insights

The Solvias Company Brochure

Analytical Solutions

Polymorphism, Salts & Crystallization

Chemical Development and Catalysis

Biopharmaceutical Analysis

Process Analytical Technology

solvias

"With our services, products and technologies in the field of analytical, chemical and biopharmaceutical development, we provide integrated solutions to enhance the value-chain of our customers."

Hansjörg Walther, CEO

Our Company

Solvias supports the research and development of drug substances, drug products and the optimization of manufacturing processes for pharmaceutical, biotechnology and life sciences companies worldwide.

We offer you increased capacity and profound know-how for analytical and chemical development. Our experience and proven track record provide confidence that projects will be expertly performed and delivered on time. Our portfolio covers:

- Analytical Services
- Biopharmaceutical Analysis
- Solid-Sate Services: Polymorphism, Salts, and Crystallization
- Chemical Development and API Manufacturing up to phase II
- Catalysis
- Process Analytical Technology

The laboratories have been successfully inspected by more than 300 customers, the Swiss authorities and the FDA. The authorization of Swissmedic, the Swiss Agency for Therapeutic Products, permits Solvias to perform pharmaceutical analyses and to manufacture active pharmaceutical ingredients (API) for use in clinical trials within the standard of Good Manufacturing Practice (GMP).

Solvias is as a privately-held company located in Switzerland. The teamwork and cooperation of more than 250 highly qualified employees ensures the success of all analytical and chemical development projects.

Solvias in Brief

1 Company Information

Address for correspondence	Solvias AG Römerpark 2 4303 Kaiseraugst Switzerland	
Website	www.solvias.com	
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Executive committee	Dr. Hansjörg Walther Pedro Schläppi Dr. Stefan Krügel Urs Siegrist Hans van Nuffel	CEO CFO EVP, Head of Analytical Services EVP, Head of Chemical Development and Catalysis EVP, M&A, Confarma Group
Solvias registration number	CH-270.3.012.264-5	
Registered office	Solvias AG Römerpark 2 4303 Kaiseraugst Switzerland	
VAT registration number	468 161 (Switzerland)	No EU VAT number
Date of commencement of business	1 October 1999 (spin-off date from Novartis Services)	

2 Financial Information

Solvias shareholder	Management / employees hold the voting majority
Solvias revenue	Approx. CHF 44.6 million in 2011

