Lessons Learned: Implementation Do's and Don'ts

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2015 - Case Study

MetricStream
GRC
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Agenda

1. Organization Overview: Vision and Key Facts
2. Organization Structure: Lines of Business and Key Stakeholders
3. Business Challenge Identification
4. GRC Requirements
5. Challenges
6. Technology as an Enabler
7. Successes
8. Lessons Learned
9. Audience Questions and Discussion

Organization Overview

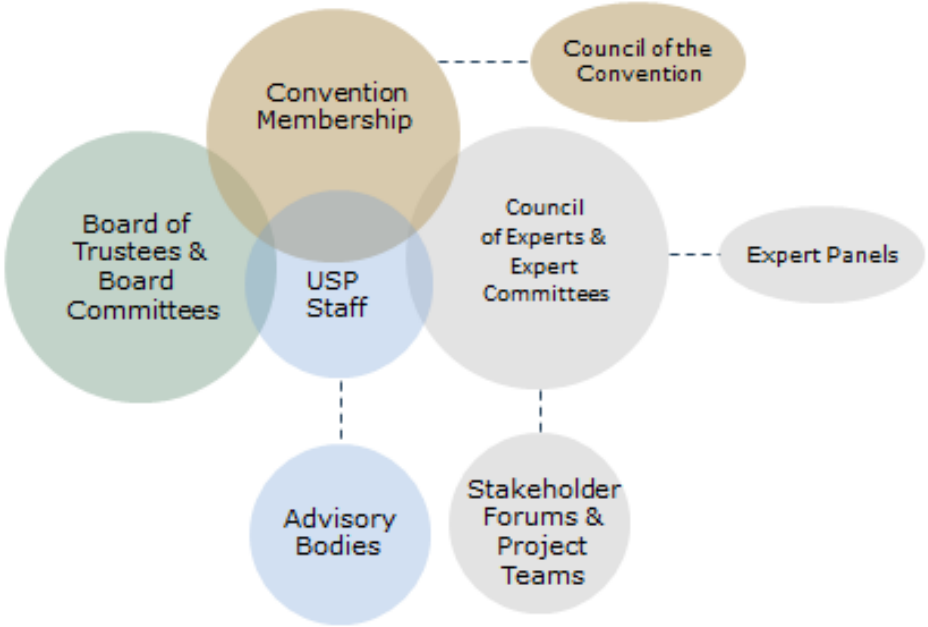
- The U.S. Pharmacopeial Convention (USP) was founded in 1820 and is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries.

- USP's Mission:
  - To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

- USP's Vision:
  - USP envisions a world in which all have access to high quality, safe, and beneficial medicines and foods. USP approaches this vision with a sense of urgency and purpose, strengthened by its cadre of dedicated expert volunteers, members, and staff, and by working collaboratively with key stakeholders across the globe.

- USP Products:
  - USP – NF is a book of public pharmacopeial standards. It contains standards for (chemical and biological drug substances, dosage forms, and compounded preparations), excipients, medical devices, and dietary supplements
  - USP Dietary Supplements Compendium
  - Food Chemicals Codex (FCC)
  - Reference Standards are highly-characterized physical specimens used in testing by pharmaceutical and related industries to help ensure the identity, strength, quality, and purity of medicines (drugs, biologics, and excipients), dietary supplements, and food ingredients.

USP's Structure



Business Challenges – QA Perspective

- USP reference standard use is written into FDA law but do not fall under the purview of any regulatory authority.
- Customer expectation is that USP operations follow the same strict quality system requirements that they do.
- USP does have a Quality Management System (QMS) that has been certified to ISO 9001 and accredited to ISO 17025.
- USP is actively engaged in moving their QMS from manual systems to electronic systems that provide more capabilities.

Challenge: Identify and Implement a global Quality Management solution for Issues and Audits that allows USP to capture and retrieve information, track and trend data, and to identify value added opportunities for improvement.

