SOP-006 v1.0 – Training and Qualification for VDC

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Title: Training and Qualification for VDC
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Owner: VDC System Owner: William O'Connell
Approved By: QA / Compliance Lead: Jane Smith

1. Purpose

The purpose of this SOP is to define the training and qualification requirements for all personnel who use, administer, or oversee the Validated Document Control (VDC) system hosted at https://williamoconnellpmp.com. This ensures that all users are competent to perform their assigned tasks in accordance with GxP requirements, 21 CFR Part 11, and validated system procedures.

2. Scope

This SOP applies to:

- All users requiring production VDC access:
  - Submitters (document uploaders)
  - Approvers (document reviewers)
  - Read-Only Users (viewers)
- System Administrators responsible for VDC technical operations
- QA / Compliance personnel conducting audits and reviews
- New hires, role changes, and annual refresher training
- Training conducted for major system changes (per SOP-004)

This SOP does not cover:

- General IT security awareness training (covered by corporate IT policies)
- AWS infrastructure training for cloud architects (not VDC-specific)
- Training for development/test environments (non-GxP)

3. Definitions

- **Training:** Formal instruction on VDC system functionality, procedures, and regulatory requirements necessary to perform assigned role.
- **Qualification:** Demonstration of competency through assessment (quiz, practical demonstration, or supervised performance).
- **Competency:** Ability to perform VDC tasks correctly, consistently, and in compliance with SOPs and GxP requirements.
- **Initial Training:** Training provided before first-time production access is granted.
- **Refresher Training:** Periodic retraining to reinforce knowledge and update users on system changes.
- **Change-Specific Training:** Training provided when system changes affect user workflows (per SOP-004).
- **Training Record:** Documentation of training completion, including date, topics, trainer, trainee signature, and assessment results.
- **Trainer:** Qualified individual authorized to deliver VDC training (typically System Owner, QA, or designated Subject Matter Expert).

4. Roles and Responsibilities

System Owner

- Overall accountability for training program effectiveness
- Approves training curriculum and materials
- Designates qualified trainers
- Ensures training conducted before production access granted
- Reviews training program annually for improvements

QA / Compliance

- Approves training materials for GxP and regulatory content accuracy
- Reviews training records for completeness
- Verifies training current during user access reviews (SOP-002 Section 9)
- Participates in training effectiveness reviews
- Ensures training records retained per SOP-008

Trainer (Designated by System Owner)

- Delivers training per approved curriculum
- Administers competency assessments
- Documents training completion in Training Log
- Provides training completion notification to System Administrator
- Reports training effectiveness issues to System Owner

System Administrator

- Verifies training completion before provisioning production access (per SOP-002)
- Maintains Training Log and training records repository
- Tracks retraining due dates
- Notifies users when refresher training required
- Provides training attendance reports to QA for periodic review

Trainee (VDC User)

- Completes required training before production access
- Actively participates in training sessions
- Completes competency assessments
- Signs training record acknowledging understanding
- Requests retraining if uncertain about procedures
- Completes refresher training by due date

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5. Training Requirements by Role

All users must complete role-specific training before production access is granted.

5.1 Submitter Role Training

Duration: 1.5 hours (90 minutes)

Prerequisites: - Corporate IT security awareness training completed - VDC user account created in Cognito (per SOP-002) - Access to VDC DEV environment for hands-on practice

Required Training Topics:

Topic	Duration	Training Method
VDC System Overview and Purpose	15 min	Presentation
GxP and 21 CFR Part 11 Basics	15 min	Presentation
Data Integrity (ALCOA+ Principles)	15 min	Presentation
Authentication and MFA Setup	10 min	Live Demo + Practice

Document Upload Workflow	20 min	Live Demo + Practice	
Document Submission Process	15 min	Live Demo + Practice	
Understanding Audit Trails	10 min	Presentation	
SOP-003 Review (Document Lifecycle)	10 min	SOP Reading	
Competency Assessment (Quiz)	10 min	Written Quiz	
Q&A and Troubleshooting	10 min	Discussion	

