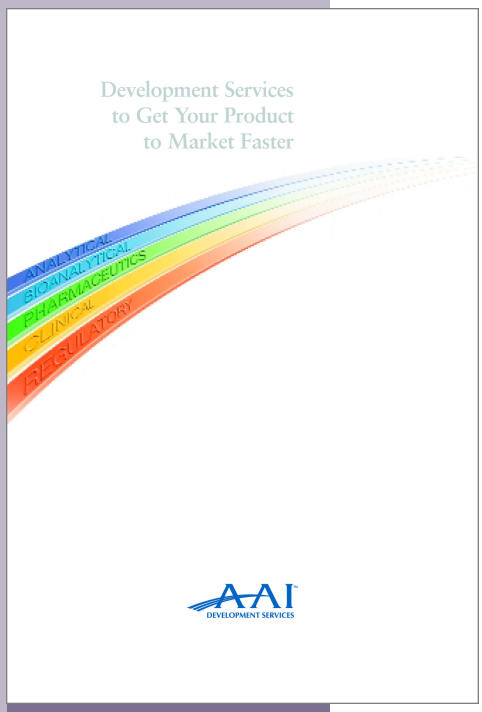
AAI Development Services



Corporate Description

AAI Development Services is a full-service product development company—a premier outsourcing partner for the world's major pharmaceutical companies, biotechnology and medical device companies. A pioneer in analytical services since 1979, we find solutions to pharmaceutical challenges every day to help our customers get to market faster. Our broad range of services are seamlessly integrated across the drug development continuum, with 13 locations in North America, Europe and Asia providing fee for service, project management and consulting solutions in Analytical Services, Bioanalytical Services, Pharmaceutics Services, Clinical Trial Services, and Regulatory Affairs Services.

Major Services

Analytical Services

- Analytical and bioanalytical testing
- Compendial microbiology testing, including sterility and container integrity analysis
- Method development, refinement and validation
- Protein and peptide analysis and characterization
- N-terminal sequencing and amino acid analysis
- Raw material testing
- Active pharmaceutical ingredient testing
- Cleaning validation
- Stability testing and storage
- Environmental monitoring and support

Bioanalytical Services

- Bioanalytical testing by LC/MS/MS, GC/MS, HPLC, electrophoresis, radiochemistry and immunoassays
- Metabolite profiling and mass balance assessment
- Pharmacokinetic/Pharmacodynamic screening
- Mammalian cell-based assays, biomarker and CYP 450 analysis
- Method development and validation

Pharmaceutics Services

- Candidate selection
- Feasibility studies
- Technology transfer
- Process validation
- Toxicology supply manufacturing, packaging and labeling
- Clinical supply manufacturing, packaging and labeling
- Preformulation, formulation and process development of:
  - Oral solid dosage forms
  - Sustained-release products
  - Oral liquid dosage forms
  - Parenteral products
  - Stabilized biomolecule formulas
  - Drug delivery systems

Clinical Trial Services

- Phase I-IV studies
- Strategic planning and project management
- Site selection
- Investigator recruitment
- Clinical trial material manufacturing, labeling, packaging and distribution
- Clinical monitoring
- Medical management and writing
- Data management and statistical analysis
- SAS programming

Regulatory Affairs Services

- Planning and consulting
- Review and counsel on clinical, CMC and bioanalytical issues
- Submission assembly and preparation
- Planning for and representation at meetings with regulatory authorities
- Agency response preparation
- Regulatory and technical management
- Instrument, equipment and facility qualification/validation

AAI Development Services
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NUMBER OF EMPLOYEES
900

DATE FOUNDED
1979

AAI™ DEVELOPMENT SERVICES