Agilent solutions
for contract research and manufacturing organizations
Cooperation between pharmaceutical companies and contract research organizations

A successful approach to increasing efficiency along the pharmaceutical value chain

The business models used in contract research and contract manufacturing organizations (CRO/CMO) make a vital contribution to the pharmaceutical industry in terms of increased productivity and reduced costs. Nevertheless, pharmaceutical companies are looking for cost-effective and efficient solutions and services, making the contract research and manufacturing businesses highly competitive.

A few key criteria determine the competitive success of a CRO/CMO when cooperating with pharmaceutical companies:

- Superior quality of data and results
- Timely delivery of results to the client
- Uncompromised and documented adherence to regulatory compliance standards

Competitive success criteria for CRO/CMO operations:

- Result creation costs – cost-per-sample – must be lower than competitive contractors or companies’ in-house resources
- Data organization must be fast, secure and convenient, and it must be easy to export complete result reports as opposed to just data
- System uptime must be optimal with powerful support tools and on-site services available
- Regulatory compliance must be assured for all hardware, software and services with documentation readily available

Agilent can make you the perfect partner for the pharmaceutical industry

This brochure outlines how Agilent can support you and help your organization meet all the success criteria. Benefit from working with the number one in compliance, the innovator of intelligent services for laboratory instrumentation and the market leader for chromatographic instruments.

Reduce analysis costs

Agilent Rapid Resolution LC can cut a lab’s cost-per-analysis by more than 80% (based on a yearly throughput of 76,500 samples)

Increase lab uptime with Agilent Lab Resource Management

As an integral part of Agilent’s Lab Resource Management program, we’ll do a top-to-bottom checkup on your lab, chart current work processes, uncover hidden costs and inefficiencies, and then offer proposals for process improvement (data from an actual lab assessment).
Raise lab uptime and reduce service costs

The second highest cost in contract research organizations is service.

Service is a substantial burden to the total cost of operations. Low system failure rates and immediate availability of qualified resources to fix problems are key to being cost-effective. Agilent's superior instrument quality and new intelligent services support you in your efforts to reduce service costs and raise laboratory uptime. Agilent's new approach to lab resource management saves 15-20% of the total lab service costs over conventional service approaches.

Focus your researchers on using your instruments

Agilent Intelligent Service offer you a new way for quick and time-saving resolution of your instrument problems. With intelligent services you can save on average 1 hour of your analyst time during service calls. Start with problem solving right away and cut out wait and problem description time when you call Agilent and use intelligent services.

Reduce lab downtime and improve your lab operations

Agilent Lab Resource Management (LRM) reduces the time from error detection to repair through onsite availability of service engineers and high use parts for quick repair.

- Lab service costs reduced by 15-20%
- Simplified business process for your support needs
- A single point of contact for all service needs

Highly skilled technical staff for fast problem resolution

In an independent survey for global service and support performance Agilent came out leader in service and delivery. Global training curriculums for service personnel ensure the same high level of quality for our support engineers all over the world.

With Agilent services you can:

- Use your instrument effectively
- Resolve service issues efficiently
- Avoid unscheduled shutdowns

Agilent Intelligent Services setup for immediate and comprehensive error reporting.

Average ratings of global service and support performance on a scale of 1 (strongly disagree) to 10 (strongly agree) - Agilent leads in every delivery attribute (data from 2004 independent market survey)

For more information visit: www.agilent.com/chem/cro
Agilent solutions reduce your total cost of ownership

Why choose Agilent as your instrumentation partner?

- Superior quality – reduces cost of operation and instrument downtime, and increases reliability
- Ease-of-use – what you experience during system operation
- Serviceability – Agilent system intelligence provides a new generation of service

Agilent instrumentation is the industry standard for GC, LC, MS and spectroscopy – your clients and your colleagues already depend on our systems to keep their operations running. Innovations such as the recent 1200 Series Rapid Resolution LC, which ensures that up to 20 times faster separations, can be implemented in a reliable, non-disruptive fashion. This makes it easier for you to adapt these innovations to your applications.

GC and LC systems for your method development and QC applications

For routine quantitative and qualitative drug analysis the patented design of the Agilent 1200 Series LC offers you a robust system for highly reproducible results, which is ideally suited for 24/7 operations.

For gas phase chromatographic separations such as residual solvent analysis of organic volatiles the Agilent 7890A Series GC is the ideal companion for the 1200 Series LC. Both systems offer unparalleled reliability in combination with built-in self diagnostics and advanced remote diagnostics that ensure maximum system uptime.

Benchmark studies with users have shown that Agilent LC systems have always been renowned for their high quality. Over the last two years Agilent has improved this quality even further as shown by the Quality Index (QI*) for Agilent LC systems, which has doubled during this period - proving the high reliability and robustness of the design and the manufacturing process.

(∗QI shown here is based on annual failure rate data for a standard LC system)
**Agilent mass spectrometry**

Agilent offers a broad portfolio of powerful, reliable LC/MS and ICP-MS solutions for applications as diverse as discovery of cancer biomarkers and quantification of drug metabolites or heavy metal impurities in pharmaceuticals.

