

The experience, resources
skills *and* systems ...

VALIDATED

... to get automation
and validation done.

ROVISYS
— Vision. Independence. Results. —

Pharmaceutical and Biotechnology
automation and validation



You lead the world in your market, or intend to. Your expectations are high, demands rigorous and pressures intense. You need to compress time, expand capabilities, improve efficiencies and

increase possibilities. Talent, knowledge, experience and resources are insufficient by themselves. For your company to achieve its objectives, these four qualities must be unified with values, focus and systems that consistently create results that matter.

You need a project partner with the vision to see the big picture, even if it works on just a small part of it. A company with the independence to recommend and implement the technology and solutions best for you now and in the future. A company with verifiable systems for producing results—and the track record to prove it.

The RoviSys Company: World-class automation and integration capability, substantial validation experience and the proven ability to put it all together. More than automation, more than validation—*Holistic validation*, from objectives to results. From RoviSys.

Seeing it through from philosophy to finish: holistic validation from RoviSys

What is holistic validation? It's being able to go successfully from requirements to post-implementation audit. It's identifying and understanding the philosophies and objectives behind your specifications, the whys behind the what. And it's seeing how the current project fits into your overall needs, current systems and potential opportunities.

So what you want done, gets done, while your possibilities remain open.

At RoviSys, holistic validation also means working how you want to get things done, including:

- Initiating and moving projects from validation requirement development all the way to validated and functioning production
- Collaborating with your corporate or outside compliance resources to engineer and implement the systems you need to achieve your objectives
- Performing the individual engineering, documentation or implementation work you specify.

One of the leading independent process automation solutions firms in North America, The RoviSys Company is also one of the most capable and proven biopharm automation

and validation implementation and services providers. RoviSys has completed nearly 2,000 automation, controls, integration and development projects for nearly 300 clients, including some of the world's largest pharmaceutical and biotechnology companies. Specific validation capabilities include:

- Process description
- Functional requirements specification
- Implementation

Yet RoviSys brings you more than the powerful combination of automation expertise and validation experience. You also get secure around-the-clock access to the progress and details on all your projects with GrandView.

Beyond validation: integrating the new, overcoming the unexpected

Things change: new technology arrives, vendors come and go, requirements shift, unexpected obstacles pop up. Staying on track requires resources, systems and experience—qualities you put on your side with RoviSys. Not only do we routinely evaluate and implement new technologies in new ways, but systemically adjust and redeploy project resources as needed to meet your time, budget and capability needs.

GrandView project management and collaboration that works, progress you see

Developed to incorporate RoviSys' in-house project execution methodologies, GrandView is now a commercially available and time-tested project management, execution and collaboration system.



Every RoviSys client gets secure web access to GrandView, enabling you to see all your project

documents, communicate with one or all team members and review all correspondence. And it includes a project audit trail that cannot be modified or erased, a key validation feature.

With GrandView, you get historical and up-to-date information on all your projects all the time. Its project execution systems enable more projects to finish on time and budget. Another reason why, when results matter, you want RoviSys.

**World-class
automation, validation
and implementation
from ...**

VALIDATED

**... a
leading independent
total process automation
solutions provider**

ROVISYS
Vision. Independence. Results.



RoviSys automation and validation services

Services for pharmaceutical and biotechnology manufacturers

To meet the needs of biotechnology and pharmaceutical companies for advanced validated process automation systems and services, RoviSys provides the following according to Good Automated Manufacturing Practice (GAMP) and other relevant guidelines and regulations:

Design and documentation

- Compliance analysis
- Validation documentation
- User requirements specification
- Process descriptions
- Functional requirements specification
- Programming standards development
- Validatable control system design

Implementation

- Validatable control system implementation, including complex batch integration
- Comprehensive and validatable controls, information integration and software engineering solutions
- Data conversion
- Graphical interface

Validation

- Verification and qualification documentation
- Verification and qualification execution

Integration

- Integration with your process and business systems and customers

Client references

... are available on request.

Additional information on GrandView

More detailed information on the GrandView project management, collaboration and communication system is available at rovisys.com or by contacting Tom Dormo at 330-562-8600 or tom_dormo@rovisys.com.

Integrated resources, proven experience

RoviSys began in 1989 as one of the first independent control systems integrators. Today, it is a leader in independent process automation solutions, its 100 professionals working together under one roof to create systems, solutions and services that move you beyond limitations to results.

A total process automation company? A mega integrator? Results, not labels, matter. And RoviSys has completed more than 2,000 projects for 300 pharmaceuticals, chemicals, glass, plastics, refining, power and other clients. Want to quickly complete a single-discipline project? Roll out an enterprise-wide automation, integration, development or validation initiative? RoviSys can help you get it done right by integrating:

- Excellence in key automation-related skills and disciplines
- Implementation resources to rival even the largest technology vendors
- Deep experience applying leading technologies across many industries

RoviSys' ability to bring *vision* to solutions, *independently* recommend the most effective combinations of technology and services plus intently focus on producing *results that matter* have made it the choice of those seeking advanced and proven solutions.

Service areas

- Engineering, implementation and support of focused control and integration projects
- Analysis, engineering, implementation and support of strategic process-, plant- and company-wide control, automation and information integration solutions
- Engineering custom software for control, process and automation applications plus developing software products for private label and OEM uses
- Validation implementation/documentation for pharmaceutical and related industries
- Implementing MES/process-to-business information strategies and solutions

For more information

Contact John Turk, director of pharmaceutical and biotechnology automation services, at 330-562-8600 or john_turk@rovisys.com.

