Compliance Workshop for Regulated Mobile Applications

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Regulatory Knowledge, Practically Applied.

Agenda

- Introduction
- Practical examples of “regulated or GxP mobile applications”?
- Risk/Benefit
- Case Study and Workshop

Approach

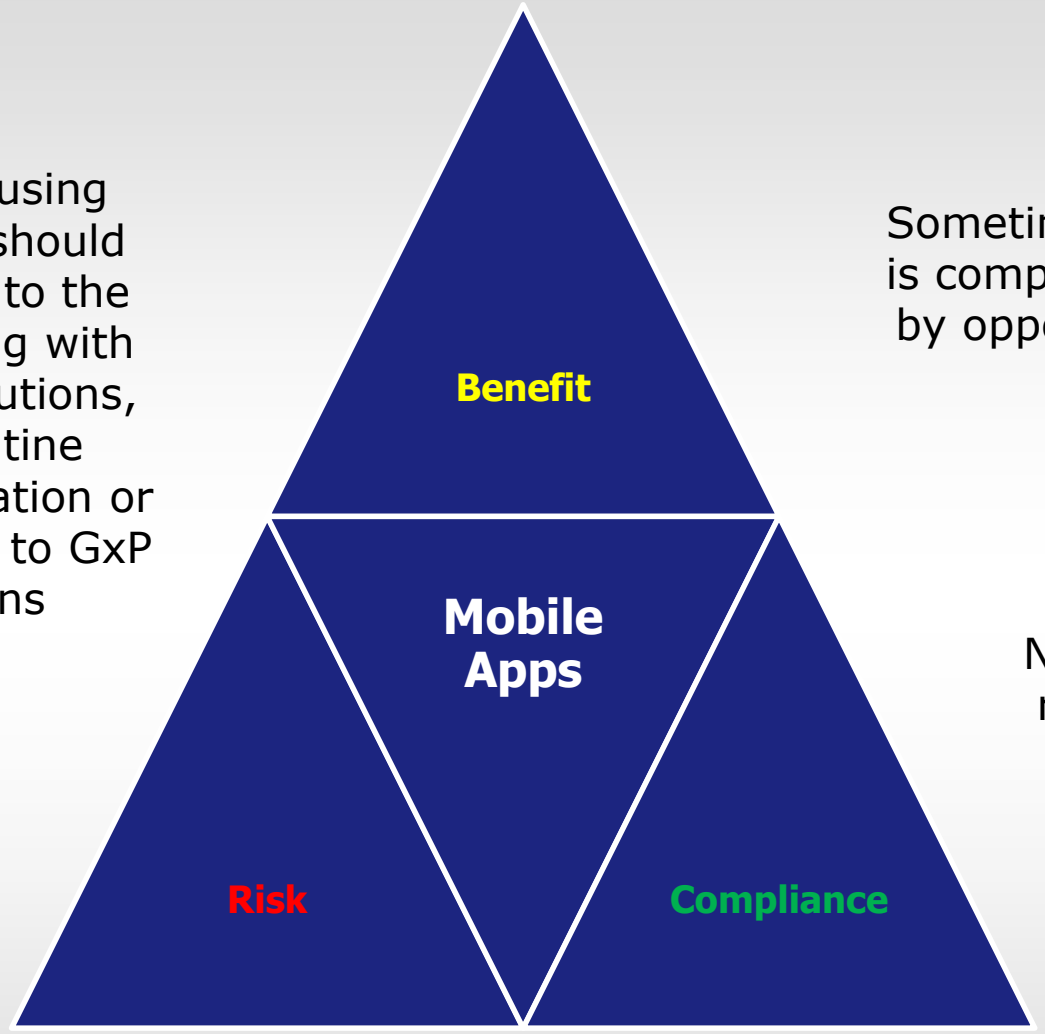
- Perspective of delivering solutions for commercial projects
- High-level overview of compliance, technology and business process challenges

Terms (FDA)

Mobile Application **(Mobile App)**	A software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server.
Mobile Medical Application **(Mobile Medical App)**	A mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either: • is used as an accessory to a regulated medical device; or • transforms a mobile platform into a regulated medical device.

