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Regulated Mobile Applications

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Significance

- “According to industry estimates, 500 million smartphone users worldwide will be using a health care application by 2015, and by 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications These users include health care professionals, consumers, and patients.”

US FDA

Overview

- What do we mean by “regulated mobile applications”?
- What are the risks and regulatory expectations?
- How can we leverage GAMP good practice principles?

BBC NEWS

Opportunities…

- A smartphone app that uses a phone's camera to analyse urine
- Can tested for the presence of 10 elements - including glucose, proteins and nitrites
- Tests for 25 different health issues
  - could help diagnose and treat diseases in the developing world.

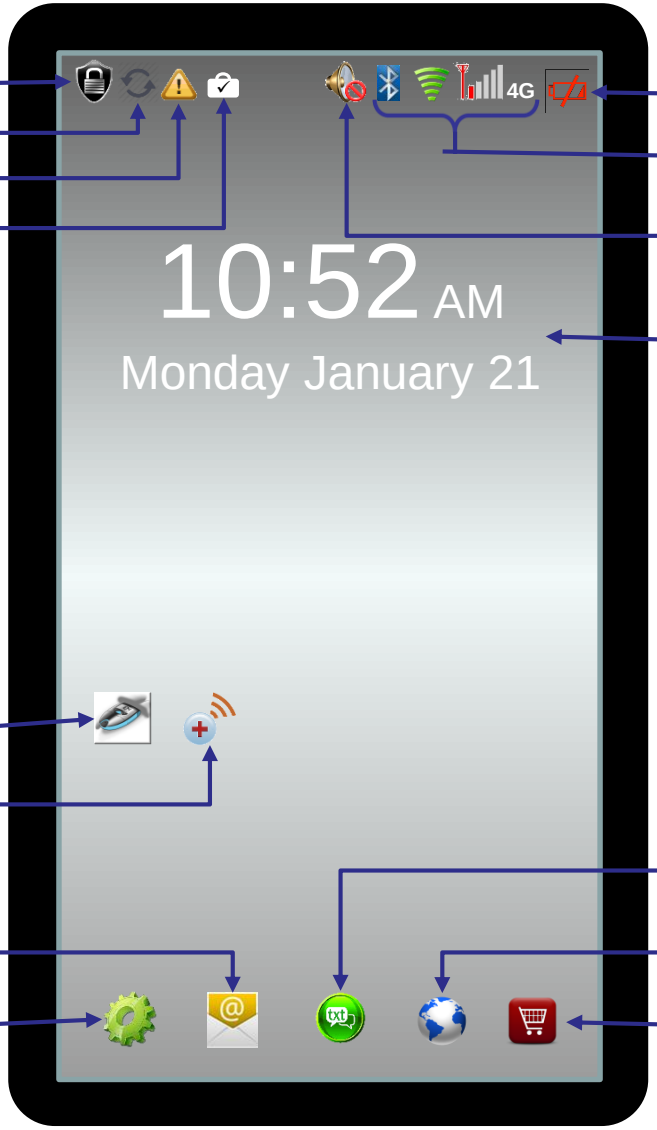
BBC NEWS

Risks…

- Apps may delay skin cancer diagnosis
  - using phones rather than seeking expert help could be harmful
- The University of Pittsburgh tested four applications with 188 pictures of cancers and other skin conditions.
- Three of the apps using automated algorithms wrongly labelled the cancerous lesions as unproblematic in almost a third of cases.

Example Uses

- To improve patient compliance to a medical regimen
- As a marketing tool
- As an aid to diagnosis
- As a channel for patient reporting
- As an interface to a medical device
- To control a medical device



Is security software needed?

Does the app need to synchronize?

Does the app generate notifications?

Does the app need to auto-update?

What happens when battery power fails?

Are there dependencies on communication? Short range, Wi-Fi, or cellular?

Are there audible alarms that should not be disabled?

Is there a critical dependency on clock or calendar functions?

Is the app always opened by the user or does it run in the background?

Does the app have a special dedicated communication channel?

Does the app send SMS messages (i.e. text messages)?

Does the app send email?

Are there specific browser requirements?

Are there specific device configuration requirements?

How does the user obtain the app?

What are “Mobile Medical Apps”?

“Mobile medical apps are medical devices that are mobile apps, meet the definition of a medical device and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.”

