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BVMA member since 1998
Audits passed in 2000, 2003,
2006, 2009, 2012 and 2015



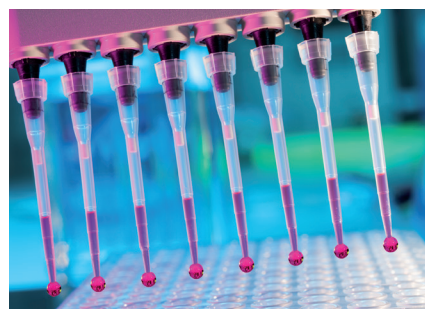
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HISTORY AND MISSION

SYNLAB pharma institute offers a very broad range of laboratory services to the bio, pharmaceutical and cosmetic industries as well as to manufacturers of medical devices, novel foods and crop protecting agents.

SYNLAB pharma institute is part of the SYNLAB group - Europe's largest laboratory service provider. The SYNLAB group has affiliates in 35 European countries, around 14,000 employees and about 300 laboratories.



HIGHLIGHTS

SYNLAB pharma institute (SPI) supports the whole life cycle of drug development, from pre-clinical through clinical studies to release and manufacturing of the product.

Our portfolio at **SPI** includes:

- ▷ clinical laboratory services
- ▷ bio-analytical services
- ▷ biomarker testing
- ▷ personalised medicine concepts
- ▷ global central lab services
- ▷ cross-border sample logistics
- ▷ long-term sample storage
- ▷ stability testing
- ▷ production monitoring
- ▷ hygiene & bacteriology testing

Take advantage of our extensive expertise gained from supporting more than 3,000 preclinical projects and clinical trials.



SERVICES

GCP, GCLP, GLP & GMP for

- ▷ Pharma
- ▷ Biotech
- ▷ Medical Devices
- ▷ Novel Foods
- ▷ Cosmetics
- ▷ Crop Protection Agents

Customized Analytical Services

- ▷ biomarker development
- ▷ PBMC cell separation
- ▷ assay development
- ▷ method validation (EMA/FDA)
- ▷ pharmacogenomics
- ▷ rapid processing of larger batches

Clinical Trial Services

- ▷ 24/7 lab service for Phase I trials
- ▷ special services for paediatric trials
- ▷ full analytical spectrum
- ▷ genetic testing
- ▷ microbiology / virology
- ▷ histopathology and cytology

Bio-analytical services

- ▷ PK / PD assays
- ▷ structure elucidation
- ▷ identification of metabolites
- ▷ small / large molecules
- ▷ bioassays & cell based assays
- ▷ immunogenicity

Global Central Lab Services

- ▷ visit-specific kit building
- ▷ extended sample storage
- ▷ worldwide shipping logistics
- ▷ customized data management
- ▷ secure online access to lab data

GMP Analytical Services

- ▷ release and stability testing
- ▷ phys.-chem. assays (ES, USP, JP)
- ▷ analysis of impurities
- ▷ microbiological impurities
- ▷ bio burden

Global Strengths

- ▷ one global single database
- ▷ identical lab reports worldwide
- ▷ customized flagging
- ▷ global quality insurance
- ▷ one key contact eases communication

Manufacturing Services

- ▷ sterility testing
- ▷ clean air/water analysis
- ▷ hygiene
- ▷ bacteriology
- ▷ quality monitoring
- ▷ temperature-controlled storage

