The client in this case study, referred to as the Global Pharma Company for privacy consideration, specializes in the development of branded prescription products. The LabWare LIMS was originally implemented to manage the Quality Control and Quality Management process. However, the client quickly determined that the initial configuration and deployment of the system was ineffective and hampering the business process. In order to correct the issues with the system and allow for implementation of new system functionality desired by the business, the Global Pharma Company offered HighPoint Solutions the opportunity to propose a team to reconfigure the LIMS. HighPoint returned with the idea of a four person full-time team: a LabWare developer; a business analyst; a system administrator; and a project/program manager (Figure 1). The testing and validation resources were contracted from a third party by the client and were not part of the HighPoint team.

**LabWare Developer**

The role of the LabWare Developer is responsible for the creation and modification of the configuration of the system. The developer begins by being engaged during requirements gathering and Voice of the Customer in order to fully understand the business challenges that need to be addressed by the system. The Developer has primary responsibility for the design and configuration of the system, as well as correcting errors that are discovered during system testing. The Developer presents system demonstrations to the users and directs users through Guided Feedback sessions, where the users navigate through the system themselves to gain familiarity with the configuration. The Developer writes technical documentation for the system, including the Installation Configuration Specification, the System Setup and Installation Procedures, and the Application Configuration Specification.
Business Analyst
The role of Business Analyst is responsible for the creation and modification of the documentation associated with the system, as well as leading requirements gathering. Strong communication skills allow the Business Analyst to accurately construct workflows and requirements that represent the needs of the business and may be used by the Developer to configure the system. Documentation the Business Analyst is responsible for includes the User Requirements Specification, the Functional Requirements Specification, and Business Process Continuity Plan. Following configuration, the Business Analyst constructs all training materials and leads training sessions for the users.

System Administrator Role
The System Administrator is responsible for assisting the Developer with the creation and modification of the configuration of the system, as well as handling user questions and requests. Simple requests such as password resets, questions regarding system use, and user account creation are addressed immediately. Other requests, such as adding additional analyses or updating a report, are added to a Change Request Tracking Log. When preparing for upcoming releases, the Change Request Tracking Log is reviewed and requests are prioritized based on business need and configuration complexity. High priority requests are selected for implementation within the next release.

Once the release scope or requirements are defined, the system administrator begins the continuously proven configuration process. This process entails gathering detailed user requirements and creating an initial prototype (Prototype I). This prototype is then demonstrated to the users and they are given time (usually 2-3 weeks) to have a hands-on review of the system. Prototype I ends with collecting user’s feedback about the system and then making those changes. The next prototype stage repeats this process with incorporating additional detailed user requirements. This process is completed by finalizing user requests of the system and then gathering reporting requirements and creating them. Upon completion of this process, the system’s configuration is ‘locked’ and the system administrator moves to a supporting role for validation along with supporting the everyday tasks.

Project Manager Role
The responsibility of the Project Manager is to ensure the LabWare Developer, Business Analyst, and System Administrator are able to be successful in completing their tasks which ultimately leads to successful completion of the project. In order to do this, the PM has many tasks including creating open lines of communication between the team and the business owners. A key piece of this communication comes from weekly status reports along with leading weekly status meeting to update the client and end users on the position of the project. Items covered in the meeting include overall status, budget statistics, timelines, issues and concerns from all parties involved.

The experienced LabWare team provided by HighPoint Solutions worked together with the client to maintain the validation quality management system and address all user requests and concerns over an extended period of time. The LabWare LIMS was consistently revised and further developed to meet the fast growing demands of the business.