3 Capabilities

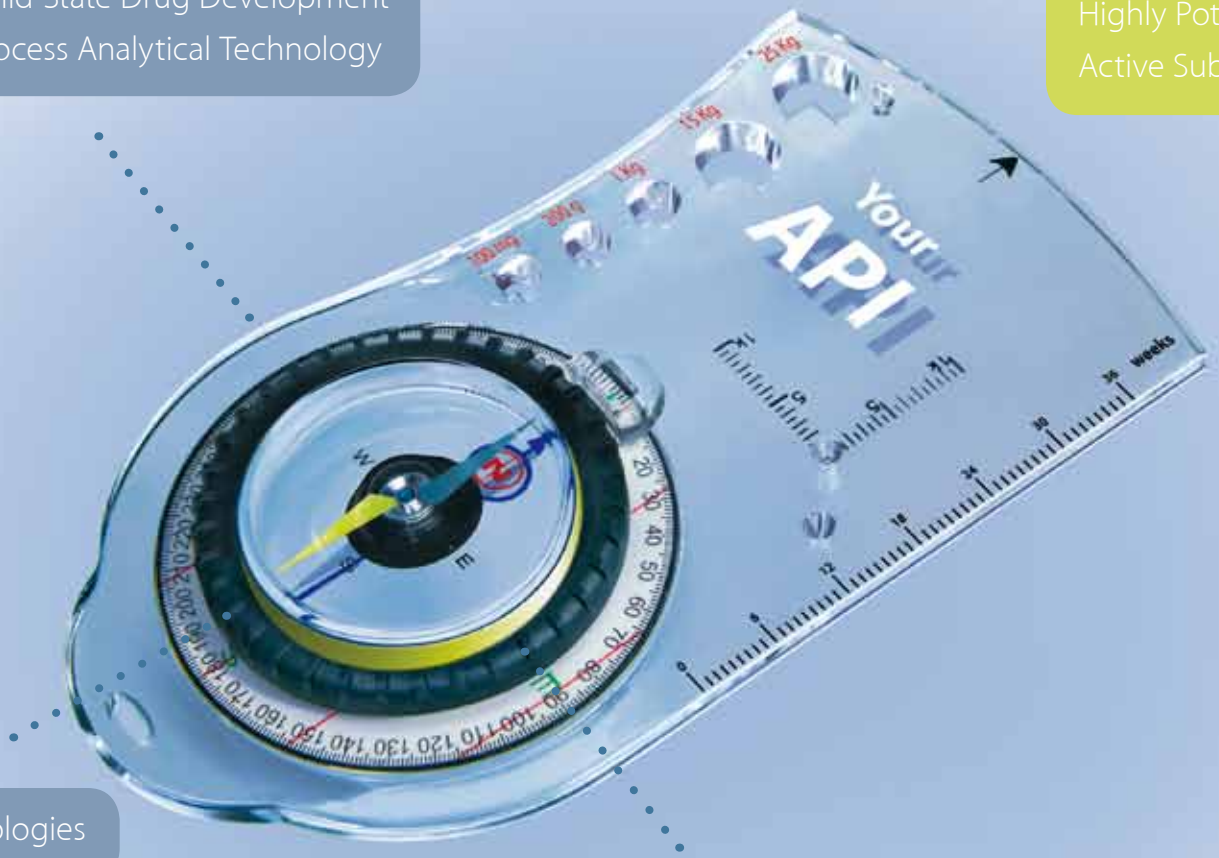
Employees	Approx. 250 employees 47 % graduates/Ph.D.

Our Integrated Services

Research ➡ Preclinical Phase ➡ Clinical Phase I - III ➡ Market

Analytical Services
Analysis of Biopharmaceuticals
Solid-State Drug Development
Process Analytical Technology

Your
Drug Substance
Drug Product
Highly Potent &
Active Substance



Technologies

Chemical Development/API Manufacturing
(up to phase II)
Catalysis Solutions

Our Project Management

The key to successful service delivery

Our project managers take responsibility for the management and coordination of customer projects from kick-off to final delivery. We also provide a clear, transparent structure for planning and performing your projects.

Your requirements will be handled by a team of dedicated project managers, typically holding a Ph.D. in natural sciences. They use their in-depth experience in development projects for the pharmaceutical industry, best practice methodologies, and leadership to coordinate the specialists assigned to your project.

An important added value in the performance of your project is effective and timely communication using, for example, frequently scheduled telephone conferences, personal discussions on site and regular reports as well as a comprehensive final project report.

Our Quality

To guarantee the standard most suitable to your needs

Our aim is to fulfill comprehensively all the contractual and project-specific requests of our customers according to the guidelines of the authorities.

Through continuous quality management, we ensure the ongoing improvement of our processes, services and products, and continually increase the efficiency of our activities. Our quality management system and independent quality assurance unit guarantee that our customers receive products and services of a permanently high standard of quality.

Solvias has been successfully inspected and qualified by more than 300 customers. Furthermore, we have established Quality Agreements with a large number of companies in order to describe the responsibilities, restrictions and other aspects of the service relationship.

Certification to ISO 9001

Our quality management system is based on our business processes in compliance with ISO 9001:2008. It has been certified by the Swiss Association for Quality and Management Systems (SQS) under the registry number 11237-04.

GMP Compliance

Solvias has been duly authorized by Swissmedic, the Swiss Agency for Therapeutic Products, to manufacture medical products. This authorization allows Solvias to perform pharmaceutical analyses and to manufacture active pharmaceutical ingredients (API) for use in clinical trials within the standard of Good Manufacturing Practice (GMP). The certificate is based on inspections performed in accordance with the requirements of good practice in manufacturing and quality control of the Pharmaceutical Inspection Convention/Cooperation Scheme (PIC/S) and the Directives of the European Commission.