Learning Objectives: By the end of training, Submitters shall be able to: - [ ] Explain the purpose of VDC and why it is validated - [ ] Define "audit trail" and explain why it is required - [ ] Log in to VDC using email and MFA (TOTP code) - [ ] Upload a document with correct metadata (title, description) - [ ] Submit a document for approval - [ ] View audit trail for their submitted documents - [ ] Explain why they cannot approve their own submissions - [ ] Describe what happens to documents after submission (pending approval)

Competency Assessment: - Written quiz: 5 questions, 80% pass rate (4/5 correct) - Practical demonstration: Upload and submit one document successfully in DEV environment

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5.2 Approver Role Training

Duration: 2 hours (120 minutes)

Prerequisites: - All Submitter training topics completed (1.5 hours) - Approver user account created in Cognito with Approver group membership - Access to VDC DEV environment for hands-on practice

Required Training Topics (in addition to Submitter topics):

Topic	Duration	Training Method
Approver Responsibilities and GxP Implications	15 min	Presentation
Electronic Signature Meaning (21 CFR Part 11.50)	10 min	Presentation
Reviewing Documents for Approval	15 min	Live Demo + Practice
Approval Process and Audit Trail Creation	15 min	Live Demo + Practice
Rejection Process and Documentation Requirements	15 min	Live Demo + Practice
Self-Approval Prevention (Separation of Duties)	10 min	Presentation
SOP-003 Review (Approval Workflow)	10 min	SOP Reading
Competency Assessment (Quiz)	15 min	Written Quiz
Q&A and Troubleshooting	15 min	Discussion

Learning Objectives: By the end of training, Approvers shall be able to: - [ ] Explain the GxP significance of document approval - [ ] Define "electronic signature" and its legal meaning - [ ] Access the Pending Approvals queue - [ ] Review a document for completeness and accuracy - [ ] Download a controlled copy for review - [ ] Approve a document with appropriate justification - [ ] Reject a document with clear, documented reason - [ ] Explain why self-approval is blocked by the system - [ ] Verify that approval actions create audit trail records

Competency Assessment: - Written quiz: 10 questions, 80% pass rate (8/10 correct) - Practical demonstration: - Approve one document in DEV environment - Reject one document with documented reason - Verify audit trail shows both actions

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5.3 System Administrator Training

Duration: 4 hours (240 minutes)

Prerequisites: - AWS Solutions Architect Associate certification (or equivalent cloud knowledge) - Familiarity with CloudFormation, Lambda, DynamoDB, S3, Cognito - Linux command line proficiency - Understanding of GxP and CSV concepts

Required Training Topics:

Topic	Duration	Training Method
VDC Architecture and AWS Services Overview	30 min	Technical Presentation
Validation Overview (URS, FS, RTM, IQ/OQ/PQ)	30 min	Documentation Review
User Account Management (SOP-002)	30 min	Procedure Review + Practice
CloudWatch Monitoring and Alerting	30 min	Live Demo + Practice
Backup and Restore Procedures (SOP-008)	45 min	Procedure Review + Practice
Incident Response (SOP-005)	30 min	Procedure Review
Change Control Process (SOP-004)	30 min	Procedure Review
Troubleshooting Common Issues	30 min	Case Studies
Competency Assessment (Practical)	45 min	Hands-on Test

Learning Objectives: By the end of training, System Administrators shall be able to: - [ ] Describe VDC architecture and AWS service integration - [ ] Provision user accounts per SOP-002 - [ ] Monitor system health via CloudWatch dashboards - [ ] Perform backup verification per SOP-008 - [ ] Execute restore procedures for common scenarios - [ ] Respond to incidents per SOP-005 - [ ] Submit change requests per SOP-004 - [ ] Troubleshoot common errors (authentication, API, DynamoDB)

Competency Assessment: - Practical demonstration (hands-on in DEV environment): - Provision a new user account with Submitter role - Verify DynamoDB Point-in-Time Recovery enabled - Query

