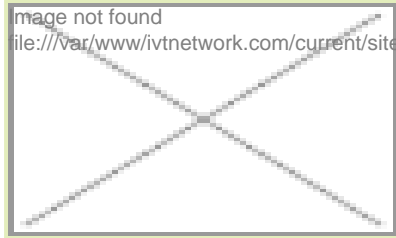

Risk Assessment and Lifecycle Management in Stability Testing

By **Naotaka Hata** Sep 26, 2017 10:35 am PDT



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A risk assessment tool that may be applied to different stages and situations during stability testing has been developed. There are more than 200 questions involved in the risk assessment tool addressing stability-related factors such as storage and testing facilities. Conducting periodic risk assessments have shown to reduce repeatable problem concerns.

INTRODUCTION

Stability testing involves different types of stability storage processes such as stress testing, accelerated testing, long-term testing, and photo-stability testing. As stability testing protocols usually require 3 years for completion, the risk for product quality and business opportunity increases during the testing period (Figure 1). All stability programs must be executed with consistency and compliance.

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