



Peptide Contract Manufacturing and Development

Accelerating Your Peptide to Market

Edition: 2024

Who We Are

The Peptide Experts



Comprehensive CDMO Offering End to End Solutions

Preclinical Manufacturing

Manufacturing of non-GMP grade peptides for early research, lead development, pharmacology, and toxicology studies.

Process Development

Process development and manufacturing of peptides covering a wide variety of scales and synthesis technologies.

Analytical Methods Support

In-house analytical method development and validation services to support the advancement of your peptide through the various phases of drug development.

GMP Manufacturing

Multiple manufacturing suites capable of producing GMP peptide APIs, from phase I to commercial, at a range of scales, from kilograms to tons.

QC, Stability, & Regulatory Support

- QC release testing
- Stability study support
- Reference standard
- Non-sterile vialing
- CMC writing and updates
- DMF writing/submission

Leading Management Team

Extensive Biologic and Pharma Expertise



Brian Gregg

CEO



BACHEM

Steve Kiel

CFO



Deloitte.

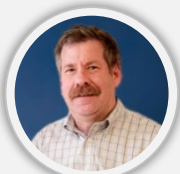
Peter Hutchings

Executive
VP of Sales



BACHEM

Brant Zell
Senior VP of Quality



PolyPeptide
GROUP
THE ULTIMATE PEPTIDE PARTNER



Raymond Ye
VP of Quality Control



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WuXi AppTec

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VP, Manufacturing



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Guoqing Zhang
VP of Global R&D



API
AmbioPharm, Inc.

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GM, Shanghai Site



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Kathleen Noack
VP Sales, Europe



SENN
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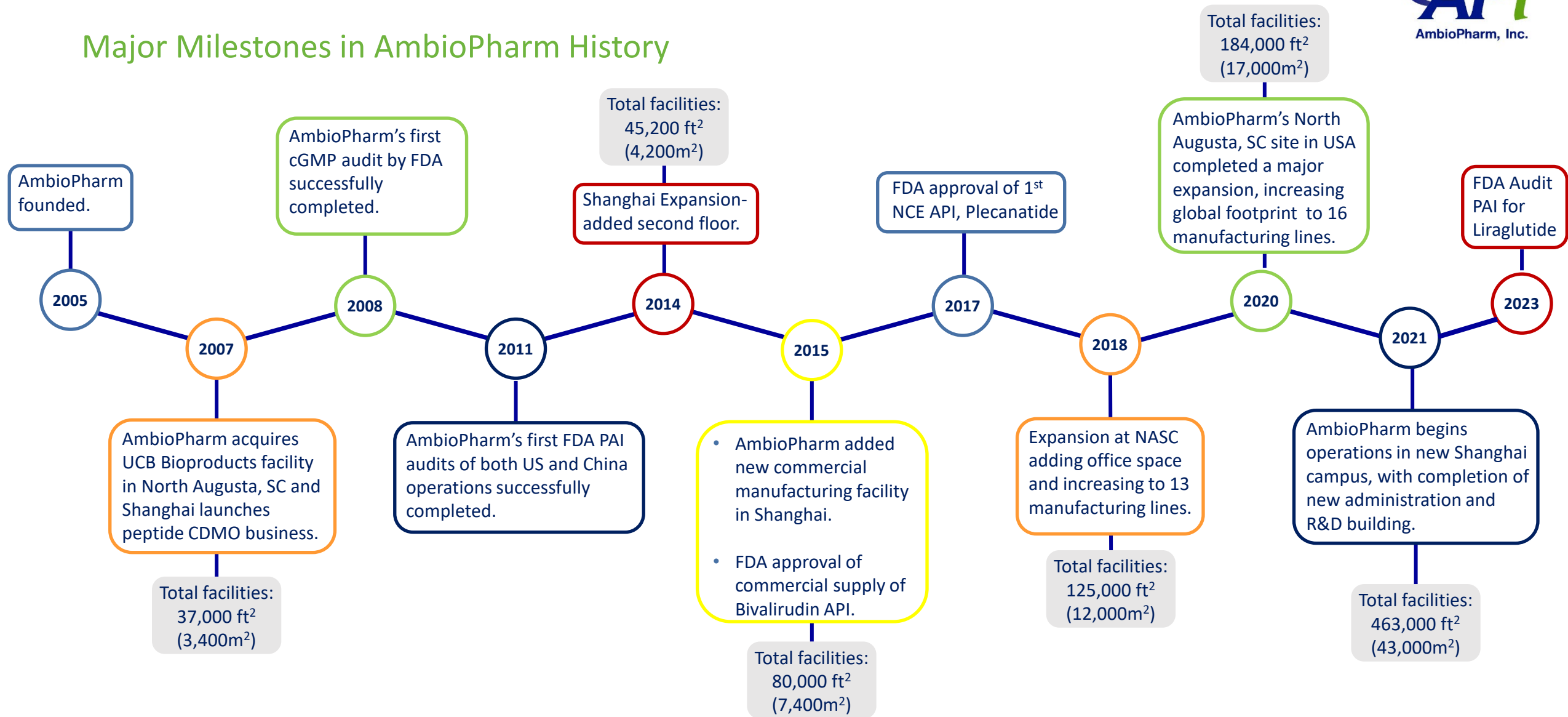
Gary Hu
Sr VP Sales, Asia