5.4 QA / Compliance Training

Duration: 3 hours (180 minutes)

Prerequisites: - GxP and CSV knowledge (industry experience) - Familiarity with 21 CFR Part 11, EU Annex 11 - Understanding of audit trail requirements

Required Training Topics:

Topic	Duration	Training Method
VDC Validation Package Review (URS, FS, RTM, IQ/OQ/PQ)	45 min	Documentation Review
Audit Trail Review Procedures (SOP-007)	30 min	Procedure Review + Practice
Periodic Review Process (SOP-007)	30 min	Procedure Review
Change Control Oversight (SOP-004)	30 min	Procedure Review
Deviation and CAPA Review (SOP-005)	30 min	Procedure Review
Regulatory Inspection Readiness	30 min	Presentation + Case Study
Competency Assessment (Case Study)	30 min	Written Analysis

Learning Objectives: By the end of training, QA personnel shall be able to: - [ ] Navigate validation documentation (URS, FS, RTM) - [ ] Conduct quarterly audit trail review per SOP-007 - [ ] Assess change requests for validation impact - [ ] Review deviations and CAPA effectiveness - [ ] Prepare for regulatory inspections (FDA, EMA) - [ ] Verify ongoing compliance with 21 CFR Part 11

Competency Assessment: - Case study analysis: Review sample audit trail and identify 3 compliance issues - Practical demonstration: Conduct audit trail review on 10 sample documents

6. Training Delivery Methods

6.1 Instructor-Led Training (ILT)

- **Format:** Live presentation with Q&A
- **Duration:** Per role requirements (1.5 - 4 hours)
- **Location:** Conference room or virtual meeting (Zoom, Teams)
- **Trainer:** System Owner, QA Lead, or designated SME
- **Materials:** PowerPoint presentation, SOP documents, hands-on exercises
- **Documentation:** Attendance sheet, signed training records

6.2 Self-Paced eLearning (Optional)

- **Format:** Recorded video modules with embedded quizzes
- **Duration:** Same content as ILT, completed at trainee pace
- **Platform:** Learning Management System (LMS) or video hosting
- **Completion tracking:** LMS reports or manual tracking spreadsheet
- **Note:** Self-paced training must still include competency assessment

6.3 Hands-On Practice (Required for all roles)

- **Environment:** VDC DEV environment (separate from production)
- **Supervised:** Trainer observes first-time tasks
- **Practice exercises:**
  - Submitters: Upload → Submit → View Audit Trail
  - Approvers: Review → Approve → Reject → Verify Audit
  - System Admins: User provisioning, backup verification

6.4 Read-and-Understand (for SOP reviews)

- **Format:** Trainee reads SOP independently
- **Verification:** Signature on training record acknowledges reading
- **Combined with:** Q&A session to clarify questions

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7. Competency Assessment

All trainees must demonstrate competency before production access is granted.

7.1 Written Quiz (Submitters and Approvers)

Submitter Quiz (5 questions, 80% pass = 4/5 correct):

1. **What is the purpose of the VDC system?**
   - A. To store personal files
   - B. To manage controlled documents in a GxP-compliant manner ✓
   - C. To replace email
   - D. To track project tasks
2. **What is an audit trail?**
   - A. A hiking path in the forest
   - B. A record of all actions performed on a document ✓
   - C. A backup copy of documents
   - D. A user manual
3. **What happens after you submit a document?**
   - A. It is immediately available to all users
   - B. It is sent to your manager via email
   - C. It enters "Pending Approval" status and is routed to Approvers ✓
   - D. It is deleted from the system
4. **Can you approve your own submitted documents?**
   - A. Yes, if you have Approver role
   - B. No, self-approval is blocked to ensure separation of duties ✓
   - C. Yes, but only in emergencies
   - D. Only with manager approval
5. **What is required when logging in to VDC?**
   - A. Email and password only
   - B. Email, password, and MFA code (TOTP) ✓
   - C. Username and secret question
   - D. Biometric scan