FDA

Solvias has been successfully inspected by the US Food and Drug Administration (FDA) in March 2001, June 2005, November 2008 and in April 2011. The inspection reports are filed under FEI 3008735083 and DUNS 485685130. Furthermore, Solvias is registered under CFN 9617363 as a control testing laboratory for analyzing pharmaceutical products.

Analytical Solutions

For all stages of drug development and manufacturing

Solvias provides comprehensive analytical solutions to companies in the pharmaceutical and biopharmaceutical industries for raw materials, intermediates, APIs and drug products. We offer state-of-the-art tools, extensive know-how and flexible capacity combined with competitive pricing.

The portfolio includes separation technologies extended with various hyphenated techniques, such as LC-MS or GC-MS and complements with a wide range of expertise and instrumentation in elemental analysis.

Highly Potent and Cytotoxic Substances

As more and more highly potent and cytotoxic compounds enter drug development, there is a growing awareness of the hazards related to the handling and analyzing of such compounds. We have the appropriate equipment, defined procedures, and trained personnel to perform virtually all analyses on such compounds. Furthermore, Solvias is authorized and has defined procedures to work with narcotics.

Method Development and Validation

We have an outstanding track record in analytical method development for APIs, intermediates, and raw materials as well as for drug products and excipients. Our validation programs are adapted to the development stage of the drug following ICH guidelines.

Quality Control Analysis

Our extensive method portfolio allows us to carry out virtually all kinds of quality control analysis. Based on your needs we perform complete product testing as a one-stop provider or implement individual tests. This includes also compendial tests (USP, Ph. Eur. JP, etc.) and customer-specific tests.

Stability Studies

Throughout the lifecycle of a drug product, stability studies offer important information, from development to manufacturing of APIs. Wide storage capacity for all climate zones and our large method portfolio allow us to carry out all analytical testing typically required for stability studies according to ICH guidelines.

Analytical Characterization

Solvias offers characterization of new drug substances to meet the regulatory requirements for registration dossiers from physico-chemical parameter evaluation and preformulation up to the setting up of complete analytical test programs.

Reference Substances

Well-characterized reference substances make a crucial contribution to the accuracy of analyses in the pharmaceutical industry. Solvias can provide synthesis, isolation, purification and characterization of your reference substance and supply you with a certificate of analysis.

Extractables and Leachables

Benefiting from its vast experience in analytical services, including trace analysis in numerous matrices, Solvias has the experience and capability to provide services for investigating extractables and leachables in accordance with the guidelines of the EMEA and FDA for primary packaging materials and container closure systems.

Microbiology Services

Solvias offers a comprehensive service for microbiological testing of pharmaceuticals and pharmaceutical water.

Many important microbiology methods have recently been harmonized between the USP, Ph. Eur., and JP. Solvias has adopted harmonized methods and can help with product-specific method adaptations and revalidations that may be necessary to comply with the new requirements.

Biopharmaceutical Analysis

Individually tailored to meet your needs

We have an excellent reputation for analysis of monoclonal antibodies, fusion proteins and other protein biologics. At the heart of our services are method development and validation of QC and stability-indicating methods under GMP, according to ICH guidelines.

Our expertise has been applied to complex analytical challenges such as biosimilars (follow-on biologics), PEGylation, glycans, post-translational modifications and excipients such as Tween 80.

We also offer you access to high-quality DNA sequencing, PCR technology and customized molecular biology facilities.