US FDA

Part of a GxP System

- Mobile apps may also be components or parts of a GxP regulated computerized system:
  - Interface for warehouse management, including goods receipt or movement
  - Dashboard interface to a large number of laboratory systems
  - Interface to manufacturing equipment, possibly with the ability to adjust set-points
  - Access to enterprise applications such as ERP

Environment

- Complex
- Rapidly changing
- Volatile
- Regulatory situation unclear

- Blurring boundaries: software, hardware, drug/device, web ecosystem, product, internal/external

- National / regional differences
- Many viewpoints
- Drug companies becoming software companies…

FDASIA

- Food and Drug Administration Safety and Innovation Act (2012), required
  - “A proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”

FDA

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 25, 2013

MEDDEV 2.1/6

MEDICAL DEVICES: Guidance document

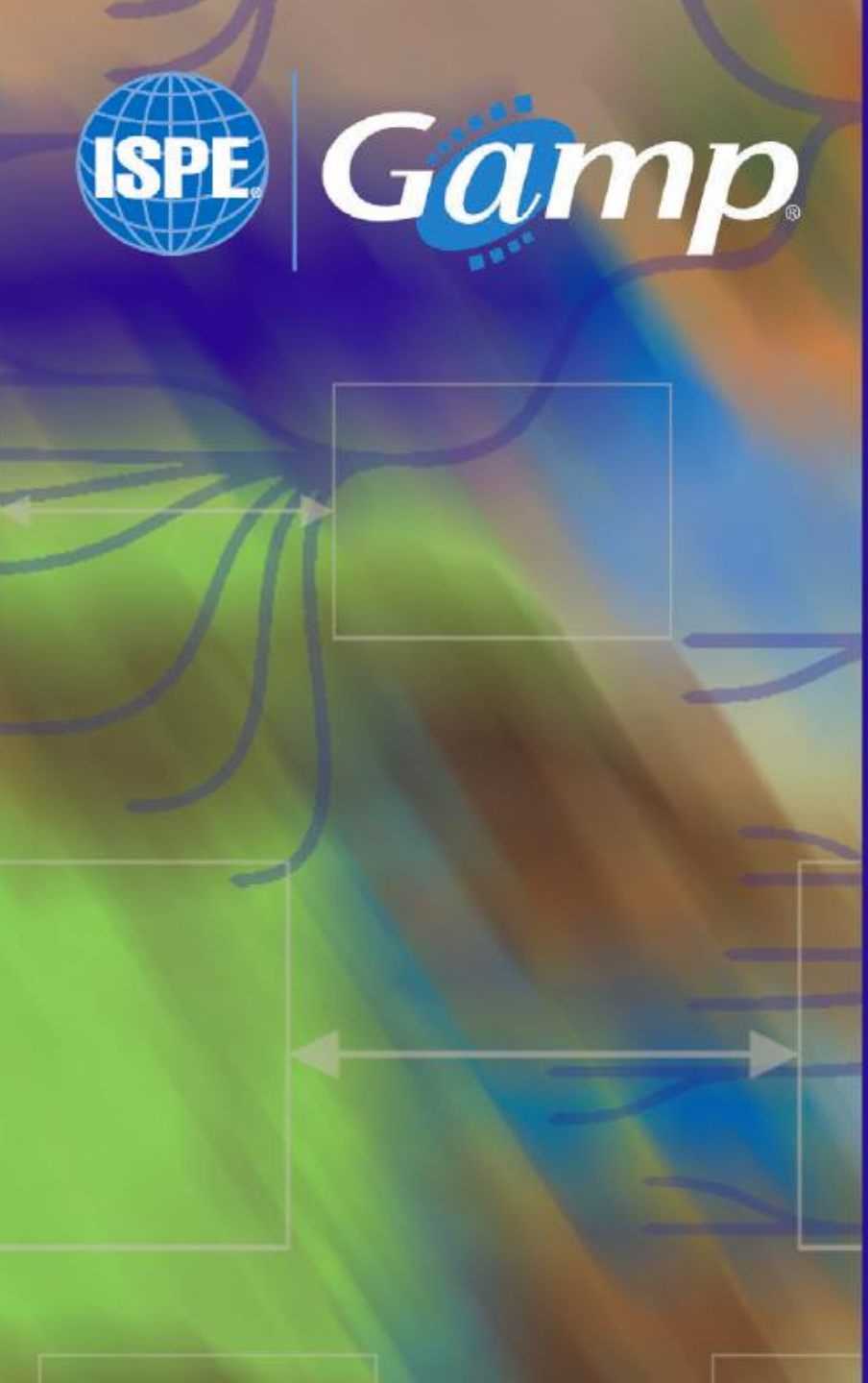
Qualification and Classification of stand alone software

GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES

January 2012

Other References

- *Regulation of medical software and mobile medical 'apps',* Australian Therapeutic Goods Administration, 13 September 2013
- *Guidance on medical device stand-alone software (including apps),* UK Medicines and Healthcare Products Regulatory Agency, 19 March 2014
- *Medical Information Systems – guidance for qualification and classification of standalone software with a medical purpose;* Swedish Medical Products Agency



