Delivering GxP compliant mobile applications – a practical case study

Presented by: Mark Stevens

Formpipe. GxP
Simply Compliant

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Agenda

- Introduction
- What is a GxP mobile application?
- Case studies
- Experience and views
- Summary

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Approach

- Perspective of delivering solutions for commercial projects
- High-level overview of compliance, technology and business process challenges
- Experience of service provider, mobile application development and sponsor

Introducing the speaker

- Mark Stevens
- Chemical Engineer
- Pharma / Biotech / Food
- Design, construction, validation, CSV, clinical, QMS, demolition
- Remediation, compliance improvement and new technology introduction

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GxP mobile application experience

- Since 2007
- Global mobile network provider
- Cold chain supply
- Mobile app developers to blue-chip corporations
- Hosted data centre providers
- SaaS providers

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The opportunity

- Rapidly emerging technology with clear business benefits:
  - Cost
  - Accessibility and availability
  - Converging / Combination health solutions
  - Competitive advantage

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The challenge

- Maintain patient safety, data integrity and security
- What is ‘GxP compliance’?
- New technologies, development methods and service providers
- Ownership and responsibility of data
- Inconsistent terminology across regulations, guidelines and organisations

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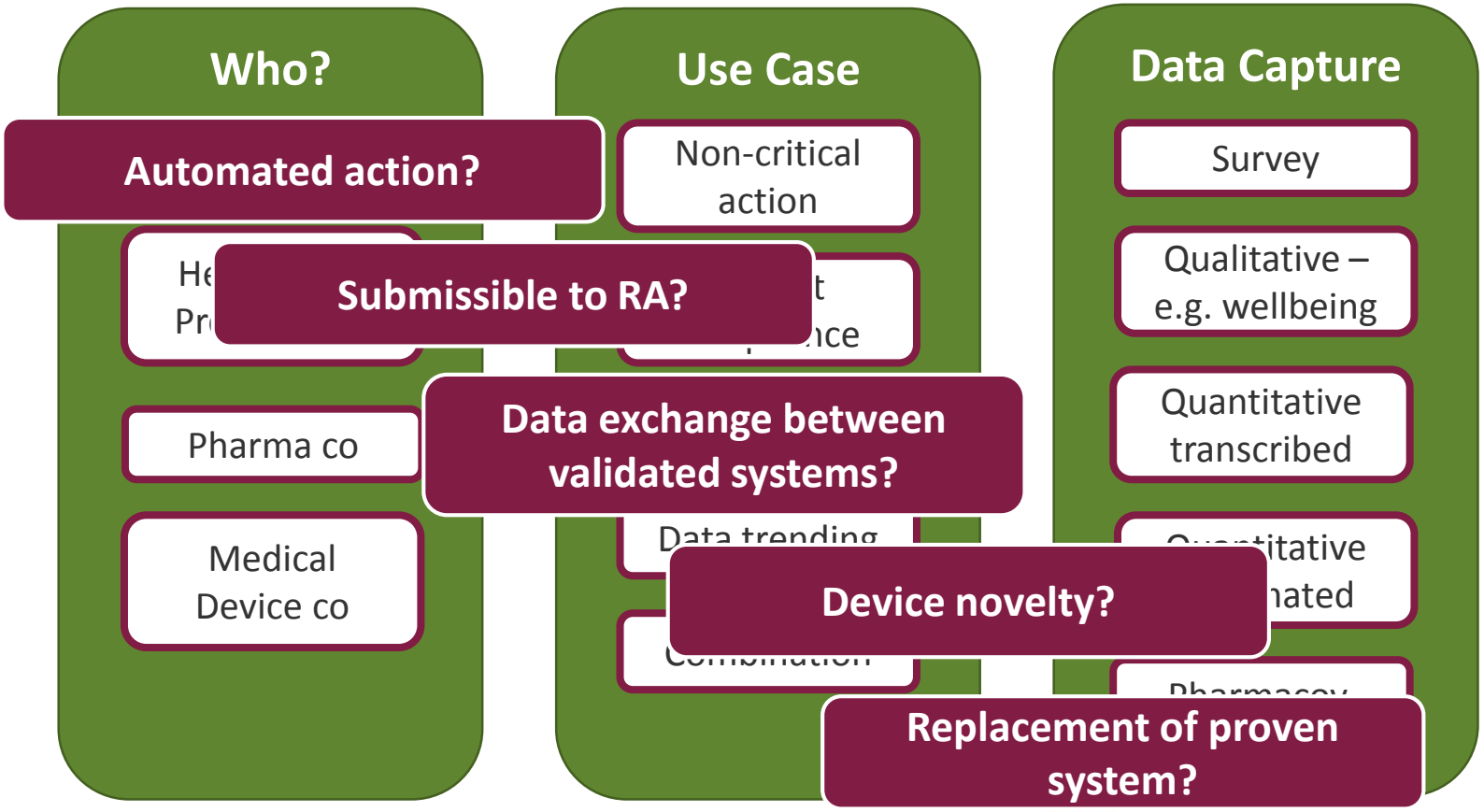
What is a mobile GxP application?