Approver Quiz (10 questions, 80% pass = 8/10 correct): - All 5 Submitter questions above, PLUS:

6. **What does your electronic signature mean when you approve a document?**
   - A. You typed your name in a box
   - B. You clicked a button
   - C. You attest that the document is accurate and meets

requirements ✓
- ◦ D. You forwarded the document

7. **What is required when rejecting a document?**
   - ◦ A. Nothing, just click Reject
   - ◦ B. A clear, documented reason for rejection ✓
   - ◦ C. Manager approval
   - ◦ D. Notification to IT

8. **Why does the system prevent you from approving documents you submitted?**
   - ◦ A. It's a software bug
   - ◦ B. To enforce separation of duties and prevent conflict of interest ✓
   - ◦ C. To slow down the approval process
   - ◦ D. To save database space

9. **Where can you see the audit trail for a document?**
   - ◦ A. It's not visible to users
   - ◦ B. On the document detail page, click "Audit Trail" link ✓
   - ◦ C. Only QA can see audit trails
   - ◦ D. Audit trails are only created after approval

10. **When you approve a document, what information is captured in the audit trail?**
    - ◦ A. Only your name
    - ◦ B. Only the date and time
    - ◦ C. Your identity (email), timestamp, action (APPROVE), and document ID ✓
    - ◦ D. Just the document title

Grading: - Pass: 80% or higher (Submitters: 4/5, Approvers: 8/10) - Fail: Below 80% → Retraining required, retake quiz after 24 hours

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7.2 Practical Demonstration

Submitter Practical Assessment: Trainee must successfully complete in DEV environment: 1. Log in using email and MFA code 2. Navigate to Upload page 3. Upload a document (any PDF file) 4. Enter document title and description 5. Submit document for approval 6. Navigate to Submissions page and verify document shows "Submitted" status 7. View audit trail and verify upload and submit events recorded

Pass Criteria: All 7 steps completed without errors

Approver Practical Assessment: Trainee must successfully complete in DEV environment: 1. Log in using email and MFA code 2. Navigate to Pending Approvals page 3. Select a document for review 4. Download controlled copy and review (simulated) 5. **Test 1:** Approve one document, verify audit trail shows approval event 6. **Test 2:** Reject one document with reason "Missing required information", verify audit trail shows rejection with reason 7. Verify both actions appear in audit trail with correct timestamp and approver identity

Pass Criteria: All 7 steps completed without errors, audit trail correctly captures both actions

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7.3 System Administrator Practical Assessment

System Admin Practical Assessment (DEV environment): 1. Provision new user account via AWS Cognito Console 2. Assign user to "Submitter" group 3. Verify user appears in Cognito User Pool 4. Verify DynamoDB Point-in-Time Recovery enabled on VDC_Documents table 5. Query CloudWatch Logs for recent audit events (last 24 hours) 6. Simulate document deletion from S3 (create test document, delete, restore from versioning) 7. Document all steps with screenshots

Pass Criteria: All 7 tasks completed correctly, documentation clear

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7.4 Retesting After Failure

If trainee fails competency assessment: 1. Trainer reviews incorrect answers with trainee 2. Provide additional coaching on failed topics 3. Trainee must wait minimum 24 hours before retesting 4. Maximum 3 attempts allowed 5. If fails 3 times, escalate to System Owner and QA for evaluation