Rapidly emerging technology with clear commercial benefit

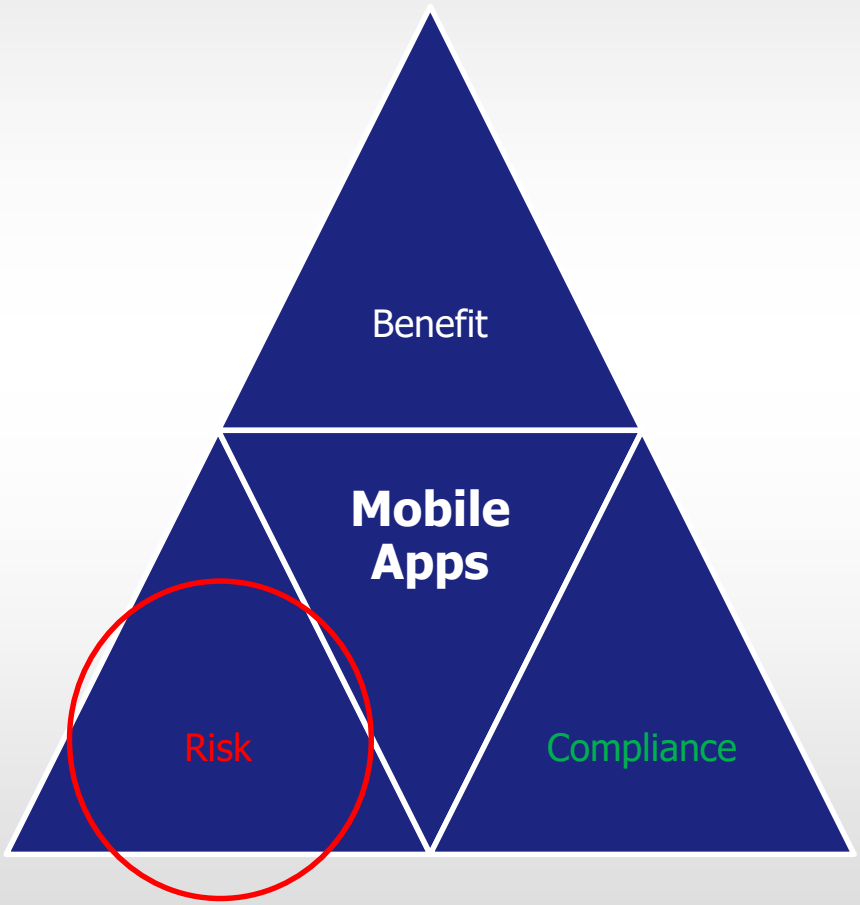
The risks of using mobile apps should be compared to the risks of staying with traditional solutions, such as routine clinical observation or remote access to GxP applications



Sometimes risk is compensated by opportunity

Need to balance risk vs. benefit

Risks



Identified by:

- Loss of governance
- Communication failure
- Regional regulatory requirements
- Ownership and Responsibility for Data
- Compliance risks
- Management interface compromise
- Insecure data deletion
- Malicious attack

