



GILEAD

Advancing Therapeutics.
Improving Lives.

Vault QualityDocs Implementation Best Practices

Wendy Goretski, Gilead

Dana Sook, Veeva

Speakers



Wendy Goretski

Associate Director, Business IT

Experience across Quality, Supply Chain and IT with a focus on software development and delivery. She has worked at ALZA, Johnson & Johnson, Janssen Alzheimer Immunotherapy, Jazz Pharmaceuticals and she is currently at Gilead Sciences.



Dana Sook

Practice Manager, Quality

Over 15 years of experience implementing content management solutions for life sciences customers.

Gilead Overview

Mission: Discover, develop and deliver innovative medicines in areas of unmet medical need

- Founded 1987, public since 1992
- 10,000+ employees across 6 continents
- 25 marketed products
- Provide medicines to over 170 countries

Focus on patient needs

- **World-wide access:** All people should have access to our medicines, regardless of where they live or their economic status
- **Primary therapeutic areas:** HIV, Liver Disease, Cardiovascular (PAH, angina), Oncology (B-cell malignancies), Respiratory (influenza, cystic fibrosis)

A Global Effort: Gilead Around the World



- Almost 11,000 employees
- In 35 countries, spanning 6 continents
- >25 products
- 15 acquisitions

Key Drivers for Change



People

Complicated workflows

Non-intuitive interface

User frustration and
inefficiencies



Process

Complex and
inconsistent processes

Current system is not
scalable



Technology

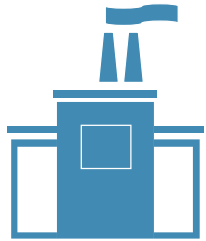
Outdated platform

High maintenance costs

Lack of visibility –
difficulty creating reports

Expanding GVault (Vault QualityDocs)

Contract Partners



Collaboration and manage data generated to support development and manufacturing

Internal GDocs Replacement



Enterprise-wide initiative led by IT, Dev Ops, and PDM to replace legacy system

Kite



Incorporating acquired company

Scope of Documents

All Documents in GDocs are in Scope

For example:

Effective Documents

- Policies
- Standards
- SOPs
- Test Methods
- Work Instructions
- Manuals
- Specifications

Approved Documents

- Validation documents
- SDLC documents
- Protocols
- Assessments
- Master Batch Records
- Training content

Records

- Reports
- Forms
- Executed protocols
- Contracts

Guiding Principles and Goals

Goals



Increase user satisfaction



Enhance compliance



Faster response to business needs



Easy to support

- **Ease of use** by reducing number of clicks, and workflow steps for review, approve, and status
- **Ease of navigation** with powerful search and use of metadata
- **Enable self-service** by removing dependency on doc control and balanced with appropriate control
- **Simplify, harmonize, consolidate** where possible, and limit disruption to business operations
- Establish / leverage **document owner** accountability
- Operate as **one Gilead**
- Use **out-of-the-box** as much as possible
- Plan with the future and **sustainability** in mind

Success Criteria

Easy to Use



Increase end user acceptance from 35% to 75%

Smart Workflows



Reduce gating deviations by 50%

Technology & Integration



Use vendor's executed IQ/OQ documentation

Easy to Configure & Support



Increase from 2 to 6 releases and allow system changes between releases



Enhance Compliance

Reduce system deviations per year by 80%



Business Efficiencies

Reduce doc control support for doc routing by 50%

Implementation

Change Management

- **Change management** team engaged at project outset
- Project **visioning workshop**
- **User engagement** with community and stakeholders
 - Striving for a **better experience** than last system implementation by engaging more with the business
 - Provide **two-way feedback** mechanism
 - Build support for **new way of operating**
 - **Facilitate implementation** at sites/functions