BACHEM
AMERICAN
PEPTIDE

Our Timeline

Major Milestones in AmbioPharm History



Our Locations

Global Peptide API Manufacturing and Support

- Operations Starting in 2007
- Research to Commercial Scales
- 1,000kg+ Annual Peptide API Production Capacity
- >500 Employees Worldwide
- FDA-inspected
- SPPS/LPPS/Hybrid Synthesis
- Complex Peptide Expertise (disulfides, macrocycles, conjugations, and more)
- Services include:
 - Process Development
 - Crude Synthesis
 - Purification
 - Lyophilization/Isolation
 - Analytical & Stability Services
 - Regulatory Support Services



US Headquarters

- North Augusta, South Carolina USA
- ~200 employees
- Approx. 82,566 ft² (7,670 m²)



Shanghai Campus


















- Shanghai, China
- ~300 employees
- Approx. 380,550 ft² (35,354 m²)

AmbioPharm Facilities

Capabilities by Site

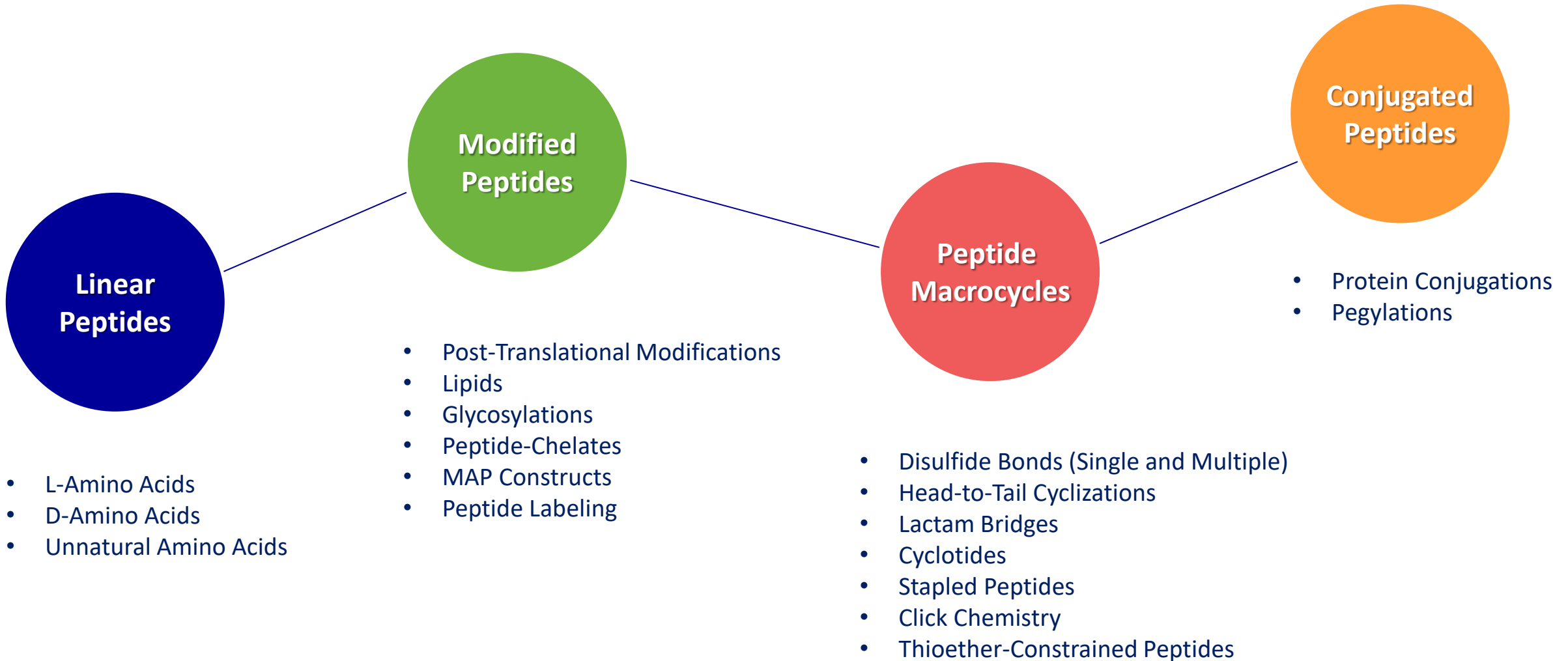


 = Current Capabilities  = Future Capabilities

	USA Headquarters	Shanghai Campus
Microwave SPPS		
Traditional SPPS		
LPPS		
Hybrid Synthesis		
Process Development		
Optimization & Scale Up		
Downstream Processing		
Tangential Flow Filtration		
Quality Control		
Analytical Services		

