)	May 2007	N/A
US FDA	Pre-Approval Inspection (PAI for ZGI's rThrombin)	May 2007	January 2008
EMEA	Biennial Inspection (General GMP)	June 2007	N/A
Japan PMDA	Pre-Approval Inspection (PAI)	Oct/Nov 2007	April 2008
Brazil ANVISA	Certification Inspection	December 2007	Certified
Mexico MOH	Reduced Testing Permit/General GMP	February 2008	April 2008
US FDA	Biennial Inspection (General GMP for ZGI's rThrombin)	May 2009	N/A



# Services Overview

- Capability to handle multiple projects in parallel
- Process transfer and/or development
- Scale up
- Non-GMP and GMP operations at manufacturing scale
- Analytical support
- Project management
- Ongoing technical support
  - Dedicated cell culture and purification groups



# Technical Capabilities

## 5 independent cell culture suites and 5 independent purification suites

- 500L disposable wave bags
- 4 x 3,000-liter bioreactors in three independent suites
- 2 x 6,000-liter bioreactors
- Automated, fixed process tanks (200 L to 6000 L)
- Mobile process tanks (100 L to 1500 L)
- Disk stack centrifuges (Alfa Laval)
- Cross-flow filtration skids (10 to 100 LPH)
- Chromatography columns up to 1-meter diameter
- Chromatography skids (3 to 1571 LPH)
- Cartridge filter housings (1- to 6-round, 10 to 30 inches high)
- Incubators (carbon dioxide and temperature controlled)
- Class B Bulk Fill Suite



# Technical Capabilities

Our process development equipment and personnel are capable of supporting early development needs to commercial product launch

- Cell line development
- Analytical method development
- Cell culture process development
- Purification process development
- Viral clearance studies
- Process scale-up lab (300 L)
- Extended product characterization
- Process characterization
- Process validation
- Manufacturing support



# Technical Capabilities

Quality control laboratories are equipped with a broad range of state-of-the-art instrumentation for chemical and microbiological analysis

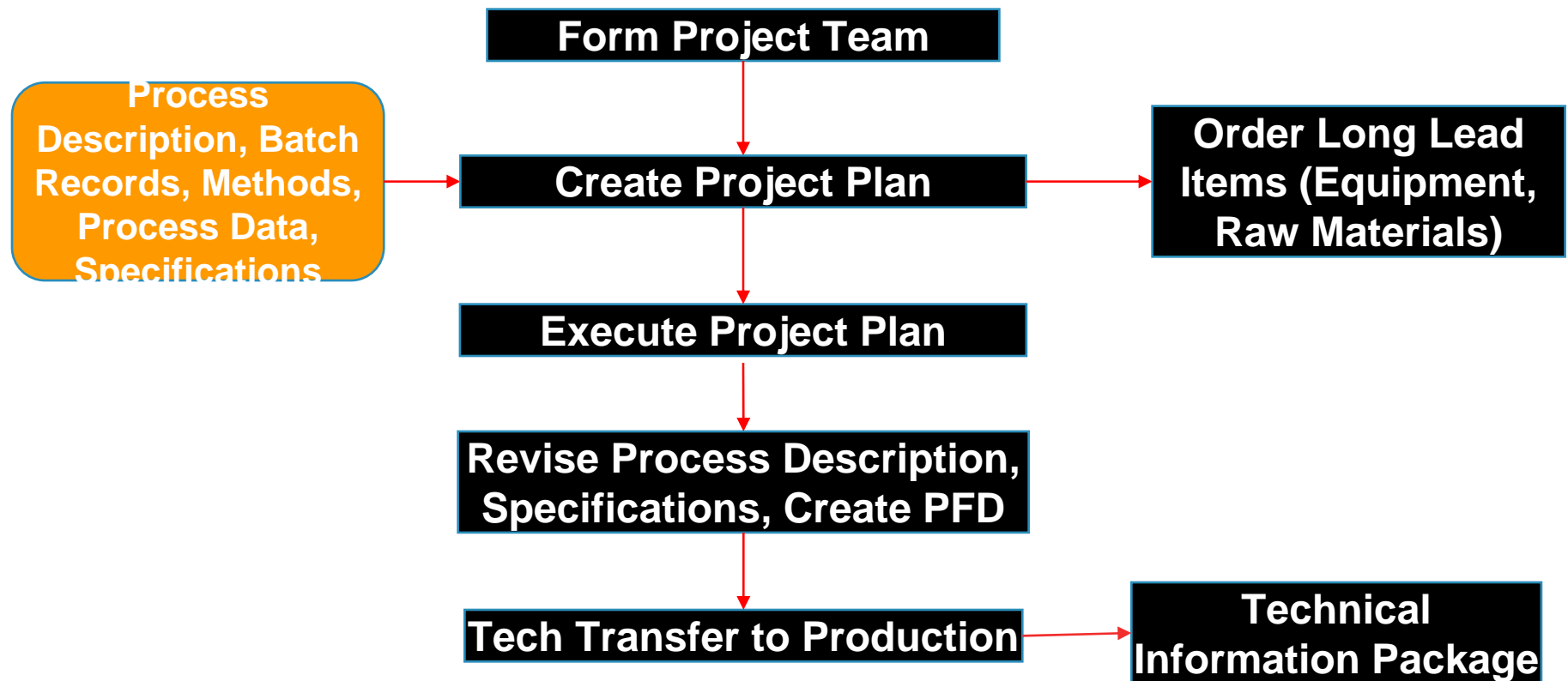
- HPLC (SEC, ion exchange, affinity, reverse phase)
- Electrophoresis (CE, IEF, SDS-PAGE)
- ELISA
- Microbial identification
- DNA quantification (threshold)
- DNA identification (PCR)
- Spectrophotometry (FT-IR, UV-VIS)
- TOC
- Oligosaccharide analysis
- Peptide structure determination (LC/MS/MS)
- Host-cell protein
- Bioburden
- Endotoxin

Trained and experienced quality control staff will transfer, validate and apply your assays to meet your in-process control and release requirements



# Technical Capabilities

Project management is a part of every client's package





# The Power of a Promise

The Abbott promise defines what we do and how we do things.

- Superior Quality
- Timeliness
- Confidentiality
- Cost Effectiveness

## The Power of a Promise

Smart. Strong. Secure.



# The Power of a Promise

## Why NOT Abbott?