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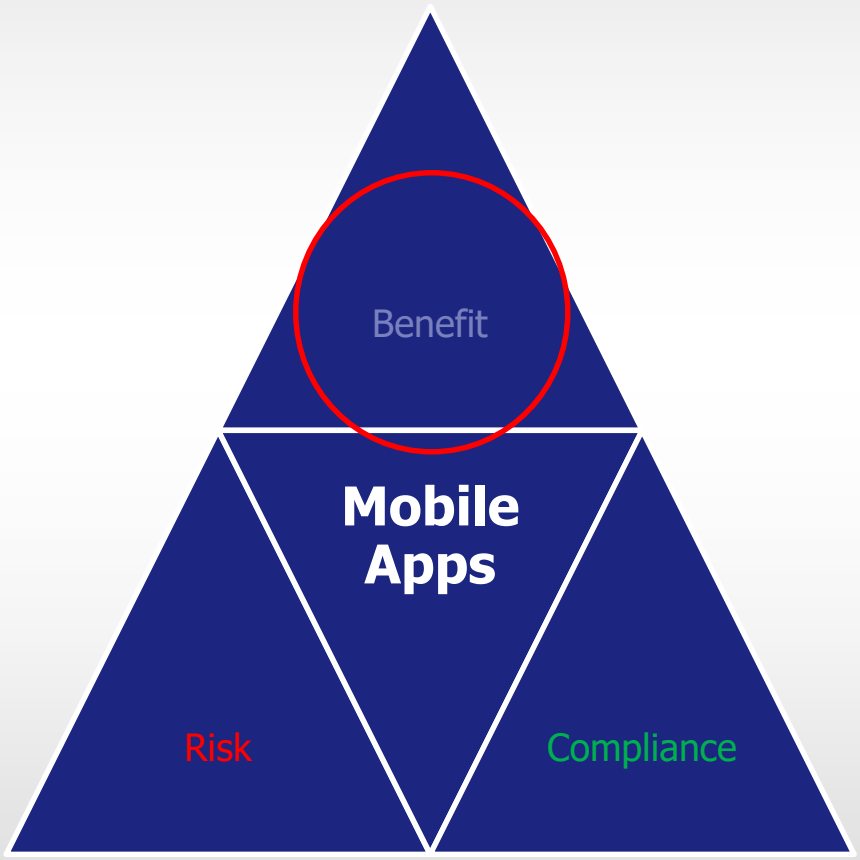
Benefits



- Tools, techniques, resources
- More effective compliance for GxP Mobile Applications
- Proactive monitoring
- Adaptability
- Faster, more effective
- Targeted Medicines
- Marketing Tool
- Better patient outcomes