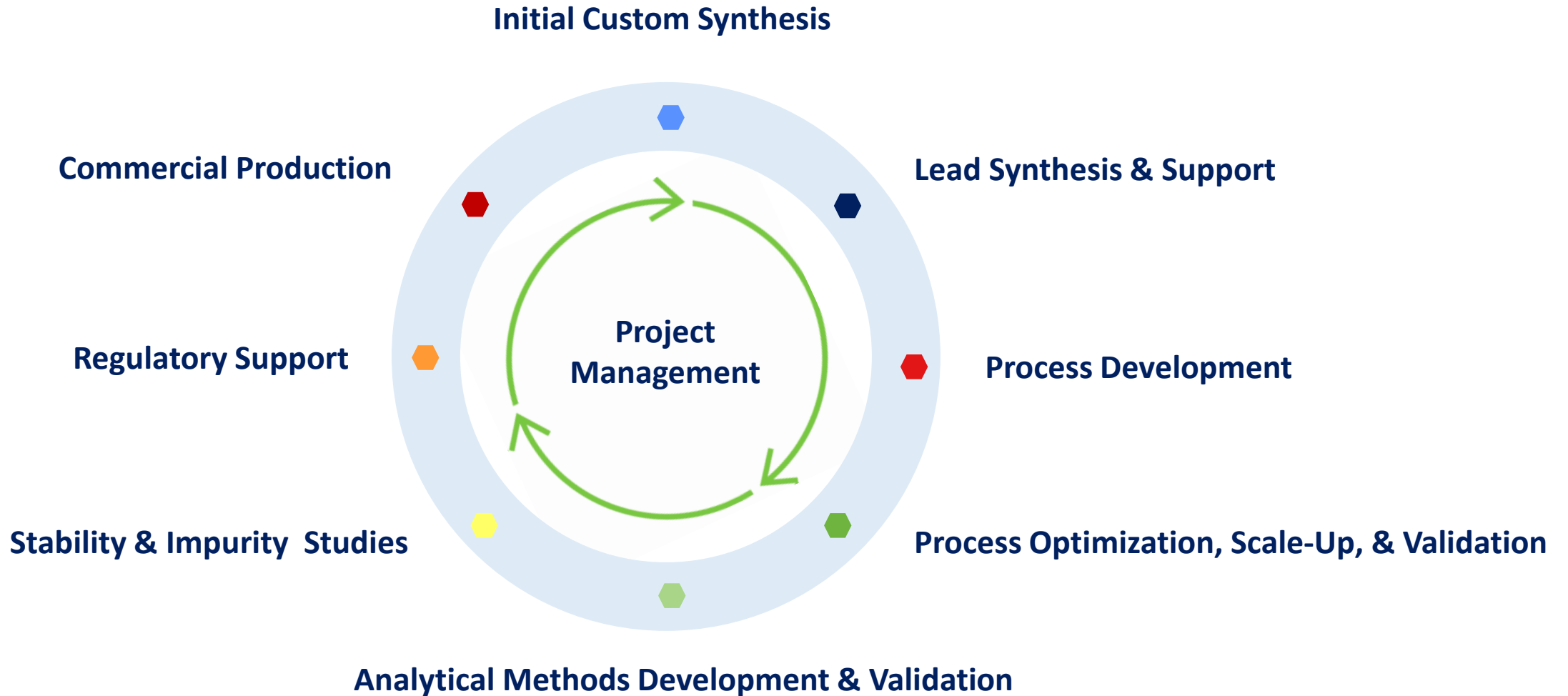
Expertise in Peptide Synthesis

From Simple to Complex Peptides



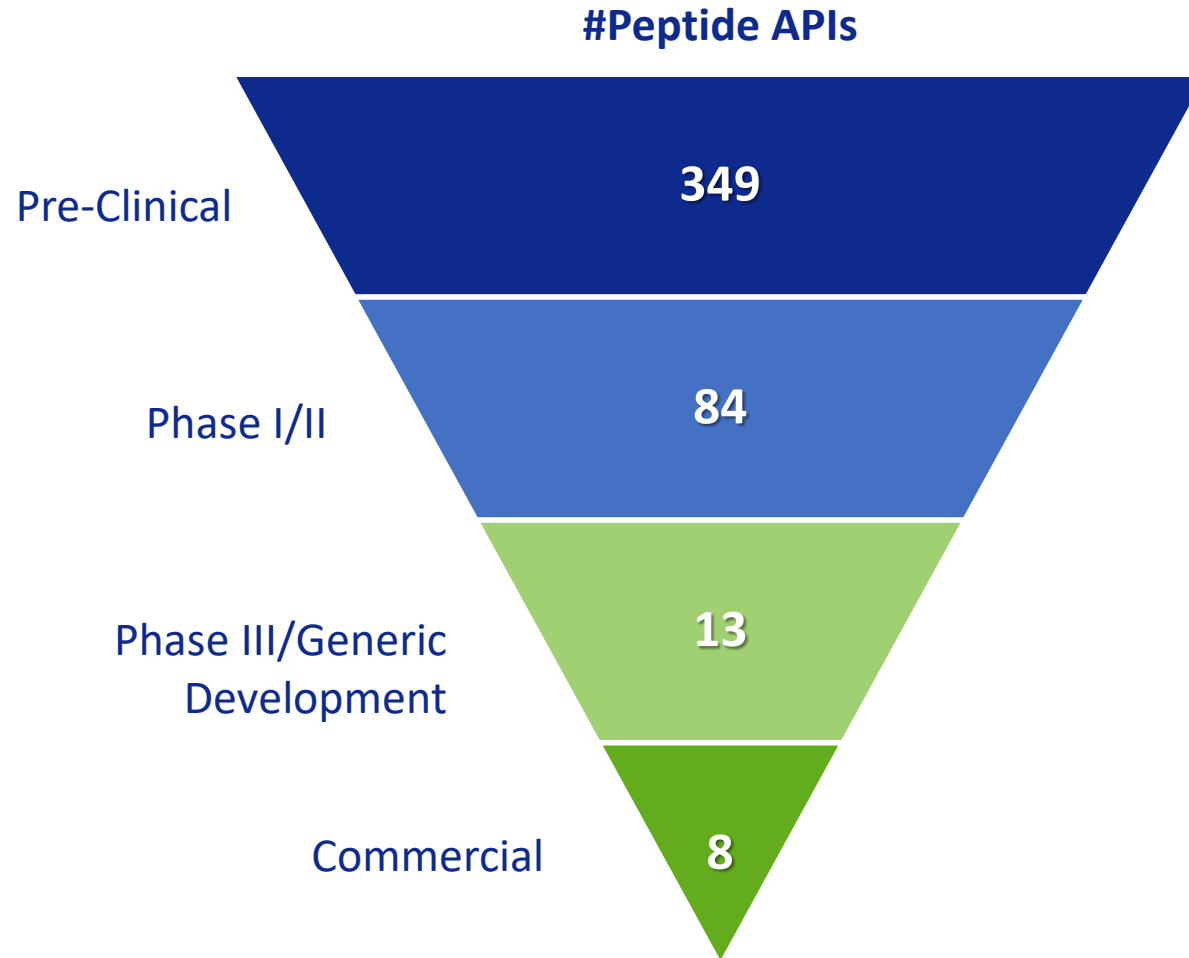
The Product Lifecycle

Supporting You Every Step of the Way



Active Projects at AmbioPharm

Capacity and Quality for a Wide Variety of Projects



16	GMP Peptide Manufacturing Lines
1000kg+	Annual Peptide API Production Capacity
>100	Active Customers

AmbioPharm Capacity



From Small Scale to Large Volume Commercial Production of Complex Peptides

Upstream Synthesis

	Microwave SPPS	Traditional SPPS	Hybrid Synthesis	Solution (LPPS)
Capacity	30mL - 15L reactors	30mL - 3,000L reactors	100L - 5,000L reactors	300L - 5,000L reactors
Scale	25mg – 1kg per batch	1g – 100kg per batch	10kg – 500kg per batch	50kg – 500kg per batch