GMP Services
- Characterization programs
- Method development and validation
- Release testing
- Stability studies

Quantity
- UV absorbance A280
- Quantitative amino acid analysis
- Nitrogen determination
- Protein assay (Lowry)
- Immunoassay (ELISA)

Physico-chemical Properties
- Molecular weight
- Isoform pattern and isoelectric point
- Extinction coefficient
- Spectroscopy CD, UV, FL, IR, Raman
- Light scattering MALS DLS
- Analytical ultracentrifugation

Structural Characterization
- Amino-acid composition
- N or C terminal amino acids
- Peptide mapping sulfhydryl groups and disulfide bridges
- Carbohydrate structure and monosaccharides
- Mass spectrometry, MALDI TOF-TOF
- LC-MS/MS, Iontrap or Q-TOF

Assays, Heterogeneity, Product- & Process-Related Impurities, and Excipients Based upon Electrophoresis and Chromatography
- Separation science: CE, SEC, HPLC, HPAECPAD, slab gel electrophoresis, capillary electrophoresis: CGE, CIEF, CZE, iCE280
- Immunological methods, ELISA, western blotting, threshold analysis,
- Carbohydrate characterization, PEgylation

QC Methods for Monoclonal Antibodies & Other Proteins
- RP-HPLC, SEC, IEC
- HPLC-MS/MS, GC-MS, CE-MS
- CE: CZE, CGE, cIEF
- SDS-PAGE
- ELISA
- Residual DNA
- Rodent parvovirus
- Bioburden and endotoxin

DNA-Sequencing & Molecular Biology Services
- Many options for DNA sequence analysis
  - cGMP
  - single strand
  - double strand (publication standard)
  - pre-cylced (for economy)
- DNA isolation and preparation
- PCR
- Transgenic animal genotyping
- Cloning services

Polymorphism, Salts & Crystallization

An integrated approach to solid-state development

The identification and selection of an optimal solid form can have a huge practical and commercial impact on your drug substance, from preclinical development through to manufacture of the final drug product. Focusing on the best overall results for your drug candidate in terms of solid-state development, we provide you a full and integrated approach – from systematic salt, co-crystal, and polymorph screening to controlled scale-up of the crystallization process, complemented by a complete range of physico-chemical studies.

Salt/Co-Crystal Selection

In a well-designed salt/co-crystal screening process, the optimal salt/co-crystal is chosen quickly, based on parameters such as solubility, hygroscopicity, crystallinity, chemical stability and suitability for production. The basis for selection of possible counter ions or co-crystal formers are toxicological aspects, as defined in the FDA GRAS (generally accepted as safe) list but also the intended application. As for example daily dosage forms have different requirements on a counter ion/co-crystal former than drugs that are dosed once weekly. We help you to select the best solid form.

Polymorphism Programs

The aim of a polymorphism program is to search for, to identify and to characterize new polymorphic forms, hydrates and solvates of a substance, and to understand the relationship between the different solid phases. To reliably search for relevant polymorphs, solvates and hydrates, a systematic and smart planning is essential. Our polymorphism screening strategy has been optimized through decades of experience and is readily tailored to our customers' needs. Depending on the stage of development of the active ingredient and on the specific details to be investigated, different study types are available.

Crystallization Screening

Having a crystalline drug candidate is beneficial to development processes and simplifies registration. The combination of our experience and state-of-the-art technology provides effective screening for the crystallization of amorphous and hard-to-crystallize substances.

Crystallization Development from Screening to Kilogram Supply

Our performant solid-state characterization – combined with a proven crystallization development program – leads to robust, reproducible, and scalable crystallization processes that generate the desired crystalline form, size, and shape.

Polymorphic Purity/Amorphous Content

Accurate and sensitive determination of polymorphic purity in both drug substance and drug product, as well as the identification of the amorphous content in the drug substance, assures product quality and reliability. Based on the substance specifics, at Solvias the best technique is selected to obtain the most sensitive levels of detection. Whether for identity testing, limit testing or quantification, methods are developed with a view to future validation and routine testing under GMP.

High-Throughput Screening

The combination of our optimized screening strategies with state-of-the-art high-throughput technology and rapid analysis by X-ray powder diffraction or Raman spectroscopy, provides the maximum information with the minimum amount of your valuable drug substance.