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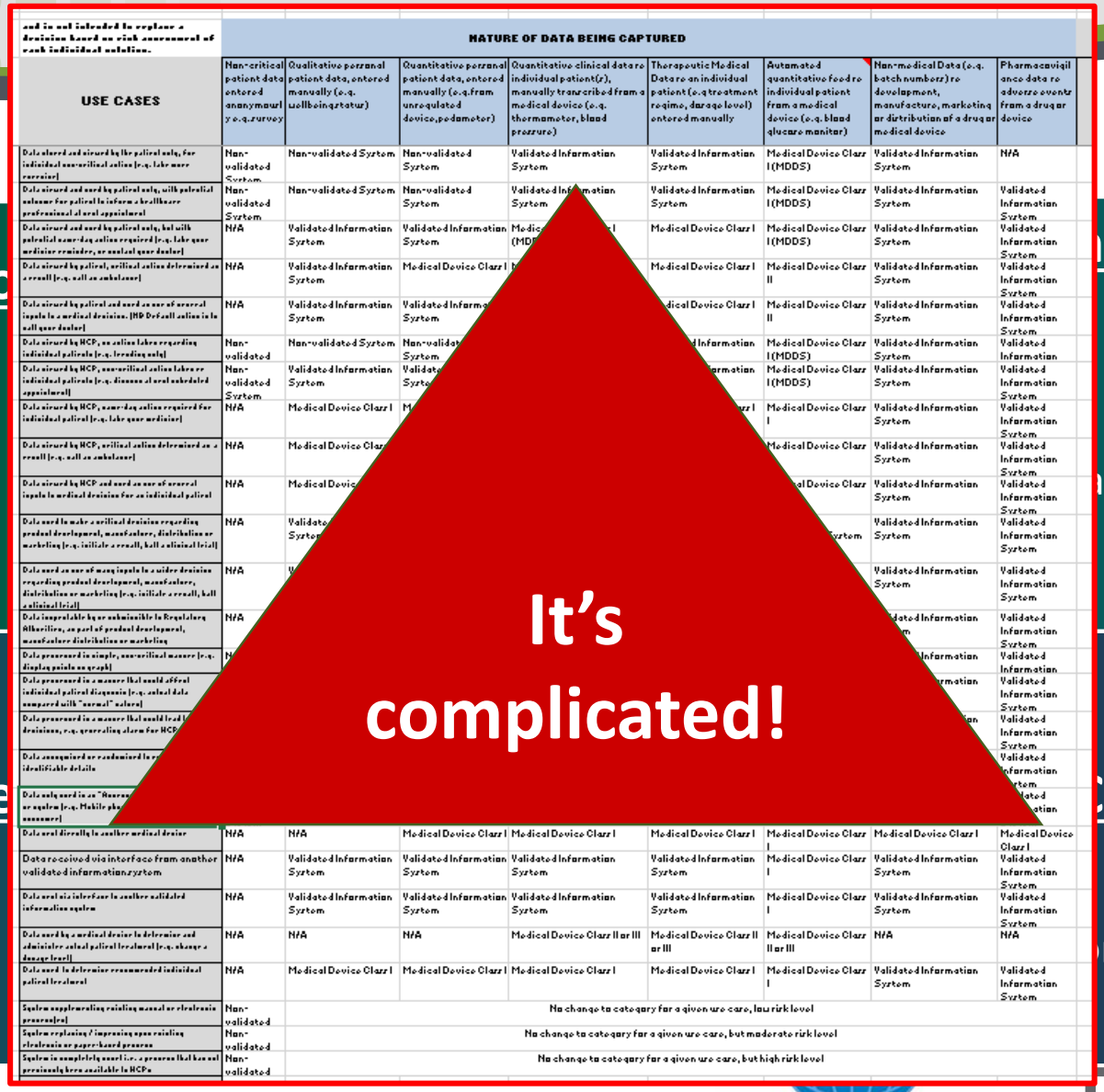
Categorisation?



and is not intended to replace a decision based on risk assessment of each individual solution.