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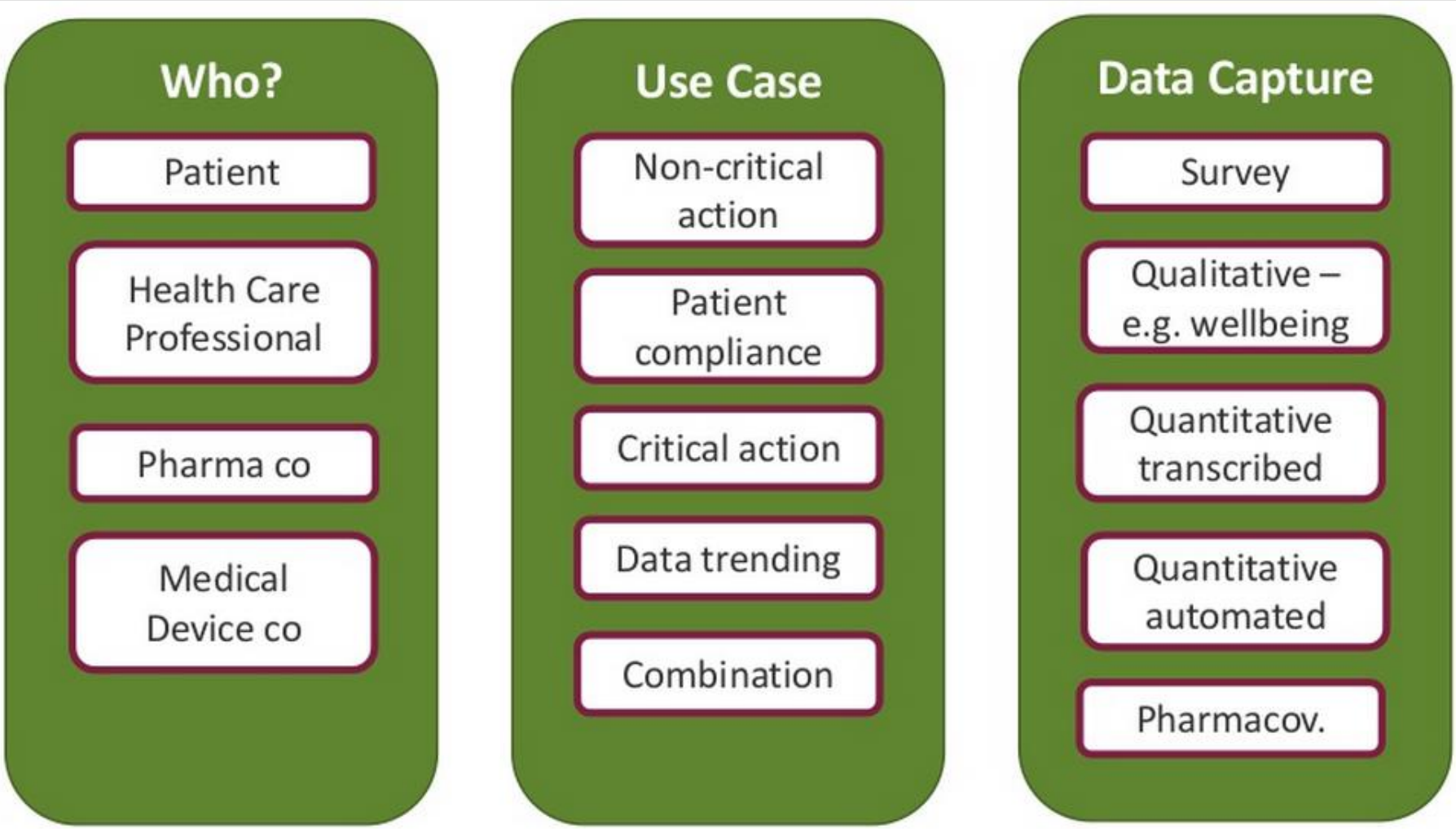
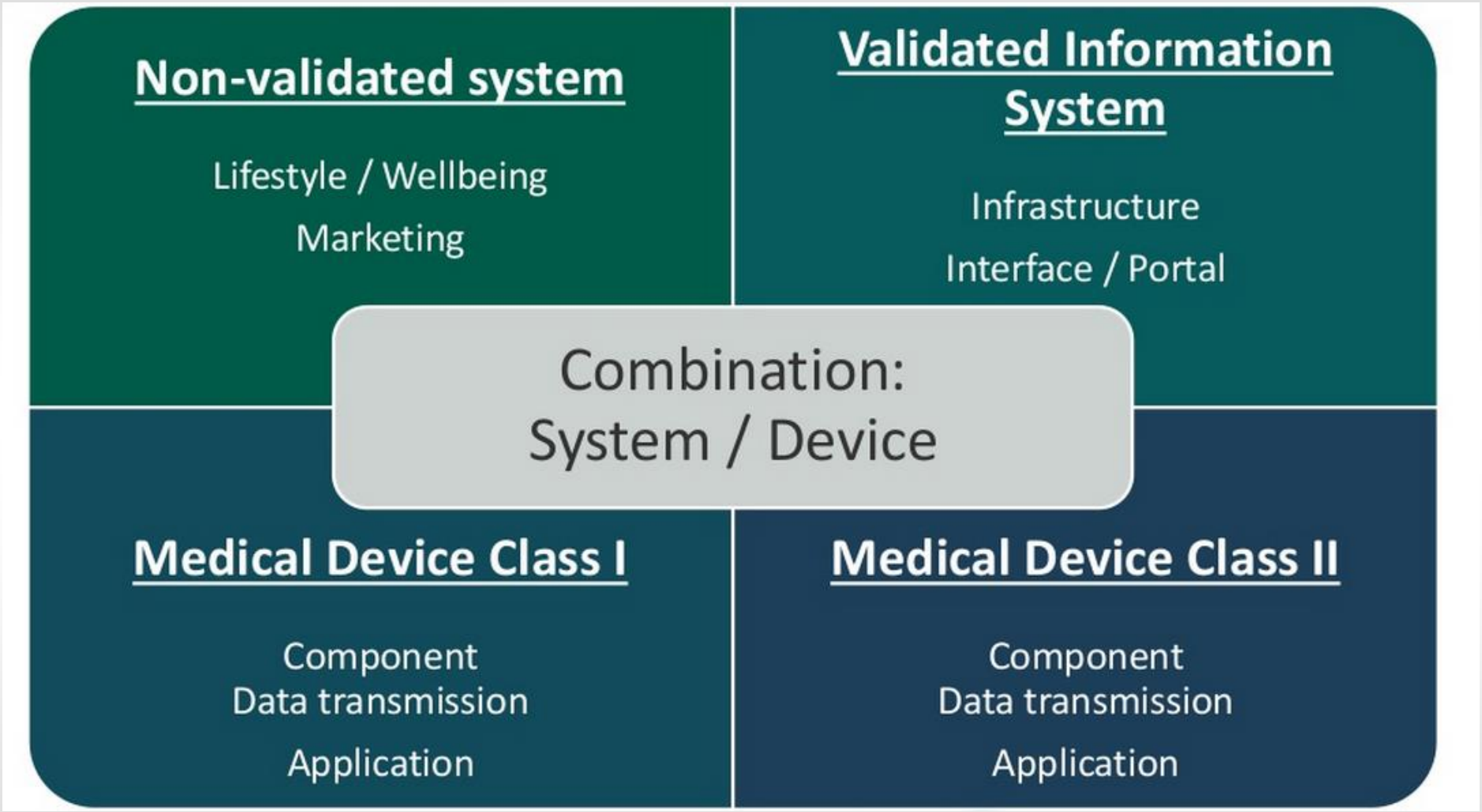
What is a Mobile GxP App?



