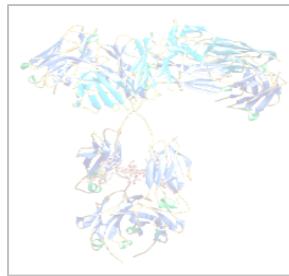




Sligo, Ireland

High Potency APIs & Finished Goods



Biologics



APIs



Finished Goods



High
Potency

www.abbottcontractmfg.com





Sligo Capabilities

	Asia					Europe			Latin America			North America					
	Shanghai China	Goa India	Cimanggis Indonesia	Katsuyama Japan	Karachi Pakistan	Ludwigshafen Germany	Sligo 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
Active Pharmaceutical Ingredient																	
Chemical						*	*					*		*	*		
Fermentation												*					
Biologic													*				
High Potency						*								*	*		
Manufacturing / Dosage Product																	
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				*	*	*	*										*
Product Packaging / Printing																	
Blisters	*	*	*	*	*	*		*	*	*	*	*				*	*
Blister Foils / Foil			*		*			*	*		*	*					*
Bottles	*			*	*	*		*	*	*	*	*				*	*
Sachets			*	*	*			*									
Sticks								*									
Wallets				*	*						*					*	*
Suppositories				*					*								
Syringe Packaging				* tubes	* tubes					* tubes	*						



Sligo Ireland

Sligo is recognized as a Center of Excellence for outstanding performance in operations, customer satisfaction, quality processes and products, along with high ratings in employee satisfaction

Development and Commercial High Potent Manufacturing

- Kilo lab
- API Production unit (ISO Class 8, OEB3 to OEB5 $<1\mu\text{g}/\text{m}^3$)
- Drug Product- oral dosage

In-house Analytical and Process Development capabilities

Stability, Compliance and Validation services



Authorizations, Certifications and Recognitions

Authorizations ➤ Full authorization from FDA, EMEA

Certifications ➤ IS393 Energy Management Accreditation

Recognitions

- Class A Organization & Centre of Excellence for High Potent Manufacturing
- Abbott Plant of the Year 2005, 2007 & 2009
- National Irish Safety Organization (NISO) Award 2007
- Investigational Medicinal Product Supply License





Abbott Ireland Pharmaceutical Operations (AIPO)