USE CASES	NATURE OF DATA BEING CAPTURED							
	Non-critical patient data entered anonymously e.g. survey	Qualitative personal patient data, entered manually (e.g. wellbeing status)	Quantitative personal patient data, entered manually (e.g. from unregulated device, pedometer)	Quantitative clinical data re individual patient(s), manually transcribed from a medical device (e.g. thermometer, blood pressure)	Therapeutic Medical Data re an individual patient (e.g treatment regime, dosage level) entered manually	Automated quantitative feed re individual patient from a medical device (e.g. blood glucose monitor)	Non-medical Data (e.g. batch number) re development, manufacture, marketing or distribution of a drug or medical device	Pharmacovigilance data re adverse events from a drug or device
Data stored and stored by the patient only, for individual non-critical action [e.g. take more exercise]	Non-validated System	Non-validated System	Non-validated System	Validated Information System	Validated Information System	Medical Device Class I (MDDS)	Validated Information System	N/A
Data stored and used by patient only, with potential outcome for patient to inform a healthcare professional at next appointment	Non-validated System	Non-validated System	Non-validated System	Validated Information System	Validated Information System	Medical Device Class I (MDDS)	Validated Information System	Validated Information System
Data stored and used by patient only, but with potential same-day action required [e.g. take your medicine reminder, or contact your doctor]	N/A	Validated Information System	Validated Information System	Medical Device Class I (MDDS)	Medical Device Class I	Medical Device Class I (MDDS)	Validated Information System	Validated Information System
Data stored by patient, critical action determined as a result [e.g. call an ambulance]	N/A	Validated Information System	Medical Device Class I		Medical Device Class I	Medical Device Class II	Validated Information System	Validated Information System
Data stored by patient and used as one of several inputs to a medical decision. [HP Default action is to call your doctor]	N/A	Validated Information System	Validated Information System		dical Device Class I	Medical Device Class II	Validated Information System	Validated Information System
Data stored by HCP, no action taken regarding individual patient [e.g. trending only]	Non-validated	Non-validated System	Non-validated System		Information	Medical Device Class I (MDDS)	Validated Information System	Validated Information System
Data stored by HCP, non-critical action taken re individual patient [e.g. discuss at next scheduled appointment]	Non-validated System	Validated Information System	Validated System		rmation	Medical Device Class I (MDDS)	Validated Information System	Validated Information System
Data stored by HCP, same-day action required for individual patient [e.g. take your medicine]	N/A	Medical Device Class I	M		ss I	Medical Device Class I	Validated Information System	Validated Information System
Data stored by HCP, critical action determined as a result [e.g. call an ambulance]	N/A	Medical Device Class				Medical Device Class	Validated Information System	Validated Information System
Data stored by HCP and used as one of several inputs to medical decision for an individual patient	N/A	Medical Devic				l Device Class	Validated Information System	Validated Information System
Data used to make a critical decision regarding product development, manufacture, distribution or marketing [e.g. initiate a recall, halt a clinical trial]	N/A	Validate System				ystem	Validated Information System	Validated Information System
Data used as one of many inputs to a wider decision regarding product development, manufacture, distribution or marketing [e.g. initiate a recall, halt a clinical trial]	N/A						Validated Information System	Validated Information System
Data interpretable by or submissible to Regulatory Authorities, as part of product development, manufacture distribution or marketing	N/A						dated Information m	Validated Information System
Data processed in simple, non-critical manner [e.g. display points on graph]	N						Information	Validated Information System
Data processed in a manner that could affect individual patient diagnosis [e.g. actual data compared with "normal" values]							rmation	Validated Information System
Data processed in a manner that could lead t decisions, e.g. generating alarm for HCP							ion	Validated Information System
Data anonymised or randomised to re identifiable details								Validated Information System
Data only used in an "Assess or system [e.g. Mobile ph assessment]								dated stion
Data sent directly to another medical device	N/A	N/A	Medical Device Class I	Medical Device Class I	Medical Device Class I	Medical Device Class I	Medical Device Class I	Medical Device Class I
Data received via interface from another validated information system	N/A	Validated Information System	Validated Information System	Validated Information System	Validated Information System	Medical Device Class I	Validated Information System	Validated Information System
Data sent via interface to another validated information system	N/A	Validated Information System	Validated Information System	Validated Information System	Validated Information System	Medical Device Class I	Validated Information System	Validated Information System
Data used by a medical device to determine and administer actual patient treatment [e.g. change a dosage level]	N/A	N/A	N/A	Medical Device Class II or III	Medical Device Class II or III	Medical Device Class II or III	N/A	N/A
Data used to determine recommended individual patient treatment	N/A	Medical Device Class I	Medical Device Class I	Medical Device Class I	Medical Device Class I	Medical Device Class I	Validated Information System	Validated Information System
System supplementing existing manual or clerical process [or]	Non-validated	No change to category for a given use case, low risk level						
System replacing / improving upon existing clerical or paper-based process	Non-validated	No change to category for a given use case, but moderate risk level						
System is completely novel i.e., a process that has not previously been available to HCPs	Non-validated	No change to category for a given use case, but high risk level						