Categorisation / Classification



Smartphone VS Computer

=

Phone

+

Mobility

Bluetooth

Photo

Medical Device

Geo localisation

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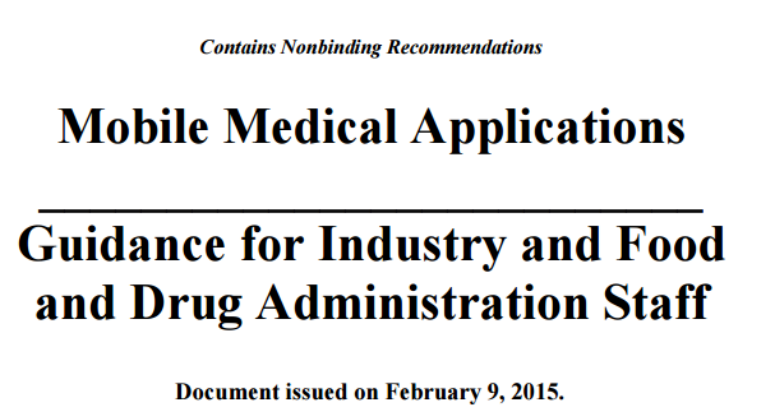
Key compliance Tools

- Industry guidance e.g. GAMP® A Risk-based Approach to Regulated Mobile Applications
- Some excellent FDA Guidance



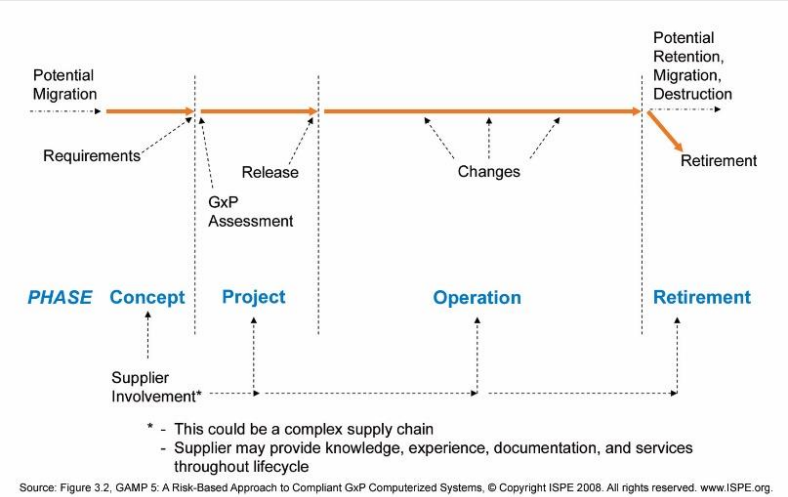
- MHRA Guidance (Medical devices: software applications (apps)

