

Mobile Application Validation in GxP Based on GAMP 5

Master GAMP 5 principles for validating mobile apps in regulated environments. Perfect for QA managers, IT validation specialists, and regulatory affairs teams.

Web & Mobile Design Instructor: Keith Brennan • 5 sections • 48 lessons • 15.00h total

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About this course

Mobile apps are increasingly used in GxP settings for data collection, batch records, and patient monitoring, but validating them brings unique challenges like OS updates and intermittent connectivity. This course addresses these issues, helping you ensure compliance with FDA, EMA, and WHO standards.

You'll learn step-by-step how to build validation strategies, conduct IQ/OQ/PQ testing, and handle data integrity on mobile platforms. The course includes video lectures, real-world case studies, and practical exercises to apply GAMP 5 categorization and risk-based approaches.

Course curriculum

Foundations of GxP and GAMP 5

- **Understanding GxP Regulations: GMP, GLP, GCP (18m)**
Covers what GxP standards like GMP, GLP, and GCP regulate, why they matter in 2026 for mobile applications.
- **GAMP 5 Framework Overview: Key Principles and Modern Approach (25m)**
Explains the ISPE GAMP 5 scope, including the second edition's focus on risk-based methods and lifecycle management.
- **GAMP 5 Software Categories for Mobile Apps (15m)**
Breaks down categories Cat 1-5 and how to classify different mobile app types within this framework.
- **Risk-Based Validation vs. Traditional Testing (12m)**
Compares risk-based approaches with test-everything methods, showing how to allocate resources efficiently.
- **Regulatory Expectations: FDA, EMA, and WHO in 2026 (20m)**
Outlines current regulatory expectations for computerized systems, with a focus on mobile-specific guidance.
- **Core Terminology and Definitions in GxP Validation (10m)**
Defines key terms like validation, qualification, and data integrity to build a common understanding.
- **Case Study: Common Pitfalls in Mobile App Validation (18m)**
Analyzes real examples where validation failed due to overlooked mobile challenges, and lessons learned.

Mobile Applications in the Regulated Environment

- **Types of Mobile Apps Used in GxP Settings (15m)**
Covers data collection tools, electronic batch records, wearables, patient-facing apps, and lab instrument interfaces.
- **Mobile Platform Challenges: OS Fragmentation and Updates (20m)**
Addresses how different operating systems and frequent app store updates impact validation stability.
- **Handling Intermittent Connectivity and BYOD Policies (18m)**
Discusses validation requirements for apps with offline capabilities and bring-your-own-device scenarios.
- **Mobile vs. Desktop Software: Validation Differences (12m)**
Compares mobile app characteristics with traditional enterprise software in a validation context.
- **GAMP 5 Categorization for Mobile Apps (25m)**
Step-by-step guide to classifying mobile apps using the GAMP 5 risk-based framework with practical examples.
- **Introduction to IEC 62304 and Mobile Medical Apps (15m)**
Explores how IEC 62304 for medical device software intersects with GAMP 5 for mobile health applications.

- **Risk Assessment for Mobile App Selection and Use (18m)**
Covers how to identify and mitigate risks when choosing or developing mobile apps for GxP processes.
- **Vendor vs. Custom-Developed Mobile Solutions (12m)**
Evaluates the pros and cons of commercial off-the-shelf apps versus custom-built solutions for compliance.
- **Data Integrity Fundamentals on Mobile Platforms (20m)**
Introduces ALCOA+ principles and how to ensure data accuracy and completeness on mobile devices.
- **Security Basics for Mobile Apps in GxP (15m)**
Discusses encryption, secure data storage, and secure transmission as foundational security controls.