GAMP Good Practice Guide

A Risk-Based Approach to Regulated Mobile Applications

Purpose

- Identify and explain the unique risks related to this type of application
- Describe solutions and controls
- Consider how the GAMP framework and principles may be applied

Purpose

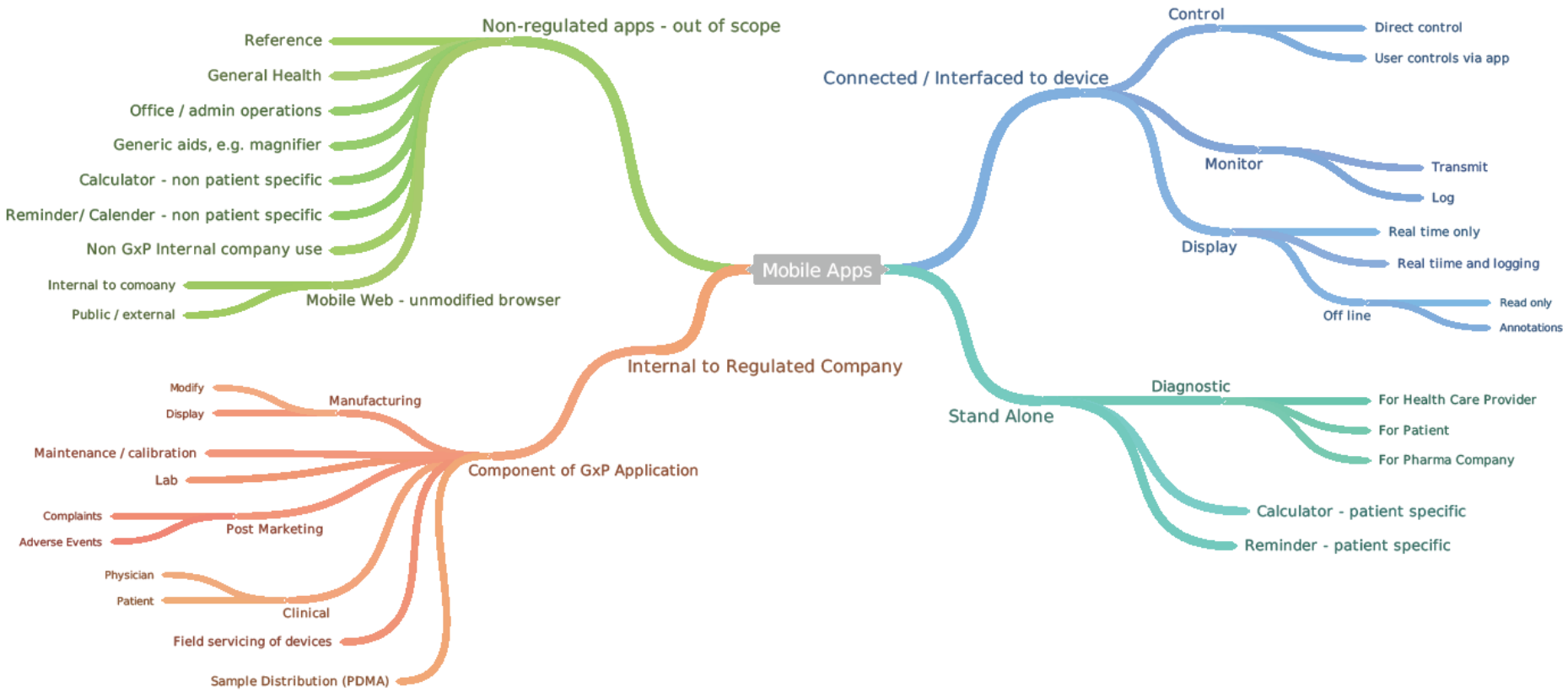
- Managing software on a variety of operating systems at different version levels on many different devices
- Ensuring compliance with applicable regulations, including implications for data integrity and data privacy / protection
- Recommendations for retiring mobile apps – including data retention and destruction

Scope

- How current industry good practice as described in GAMP guidance may be applied to mobile apps.
- Not intended to cover all detailed requirements for medical device classification, registration, development, and support.

Scope

- Detailed requirements for medical devices will vary from region to region, and it is the responsibility of organizations and individuals involved to identify, interpret, and apply such requirements as applicable
- Companies need to be familiar with the local regulations in any country where they intend to deploy a regulated mobile app.
- Relevant international standards such as IEC 62304 and ISO 13485 should be consulted.