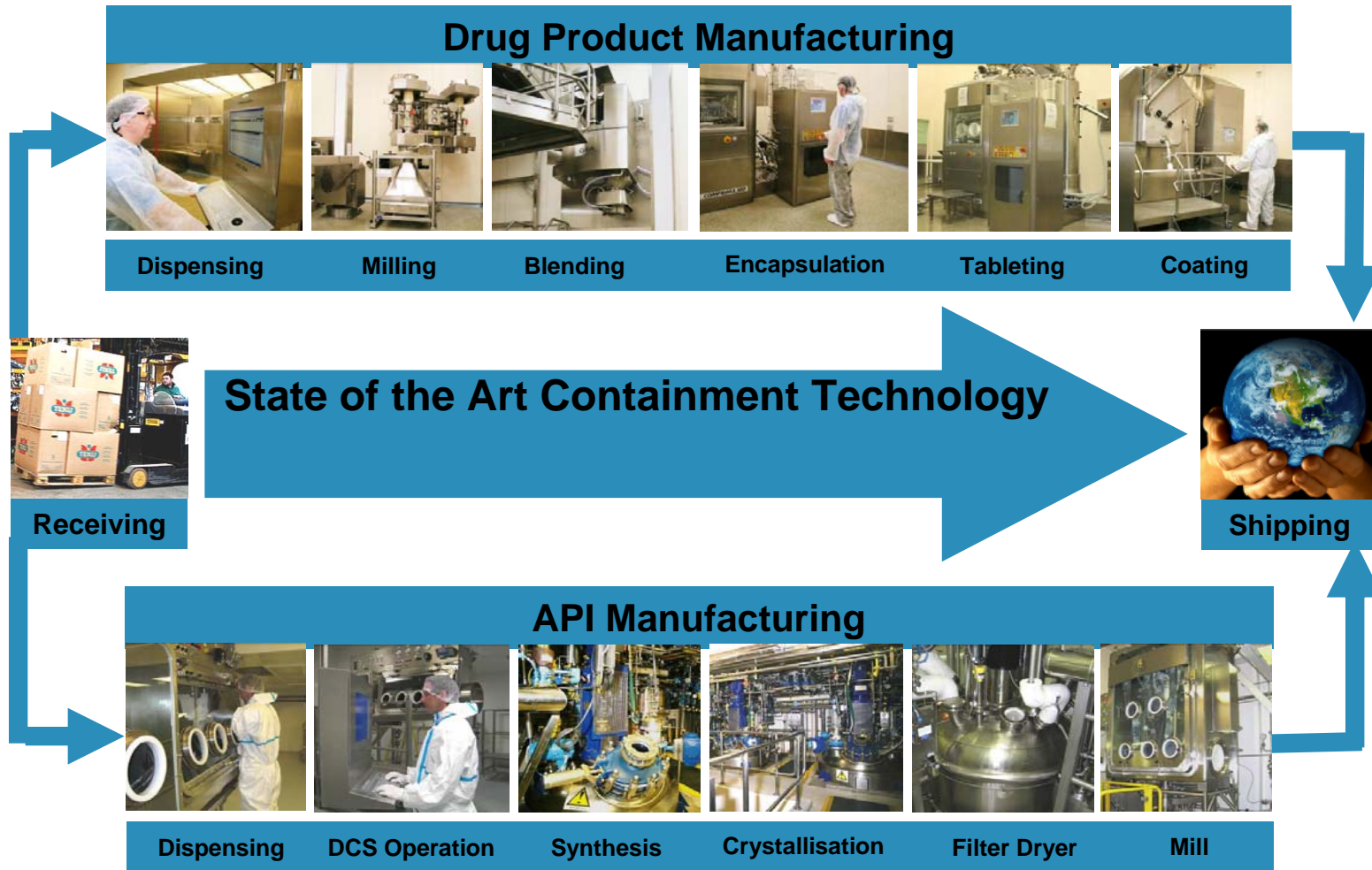
AIPO is based in Sligo in the Northwest part of Ireland and is a licensed state-of-the-art, high containment facility for the manufacture of a wide range of potent pharmaceuticals



AIPO has dedicated capabilities for Potent API and Drug Product manufacturing and also houses a dedicated kilo lab for small scale potent manufacturing



API and Drug Product Facility





API Facility

1st Floor - Class VII Area

Cell I: Glass lined head tanks 325L & 100L; glass lined vessels 630L & 400L

Cell II: Stainless steel head tank 300L; glass lined vessels 2 x 1600L

Cell III: Stainless steel head tank glass lined 630L; glass lined 3000L; Hastelloy vessel 3200L

Hydrogenation suite: stainless steel head tank 250L; stainless steel vessel 4000L

Ground Floor - Class IV Area

Contained discharge via glovebox & Split Butterfly Valve (SBV) technology

Filter dryer suites (3)

Agitated Hastelloy filter dryers

Contained in-line sieving capability - Cell III

Contained milling suite





Cell III – Split Butterfly Valve (SBV) Contained Charging



SBV for contained Intermediate Bulk Container (IBC) charging



Milling Suite



Contained stainless steel universal mill turbine/screen design with contained discharge capability to lined drums or IBCs



Mill post hoist for contained charge to mill



Dispensing / Material Transfer

Post hoist and SBV vessel docking for contained solids charging



Post hoist with 100L IBC



Filter dryer with discharge arm located under glove box



Dispensing / Material Transfer

Down flow booth for raw material, intermediate dispensing & glovebox for potent product dispensing / packaging

