



# VelQuest Services

## SmartLab™ Project Road Map Program

The **SmartLab Project Road Map Program** is designed to help VelQuest work with you to comprehensively evaluate the operational state of your quality lab operations. A full analysis includes:

- Laboratory workflows (e.g., raw materials, in-process and final product testing, metrology)
- Number/variety of test methods
- Management reporting requirements
- IT infrastructure
- Instrumentation and facility landscape

The objective of the BIA and Project Road Map service is to identify critical productivity bottlenecks and compliance risks and recommended improvements through use of VelQuest's SmartLab GMP Electronic Notebook System. In addition to the lab/departmental scope assessment, a complete financial analysis will be prepared with an "all-in" analysis. This includes VelQuest services and products as well as your company resources and capital requirements for success. This Road Map service is a fixed-fee engagement with VelQuest.

*Get a closer look at how much money your paper-based systems are costing you!*

*The SmartLab BIA and Project Road Map service will show how your quality operations can obtain 30% cost savings, 50-75% cycle time reductions and assure compliant documentation.*

*Total assessment of a SmartLab GMP ELN project scope, costs, and "go-live" timelines will have you on the path to improved productivity.*



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Although implementations vary in time and complexity, the fundamental process checklist is consistent from one site to another. The variables in any engagement include:

- IT requirements and prioritization of projects
- Facility size and layout
- Number of users
- Number of initial products automated on the system
- Associated methods
- Availability of QA documentation resources
- Number and type of instruments to be connected to the system
- IT infrastructure integration (CDS, LIMS, ERP, etc.)

VelQuest will assemble all information and write an overview plan of action with key workflow and productivity areas outlined from the BIA&PRM meeting. A full financial analysis is completed, including all anticipated costs (VelQuest and client), estimated payback times, Return-on-Investment (ROI) and Internal Rate of Return (IRR) calculations. VelQuest will present the full report to your management staff. The Road Map Planning steps are in four categories as follows (see reverse page):



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### Step 1: Business Impact Assessment (BIA)

The BIA is a pre-order process to determine the workflow process and specific initial site deployment environment. This process identifies the current processes (typically either paper-based, or paper-based with LIMS hybrid) in QA/QC. The BIA will define the expected impact of the SmartLab system from a cycle time and resource liberation perspective. During the BIA, an executive briefing and product overview is presented to your senior management and staff.

### Step 2: Project Scope Analysis

Your VelQuest business leader and subject matter experts will meet with your potential key project team members to define specific deployment environment(s) including site size, instruments, specific departments to be automated, IT systems and data report requirements and instrument integration.

### Step 3: Methods Review and Prioritization

An initial assessment of test methods are discussed and the process of method loading (using SmartTest template technology and/or MethodBuilder) into the GMP Electronic Notebook are evaluated. Current lab processes including sample preparation, equipment calibration, analytical test methods, results review and approval and data storage will be outlined.

### Step 4: Project Planning

A project plan will be proposed with implementation requirements for success. It includes the project initiation date, summary tasks with and milestone definitions. Tasks for implementation, validation and training will be reviewed, including:

1. **Instrument Connections and Validation:** All simple and complex instruments to be connected to the system and validated are reviewed.
2. **IT System(s) Connections and Validation:** Other IT systems (LIMS, CDS, ERP etc.) and specific integration and report requirements are outlined. Validation plans for the initial implementation are discussed.
3. **System Validation Activities & Documentation:** Resources required to validate your system implementation and support the plan are outlined. Key duties include all official documentation required for cGMP operations at the client site(s). VelQuest provides a comprehensive Validation Documents Suite that can be used by the client.
4. **Resource Summary & Training:** Assessment of resource requirements for initial and on-going implementation will be reviewed. Training requirements for Operators and System Administrators will be outlined.