Mobile Apps
Non-regulated apps - out of scope
Reference
General Health
Office / admin operations
Generic aids, e.g. magnifier
Calculator - non patient specific
Reminder/ Calender - non patient specific
Non GxP Internal company use
Mobile Web - unmodified browser
Internal to comoany
Public / external
Internal to Regulated Company
Component of GxP Application
Manufacturing
Modify
Display
Maintenance / calibration
Lab
Post Marketing
Complaints
Adverse Events
Clinical
Physician
Patient
Field servicing of devices
Sample Distribution (PDMA)
Connected / Interfaced to device
Control
Direct control
User controls via app
Monitor
Transmit
Log
Display
Real time only
Real tiime and logging
Off line
Read only
Annotations
Stand Alone
Diagnostic
For Health Care Provider
For Patient
For Pharma Company
Calculator - patient specific
Reminder - patient specific

Regulatory Input

- Significant influence on approach, structure, and content, especially US FDA.

“How to Use The Guide”

1. An **overview** of those aspects and **risks specific to mobile apps**, and how to address them at a high level
2. **Further information** on how to **apply the GAMP 5** life cycle and Quality Risk Management approach to mobile apps
3. More **detailed “how to”** guidance for practitioners on specific topics
4. Case study **examples**

Readership

- **“Those requiring an overview of the topic** should read …”
- **“Those seeking further information** on the mobile apps life cycle, should also read…”
- **“Practitioners requiring detailed information on developing and supporting mobile apps** should also consider …”
- **“Suppliers of mobile apps** should read…”

“What’s Special about Mobile Apps?”

- **Novel and particular aspects** of mobile apps that require specific consideration and action
- Refers to other sections within the guide that provide **further guidance** on these topics.

Overview Table with references and further reading

Analysis of these Aspects

- **Management**
  - Project
  - Operational
- **Technical**
  - Data
  - Usability
  - Platforms
  - Communication

Risk Management

- Mobile apps may be required to run on several different platforms and operating systems, and at different version levels
- In most cases will not be under the control of an IT department
- Reliability of communications cannot be guaranteed

Risk Management

- Users cannot be effectively trained
- User behavior cannot be controlled
  - they have the ability to refuse updates, upgrade the O/S, or download other software without the controls normally applied though formal change management
- Some of the users may be patients
  - in some cases they could harm themselves by misusing an app

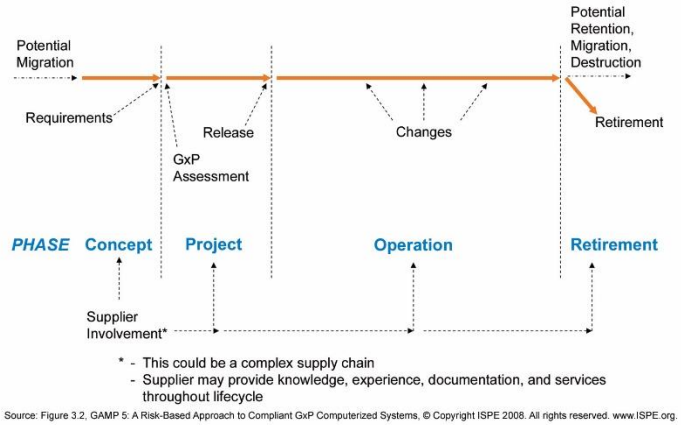
Risk Management

- Quality Risk Management (QRM) approach for mobile apps is described
- Based on GAMP 5, and aligned with ISO 14971

ISO 14971:2007
Medical devices - Application of risk management to medical devices

Life Cycle

- Mobile Application Product Life Cycle
  - concept
  - production
  - operation and support
  - retirement



- Mobile Application Data Life Cycle

Concept

- Intended use
- User population
- Initial Assessment
  - Mobile medical app?
  - Part of a GxP regulated system?
- Product Quality Plan

App definition statement - a concise, concrete declaration of an app's main purpose and its intended audience.

Production

- Supplier selection
- Prototyping and evaluation
- Requirements
  - User Interface / Usability Requirements
  - Connectivity Requirements
  - Data Security Requirements
  - Target Platform Requirements
- Testing
- User documentation, support, and maintenance.

Operation and Support

- Change Management
- Maintenance
- Problem Identification and Resolution
- Feedback Mechanism for users from within the Mobile App
  - (e.g. via a form submitted to a web service, or mail-based feedback)
- Process to deal with that feedback

Support in the Market

- An established process for medical device reporting (for Mobile Medical Apps)
- An established process for medical device field action / correction (for Mobile Medical Apps)
- Retirement, replacement, or withdrawal of product
- Retention, migration, or destruction of data

Conclusions

- Mobile apps are not going away…
- Many opportunities
- Many challenges

Conclusions

- Define intended use, and identify user community
- Identify risks and appropriate controls
- Apply a managed life cycle, following GAMP principles

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