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## 1. INTRODUCTION

### 1.1 Background

BARQA published a Guideline on the Management of Electronic Standard Operating Procedures in December 1998. Since then companies working in the GxP industries have gained experience of electronic SOPs through the design and implementation of their own systems. In September 2001, interested parties from a variety of user organisations formed a Working Party under the auspices of BARQA to co-operate and produce an update to the 1998 guideline in the form of a BARQA Position Paper.

This Position Paper has been reviewed by representatives of the BARQA GxP Committees. Comments may be submitted by e-mail to: [computing@barqachat.com](mailto:computing@barqachat.com)

### 1.2 Objectives

The objectives of this Position Paper are to review:

- The different categories of eSOP system available.
- The regulatory implications of eSOP systems.
- The benefits of introducing such a system.
- IT considerations.
- Other information that would help in developing or purchasing an eSOP system.

The document is intended to provide information on a number of key aspects of eSOPs rather than to be a fully comprehensive, step-by-step guide to all aspects of implementing and maintaining an eSOP system.

### 1.3 Scope of Application of the Position Paper

The document is designed for eSOPs used in activities regulated by Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP). Collectively, these are referred to in this document as GxPs. The document can also be used for other activities that are governed by regulatory or similar standards.

## 2. DEFINITIONS

**eSOP:** For the purposes of this document, the generic term 'eSOP' will be used to refer to electronic records of Policies, Standard Operating Procedures, Guidelines, Working Instructions, Working Procedures, Process Maps, and other procedural documentation related to the management of GxP processes.

**Electronic Record:** The FDA (Ref. 6) defines an electronic record as “...any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.” This definition has been adopted for the purposes of this document.

**Electronic Signature:** The FDA (Ref. 6) defines an electronic signature as “...a computer data compilation of any symbol or series of symbols executed, adopted, or authorised by an individual to be the legally binding equivalent of the individual’s handwritten signature.” This definition has been adopted for the purposes of this document.

**Validation:** The OECD (Ref. 4) defines validation as 'The demonstration that a computerised system is suitable for its intended purpose.' This definition has been adopted for the purposes of this document.

### 3. SYSTEM COMPONENTS AND FUNCTIONS

An eSOP system comprises the computerised system (i.e. the hardware, software and computer operating procedures) and the content (i.e. the eSOPs themselves). The software not only includes the eSOP application software but also the operating, and, if relevant, network management software. Its functions may support the creation, review, authorisation/approval, distribution and archiving of SOPs (see Appendix 1 for a typical SOP life-cycle). More complex systems may also allow management of, and access to, related documents such as the templates needed for the creation of forms and reports required by the SOPs.

Even more sophisticated systems allow the collection of information on the amount of user access to SOPs and may also include links to electronic training material and/or a glossary.

## 4. eSOP SYSTEM TYPES

### 4.1 Hybrid Systems

Complete management of SOPs by electronic means is not yet common practice and various hybrid systems are in use. These may use standard office/desktop applications or specialised software, which may be custom-built or “off-the-shelf.”

A key factor when designing an electronic SOP system is often the need to provide a more practical and user-friendly process for dealing with SOPs. For this reason a completely electronic system may not be desirable. In some cases the operating environment may dictate a system in which one or more of the key SOP management processes must remain manual.