8. Training Documentation

8.1 Training Record Template

All training must be documented using the Training Record form:

```
VDC TRAINING RECORD

Trainee Information:
Name: _____
Role: □ Submitter  □ Approver  □ System Admin  □ QA/Compliance
Email: _____
Department: _____

Training Details:
Training Type: □ Initial  □ Refresher  □ Change-Specific
Training Date: _____
Training Duration: _____ hours
Trainer Name: _____
Training Method: □ ILT  □ eLearning  □ Read-and-Understand

Topics Covered:
□ VDC System Overview
□ GxP and 21 CFR Part 11 Basics
□ Data Integrity (ALCOA+)
□ Authentication and MFA
□ Document Upload/Submission
□ Approval/Rejection Workflow
□ Audit Trail
□ SOPs (list): _____
□ Other: _____

Competency Assessment:
Quiz Score: _____ / _____ (____%)  □ Pass  □ Fail
Practical Demo: □ Pass  □ Fail
Comments: _____

Training Materials Version: _____

Trainee Acknowledgment:
I acknowledge that I have completed the above training and
understand the material presented. I am competent to perform my
assigned VDC tasks in accordance with procedures and GxP
requirements.

Trainee Signature: _____  Date: _____

Trainer Certification:
I certify that the trainee has completed the required training and
demonstrated competency.

Trainer Signature: _____  Date: _____

QA Review (if required):
□ Training record complete and accurate
□ Competency assessment passed
□ Ready for production access provisioning

QA Signature: _____  Date: _____
```

8.2 Training Log (Master List)

System Administrator maintains a Training Log (Excel spreadsheet or database) with the following fields:

User Name	Role	Initial Training Date	Initial Quiz Score	Refresher Due Date	Last Refresher Date	CR Training (CR...
Jane Doe	Submitter	2026-01-15	5/5 (100%)	2027-01-15	N/A	CR-942 (202... 06-...
John Smith	Approver	2026-01-20	9/10 (90%)	2027-01-20	N/A	-

Tracking: - Initial training completion before access granted - Refresher training due dates (annual) - Change-specific training linked to Change Request IDs - Current access status

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8.3 Training Materials Version Control

All training materials (presentations, quizzes, SOPs) must be version-controlled:

Training Materials Repository: - PowerPoint presentations: `VDC_Submitter_Training_v1.0.pptx` - Quizzes: `VDC_Submitter_Quiz_v1.0.pdf` - SOPs: `SOP-001_v1.0.pdf`, `SOP-002_v1.0.pdf`, etc. - Hands-on exercise guides: `VDC_Hands_On_Guide_v1.0.pdf`

Version Control: - Increment version when content changes (v1.0 → v1.1 for minor updates, v1.0 → v2.0 for major revisions) - Training records must reference materials version used - Obsolete versions archived, not deleted (retain per SOP-008)

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9. Refresher Training

9.1 Annual Refresher Training

Frequency: At least once per calendar year

Duration: - Submitters: 45 minutes - Approvers: 60 minutes - System Admins: 90 minutes - QA: 60 minutes

Refresher Topics: - [ ] What's new: System changes from past year (per SOP-004 Change Control Log) - [ ] Lessons learned: Common issues from Deviation Log (per SOP-005) - [ ] Regulatory updates: New FDA guidance or industry best practices - [ ] Quiz refresher: Re-take competency assessment (same or updated questions) - [ ] Q&A: Address user questions and procedural clarifications

Competency Assessment: - Refresher quiz: Same pass rate as initial training (80%) - Practical demo optional unless performance issues identified

Scheduling: - System Administrator notifies users 30 days before refresher due - Refresher must be completed within 60 days of due date - If not completed within 60 days, production access suspended until refresher complete

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9.2 Change-Specific Training

Trigger: Category 2 or Category 3 changes per SOP-004 that affect user workflows

Examples: - New document metadata fields added - Approval workflow changes (e.g., multi-level approvals) - UI/UX changes affecting user experience - New features added (e.g., advanced search, bulk actions)

Process: 1. Change Owner (per SOP-004) identifies if training required 2. Change Request (CR) documents training scope and target audience 3. Trainer develops change-specific training materials 4.

