patheon
by Thermo Fisher Scientific

Summary of Capabilities

Florence (West), SC, USA

Facility Facts:

Workforce:	120
Regulatory Approval:	FDA
Potency Capability:	Up to SafeBridge Cat. 3A
Contact Info:	101 Technology Pl. Florence, SC 29501 USA Tel: +1 (843) 676 9007

Unique Offering:

Process development and chemical production of intermediates and APIs for toxicology, pre-clinical and clinical supply under both non-cGMP and cGMP conditions.

Offerings:

- Production scales ranging from gram to hundreds of kg (max 100–200 kg)
- Process optimization, non-cGMP production of demo and toxicology batches
- Separate beta-Lactam facility (off-site)
- Raw Material sourcing and specifications
- cGMP manufacturing of pre-clinical and clinical materials
- Design of Experiment (DOE) and Quality by Design (QBD) studies
- Process safety studies
- Analytical method development and phase appropriate method validations
- Regulatory submission assistance

Technical Capabilities: 95–98% of all Commercially-used Chemical Transformations

Esterification / Saponification / Amide-formation (various methods)	(3+2)-Cycloaddition
Li / Hal-ex / E-quench (n-/s-BuLi); ultralow cryo conditions	Cyclopropanation reaction
Grignard and other metalorganic reactions	Friedel-Crafts reaction
Hydrogenation (Pd, Pt) up to 90 bar (1,305 psi) @ 8 L and 20 bar (300 psi) up to 200 L scale	Mitsunobu reaction
Carbonylation (Pd)	Knoevenagel condensation, Swern oxidation, POCl3
Reduction (boranes, silanes, hydrides), reductive amination	Suzuki Cross Coupling, Ullmann Coupling
(De-)protection of diverse functionalities	Biocatalysis, chemical and enzymatic racemic resolution
Hetero- and Homogeneous Catalysis; asymmetric hydrogenation	Nigeshi coupling, Sonogashora coupling, Buchwald coupling
... and many, many more	

Florence Key Equipment List by Lifecycle

Item			Size / Details	Early Development				Late Dev	Commercial Supply		
				Process Development	Analytical Development	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer	Regulatory
R&D/AR&D Labs – Labs 101, 102, 103, 104, 132 and 136	Process Development	Organic synthesis (R&D labs)	Up to 50 L glass reactors (-90 °C – 200 °C), lyophilization capabilities, low vacuum drying, 20 L evaporators	●	●	●	●	●			
			High Pressure Capabilities: 70 mL to 8 L (up to 1000 psi); Stainless Steel, Glass	●	●	●	●	●			
			Reaction Calorimetry Capabilities; Mettler RC1, HEL (similar and automate) capacity 35 mL to 1 L	●	●	●	●	●			
			Chromatography Capabilities: Biotage Flash 150 / Flash 75, Biotage SP4	●	●	●	●				
	AR&D	Analytical	Method Development	●	●	●	●	●			
			Equipment: HPLC (UV, ELSD, MS), UPLC, GC (FID, MS, headspace), titration (acid/base, AgNO3), KF (volumetric, coulometric, headspace), FTIR, DSC, melting point	●	●	●	●				
GMP Production	Pilot Plant	Glass-lined Reactors	200 L – 2000 L, -30 °C to 200 °C			●	●				
		Hastalloy C Reactor	400 L, -80 °C to 200 °C			●	●				
		High Pressure Reactor	200 L glass-lined up to 300 psi, -30 °C to 200 °C			●	●				
	GMP Kilo Labs	GMP Production	200 L glass-lined, -30 °C to 200 °C			●	●				
			Four (4) Labs with several walk-in bench top hoods			●	●				
			Biotage Flash 400/150/75			●	●				
			Four (4) rotary evaporators			●	●				
	Isolation / Drying	Nutsche Filters	Glass-lined, Stainless Steel			●	●				
		Centrifuge	Stainless Steel			●	●				
		Filter Dryer	Hastelloy (0.4 m^2)			●	●				
		Tray Dryers	Teflon-lined, Stainless Steel			●	●				
		Milling / Blending	Fitz Mill / Manual Screening			●	●				
		Lyophilizer	Stainless Steel			●	●				
	QC Support	Analytical equipment	HPLCs (UV, ELSD, MS), UPLC, GC (FID, MS, headspace), FTIR, Autotitrator, KF Volumetric Unit, KF Coulometric Unit, DSC, Melting Point			●	●				
Beta-Lactam Lab	Production	Organic Synthesis	Two (2) walk-in bench top hoods	●		●	●				
			Up to 50 L glass reactors (-90 °C – 200 °C), rotary evaporators	●		●	●				
			HPLC (UV)	●	●	●	●				
			Disposable Table-top filters	●		●	●				
			Tray Dryer (Stainless Steel)	●		●	●				

* For detailed equipment information please contact your Thermo Fisher Scientific representative.

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