

Amatsigroup



Your drug development partner PORTFOLIO



CHEMICAL ENTITIES

DRUG SUBSTANCE

DRUG PRODUCT

OTHER SERVICES

PRECLINICAL	CLINICAL PHASES I & II	CLINICAL PHASE III, COMMERCIAL & LIFE CYCLE MANAGEMENT
 Analytical method development Stability studies 	 Release testing Analytical method development Analytical method qualification / validation Stability studies and quality control 	 Release testing Analytical method update Analytical method validation Stability studies
 Preformulation / formulation screening Formulation development and manufacturing Analytical method development Stability studies GLP analysis of non clinical formulations 	 Formulation and process development Process confirmation run, production of reference material Clinical trial manufacturing Analytical method development Analytical method qualification / validation QC testing and batch release Stability studies 	 Commercial manufacturing (small commercial batches and orphan drugs) Process validation Release testing Analytical method update Analytical method validation Stability studies Life cycle management of mature products and analytical methods
 Pharmacology (Proof of concept) Pharmacokinetics Bioanalysis for toxicology studies 	 ADME studies Clinical PK: development, validation and assay of samples Quality Control of raw materials Clinical packaging & logistics 	 Quality control of raw materials and drug products Clinical PK: development, validation of bioanalytical method & assay of samples Clinical packaging and logistics

EPT 2017



Amatsigroup



Your drug development partner **PORTFOLIO**

BIOLOGICAL ENTITIES

PRECLINICAL	CLINICAL PHASES I & II	CLINICAL PHASE III & COMMERCIAL
 Microbial strains and cell lines Upstream and downstream process development Analytical method development Manufacturing Stability studies 	 Bioprocess development Process confirmation run, production of reference material Analytical method development Analytical method qualification / validation Clinical trial manufacturing Stability studies 	 Process upscaling and validation Analytical method update Analytical method validation Manufacturing of commercial batches Stability studies
 Preformulation / formulation screening Formulation development and manufacturing Analytical method development Stability studies 	 Formulation and process development Process confirmation run, production of reference material Clinical trial manufacturing Analytical method development Analytical method qualification / validation QC testing and batch release Stability studies 	 Process upscaling and validation Analytical method update Analytical method validation Commercial manufacturing Stability studies
 Pharmacokinetics Bioanalysis for toxicology studies Quality Control testing of raw materials Transfer Consultancy 	 ADME studies Clinical PK: development, validation and assay of samples Quality Control testing of raw materials Process transfer Clinical packaging and logistics 	 Quality control testing of raw materials Process transfer Clinical packaging and logistics

DRUG SUBSTANCE

DRUG PRODUCT

OTHER SERVICES