Stainless steel 50 and 100L IBCs for product / intermediate transfer between dryer and milling stations, dispensary and vessels





Kilo Lab

Equipped with walk-in fume hoods and glovebox for small scale processing





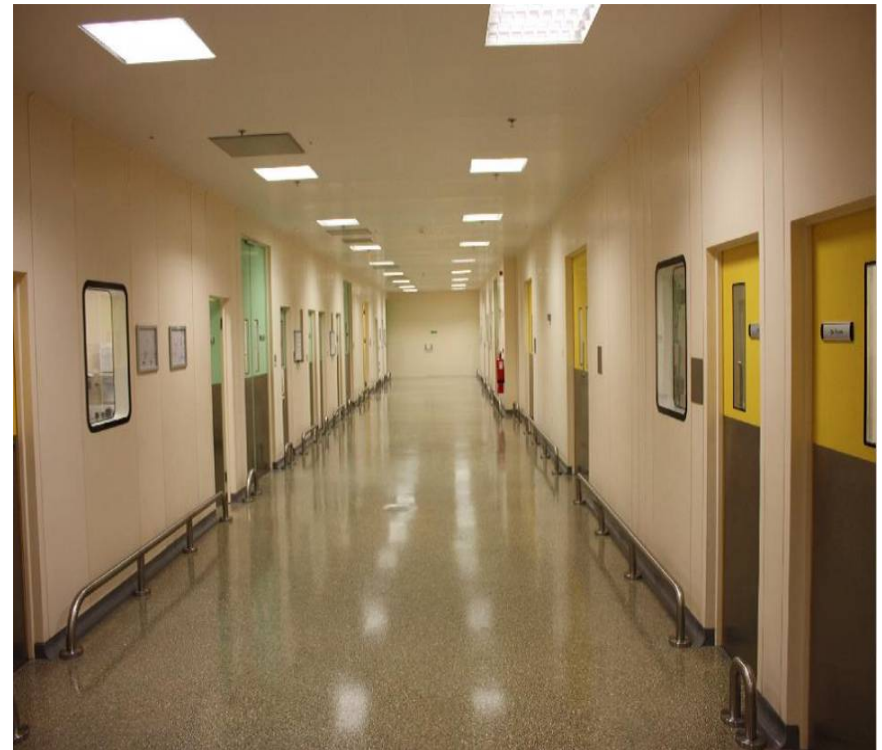
API Scale and Capacity

Production Cell	Scale Range
Cell I	5 - 50 kg
Cell II	50 -100 kg
Cell III	150 - 250 kg
Kilo Lab	g / kg quantities



Drug Product Facility

- The facility is designed for potent solid oral dosage forms
- The facility comprises a 14,000ft² production area and 11,000ft² warehouse
- Production areas comply with ISO class 8 / class 100,000 standards (HEPA filtered once through air)
- Operations are performed in production suites with gown in / gown out and material airlocks
- Equipment designed to provide 1-10 $\mu\text{g}/\text{m}^3$ 8hr Time Weighted Average (TWA) containment levels
- Air cascades prevent cross contamination between production suites





Development / Clinical Trial Supply

- Processing suites contain dedicated gown in / gown out with decontamination showers to support non-contained sampling / process evaluation
- Novel commercial scale equipment with the capability of processing development / pilot scale batches is available
- Simplified process scale-up considerations
- Procedures in place to support both development activity and clinical trial manufacture in a commercial facility
- Licensed for Investigational Medicinal Product supply



Process Capabilities

- Tablet and capsules may be manufactured in the drug product facility using the following processes
 - Direct blending using IBCs
 - High shear wet granulation and drying using single pot processors
- All unit operations and material transfers between operations are contained using custom design and split butterfly valve technology





Dispensing



Active Pharmaceutical Ingredients dispensed in the glove box and charged to API charge pots or bags

Excipients are dispensed in a down flow booth and charged to IBCs





High Shear Wet Granulation



300L Single Pot Processors provide recipe controlled granulation and drying operation in one vessel.

