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Clarkston Consulting Expands Regulatory and Compliance Practice

As part of this services offering, Clarkston Consulting will identify and implement best practices around a variety of federal government regulatory and compliance issues

DURHAM, NC (June 23, 2003). Clarkston Consulting, a nationally recognized management and technology consulting firm, today announced expansion of its regulatory and compliance offerings.

Clarkston has extensive experience in FDA 21 CFR Part 11 compliance, working with the leading life sciences and consumer products companies. The expanding practice will bolster the firm's regulatory and compliance services to support other key areas including guidance from government organizations such as the Office of the Inspector General, the Food and Drug Administration, OSHA, the SEC and others. Clarkston's expanded practice will provide contract and pricing compliance, corporate financial governance and occupational and safety compliance.

According to Paul W. Allen, managing partner of life sciences of Clarkston Consulting, "There is an increased urgency in the market to focus on compliance issues as companies look to exceed standard regulations. Recent events have brought to light the degree of compliance that companies must achieve. As government organizations become more vigilant and companies see the subsequent consequences, ensuring compliance has taken on a new level of urgency."

Clarkston's regulatory and compliance practice will focus on the following key phases:

- **Gap analysis:** Clarkston will first conduct an extensive audit of the existing business processes and IT environment, map that information back to industry best practices and identify areas for improvement.
- **Road map:** The next step involves developing a road map based on a completed cost-risk matrix that prioritizes projects by risk index and cost.
- **Implementation:** This final phase involves both change management and system/process implementations. Specifically, Clarkston will focus on people, processes and technology.

In addition to the firm's current work around FDA compliance, the Clarkston compliance-based practice will focus on many areas, including:

Contract and Pricing Compliance: The government is becoming increasingly concerned with rising drug prices; however there is a lack of formal regulations



and regulatory guidance. Clarkston anticipates that agencies such as the Office of the Inspector General, Medicare/Medicaid, Health and Human Services and Veteran's Administration will become more involved in the future. Changes in this area will likely affect the sales, marketing and financial departments of pharmaceutical and life sciences companies.

Corporate Financial Governance: With oversight from a number of different bodies including the SEC and Department of Labor, corporate governance spans a wide variety of issues that impact the board of directors, shareholders, employees and others. The need to support new expectations for timely and accurate financial data can be difficult. By setting up the right procedures, organizations can be more in tune with critical financial issues.

Occupational Safety and Health Compliance: Typically overseen by OSHA, occupational safety and health issues typically affect production, manufacturing and laboratory environments - but can in fact govern almost any facility in the United States. Compliance is critical if companies are to maintain operations and ensure safe working environments.

Janel Firestein, a regulatory and compliance expert who has worked with several of the top 50 pharmaceutical companies, will serve as director of the practice. In this role, Firestein will lead a team of consultants and work with Clarkston's chief services officer, Joseph D'Ambrosio, to develop new services.

About Clarkston Consulting

Clarkston Consulting is a nationally recognized management and technology consulting firm that creates successful business strategies and implements technology solutions. Clarkston's business value acceleration approach bridges the gap between strategy and technology to build a sustainable business advantage for Fortune 1000 manufacturers within the life sciences and consumer products industries. The firm's excellence has been recognized through numerous industry, vendor and client awards. Clarkston's exceptional client satisfaction rating as measured by The Conference Board is heralded as among the highest in the consulting industry. To learn more about Clarkston, visit www.clarkstonconsulting.com.

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