Advantages	<ul style="list-style-type: none"> • Cost effective for peptides longer than 10 amino acid residues • Faster development time 		<ul style="list-style-type: none"> • Complex peptides • Long peptides • Scalable up to 100kg 	<ul style="list-style-type: none"> • Cost-effective for shorter peptides • Scalable to metric ton • Avoid HPLC chromatographic purification for certain conditions

Downstream Processing

	HPLC Purification	Lyophilizers	Centrifuges	Precipitation/ Crystallization
Capacity	5cm-100cm columns (25mg-40kg/batch)	up to 1,000L	up to 1,000L (up to 1kg-100kg/batch)	up to 1,500L (up to 10-50kg/batch)

Solid Phase Peptide Synthesis (SPPS)

Traditional SPPS

Reactor Type	Scale
Synthesis	1L, 5L, 10L, 30L, 50L, 80L, 200L
	500L
	1000L
	3000L (in construction)
Auxiliary (Synthesis/Isolation/ Work-Up Reactors)	500L
	3000L
Cleavage	100L
	500L
	2000L
Precipitation	1500L
	2500L



1000L Reactor



3000L Reactor

Upstream

SPPS Shanghai Equipment



1000L SPPS Reactor (filter dryer reactor)

Multiple smaller reactors
are also available.

UPSTREAM – SPPS			
		Approximate Crude API Throughput	
Reactor	Liters	Kg/month	Kg/year
SPPS reactor	5L*5	0.02kg*5	1 kg
SPPS reactor	10L*5	0.1kg*5	5 kg
SPPS reactor	20L*5	0.2kg*5	10 kg
SPPS reactor	50L*10	1kg*10	100 kg
SPPS reactor	100L*6	2kg*6	120 kg
SPPS reactor	200L*10	5kg*10	500 kg
SPPS reactor	1000L*2	30kg*2	600 kg

Solid phase synthesis reactors made of glass (5L-100L), PTFE (200L), or Halar-coated stainless steel (1000L) are available.