GRC Requirements

- **General**
  - Global application - transparent
  - Electronic/paperless
  - Email generated workflow assignments with direct link to that assignment
  - Ability to capture information and report on that information – trending
  - Ability to add attachments in various formats
  - Enhanced reporting and audit trail features

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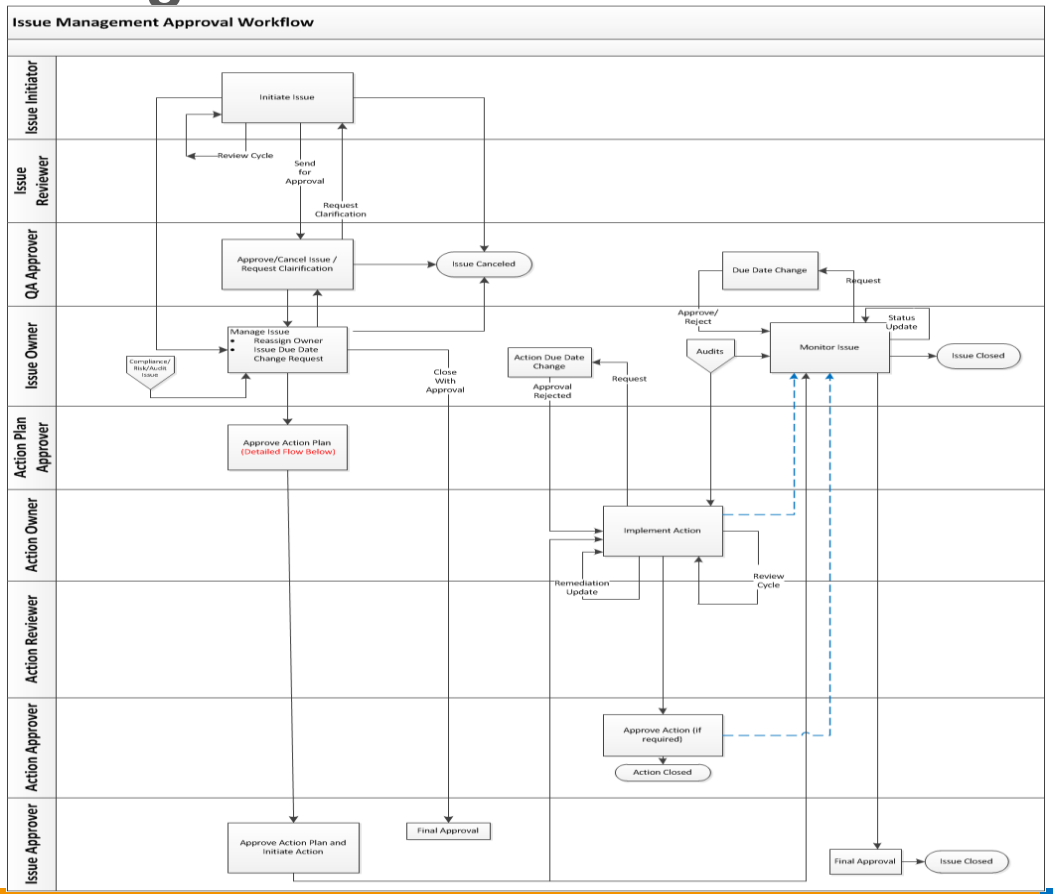
- **Solution for Internal Audit Program**
  - Audit planning capability
  - Audit assignments – by date and auditor (auto-generated)
  - Auto-report creation including checklist features
  - Ability to link to the CAPA system

MetricStream Audit Module

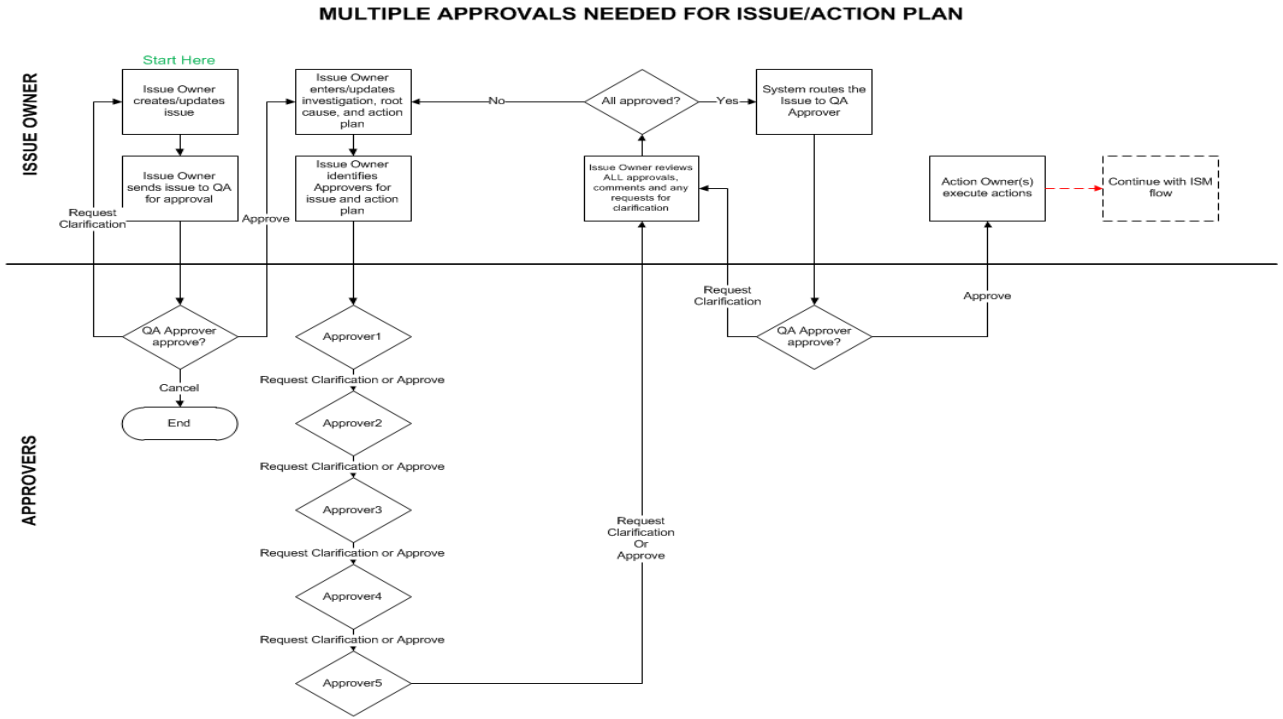
- **Solution for CAPA program**
  - Single system to manage all types of nonconformances
    - Deviations, CAPAs, Lab investigations
  - Self-contained, all-inclusive workflow
  - Ability to track, trend and report globally