What is it that you are trying to deliver

- Who is your end user and what is your intended use case?
- Apply knowledge, design methodologies and risk based approaches you already use
- Pragmatism

Life Cycle

- **Mobile App Product Life Cycle**
  - concept
  - production
  - operation and support
  - retirement



- **Mobile App Data Life Cycle**
  - What data will be collected and how will it be stored?
  - How will the data be used?
  - Who will have access to the data, and why?
  - Retention period for the data
  - User ability to access, view, transfer, or delete data:

Regulatory Expectations

- Quality System Regulation (QS Regulation) purchasing controls for safe distribution, control, and operation
- Validation of mobile medical apps along with the mobile platform to ensure safe and effective operation of the mobile medical app
- An established process for medical device reporting (AEs) for Mobile Medical Apps)
- An established process for medical device field action / correction (for Mobile Medical Apps)
- Retirement, replacement, or recall
- Data Management Policy

Environment

- Complex
- Rapidly changing
- Volatile
- Regulatory situation unclear

- National / regional differences
- Many viewpoints
- Opportunities …

- Blurring boundaries
  - Software
  - Hardware
  - Drug/device
  - Web ecosystem
  - Product
  - Internal/external

Regulatory Position

- Unlikely to aggressively pursue compliance for low-risk applications (?)
- May be driven by any arising public health issues
  - Maybe via medical device reporting red flags

"Standby mode"

"Significant flexibility built-into regulations"