Building the Team

- **Global representation**
 - Expanded reach to include larger population of site / function users for feedback
- Expectation for team members to **invest time**
 - Underestimated time required by ~2 times
- To **remain nimble**, develop a focus and extended team
 - Focus team: ~12 people
 - Extended: Up to 120 people
 - 2 people / site attended workshops in Foster city
 - 20 people / site attended the roadshow and participated in UAT

Team Criteria: Process Design and Configuration

GOAL: Fully-configured system that meets document management needs for all sites and functions

Focus Team

WHO: 7-10 people

- Broad background & experienced
- Well distributed across functional areas
- Business savvy and persuasive communicator
- Collaborative, participatory
- Empowered and credible
- Forward-looking, yet pragmatic
- Owners of content

WHAT: Process definition

- Define the to-be processes and configure the tool with vendor

HOW: Meet onsite in Foster City

- Dedicated to process design and tool configuration

Extended Team

WHO:

- People from all sites and functions to ensure broad involvement
 - Site and functional subject matter experts (SMEs)
 - Owners of local content

WHAT:

- Demonstrations of configured tool, evaluate application functionality for all sites and functions

HOW:

- 4-5 Days each round of configuration
- Conducted by core team or locally as resource availability permits

Evolution of Team Approach

	Expected	Actual
Number of workshops	3 workshops with focus team	5 workshops
Approach	<ul style="list-style-type: none">At 60% configured, go on roadshow (site- to-site) and get input from each site	<ul style="list-style-type: none">At 60% configured, brought in all representatives from sites or function to Foster City (extended team)At 80% configured and with local advocates in place, went on roadshow
Challenge	<ul style="list-style-type: none">Difficult for harmonizationGetting feedback site-by-site does not allow everyone to see the big picture	<ul style="list-style-type: none">Understand one-Gilead and collaboratively made changes based on feedback

Deployment Scenarios Considered

One – wave	Two – wave			
<p>Single big-bang deployment</p> <ul style="list-style-type: none">• Deploy to all users and all sites• Migrating all documents at one time	<p>Read-only followed by edit access</p> <ul style="list-style-type: none">• Wave 1: Deploy all documents and workflows to all users in read-only mode• Wave 2: Enable edit access after users are comfortable with look and feel	<p>Pilot followed by one-wave migration</p> <ul style="list-style-type: none">• Wave 1: Add in pilot group to test drive the system• Wave 2: Migrate all documents and deploy to remaining users	<p>By Document "Class"</p> <ul style="list-style-type: none">• Wave 1: Records, CVs and job descriptions• Wave 2: all other documents	<p>By function / site</p> <ul style="list-style-type: none">• Wave 1: one function/site• Wave 2: all other functions/sites

Evolution of Deployment Strategy

Big-bang

Pros

- **Minimizes disruption** – For current GVault (partners and Gilead) users
- **Reduces user confusion** – All content migrates at once
- **Lower complexity** – For migration, validation, system integrations