Material Sciences Consulting and Patent Support

Our partners' patent and search team provides an effective resource for protecting your valuable intellectual property and maintaining a competitive advantage. Independent and neutral reproduction of published patented examples or analyses of marketed drugs for polymorph composition result in testimonials to be used for litigation. In addition the experts can provide independent evaluation of studies or individual data, complemented by comprehensive reports.

Chemical Development and GMP Manufacturing

Integrated chemical development services for early drug development

Cost-effective development and manufacturing of complex intermediates and APIs, often chiral, is at the core of Solvias' expertise. Our mastery of homogeneous asymmetric catalysis as an advanced synthetic tool combined with decades of proven innovation in multistep synthesis has made us a leader in the creation of novel solutions for our customers.

We provide you with a complete package of chemical and analytical services for your intermediates and pharmaceutical products.

API Synthesis for Early Drug Development (GMP)

We provide quick and extensive support for your preclinical and early-phase drug development program by delivering gram to kilogram quantities of your API (up to phase II of clinical studies), at the highest standards and on time. This includes robust, scalable syntheses with purification and quality control procedures under GMP.

Custom Synthesis (non-)GMP

We offer you small-scale synthesis up to kilo scale of complex molecules for research and development including the synthesis of drug candidates, lead analogs, scaffolds, building blocks, and metabolites.

In addition, impurities, degradants or metabolites can be isolated by preparative HPLC and characterized by using techniques such as nuclear magnetic resonance (NMR), mass spectrometry (MS), Raman, infrared (FTIR) and ultra-violet (UV). Also hyphenated techniques such as LC-MS/MS with LC-accurate mass capability can be applied to fully characterize your material.

Our state-of-the-art kilo lab is well equipped to handle a wide range of chemistry on scale under virtually unlimited reaction conditions. This includes cryogenic (–80 °C), high-temperature (350 °C), hazardous and high-pressure chemistry (up to 300 bar). The infrastructure covers a variety of different reactor materials and together with our containment facilities we are able to handle toxic, noxious, corrosive or metastable reactants. We are ready to support you for your challenging chemistry according to your specifications and on schedule.

Process R&D

The chemical development experts at Solvias can rapidly develop scalable, robust and cost-effective chemical processes and optimize reaction conditions for your complex, often chiral, intermediates or APIs. Supported by our analytical chemists we are a powerhouse for chemical and analytical development.

Our expertise in process R&D is evidenced by the launch of numerous production processes for our customers' APIs. Newly designed processes can be readily transferred to our kilo lab in the form of a proof of concept study, or for scale-up and delivery of material to support your pre-clinical studies. We can also enable you to transfer the process to a custom manufacturer of your choice.

Catalysis Development/ Chiral Ligands

From screening lead to process implementation

With over 100 early-stage development processes and more than 40 pilot and production-scale processes developed for the pharmaceutical, agrochemical, and fine chemical industries, Solvias has an outstanding track record in the successful implementation of catalysis technology.

Solutions on a Plate with Solvias HTS – The Fastest Way to Your Chiral API

The catalysis screening (Symyx workflow) has led to more efficiency and standardization of Solvias HTS for catalysis. Now offered are flexible HTS screening arrangements that allow our customers to choose a pre-designed 96-well plate for their substrates, and, if desired, modify the plate with their own ligand and catalyst choices. Screening is the critical first step to finding the leads that our customers develop into chemical processes for API manufacture, and we offer this service with maximum flexibility, quick results, and competitive pricing.

Solvias uses HTS to find leads for asymmetric hydrogenation, CX-coupling, heterogeneous hydrogenation, and miscellaneous catalytic reactions that can be adopted to HTS protocols. Leads obtained from HTS can be seamlessly optimized and developed after screening by Solvias experts culminating in a technology transfer to the client or kg scale-up in Solvias laboratories.

Biocatalysis

Our service ranges from initial screening to broad process development for biocatalytic route. The enzyme collection at Solvias contains 200 proprietary enzymes (mainly Ketoreductases) from various established providers, which are available in industrial quantities.

