

# Next-Generation Life Sciences Testing Services

Quality assured. Benefits realized.

Leading Quality Assurance/ Testing Organizations require a balance of the right skill sets, latest technology innovations, methodologies and leading practices.

Compliance, Validation and Testing are becoming higher priorities for Life Sciences companies, primarily driven by increasing regulatory scrutiny on quality. However, companies continue to struggle in implementing quality processes that help achieve the expected business benefits while meeting compliance needs and being cost-effective at the same time. In order to achieve these goals, organizations need to bring the right mix of innovation and industrialization to quality processes.

Whether you are looking for testing capabilities in Validated or Non-Validated environments, Capgemini's Testing Services provides a comprehensive portfolio of testing solutions that are designed to suit Life Sciences companies' and their operating needs. The practice includes thought leaders and a large pool of certified professionals with deep domain knowledge in Life Sciences and extensive experience with various quality management tools from HP®, Rational®, Empirix, Microsoft VSTS®, Segue® and

Open Source. From discovery through distribution, our solutions and people can support all key areas of your business.

In our constant endeavors to innovate and leverage leading practices, we have established Test Innovation Labs that serve as R&D centers responsible for industrializing innovations within projects and domain-specific testing assets related to Life Sciences.

Our testing services have produced clearly identifiable results, notably the reduction in cost of testing by **up to 30%**, enhanced quality levels (the prevention of high-severity defects by **more than 97%**), improved time-to-market, and importantly, mitigation of technical and business risks.

*Capgemini Differentiator: "...probably the most comprehensive offering of the market."*<sup>1</sup>

*"Approximately 40% of the testing personnel of Capgemini have domain knowledge, making it the company most oriented towards domain knowledge."*<sup>2</sup>

Our knowledge of the Life Sciences environments, including the Pharmaceutical, Biotech and Medical Devices areas, enables us to tailor our testing and validation services to your needs. In addition, we can support your overall quality efforts through our experience in areas such as compliance, Six Sigma implementation, change management and IT governance.

• **Testing-as-a-Service (TaaS)**

Our TaaS offering is intended to help our clients find the most agile, flexible and cost-effective platform for securing support for testing resources and tools.

• **Compliance Assurance for Lifesciences (CALS)**

CALS methodology is specifically tailored to address the regulatory and compliance needs of Life Sciences clients.

**Testing-as-a-Service (TaaS)**

The next generation of testing services, Testing-as-a-Service, is increasingly being considered as a viable testing model/methodology by many companies to reduce capital expenditure and gain better control of their IT resources.

In a recent survey conducted by Capgemini, we found that over half of the respondents' companies have already begun to take advantage of "As-a-Service" delivery models that provide on-demand capabilities in support of the ever-changing business environment. We believe that within the next twelve months, a growing number of companies will begin to take advantage of the cost savings and agility that cloud computing has to offer.

Our solution is particularly suited to organizations that need to:

- Quickly provision test environments for development and maintenance
- Adjust their needs for testing tools on a frequent basis to support business needs
- Reduce the costs of test projects
- Cost-effectively address challenges due to ad hoc testing needs
- Manage a wide range of test projects of varying scale and duration, from very small test tasks to large projects involving continuous testing

**Value Proposition for TaaS**

Capgemini's Testing-as-a-Service offering includes support for performance and load testing, test automation, and functional testing. We deliver this service via non-traditional arrangements that are based on our 40+ years of experience in the delivery of quality assurance and testing services for our clients. In addition to these services, many of our clients have asked for assistance in reducing their costs and in making better decisions about the testing tool licenses they purchase.



Figure 1. Capgemini Service Offerings

<sup>1,2</sup> Nelson Hall: "SOFTWARE TESTING ASSESSMENT AND FORECAST," Dominique Raviart, April 2010.

## Compliance Assurance for Life Sciences (CALs)

Over the past few years, we have expanded our global regulatory practice to serve Life Sciences companies in their computer systems implementation and integration efforts. We have offered a wide range of services to support Global Regulatory Compliance and to mitigate risks inherent in Life Sciences initiatives in a regulated environment.