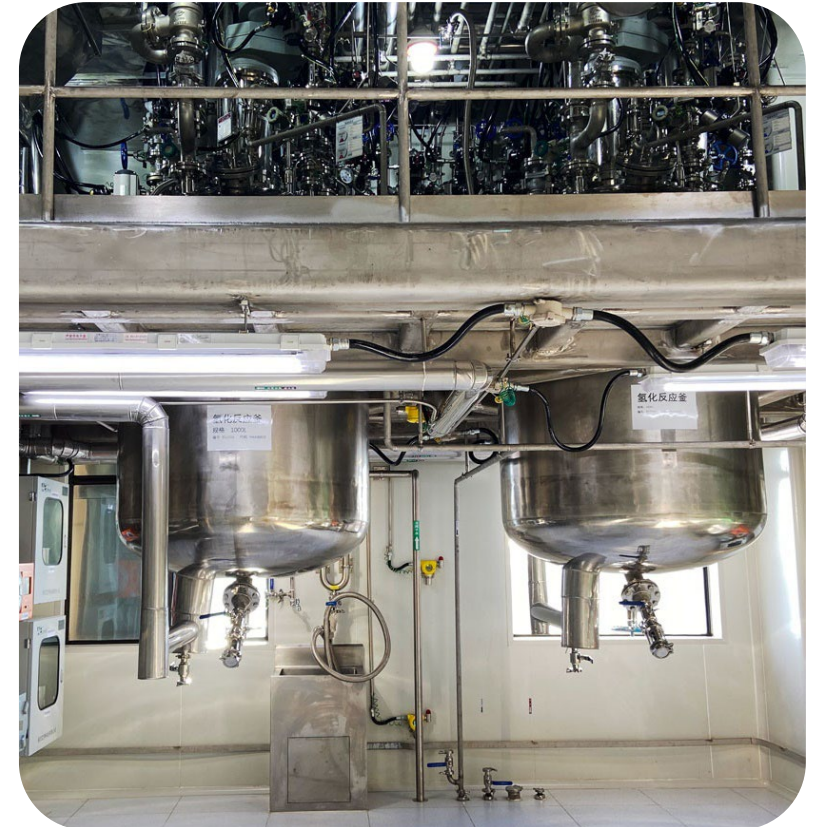
Liquid Phase Peptide Synthesis (LPPS)

Choosing Equipment to Match the Project

Reactor Type	Scale
Synthesis	10L, 20L, 30L, 50L, 80L, 100L
	200L
	300L
	500L
	1000L
	2000L
Hydrogenation	500L
	1000L
Workup	1000L
	3000L
	5000L
Clean Room	1500L



5000L Precipitation Reactor



1000L Hydrogenation Reactors

Upstream

LPPS Shanghai Equipment



5000L Precipitation Reactor

*Multiple smaller reactors
are also available.*

UPSTREAM – LPPS			
		Approximate Crude API Throughput	
Reactor	Liters	Kg/month	Kg/year
Glass jacketed reactor	100L*6	1kg*6	60 kg
Stainless steel jacketed reactor	200L*2	2kg*2	40 kg
Stainless steel jacketed reactor	500L*2	5kg*2	100 kg
Stainless steel jacketed reactor	1000L*3	10kg*3	300 kg
Glass-lined SS jacketed reactor	2000L*3	20kg*3	600 kg
Glass-lined SS jacketed reactor	3000L*3	30kg*3	900 kg
Glass-lined SS jacketed reactor	5000L*3	50kg*3	1500 kg

Liquid phase synthesis reactors made of glass (100L), stainless steel (200L-3000L), or glass-lined stainless steel (300L-5000L) are available.

Purification

Reversed Phase HPLC



60cm HPLC

Equipment	Column Size
Preparative HPLC	5cm
	8cm
	15cm
	20cm
	30cm
	45cm
	60cm
	100cm

Purification

Reversed Phase HPLC Equipment in NASC, US



1 m ID Column

REVERSE-PHASE PURIFICATION CAPACITY			
		Approximate API Purification Throughput	
Column	Internal Diameter (cm)	Kg/month	Kg/year
ND.229	45	6.8	82
ND.542	45	6.8	82
ND.261	60	12	144
ND.326	60	12	144
ND.373	60	12	144
ND.544	60	12	144
ND.689	100	33	396

Each preparative HPLC column has attached pumping skid to deliver required mobile-phase buffers / solvents.

Also available are multiple 10cm, 15cm, 20cm and 30cm columns with associated pumping skids for small-scale projects.

