



Regensburg, Germany

Facility Facts:

Workforce:	~49
Regulatory Approval:	EMA
Potency Capability:	Up to Cat 3a
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Unique Offering:

Rapid scale up and chemical production of intermediates and APIs for Phase I and Phase II clinical trials under cGMP / ISO conditions.

Offerings:

- Small molecule production (Miniplant)
- Rapid scale up from lab to Miniplant scale (1 – 100 kg range)
- cGMP manufacturing of Phase I / Phase II materials
- Demonstration batches for technical transfer projects to Linz site
- Solid state investigations
- Process implementation and development
- Chemical process optimization
- Process safety studies (ARC, DSC)
- Analytical method development and basic method validations
- Forced degradation and stability studies
- Reference standard synthesis and characterization
- Supporting basic polymorph studies and salt screenings
- Analytical method development and basic method validations
- Reference standard synthesis and characterization

Technical Capabilities: Organic Synthesis

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 4.5 bar (65 psi) @ 250 L scale	Mitsunobu reaction
Carbonylation (Pd)	Knoevenagel condensation, Swern oxidation, POCl ₃
Reduction (boranes, silanes, hydrides), reductive amination	Suzuki Cross Coupling, Ullmann Coupling
(De-)protection of diverse functionalities	Flow Chemistry
Radical reaction (e.g. radical bromination)	Biocatalysis, chemical and enzymatic racemic resolution
Hetero- and Homogeneous Catalysis; asymmetric hydrogenation	... and many, many more

Regensburg 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	
Lab – Building 16 – Phase I/Phase II/Phase III Size / Details Development Reactors	Organic synthesis R&D labs	14 bench boxes, 40 ventilation hoods, pressure reaction up to 20 bar at 20 L scale	●	●	●	●				
	GMP lab	40m ² , ISO 8 cleanroom: separate preparation room, 2 ventilation hoods, 1 walk in hood, glassware up to 30L volume	●	●	●	●				
	Cat 3a lab	20 m ² , separated by lock room, 1 ventilation hood, glassware up to 5 L	●	●	●	●				
	13 x HPLCs	UV, fluorescence, MS, CAD, RI, post column derivatization, conductivity; GPC (SEC)	●	●	●	●				
	7 x UPLCs	UV	●	●	●	●				
	3 x GCs	Also HS inj., FID	●	●	●	●				
	NMR	400 MHz, auto sampled	●	●	●	●				
	IR, DSC, Optical rotation, turbidity meter, LOD		●	●	●	●				
	Titration	Acid/base, chloride, KF	●	●	●	●				
	Process Safety	ARC (Omnicel), DSC	●	●	●	●				
Miniplant and Pilotplant – Building 66 Isolation / Drying	All glass	100-200L, -30°C to 140°C			●	●				
	Glass lined	30-2000L, -30°C to 140°C			●	●				
	Hastelloy	250-400L, -100°C (Liquid N 2)			●	●				
	Stainless Steel	250-1500L, -30°C to 200°C			●	●				
	Stirred mobile vessels	Up to 800L			●	●				
	Flow reactor for hazardous chemistry	BuLi reactions			●	●				
		Carbene-type chemistry			●	●				
		Ultralow temperature (-80°C)			●	●				
	Downstream processing	Pressure filters	Stainless Steel			●	●			
			Glass Lined			●	●			
			Hastelloy			●	●			
			Agitated pressure filter			●	●			
		Centrifuges	Stainless Steel			●	●			
Vacuum pumps					●	●				
Metering pumps (PTFE)					●	●				
Rotavap		Up to 50L			●	●				
Tray dryers					●	●				
Sieving		Quadro Comil			●	●				
High vacuum short path distillation	Theoretical capacity up to 1.5 kg/h (depending on boiling point of material)			●	●					
GMP isolation area	Two independent cleanrooms (ISO 8)			●	●					

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