Racemic Resolution

Separation of racemic mixtures by the formation and crystallization of diastereomeric salts (classical resolution) is an important process in the pharmaceutical industry. Classical resolution is generally performed using either 32 chiral acids or bases, respectively, depending on the substrate and pKa values. Experiments are generally conducted on a 0.4 ml scale and analysis and determination of enantiomeric excess (ee) using supercritical fluid chromatography (SCF).

Chiral Ligands and Catalysis

Through in-house development and licensing Solvias has acquired the largest proprietary ligand portfolio in the world. The portfolio consists of a variety of families of chiral phosphine ligands as well as achiral phosphine and palladacycle ligands which can be utilized for CX-coupling. Key in-licenced technologies include the Hartwig CN-coupling system from Yale as well as the catASium® and cataCXium® ligand families from Evonik Degussa. All ligands in the Solvias portfolio are readily available for commercial-scale applications, and their performance (quality, chemical stability, ease of handling, safety) and supply chain meet all applicable pharmaceutical industry requirements.

Process Analytical Technology

Customized solutions based on spectroscopy

Our solutions for process analytics enables you to monitor, understand and optimize your chemical reactions and pharmaceutical processes, even under the most difficult conditions. Using either standard products or customized solutions, we enable the efficient measurement of your gases, liquids and solids.

Fiberoptic Probes

Solvias offers a high variety of probes for online and inline measurements of liquids, gases and solids in laboratories and production plants. In addition to our range of standard fiber-optic sapphire probes, customer-specific designs and materials are possible.

Process Spectrometer

Inline process spectrometers are designed for direct immersion within chemical production processes and are also available with a pressure-tight housing for use in Ex-zones 1 and 2. A single spectrometer can be coupled with up to six fiberoptic probes for transmission, transflection, and ATR applications via standard SMA connectors.

Process Analytical Solutions

Efficient and effective project support for customer-specific PAT (Process Analytical Technology) solutions for the lifescience, chemical and petrochemical industry. The service includes consulting, feasibility studies, installation and qualification of the equipment and the training of the operators.

Software Solutions

Workflow-based software solutions for both the laboratory and production areas, integrating the analytical instruments of your choice. GMP ready software solutions and validation services for automation of laboratory workflows and process analytics.

Computerized System Validation

Computerized system validation establishes the GxP compliance of all equipment controlled by computers and relevant for the quality of products.

Chemical Hazards Monitors

High-performance analyzers for continuous monitoring of highly toxic or carcinogenic substances in plant air or in the workplace. Based on GC technology, these monitors offer a high level of selectivity and sensibility, as well as low detection limits, combined with high reliability.

ARGUS/Dissolution

The automation and data management solution for pharmaceutical dissolution testing, content uniformity and assay. With the shortest sample-to-report time in class ARGUS/Dissolution takes laboratory performance to a new level. Dissolution profile comparison, LIMS connectivity and a powerful reporting tool are just a few of the many features included.

Patent and Search Services

The backbone to the success of your intellectual property strategy

A successful R&D process requires awareness of public knowledge, preventing duplication of R&D and patenting, minimizing the risk of infringement problems, and hence profit losses. Patent and literature searches are the instruments to gather public knowledge and provide a proper basis in decision-making processes within business activities of a company.

Information on technical developments in published patents allows companies (a) identification of future technological developments, (b) use as source of inspiration for new technological solutions, (c) protection of companies' innovations as intellectual property, (d) keeping imitations off the market. Patent services assist to increase the company's value via a balanced patent portfolio.

Highly dedicated experts provide patent and literature searches, patent drafting and patent opinions for all chemical and pharmaceutical fields. All services are performed by experts in our partners companies who work in collaboration with you.

Patent Prosecution

Ownership of a patent generally depends on being the first to apply for the patent. To assist you in this complex area, we have established partnerships with qualified patent attorneys, who offer project-related advice on patent applications.

Our partners' expertise in patent laws and in the economical and commercial facets of patents enables them to assist you in making informed decisions and achieve an optimal cost-benefit ratio.