Cons

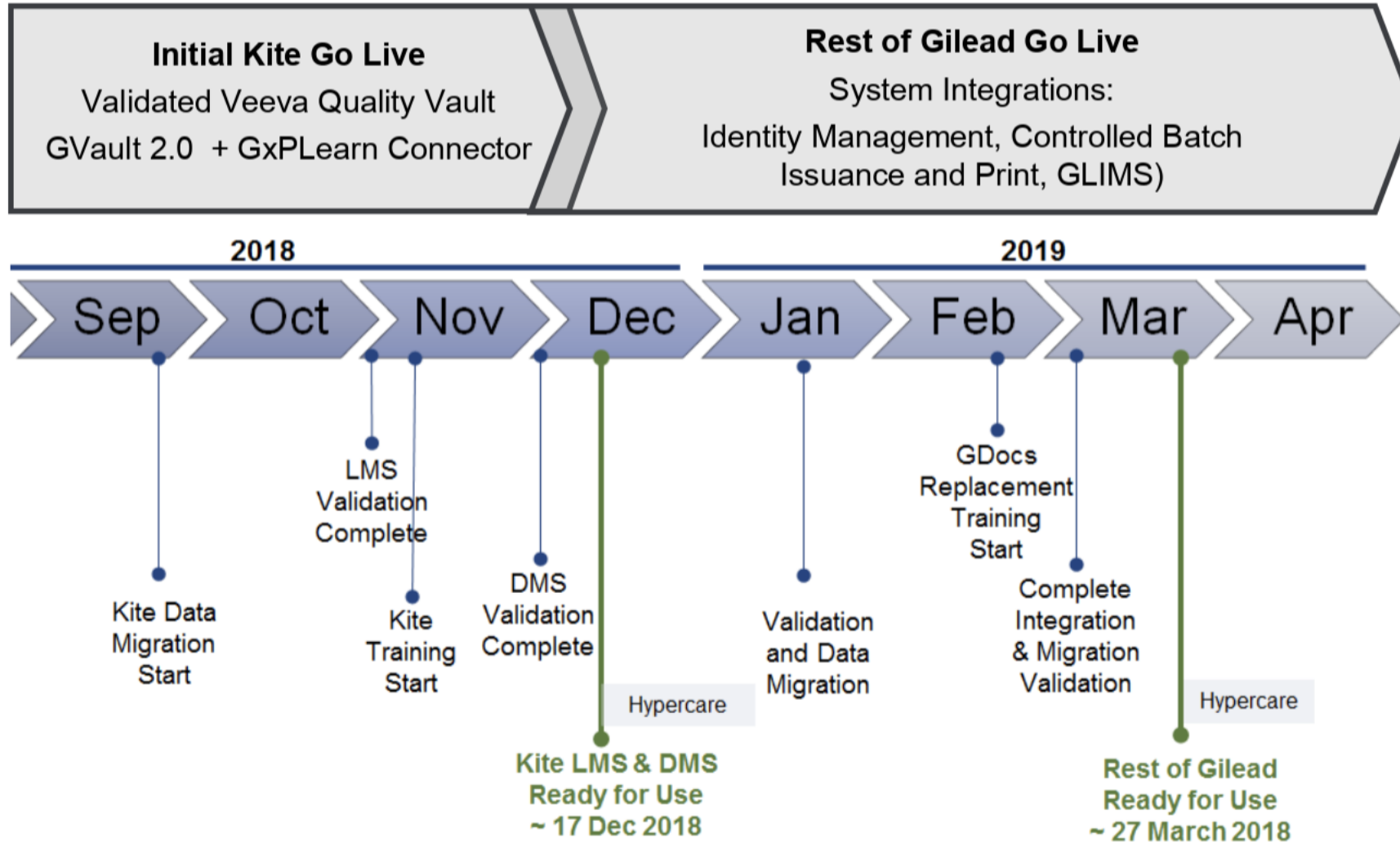
- **Longer testing cycle** – Higher user involvement in testing to lower risk of errors
- **Resource strain** – Core/focus/training/hypercare teams support ALL docs, users, sites – at once
- Perceived higher risk

Phased

Two-wave

- Migrate content from Kite (acquisition) and then GDocs
- Very strong business need and clear division of content
- Easily pivoted from big bang to phased approach due to flexible system and prior evaluation