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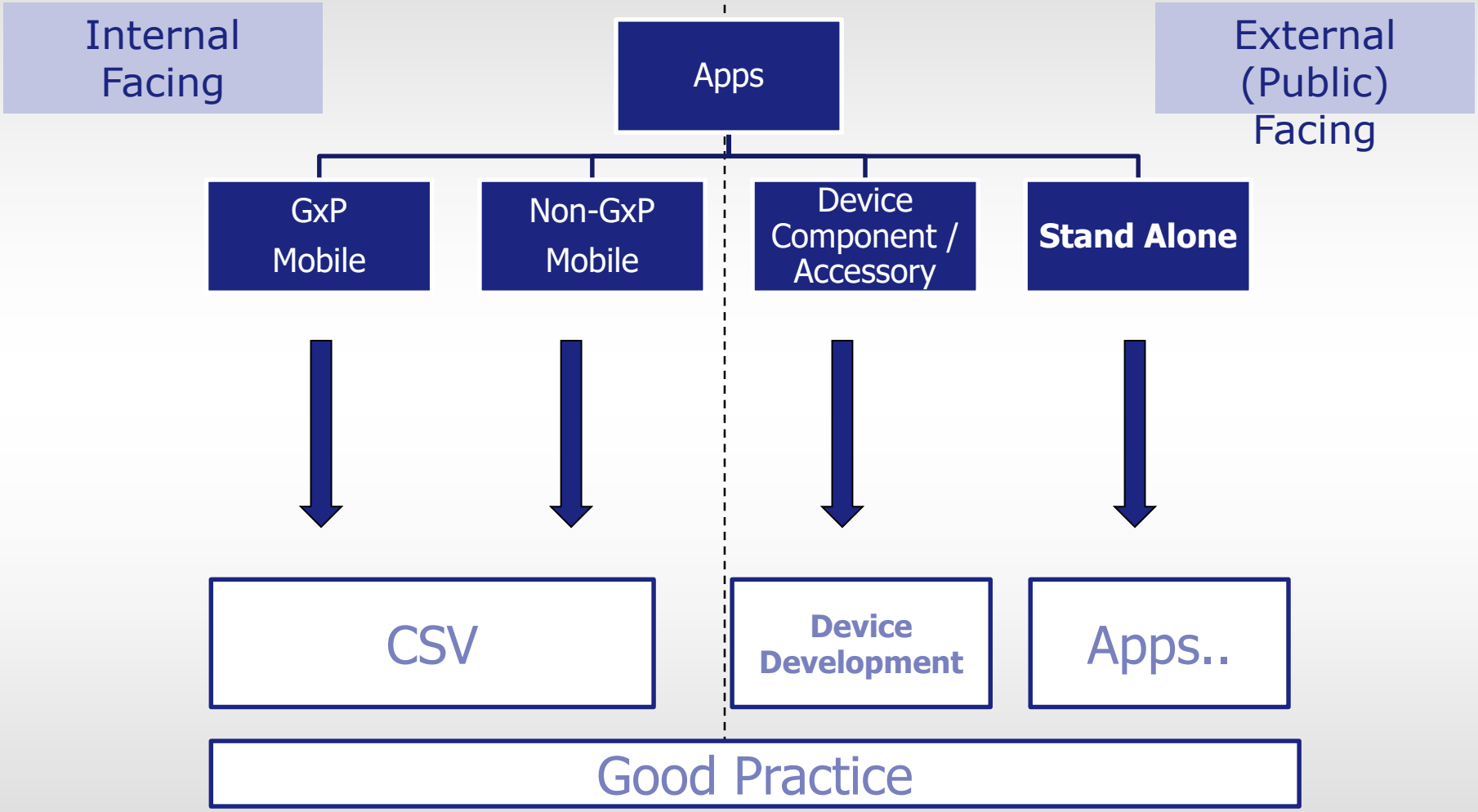
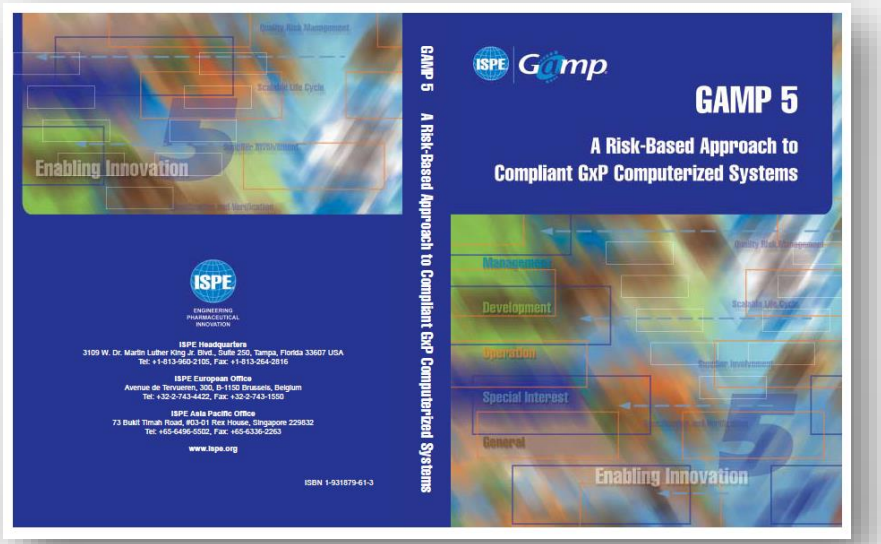
Landscape