MetricStream Issue Management Module

Issue Management Process Flow



Issue Management Approval Workflow

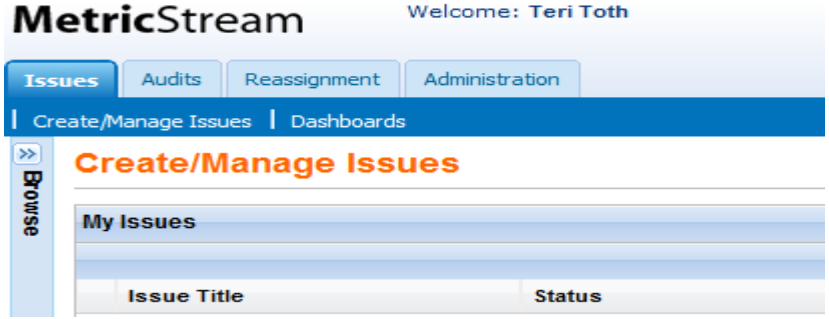


Challenges

- Relationship with MetricStream (MS) assigned Project Manager
- Availability of MS “Sandbox”
- Communication – time zone, language and culture
- Single Sign On and User Role set-up
- Issues with email set-up
- IT uncertainties
  - Hosting options
  - IT documentation and training
  - Reporting and Dashboards
- Alignment of understanding of USP “Requirements”
  - Pharmaceutical industry QMS
  - Approval routing – resulted in customization of the Issue Management Module
  - Documentation expectations
- MS’s internal testing procedures
- MS project team staff turnover

Successes

- The right team makes all the difference
  - Project Manager
  - Business Analyst
  - Development Manager
  - QA
- We chose the right product
  - User friendly
  - Self-contained workflows
  - Ability to track and trend
  - Global and transparent
- Tools that helped
  - User Guides formatted to reflect our system
  - Workflow “cheat sheet” for users
  - Varied training sessions based on user needs
    - Power Users



Lessons Learned

- Assemble an internal cross-functional team that includes all relevant stakeholders
- Create a clear, detailed requirements document (internal)
- Assemble a comprehensive Request for Proposal (RFP) that includes specific use case scenarios
- Vet your vendor thoroughly to be sure they understand your requirements and that they can meet your requirements
  - Don’t provide your budget
  - Onshore vs. Offshore
  - Owned vs. Hosted
  - “Play in the sandbox”
- Be sure you know what “out-of-the-box” really means

Lessons Learned

- Require and review vendor documentation process (e.g., UAT for customer, vendor testing protocols, system set-up and take-down procedures, version/change control)
- Require and review vendor customer support process and documentation – include support for pre-implementation and post-implementation
- Timelines – clear and agreed to (documented). Include penalties for missing key due dates.
- Establish routine progress report meetings during implementation - document action items, responsibilities and due dates
- Establish a Change Management process for pre- and post-implementation
- Creating a good partnership with your supplier is key to working through the challenges that will occur

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QUESTIONS AND DISCUSSION

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