Isolation

Lyophilization, Crystallization, and Precipitation

Equipment	Scale
Manifold Lyophilizers	Various
Tray Lyophilizers	100L
	200L
	400L
	500L
	800L
1000L	
Vacuum Tray Oven Dryers	Various
Precipitation Reactors	300L
Rotary Evaporators	50L
Inverted Centrifuges	100L



1000L Tray Lyophilizer



300L Precipitation Reactor



100L Inverted Centrifuge

Isolation

Lyophilizer capacity in NASC, US



Lyo Capacity Table (Same Product, ~40 cycles per year, reported in kg/year)				
		API Concentration (g/L)		
Lyophilizer	Lyophilizer Volume (L)	10	30	50
Lyo 5 (ND.240)	100	40	120	200
Lyo 10 (ND.129)	200	80	240	400
Lyo 20 (ND.227)	400	160	480	800
Lyo 40 (ND.300)	800	320	960	1600
Lyo 40 (ND.371)	800	320	960	1600
Lyo 40 (ND.539)	800	320	960	1600
Lyo 40 (ND.540)	800	320	960	1600
Lyo 50 (ND.638)	1000	400	1200	2000

Figure in the table is considering 5-7 days for Lyo cycle plus 2 days turn around between batches of the same API.

Utilizing only 50% of the lyophilization capacity (highlighted 3 Lyophilizers in orange and green), we can still produce 3,120 kg to 5,200 kg, depending on the API solution concentration.

Green Initiatives

Measuring and Improving Sustainability



Solvent Recycling

Recycling acetonitrile, DMF, MTBE plus nitrosamine testing

Green Solvents

Replacing traditional solvents with NBP, 2-Me-THF, and other "green" solvents

Ecovadis-Rated

Discovering how to improve our sustainability efforts

Isolation Methods

Using crystallization or precipitation in place of lyophilization

Transport

Reducing CO₂ through reduced raw and finished material transport distances

Comprehensive Analytical Capabilities

Offering Both non-GMP and GMP Support

Non-GMP and Preclinical Support

- ◆ Purity Method Development
- ◆ Non-GMP Batch Release and Stability Studies

Clinical and Commercial Support

- ◆ Analytical Method Development and Validation
- ◆ Quality Control Testing and Support
 - Raw Materials Testing
 - In-Process Testing
 - Release Testing
 - Stability Studies
 - Forced Degradation Studies (Stress Tests)
 - Impurity Characterization and Profiles
 - Reference Standard Qualification
 - Nitrosamine Determination



Ancillary Services

Supporting our Clients Preclinical – Commercial Needs



Additional API Support

- Non-Sterile Vialing
- CMC Writing and Updates
- DMF Writing and Submission
- Regulatory Submission Support
- Technology Transfer
- Storage

Analytical Testing and Services

A Selection of Services and Test Methods Offered



Service	Test Methods
Amino Acid Composition	Amino Acid Analysis
Appearance or Color & Clarity	Visual
Bacterial endotoxins	Chromogenic or LAL Gel Clot
Bioburden	Aerobic and Spore Count
Buffering Capacity	pH and Chemical Analysis
Counter-ion Content	RP-HPLC or IC
Density	Density Meter
E. Coli test	USP<62>
Elemental Impurities	ICPMS
Extractables and Leachates	LCMS/HPLC/GCMS
FTIR	IR Spectroscopy
Identification of Related Substances	LC-MS
Mass Balance	% Peptide Content + % Counter-Ion + % Water
Melting Point	Differential Scanning Calorimetry

Service	Test Methods
Monoisotopic Mass (ID)	ESI Mass Spectral Analysis
Nuclear Magnetic Resonance (NMR) - 1D	¹ H / ¹³ C NMR
Nuclear Magnetic Resonance (NMR) - 2D (for Ref Std)	Comprehensive 2D NMR with Interpretation Report
Optical Rotation	Polarimeter
Osmolality	Osmometer
Peptide Content	% N by Elemental Analysis or HPLC Assay (%wt/wt)
Peptide Mapping	By HPLC after Development
pH	pH Meter
Purity	RP-HPLC or UPLC
Related Substances	RP-HPLC or UPLC
Residual Organic Solvents (Organic Volatile Impurities)	HSGC or GCMS
Sequence Analysis	MS-MS Sequencing
Solubility	Visual
Water Content	Karl Fischer

Quality Management Systems

cGMP Compliance



Personnel
Responsibility, Qualification,
Training



Production
Tech-Transfer, Process Control,
Re-process, QA On the Floor



Equipment and Building
Good Engineering Practice
(GEP)



