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## White Paper Series Introduced by Protocol Link

**VERNON HILLS, IL – (July 28, 2008)** Protocol Link, Inc., a leading project management and consulting firm to the FDA-regulated life sciences industry, today introduced a White Paper entitled “Process Characterization,” its first of a series of publications from Protocol Link geared toward providing relevant and timely information to professionals working in the FDA-regulated pharmaceutical, biotech, and device industries.

In this White Paper, author Michael Brown, P.E., Vice President of Protocol Link, describes the purpose and key elements of the process characterization exercise. The process characterization serves as the engineering basis of design, establishes critical process parameters for process validation, identifies information to be recorded in batch records, guides in the development of data acquisition and process monitoring and control strategies, and serves as a reference for future process changes and improvements. Key elements include process flow diagrams, critical quality attributes, critical process parameters (a.k.a. critical control points), and a failure modes and effects analysis (FMEA) to assess process capability and potential failure modes.

“In the industries that Protocol Link serves, process characterization is an essential exercise that must take place to ensure that a process performs its intended purpose as required by the regulations,” said Michael Brown.

Mr. Brown has more than 20 years of experience in the pharmaceutical and medical device manufacturing, engineering design, and construction industries. He is a certified Professional Engineer and holds a B.S. in Chemical Engineering from the University of Illinois—Champaign.



*Photo of Michael Brown*

### **About Protocol Link**

With an established client base worldwide, Chicago-based Protocol Link, Inc., is a leading project management and consulting firm dedicated to providing comprehensive regulatory compliance, quality assurance, cGMP documentation, validation, and technology services to FDA-regulated life sciences companies worldwide. Founded in 1996, Protocol Link’s mission is to provide customer-focused services with ethical conduct, mutual trust, and personnel empowerment. Additional information can be obtained by visiting Protocol Link’s Web site at: [www.protocollink.com](http://www.protocollink.com).

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