- Agilent 6100 Series Quadrupole LC/MS systems for mass based detection in chromatographic separation
- Agilent 6210 Time-of-Flight LC/MS system for accurate mass determination of biomolecules and organic compounds
- Agilent 6300 Series Ion Trap LC/MS systems for highest sensitivity and structural confirmation of biomolecules
- Agilent 6410 Triple Quadrupole LC/MS system for accurate quantification of trace compounds in complex matrices
- Agilent 6510 Quadrupole Time-of-Flight LC/MS system for detection of critical, low-level components that are out of reach of other Q-TOF systems.

**Electrophoretic separations with lab-on-a-chip technology and capillary electrophoresis**

The Agilent 2100 bioanalyzer is today’s industry standard for RNA sample QC, replacing labor-intensive gel electrophoresis and a fast alternative for DNA fragment and SDS-PAGE analysis. Agilent’s capillary electrophoresis system provides convenient and reproducible separation of ions, drugs of abuse or oligonucleotides in shorter time with less solvent consumption than standard chromatography.

**Dissolution testing systems based on UV-visible spectroscopy**

The Agilent 8453 dissolution testing system offers you complete control of the entire dissolution sequence, including test preparation and clean-up and provides you with a single final report.

**Agilent consumables**

Agilent consumables and parts are essential for the overall system. They are designed for reproducible results. Only Agilent parts and columns allow you to achieve maximum benefit from your analytical instrumentation.

- Agilent GC columns are higher quality and out-perform any other column on the market
- Agilent ZORBAX LC columns are optimized for high-throughput analysis or for large-scale purification

For more information visit: [www.agilent.com/chem/cro](http://www.agilent.com/chem/cro)
Software makes the difference – reduce time from acquisition to final results

Agilent lab informatics for fast, easy and secure data organization

Instrument control and report generation are the core tasks that all chromatographic data systems must perform. The differentiation between systems lies in the time and effort it takes you to generate final results and create well-formatted reports for your customers.

Agilent OL for managing lab-related IT challenges

Agilent OL is the operating system for your lab. It controls all chromatographic instruments, manages all analytical data and automates your business processes in a single system. Agilent OL helps you in overcoming some of your key bottlenecks.

- Automate and speed up your final review and approval procedures instead of following time-consuming manual processes
- Reduce instrument downtime to a single day through automated execution of instrument maintenance tasks
- Reduce the time for on-site audits by 50% or more by storing and managing your validation documentation in Agilent OL

Agilent chromatographic data systems for maximum flexibility

Chromatographic data systems from Agilent are designed to control the full functionality of Agilent’s chromatographic instrumentation. But they offer much more. Agilent software controls chromatographic instruments from a total of 27 vendors, including all leading suppliers. This multi-vendor control offers you a unique productivity benefit, if your laboratory needs to deploy diverse instrumentation:

- All data are in the same system
- Result reports – independent of instrument brand – can be compared easily and users only have to operate one software package for all their instruments
- Data integrity, data security and electronic audit-trail to support all major compliance guidelines are built-in.

- Perform advanced calculations within Agilent OL for validated final reports
- Find any record in the system within seconds with powerful search routines

Workflow automation for higher productivity

The business process management (BPM) module of Agilent OL offers you automated execution of your lab processes. It is flexible and lets you automate virtually any process through its process template designer. As an example, automating result review and approval can reduce the review cycle time from several weeks to 2-3 days.
Audit security with Agilent compliance know-how and services

Reduce risk and costs with new paperless multi-vendor instrument qualification service

“I believe Agilent provides the most complete range of compliance validation services in the world.”

Ludwig Huber, Compliance Fellow at Agilent Technologies

Benefit from the know-how and innovations that Agilent, as a leading supplier in compliance, can offer you. With Dr Ludwig Huber, compliance fellow at Agilent and author of countless articles and books on validation, Agilent stays on top of the latest directions in governmental regulations and continuously innovates compliance products such as:

- Multi-vendor, chromatographic data management compliant with GLP/GMP and 21 CFR part 11
- Automated instrument qualification for minimized instrument downtime
- Multiple vendors instrument qualification with a single, easily comparable set of procedures
- Paperless qualification protocols
- Automated and streamlined validation of Agilent data systems with patented autodoc creator

Agilent offers innovative compliance products making it easy and efficient for you to keep up with ever-changing validation requirements. With compliance from Agilent you meet regulatory standards easily with minimal interruption of your daily operations.

An independent 2007 LCGC magazine survey ranked Agilent No. 1 in general compliance services, hardware and method validation and system suitability.

Total cost of lab instrument compliance program

1. Review and approval of every protocol and report
2. Labor of instrument testing
3. Administration of service providers
4. Development and maintenance of corporate protocols and SDPs
5. Instrument downtime
6. Inefficiencies caused by lack of enterprise-wide consistency
7. Records maintenance & sharing

Typical high quality corporate qualification program. Paper-based system developed and operated to high standard

Qualification program using all the advantages of Agilent Enterprise Edition

For more information visit: www.agilent.com/chem/cro