Revised Project Plan

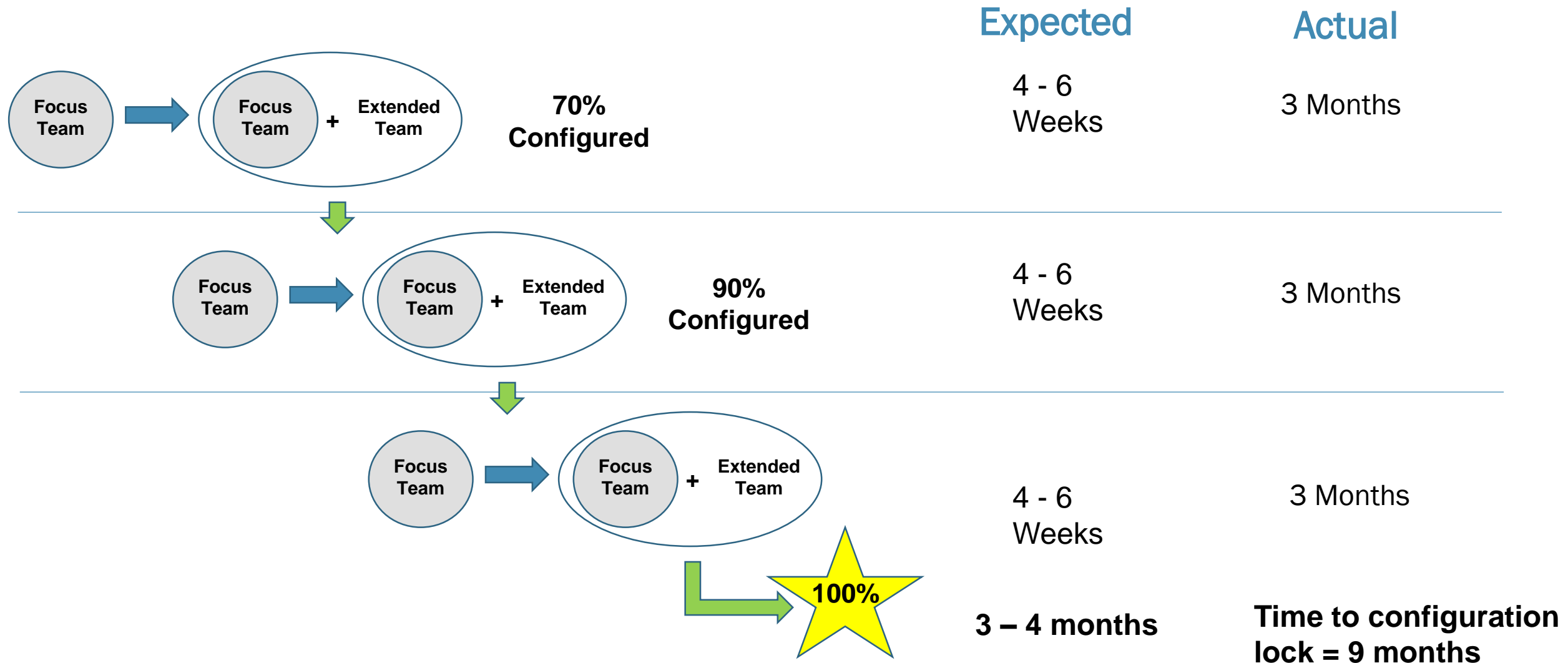


Configuration

Considerations

- **Teams** – It takes longer than you think
- **Harmonize / simplify** – Opportunity to harmonize and simplify with flexibility to accommodate specific business practices
 - Enable GMP, GLP, and GCP documents to exist in the same system
- **Document steward role** – Creating document steward role
 - For sites ready for self-service

Configuration



Document Simplification Highlights

Simplification of Doc Type hierarchy

- Aligned with SOP OpEx to define doc types with clear purpose and training requirements
- Intuitive for users

Adding **metadata** for document properties

- Provides standard information to organize documents
- Simplifies training assignments and impact assessment of changes
- Provides scalability and flexibility

Document **relationships** capture references, supporting and impacted documents

Results

- **Reduced** document types from 350 to 75
- **Simplified** naming structure
- **Better alignment** of workflows with the business
 - Workflow review and approvals reflect risk and impact of the document

Document Steward Role

- A new role to allow organizations to take on oversight of their documents
- Document controllers will also have the same rights as document stewards
 - Plus a few more rights (such as setting effective dates)
- The changes in the system will support current operations and open the doors to new ways of managing the flow of documents