Working volume 120-300L

Granulation suspensions containing potent actives may be prepared in a custom Liquid Preparation Vessel





Milling and Blending Suite

- Milling is performed from a discharge to a receiving IBC
- Milling is fully contained using split butterfly valve technology
- Milling customized for development and commercial batch sizes
- Contained bin to bin transfers may be performed
- Blending is performed in the IBC's using a post hoist blender
- A range of IBC sizes (5ft² – 20ft²) allows development scale batch sizes and facilitates process scaling





Encapsulation

- Imatic 150 Capsule Filling Machine
 - 150,000 capsules per hour
 - Continuous motion
 - Dostator type filling
 - Machine regulation of fill weight
 - Containment levels $<1 \mu\text{g}/\text{m}^3$ 8 hour TWA
 - Full Clean In Place (CIP) capability
- Precisa 16 weight checker
 - 100% capsule weight checker
 - 168,000 capsules per hour
- On-line metal checking





Tabletting and Tablet Coating



Tablet coater

- 250L capacity perforated pan coater
- Development scale (25L) capability within same pan facilitates process scale up
- Contained coating for potent cores
- Potent coating suspensions

- Centrifugal die filling
- Full CIP capability
- Max 300,000 tablets per hour
- Development capability (10kg+) with punch blank system

Rotary tablet press



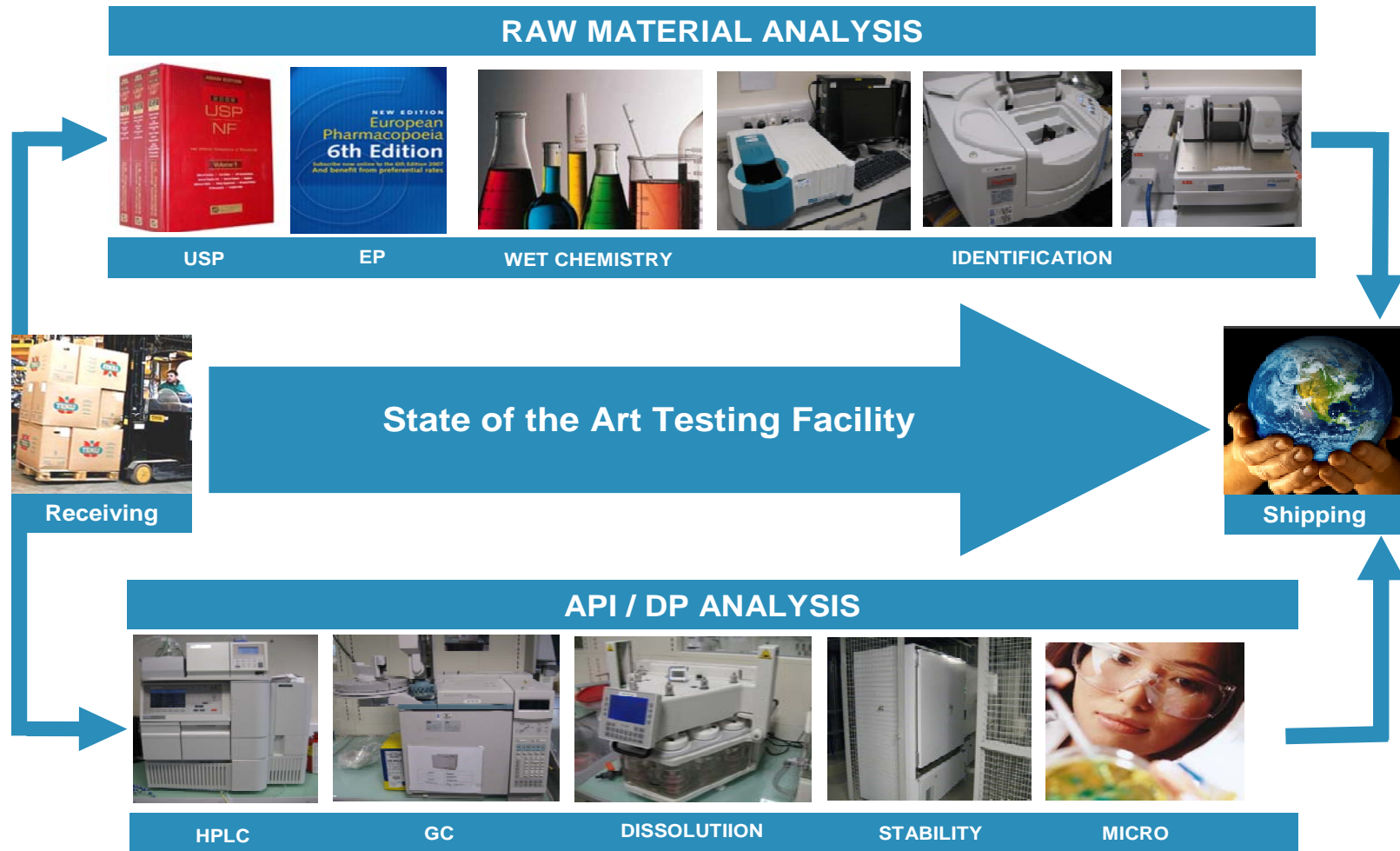


Drug Product Scale and Capacity

Equipment	Min / Max Scale
Milling	N/A
IBC Blending	5ft ³ IBC 42 – 100 L 10ft ³ IBC 85 – 198 L 20ft ³ IBC 180 – 420 L