It's complicated!

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What is a mobile GxP application?

- Many things to many different people, even within a single organisation
- Rapidly changing
- Existing applications evolving
- Something relatively unknown from a regulatory compliance perspective

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How do we achieve GxP compliance?

- Industry guidance, e.g. GAMP® A Risk-Based Approach to Regulated Mobile Applications
- **End use** driven. What is it being used for?
- Apply the knowledge and risk-based approaches you already use
- Keep it **simple**!

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Case Studies

- Some real-world examples

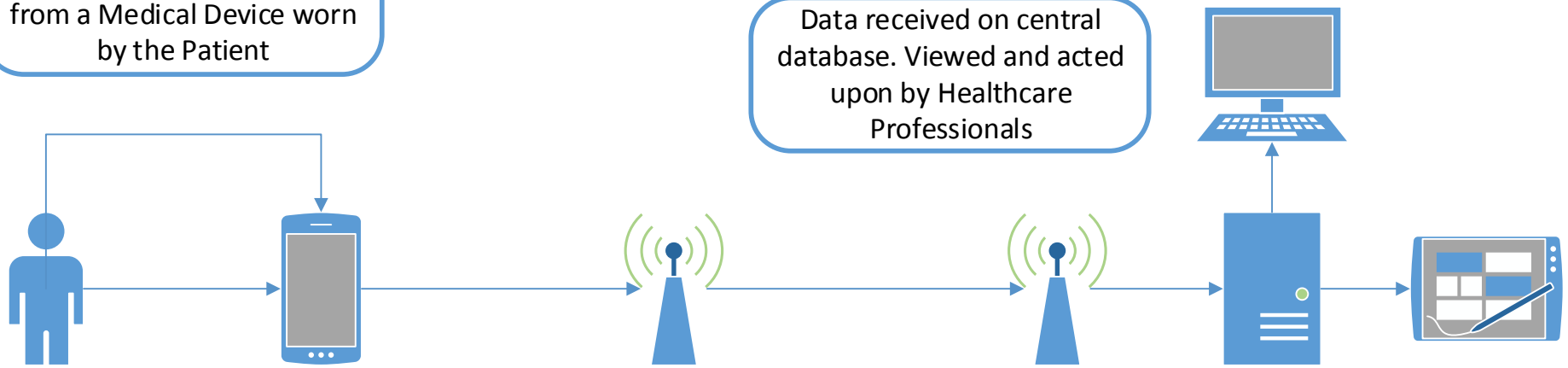
Case Study 1

- Development of a mobile application ‘platform’ to be offered to multiple clients
- Matrix of users, use cases, data being captured, transaction types and novelty of approach
- Variability of end-use (application) the biggest factor by far

Case Study 2

Mobile App receiving data from a Medical Device worn by the Patient

Data received on central database. Viewed and acted upon by Healthcare Professionals



Data also entered by patient

The App is clearly seen as part of a **Medical Device Data System (MDDS)** for regulatory purposes

The "Class" of Device and System is dependent on **how** the sensing / monitoring part of **the device is used** and **how the information is used**, not the nature of Mobile App software