New Document Numbering

Doc numbering changes

- Added a Veeva-assigned standard doc number: different prefix and new sequence number
- Changing doc numbering very impactful to the business
- Captures GDocs number in “Legacy Document Number” field for traceability

General

Name SPC-00018 DRUG
PRODUCT MANUFACTURING
SPECIFICATION - Tenofovir
Alafenamide Tablets 25 mg

Title DRUG PRODUCT
MANUFACTURING
SPECIFICATION - Tenofovir
Alafenamide Tablets 25 mg

Type Specification

Subtype Material & Manufacturing

Document Number SPC-00018

Legacy
Info

Legacy Information

Legacy Author T. Joshi

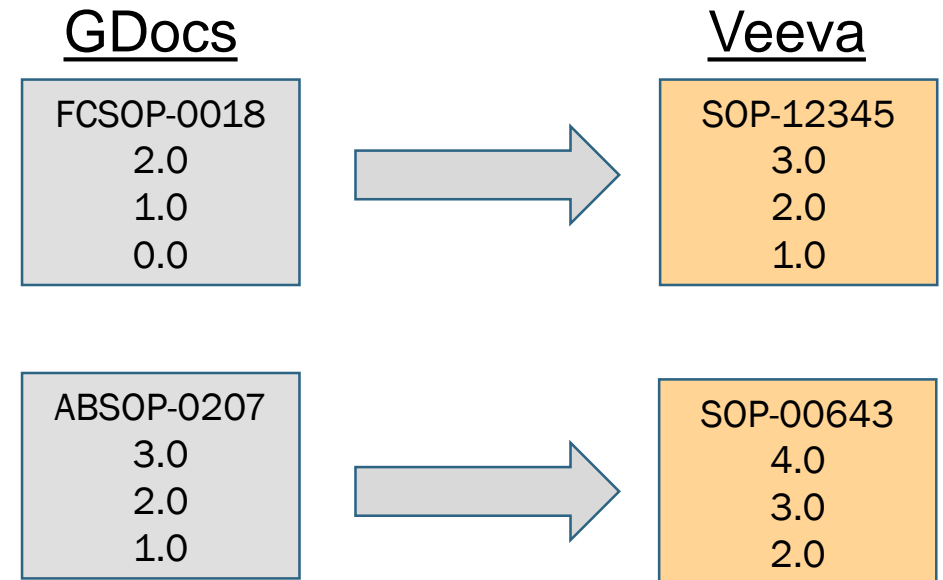
**Legacy Document
Number** GSPEC-M279

**Legacy Version
Number** 5.0

Data Migration

Data Migration Highlights

- Leading from business side
- Migrated from one Gilead system – GDocs
 - Leveraging legacy and new doc numbering
- Added Kite (acquisition) content
 - Organization is adopting new doc numbering
- Document version number incremented
 - GDocs documents have version 0.0 and not supported by Veeva Vault
 - All Version Numbers will be incremented by 1, regardless of whether they start with 0.0



Assigned New Doc # and Version During Migration

The screenshot displays a document viewer interface. At the top, the document title is "SOP-00185 High Purity Water System Maintenance (3.0)", which is circled in orange. Below the title, a status bar indicates "EFFECTIVE" and "2" stars. A message states "This document is currently governed by change control [DCC-000111](#)". The viewer shows page 1 of 14. The document content includes a header with the Gilead logo and "STANDARD OPERATING PROCEDURE". Below the header, the "DOCUMENT NO:" is "ABSOP-0207" (circled in orange) and the "REVISION:" is "(2.0)". The "TITLE:" is "High Purity Water System Maintenance". The main content is divided into sections: 1. Application, 2. Basis, and 3. RESPONSIBILITIES. A magnified panel on the right shows "Legacy Information" with "Legacy Document Number ABSOP-0207" and "Legacy Version Number 2.0".

