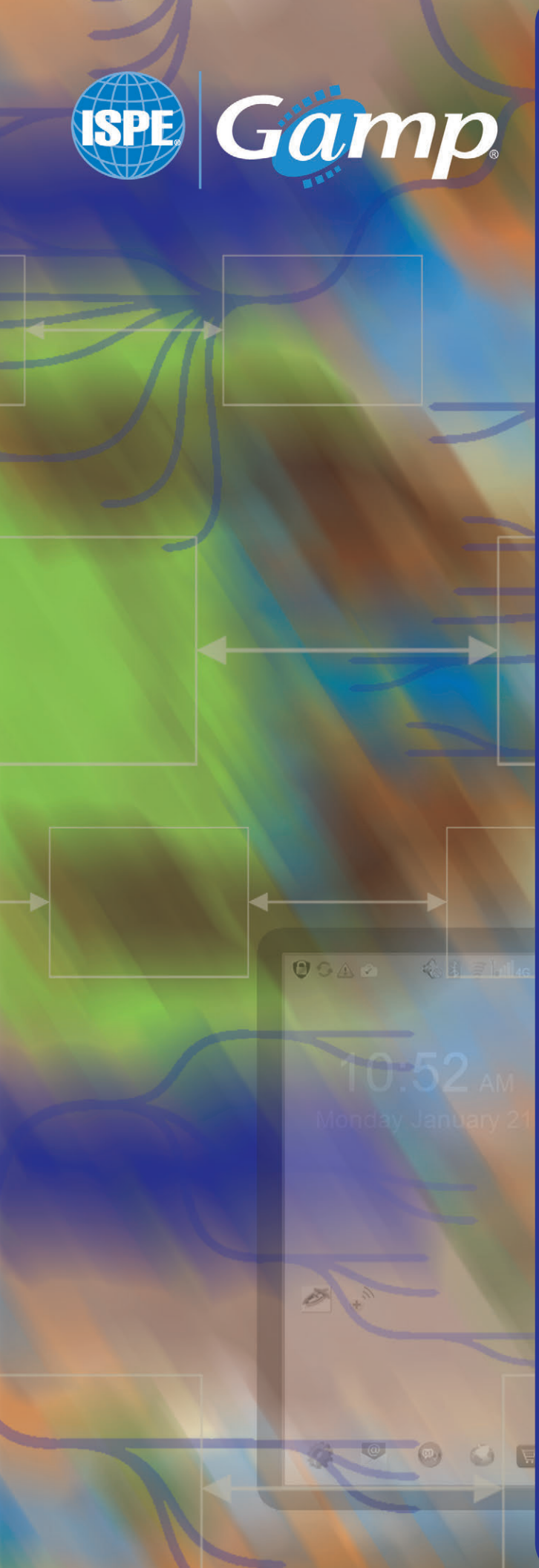
ISPE Gamp

GAMP Good Practice Guide

A Risk-Based Approach to Regulated Mobile Applications



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A Risk-Based Approach to Regulated Mobile Applications

Disclaimer:
This Guide is intended to provide a risk-based approach to implementing and supporting regulated mobile apps. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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Preface

The use of mobile platforms – including smartphones, tablets, and wearable devices – by the general public has increased hugely. In 2013, sales of smartphones exceeded the sales of standard mobile phones, and this trend shows no sign of slowing. As reported on the FDA website, 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. With this much computing power in everyone's pocket, it was inevitable that regulated companies would recognize an opportunity to use it for a variety of purposes. Some examples are:

- To improve patient compliance to a medical regimen
- As a marketing tool
- To make medical literature more available to physicians
- As a channel for patient reporting
- As an interface to a medical device
- To control a medical device

In addition to the above, mobile devices are an attractive option as interfaces to GxP systems in a manufacturing plant or laboratory, e.g.:

- Tool 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 setpoints
- To access enterprise applications, such as Enterprise Resource Planning (ERP)

The universality of the mobile device market makes it increasingly attractive to develop mobile applications for varied uses. It may not be immediately obvious to all teams and departments that there are regulatory implications. Hence building awareness within all affected areas of regulated companies is critical.

By their very nature mobile devices present a significant challenge to control. The possibility of putting regulated applications, some of which may be classified as medical devices, into the pockets of the public is new ground for the industry. Never before has regulated software run on platforms where life science companies have little or no control over the platform.

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Company affiliations are as of the final draft of the Guide.

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