Single Pot Processors (x2)	120 – 300 L
Tablet Press	Max 300,000 tabs/ hr
Capsule Filling Machine	150,000 caps/ hr
Tablet Coating	29 – 250 L



QC Routine Capabilities





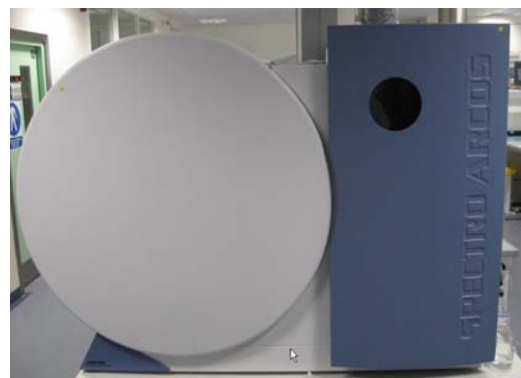
Additional Lab Capabilities



Gas chromatography



Liquid chromatography



Spectro inductively coupled plasma (ICP)



Diffraction X-ray



Development to commercialization

Abbott Potent API and Drug Product Manufacturing

DEVELOPMENT

Kilo Lab

- API Production Scale: g to kg
- Contained Glovebox
- Walk-in Fume Hood

Flexible API Production Capacity

- Hydrogenation Capability (4000 L)
- Production Suites (3) Range: 5-250 kg
- Contained Production and Transfers

COMMERCIALIZATION

Drug Product — Oral Dosage

- Single Pot High Shear Granulators
- In-Bin (IBC) Blending: 50-420 L
- 150,000 Capsules/hr
- 300,000 Tablets/hr and Coating
- Licensed for Clinical Trial Supply

ISO Class 8 • FDA / EU Inspected • Containment Levels up to EB5 (<1 mcg/m³)



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.



Why choose AIPO ?

Class A Organization & Center of Excellence for High Potent Manufacturing

FDA / EU Approved

Abbott Plant of the Year 2005 & 2007

National Irish Safety Organisation (NISO) Award 2007

Potent Products supplied globally

Investigational Medicinal Product Supply licence

In-house Analytical and Process Development capabilities

Stability, Compliance and Validation services

IS393 Energy Management Accreditation



The Power of a Promise

Why NOT Abbott?