DOCUMENT NO: ABSOP-0207 **REVISION:** (2.0) Page 1 of 11

TITLE: High Purity Water System Maintenance

1. Application
This Standard Operating Procedure (SOP) applies to maintaining the feed water to meet the system specifications, the sanitization and cleaning of the reverse osmosis system and storage tank and replacement of the storage tank vent filter.

2. Basis
This SOP is based on:
ICH Q7 "Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients":
Section 4 **BUILDINGS AND FACILITIES:** 4.7 Sanitation and Maintenance.
Health Canada "Good Manufacturing Practices Guidelines for Active Pharmaceutical Ingredients", GUI-0104: Sanitation C.02.007

3. RESPONSIBILITIES
3.1 It is the responsibility of the Maintenance department to ensure that this procedure is carried out when performing maintenance on the HPW system.

Legacy Information
Legacy Document Number ABSOP-0207
Legacy Version Number 2.0

Magnified screenshot of Legacy Document Metadata.

The content of the document will not be modified during migration.

Considerations for Migration Dry-runs

- Goal is to minimize number of issues before production
- Balancing the number of dry-runs with resource and time constraints
- Doing partial and full dry-runs
- Build experience and knowledge on the types of potential migration issues

Dry-run	33%	Content Migrated
Dry-run	90%	Content Migrated
Dry-run	98%	Content Migrated
Production	100%	Content Migrated

User Acceptance Testing (UAT)

Approach to UAT

- Original timeline did not include enough time for UAT
- Include it as part of the change management process
- Involved end users in UAT
 - Extended team included site and functional representation
 - Total participants ~50

Resolved

Second level approval moved to end of workflow

Only people with elevated permission can view superseded documents

Document numbering concerns were not raised

Prevent edits to documents in a pre-approval routing

Retirement approvals removed from signature page

Add license / certification document type to support EU operations

Validation

Different Roles with the Same Goals

- 1 Veeva serves the life sciences industry – they work to similar validation standards
- 2 Leverage Veeva’s shared, once-for-all-customers validation approach
- 3 Take advantage of the validation documentation that is delivered with each release
- 4 Consider making your SDLC activity-based, and not deliverable-based
- 5 More frequent releases doesn’t mean more work – **leave the IQ and OQ to Veeva**

Validation Deliverables	Veeva	Gilead	Customer Action Req'd
Master Validation Plan (MVP)	✓	✓	Leverage or Develop
Functional Requirements Specs (FRS)	✓		Reference in MVP
IQ/OQ Protocol/Scripts/Results	✓		Reference in MVP
Trace Matrix (through OQ)	✓		Reference
Validation Summary Report (VSR)	✓	✓	Reference
Configuration URS		✓	Develop
PQ Protocol/Scripts	✓	✓	Leverage or Develop
PQ Summary Report		✓	Develop
Trace Matrix (through PQ)	✓	✓	Leverage or Develop

Summary

Lessons Learned



More time

- Decision-making
- User acceptance testing (UAT)
- Resources (time commitments)



Engage with the business

- Requirements, change management, communication, etc.



Business ownership of data migration process

- Do sufficient migration testing of data i.e. migration dry-runs



Design a flexible system

- Integration of Kite was much easier and straight-forward

Benefits: Process Improvements

Easy to Use



- ✓ Improve search – ability to find the information sought
- ✓ Single user interface
- ✓ Visibility to draft Documents
- ✓ Easy to create custom reports

Smart Workflows



- ✓ Easy to upload and route content
- ✓ Notify the business owner when a change is being made
- ✓ Simplified workflows for business enabling documents

Technology & Integration



- ✓ Allow users to access the system from anywhere
- ✓ One application to issue and reconcile protocols, data sheets and batch records
- ✓ Built-in reporting and dashboards capability

Easy to Configure and Support



- ✓ Enable business changes and growth
- ✓ Modify the system quickly to respond to changes in business process & industry practice

Thank You