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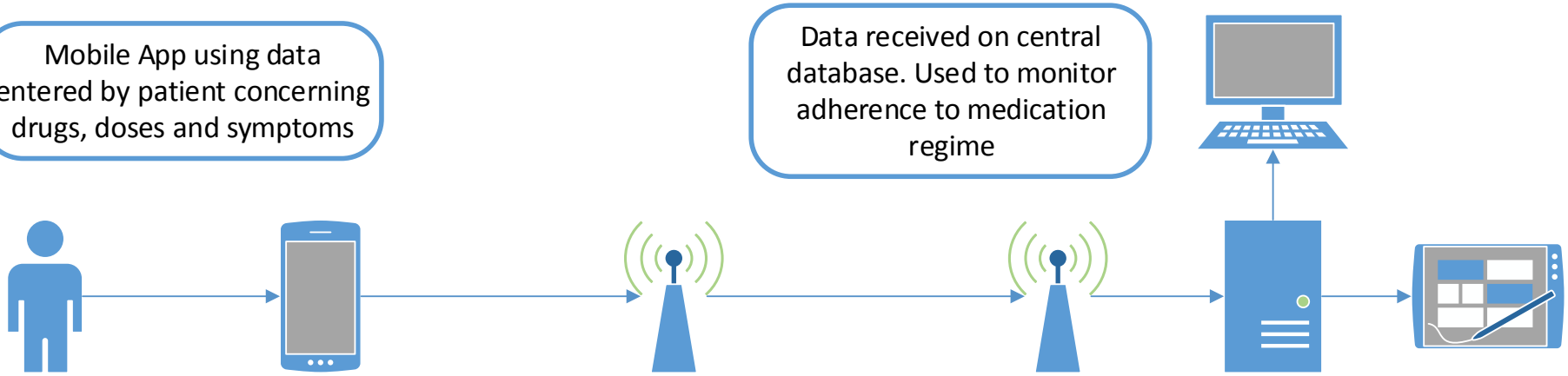
Case Study 3

Mobile App using data entered by patient concerning drugs, doses and symptoms

Data received on central database. Used to monitor adherence to medication regime



Version 1 of the App will **not** be classed as a Medical Device, but…

Developing and Documenting the App as a ***potential Medical Device*** (future versions by be connected to monitoring devices)

Developing the central database as a ***potential validated computerised system*** (dependent upon future end-use)

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Our experience from commercial projects

- Classification of Devices and Systems being driven by **end use**, rather than complexity of technology
- Regulated company taking the view of developing with **potential future use** in mind
- **Reluctance** to make claims of mobile applications as medical devices / validated systems due to the anticipated delays, complexity and cost

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Our experience from commercial projects

- Projects often evolve from (unregulated) proof of concept to pilot study without robust challenge of **requirements specification**
- Multiple client groups involved during development lifecycle – often with **different or inconsistent requirements**
- Significant **reliance on vendors** to understand and achieve customer-specific regulatory requirements
- Great **results and success** are being achieved when there is a high level of **collaboration** between vendors and regulated customer

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Who is responsible for what?

- GAMP5® definition of responsibilities still works well
- **Regulated Company** responsible for regulatory status / classification / risks of their "product" based upon end-use
- **Supplier** (e.g. Mobile App Developer) responsible for developing and documenting their software in a way that meets guidelines and best practice

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Regulated company viewpoint

- A defined CSV process
- A defined Medical Device Design process
- Use the existing Supplier Approval / Audit process
- Meet requirements of established processes within the corporation

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Mobile App vendor viewpoint

- What is ‘GxP Compliance’?
- Life science want a QMS and (more) documentation in a familiar format
- Each App may have significant differences in requirements (end use)
- Each client can have differing requirements. Why?
- This is only one market vertical – it needs to be cost-effective to support this business

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What is it we are looking to achieve?

- We are developing new Devices and new Systems where the end use may still be unclear or open
- We are engaging with new partners and technology providers in order to realise these
- …so we need to approach things in a pragmatic way that reflects this.

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Commercial reality

- Both parties need to **compromise** on standard processes and documentation
- Technology changing faster than regulations – precise regulatory classification sometimes difficult
- Waterfall vs. Agile Development – Agile can be perfectly acceptable
- Define and agree the requirements for each project – **end use** is the driver

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What do we need to validate?

- What is the App actually being used for?
- If it goes wrong, could anyone be hurt?
- Risk Assessment
- Is it (part of) a Medical Device?
- Is it (part of) a Validated System?

Planning for success

- Defining Requirements in a traceable and testable manner
- Good Design Documents that help future maintenance
- Risk-based testing of software, with evidence recorded
- Testing on the right platform(s)
- WiKi / SaaS / Agile / Cloud-based applications can achieve what we need!
- Roadmap – future use?

Summary

- Mobile applications offer huge patient and business benefits in GxP applications
- Compromise between existing computer compliance and medical device development, testing and records
- Focus on the important stuff – Requirements Spec., Risk Assessment, Trace Matrix, Test evidence
- GxP compliance is driven by the end use
- Often the ultimate use of the mobile application may be different from the original project brief

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Thank you!

mark.stevens@formpipegxp.com

US: +1 713 589 4824

EU: +44 115 924 8475

www.formpipegxp.com

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