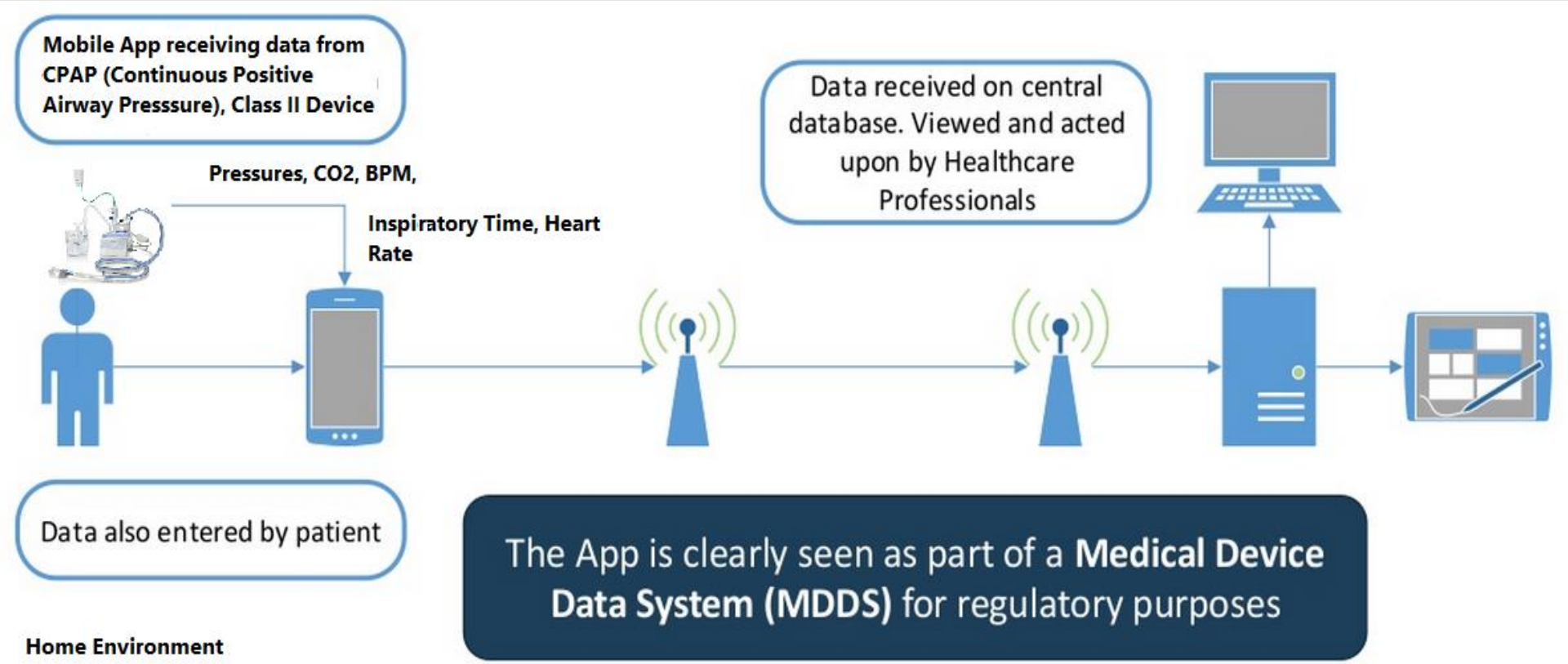


GAMP® 5

- Section 3 - Life Cycle Approach
- Section 5 - Quality Risk Management
- Section 7 - Supplier Activities
  - Relevant and useful…
  - Additional considerations apply…



Workshop Study 1



Workshop Activity 1 – Benefits & Risks
Quickfire Round

- What **benefit** could this bring to users, the public, patients, physicians or health-care providers?
- What **aspects of mobility** allow these benefits to be realised
- Perform a PHA for the use of this CPAP monitoring app?

Workshop Activity 2 – Product Requirements Definition

- Split into 4 groups.
- Groups 1 & 3 will define:

1. Intended uses, incl. clinical objectives
2. Functional/Performance Requirements
3. Human Factors, Usability Requirements, problem identification
4. Security Requirements

- Groups 2 & 4 will define:

1. Key features, characteristics
2. Data Requirements
3. Interface Requirements
4. Retirement or Update Requirements

- Discuss findings with the group.

15 mins

Workshop Activity 3 – Mobile App Supplier Assessment

- What would be your overall supplier assessment process for a supplier of this app?
- If you audited this supplier, what would you particularly look for?

Conclusions

- Mobile apps are not going away…
- Many opportunities → Therefore many challenges