In cooperation with you, the attorneys prosecute patent applications worldwide in examination, oppositions either directly at the European Patent Office or in other countries with the assistance of a network of corresponding patent attorneys.

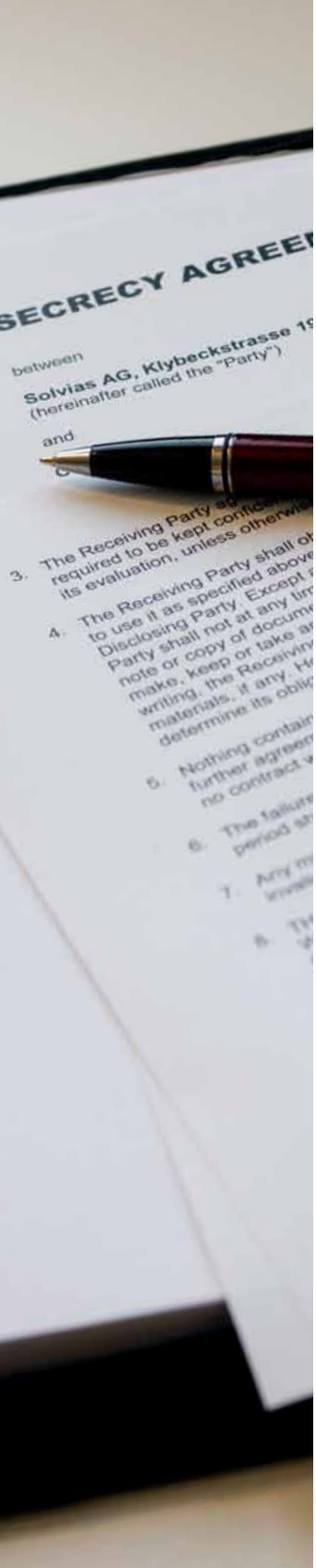
Patent- and Literature Search

Knowledge of all relevant publications is essential for almost all intellectual property related work.

The information specialists have access to all important scientific, technical and patent databases. The database search service is especially adept at chemical structure searching. Journal publications, patent applications, granted patents, conference proceedings and other documents are searched to ensure you get the information you need.

Patent Counseling

Training and education in patent rights and the corresponding patent system can help you, your R&D and marketing teams, to optimize your use of patents. Our partners offer seminars to employees covering basic principles of patent law, patent strategies and patent costs.



Secrecy

To achieve a high standard of protection

It is important to us to provide you with the full assurance that your materials and information, as well as results of the cooperation with us, are protected from improper access and use. Solvias therefore commits itself to confidentiality and secrecy and takes appropriate measures to achieve a high standard of security in customer relations.

Without complaint, our appropriate procedures and measures have met the confidentiality and secrecy requirements of all our customers in the pharmaceutical, agrochemical, speciality and petrochemical industries as well as the food industry in all stages of the product's life-cycle.

European Outsourcing Awards

2011 – Winner Category „Most Improved Process/Plant Facility„
For providing a fully integrated approach to pharmaceutical product development for Vitae Pharmaceuticals.

2010 – Nominated Category „Best Analytical Contract Project"
For CMS Analytical Services for NicOx. Beyond full analytical support, Solvias supplied reference standards of more than 20 impurities.

2009 – Winner Category „Best Analytical Contract Project"
For the complete analysis for the CMC documentation for IDM Pharma's orphan medicinal product MEPACT® (today part of Millennium).

2007 – Winner Category „Most Effective Scale-Up/Tech Transfer"
For an integrated chemical and analytical development project for a complex API intended for use in toxicology studies.

2005 – Winner Category „Outstanding Application"
Together with Novasep for showing the technological maturity of transition-metal-catalyzed reactions on a production scale.

Our Customers and Markets

Worldwide pharma and biotech, virtual – midsize – large, over 400 active customers, all top twelve pharmaceutical companies are Solvias clients

Total Sales

48 % Switzerland
32 % Europe
16 % Americas
4 % Other Countries

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