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Nota de aplicación

An Automated Application Template for Content Uniformity Studies in SDMS Vision Publisher

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This is an Application Brief and does not contain a detailed Experimental section.

Abstract

SDMS Vision Publisher serves as a reporting and authoring module incorporated as standard for NuGenesis SDMS and provides templates for Content Uniformity testing; whereas, NuGenesis SDMS acts as a data repository for analytical raw data as well as printed reports. A brief example will illustrate a Content Uniformity template for a tablet HPLC based assay. Other forms of Content Uniformity testing are also possible.

Introduction

Releasing a pharmaceutical drug product to market may require a Content Uniformity assessment to ensure that the downstream consumer receives the recommended dosage of active pharmaceutical ingredient (API). Content Uniformity serves as one of several tests (other tests include appearance, average mass, dissolution, etc.) that are performed during manufacturing and that adhere to GMP guidelines. As defined by the USP, content uniformity tests may be performed on coated tablets, transdermal systems, soft gel capsules, packaged inhalations, single packaged solids, and suppositories[1-2] A typical Content Uniformity workflow is described in Figure 1 and consists of six primary steps. Each of these steps requires accurate documentation due to the adherence to GMP guidelines. Fortunately, the Content Uniformity workflow is straightforward and can make ready use of templates.

Content Uniformity studies employ a straightforward workflow that may be readily captured in a standardized template by using electronic report and authoring tools (see Figure 1 for workflow example). A standardized template both guides the analyst through the workflow and ensures reliable data capture without skipping necessary steps.[3] Further benefits to recording Content Uniformity studies electronically include: searchable reports, electronic interface to analytical data systems (e.g., CDS, LIMS, balances), and electronic records that are 21 CFR Part 11 Compliant Ready.[3]

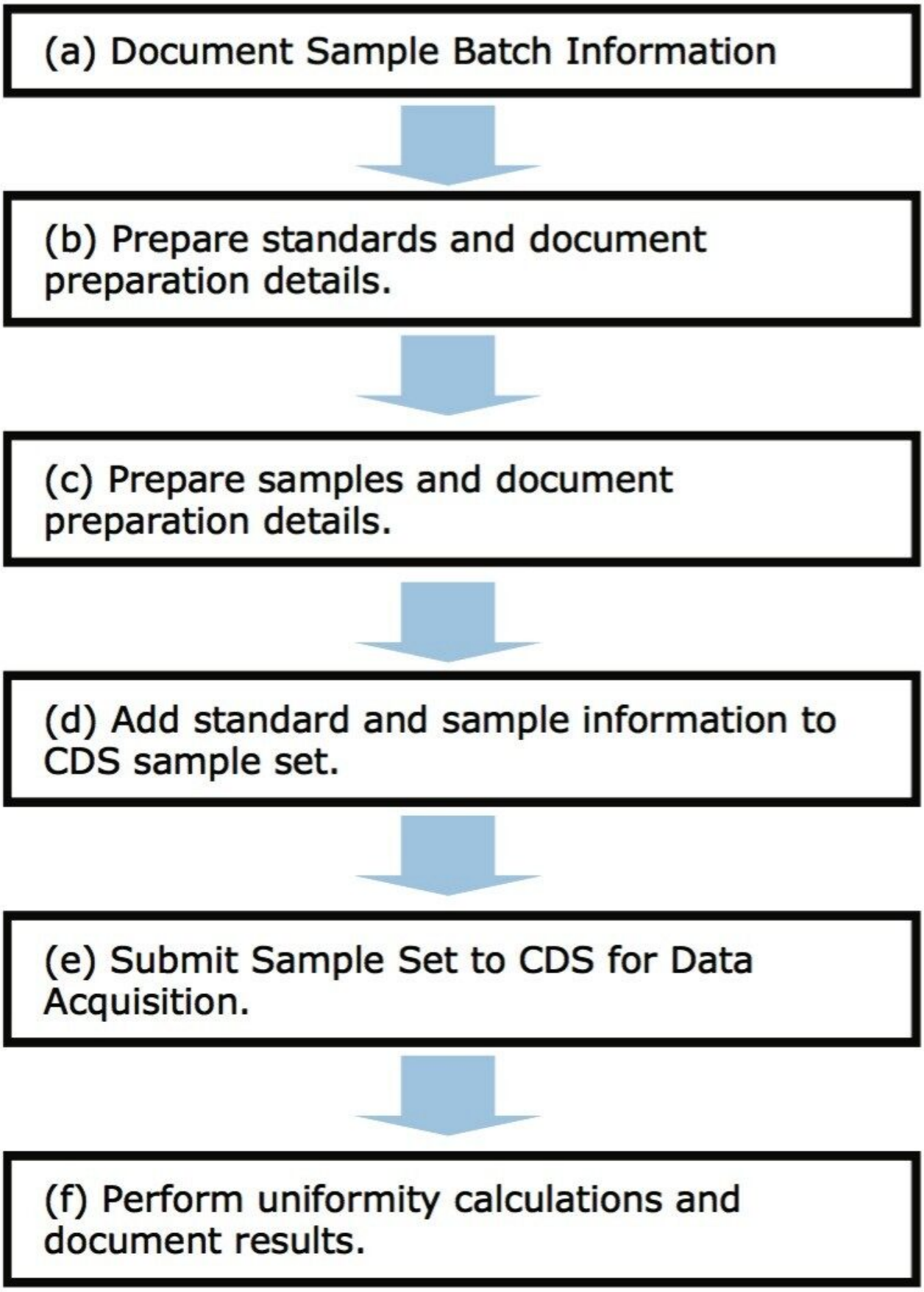

Figure 1. Typical Content Uniformity workflow when using HPLC.

SDMS Vision Publisher serves as a reporting and authoring module incorporated as standard for NuGenesis

2. 2008 USPC, 905: Uniformity of Dosage Units.

3. Ping Du, *et al J Assoc Lab Autom*. 12(3): 157–165, 2007.

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