Training delivered before change deployed to production OR within 5 business days after deployment 5. Training completion tracked in Training Log with CR-ID reference

Duration: Typically 15-30 minutes (shorter than initial or refresher)

Competency Assessment: - Abbreviated quiz (3-5 questions on new functionality) - Pass rate: 80%

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10. Training Effectiveness Monitoring

10.1 Ongoing Monitoring

System Owner and QA monitor training effectiveness through:

Key Metrics: - User error rate (errors per 100 actions) - Deviation incidents related to user procedural non-compliance (SOP-005) - Training quiz pass rates (initial attempt) - Time-to-competency (training duration vs. industry benchmarks) - User feedback scores (post-training surveys)

Review Frequency: Quarterly

Action Triggers: - If user error rate exceeds 2% → Investigate if training gaps exist - If deviation incidents spike → Review if training adequately covered topic - If quiz pass rate <80% on first attempt → Review quiz difficulty or training clarity - If user feedback <4.0/5.0 average → Improve training materials or delivery

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10.2 Annual Training Program Review

Timing: Conducted during Annual Periodic Review per SOP-007

Review Scope: - [ ] Training curriculum still aligned with system functionality - [ ] Training materials current (no outdated screenshots, procedures) - [ ] Competency assessments effective (do they test the right knowledge?) - [ ] Training effectiveness metrics acceptable (see Section 10.1) - [ ] Refresher training completion rates >95% - [ ] Trainer qualifications current - [ ] Training records complete and accessible

Deliverable: Training Program Review Report including: - Summary statistics (number trained, pass rates, error rates) - Trends (improvement or decline in metrics) - Recommendations for training improvements - Action items with owners and due dates

Approval: System Owner and QA approve report

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11. Trainer Qualification

11.1 Trainer Requirements

Trainers must meet the following qualifications:

Subject Matter Expertise: - Deep knowledge of VDC system functionality and workflows - Understanding of GxP, CSV, and 21 CFR Part 11 requirements - Hands-on experience with VDC (minimum 6 months for production system, or extensive DEV environment testing)

Training Skills: - Prior training delivery experience (preferred but not required) - Effective communication and presentation skills - Patience and ability to answer questions clearly

Authorized Trainers: - System Owner (William O'Connell) - All roles - QA / Compliance Lead (Jane Smith) - All roles - Designated System Administrator - System Admin and Submitter training only - Designated Senior Approver - Approver training only (if approved by System Owner)

11.2 Trainer Documentation

Trainer Qualification Record: - Name and role - Training topics authorized to deliver - Qualification basis (subject matter expertise, prior training experience) - Approval date and approver (System Owner)

Trainer Performance Monitoring: - Review trainee feedback on trainer effectiveness - Observe training sessions periodically (QA spot-checks) - Address trainer performance issues through coaching or reassignment

12. Training Records Retention

Retention Period: Per SOP-008, minimum 7 years

Storage Location: - Electronic: Controlled repository (SharePoint, LMS, or secure file server) - Paper (if any): Locked file cabinet in QA office

Access: - System Owner, QA, System Administrator have read access - Training records available for regulatory inspection - Individual users can request copy of their own training records

Backup: - Training Log backed up monthly (included in general backup per SOP-008) - Training record PDFs stored in version-controlled repository

13. Integration with Other SOPs

This SOP integrates with:

- **SOP-002 (User Management):** Section 6 (Account Provisioning) requires training completion before access granted; Section 10 (Training Requirement) references SOP-006
- **SOP-004 (Change Control):** Change-specific training triggered by Category 2/3 changes
- **SOP-005 (Deviation/CAPA):** Training-related deviations (user errors) trigger retraining or training improvements
- **SOP-007 (Periodic Review):** Annual training program review conducted during periodic review
- **SOP-008 (Backup/Retention):** Training records retained per 7-year retention policy

14. References

- 21 CFR Part 11, Electronic Records; Electronic Signatures
- FDA Guidance: Glossary of Computer System Software Development Terminology (August 1995) - defines "training"
- ICH Q10: Pharmaceutical Quality System (Section 2.6: Training)
- GAMP 5, Appendix O3: Validation of Laboratory Computerised Systems (training requirements)
- EU GMP Annex 11, Section 3: Personnel (training requirements)

15. Appendices

Appendix A: Training Schedule Template

Quarterly Training Schedule:

Month	Training Type	Target Audience	Trainer	Date	Status
January	Refresher	All Approvers (5	W.	Jan 15,	Scheduled