Some of the areas where CALs can be used are ERP and other projects –SAP®, JDE™, Oracle®, other -- and Life Sciences strategy projects. Most of these systems are within the scope of the following regulations and standards: US 21CFR Part 211, US 21CFR Part 820, and US 21CFR Part 11. Validation plans form an integral part of the overall implementation project plan.

- Installation and Operational Qualifications (IQ/OQ) and Summary Reports
- Performance Qualification (PQ) & Summary Report (includes PQ scripts)
- Final Validation Summary Report

### Why Capgemini?

Capgemini has one of the world’s largest dedicated QA/testing practices. Our specialist knowledge and experience makes us the testing partner of choice for **over 500** of the world’s largest enterprises. Independent and objective, we offer a comprehensive portfolio of consultative and execution testing solutions, including:

**Strategic Consulting** - working closely with you to design, develop, and deploy customized testing solutions that address the unique needs of your business and industry, such as QA, audits, and test organization strategy. In addition, we help you leverage cutting-edge thinking to further streamline your application test lifecycle, including Cloud, Virtualization, Simulation, and Model-based testing.

**Managed Testing Service using Rightshore®**—an incremental roadmap to test sourcing—whether onshore, nearshore or offshore—that can provide the right skills, in the right locations, at the right time, to deliver high value.

**Test Process Consulting and Thought Leadership**—test process maturity assessment plus performance improvement recommendations to fast-track implementation—this service uses our own industry standard **TPI® model and Quality Blueprint** accelerators.

Capgemini is the only provider that has published over a dozen books on Quality Assurance and Testing.

**Test Management, Engineering and Execution**—using **Capgemini’s world-leading TMap® methodology**, we provide leading practices for comprehensive testing coverage—reducing the business risk of production flaws, delivery delays, and operational defects. Our approach can enable industrialization and automation across the delivery lifecycle, including functional, infrastructure, security, packaged applications, migration, and end-to-end testing, as well as our on-demand Software Testing-as-a-Service.

**Strategic Alliance and Partnership**—with HP® helps Capgemini professionals easily acquire training and certification on their leading tools, have access to a **complete suite of HP quality management tools** and enable joint solutions development. We are also the only provider that sits on the Product Advisory Boards for both HP and IBM® Testing tools.

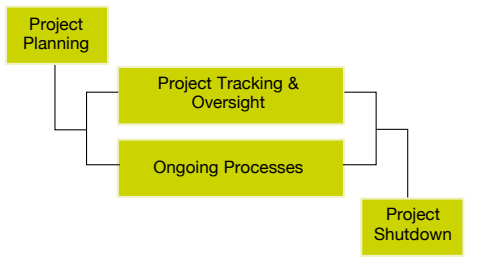


Figure 2. CALs Project Phases

### Validation Lifecycle Process

The basic steps involved in the Validation processes:

- Gap Analysis
- Plan of Action
- Risk Assessment
- Validation

### Key Validation Deliverables

- Validation Master Plan (VMP)
- System Development Review
  - Risk Assessment Document
  - Vendor/Supplier Audit
  - Requirement Traceability Matrix (RTM)
  - SIT & UAT (IQ/OQ) scenarios and scripts



## About Capgemini

Capgemini, one of the world's foremost providers of consulting, technology and outsourcing services, enables its clients to transform and perform through technologies. Capgemini provides its clients with insights and capabilities that boost their freedom to achieve superior results through a unique way of working, the Collaborative Business Experience.™ The Group relies on its global

delivery model called Rightshore®, which aims to get the right balance of the best talent from multiple locations, working as one team to create and deliver the optimum solution for clients. Present in 40 countries, Capgemini reported 2010 global revenues of EUR 8.7 billion (approximately USD \$11.5 billion) and employs around 110,000 people worldwide. More information is available at [www.us.capgemini.com](http://www.us.capgemini.com).

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