Quality Control
Laboratory Management, OOS



Environment
Monitoring System



Release
Batch Record Review/Release,
Product Release



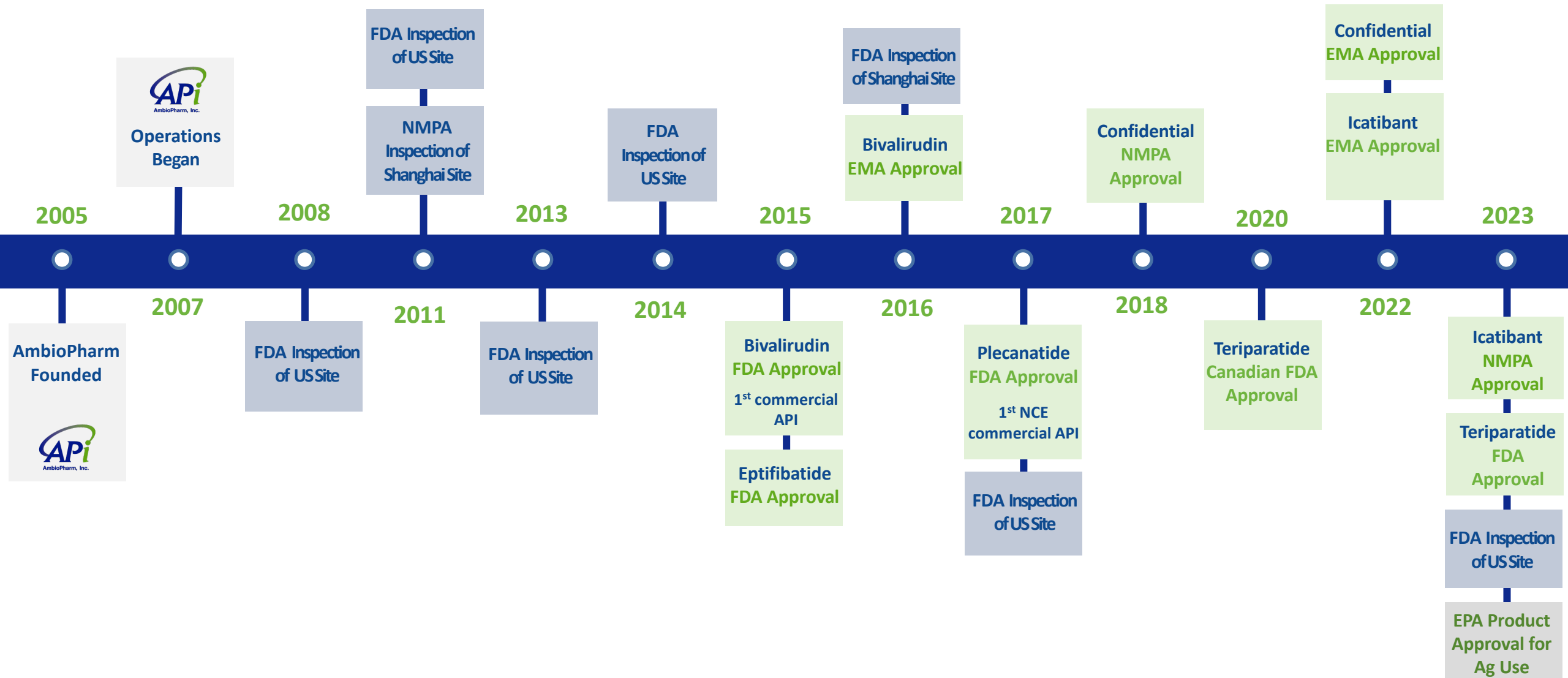
Material
Vendor Qualification, Storage
and Delivery



QMS
Master Control (*)

Track Record of Regulatory Compliance

Consistent Quality and Compliance with All FDA/EMA/NMPA Inspections



The AmbioPharm Difference

Accelerating Your Peptide to Market



Experience



Highest technical expertise in the peptide industry with extensive cGMP management experience.

Capability



Wide range of technologies and equipment to meet your peptide production needs, no matter the scale.

Capacity



Industry leading peptide manufacturing capacity, with plans for continued expansion.

Speed



Streamlined procurement, equipment redundancy, and flexibility to ensure shortened delivery times.

Quality



Recent successful regulatory inspections and product approvals across the globe.

Globalization



Multiple manufacturing facilities and global teams to serve customers worldwide.

Thank you!

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