Deep Dive: Building a Validation Strategy

- **Defining the Validation Lifecycle for Mobile Apps (22m)**
Adapts the V-model for mobile, covering phases from concept to retirement with a focus on agility.
- **Conducting a GxP Impact Assessment (18m)**
Guide to evaluating how a mobile app affects product quality, patient safety, and data reliability.
- **Data Integrity Risk Assessment Using ALCOA+ (25m)**
Applies ALCOA+ principles to identify and address data integrity risks in mobile app workflows.
- **Developing User Requirements Specifications (URS) (20m)**
How to write clear, testable requirements that align with business needs and regulatory expectations.
- **Creating Functional Requirements for Mobile Apps (15m)**
Translates user requirements into detailed functional specs, including mobile-specific considerations.
- **Supplier Assessment and Qualification for Mobile Vendors (18m)**
Evaluating COTS mobile app vendors or developers using audit questions and documentation reviews.
- **Leveraging Vendor Documentation to Reduce Testing (12m)**
How to use IQ/OQ, release notes, and SOC 2 reports from vendors to streamline validation efforts.
- **Designing a Traceability Matrix for Mobile Validation (20m)**
Building links from requirements to test cases to ensure complete coverage and audit readiness.
- **Drafting the Validation Plan (VP) for Mobile Apps (15m)**
Outlining the validation approach, resources, timelines, and acceptance criteria in a compliant VP.

Advanced Application: Execution and Compliance

- **Installation Qualification (IQ) for Mobile Apps (18m)**
Covers device provisioning, MDM integration, and verifying correct installation configurations.
- **Managing OS Version Control in Validation (15m)**
Strategies for controlling operating system updates and ensuring validation remains valid.
- **Operational Qualification (OQ): Functional Testing (25m)**
Designing and executing OQ test scripts for core functionalities, including boundary testing.
- **Role-Based Access and Security Testing (20m)**
Verifying that user roles and permissions work correctly on mobile, with focus on access controls.
- **Performance Qualification (PQ): Real-World Scenarios (30m)**
Testing mobile apps under actual use conditions, including offline/online sync and data migration.

- **Validating Offline/Online Synchronization (22m)**
Ensuring data consistency and integrity when apps switch between connected and disconnected states.
- **Data Integrity Controls: Audit Trails and Signatures (28m)**
Implementing and validating audit trails and electronic signatures per 21 CFR Part 11 and Annex 11 on mobile.
- **Security Validation: Encryption and Authentication (20m)**
Testing encryption methods, biometric authentication, and secure data handling on mobile devices.
- **Creating Compliant Validation Documentation (15m)**
Writing test scripts, handling deviations, and summarizing results in audit-ready formats.
- **Problem-Solving Session: Common Validation Issues (18m)**
Interactive session addressing frequent challenges like app crashes, data loss, and regulatory gaps.
- **Mock Audit Preparation for Mobile App Validation (25m)**
Simulating an audit to practice presenting validation evidence and responding to regulator questions.

Implementation and Next Steps

- **Continuous Validation and Change Management (18m)**
Establishing processes for ongoing validation as apps update or business needs evolve.
- **Triggers for Re-validation in Mobile Environments (15m)**
Identifying when changes like OS updates, app patches, or new features require re-validation.
- **Audit Preparedness and Documentation Best Practices (20m)**
Organizing records and demonstrating compliance during regulatory inspections.
- **Regulatory Updates and Trends in 2026 (22m)**
Discussing recent FDA, EMA, and WHO guidance changes and their impact on mobile validation.
- **Validating Cloud-Based Mobile Apps and SaaS Solutions (25m)**
Addressing challenges with cloud infrastructure, data residency, and vendor-managed updates.
- **Integrating Mobile Apps with Enterprise Systems (18m)**
Validating interfaces with ERP, LIMS, or other systems for data flow and integrity.
- **User Training and Adoption Strategies (15m)**
Developing training programs to ensure users operate mobile apps in a compliant manner.
- **Case Study: End-to-End Mobile App Validation Project (30m)**
Walkthrough of a complete validation project from planning to closure, with lessons from real implementations.
- **Future of Mobile Validation: AI and Automation (20m)**
Exploring how artificial intelligence and automation tools are changing validation approaches in 2026.
- **Best Practices and Lessons from Industry Peers (18m)**
Compiled insights and practical tips shared by validation experts in pharma and biotech sectors.
- **Course Summary and Actionable Next Steps (12m)**
Recaps key learning points and outlines steps to apply knowledge in your organization.

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