Month	Type	Audience	Trainer	Date	Status
		users)	O'Connell	2026	
February	Initial	New hire (J. Williams) - Submitter	J. Smith	Feb 5, 2026	Scheduled
March	Change-specific (CR-2026-008)	All Submitters (10 users)	W. O'Connell	Mar 20, 2026	Pending CR approval
April	Refresher	All Submitters (10 users)	J. Smith	Apr 10, 2026	Scheduled

Appendix B: Sample Training Presentation Outline

VDC Submitter Training (90 minutes)

Slide 1: Title - "VDC System Training for Submitters"

Slide 2: Agenda - What is VDC and why does it exist? - GxP and regulatory basics - Data integrity principles - Hands-on: Login with MFA - Hands-on: Upload and submit documents - Understanding audit trails - Quiz and Q&A

Slide 3: VDC Overview - Purpose: Manage controlled documents in GxP environment - Validated system (meets FDA 21 CFR Part 11) - Your role: Upload and submit documents for approval

Slide 4: Why Validation Matters (GxP Basics) - Good Practice (GxP) ensures quality and safety - Electronic records must be as trustworthy as paper - FDA can inspect our system and records

Slide 5: Data Integrity - ALCOA+ Principles - **A**ttributable: System knows who you are - **L**egible: Records are readable - **C**ontemporaneous: Timestamps are accurate - **O**riginal: Documents stored in original format - **A**ccurate: Hash verification ensures integrity

Slide 6: Logging In - MFA Required - Navigate to https://williamoconnellpmp.com/life-sciences/app - Enter email and password - Enter TOTP code from authenticator app - **Demo:** Trainer shows login process

Slide 7: Document Upload Process - Click "Upload Document" - Select file (PDF, Word, Excel) - Enter title and description (required) - System generates unique document ID - **Demo:** Trainer uploads sample document

Slide 8: Document Submission - After upload, click "Submit for Approval" - Document locked (can't edit after submission) - Routed to Approvers for review - Status changes to "Pending Approval" - **Demo:** Trainer submits document

Slide 9: What You CANNOT Do - ✖ Approve your own submissions (blocked by system) - ✖ Edit documents after submission (locked) - ✖ Delete submitted documents (integrity protection)

Slide 10: Audit Trail - Every action is recorded (who, what, when) - View audit trail on document detail page - Shows: Upload → Submit → Approve/Reject - Required for FDA inspection

Slide 11: Hands-On Practice - You will now practice in DEV environment: - Task 1: Log in with MFA - Task 2: Upload a document - Task 3: Submit the document - Task 4: View the audit trail

Slide 12: Quiz Time - 5 questions, 80% to pass - Open book (can refer to slides) - 10 minutes

Slide 13: Q&A and Next Steps - Questions? - Next: Trainer will sign your training record - System Admin will provision production access within 24 hours

Appendix C: Common Training Questions and Answers

Q: What if I forget my MFA device? A: Contact System Administrator immediately. They can disable MFA temporarily while you set up a new device. Do not share your MFA codes with anyone.

Q: Can I upload documents in draft status and finish later? A: Yes, uploaded documents stay in "Draft" status until you click "Submit for Approval." You can upload multiple drafts and submit when ready.

Q: What happens if I submit the wrong document? A: Once submitted, you cannot delete it. Contact an Approver immediately. They can reject the document with reason "Submitted in error." Then you can submit the correct document.

Q: How long does approval take? A: Approvers typically review documents within 24-48 hours. If urgent, contact Approver directly to prioritize.

Q: Can I see who approved my document? A: Yes. View the audit trail on the document detail page. It shows approver name, timestamp, and action.

Q: What if my training quiz expires (annual refresher)? A: Your production access will be suspended until you complete refresher training. System Admin will notify you 30 days before expiration.

16. Revision History

Version	Date	Author	Description of Changes
1.0	Jan 29, 2026	William O'Connell	Initial release

17. Approval

System Owner:
William O'Connell
January 29, 2026

QA / Compliance Lead:
Jane Smith
January 29, 2026