Charter *(draft v0.2)*

Subject: OASIS DITA Pharmaceutical Content Subcommittee – DRAFT Charter
Date: 21-April-2009
Version: 0.2

(1)(a) Name

Full Name: OASIS DITA Pharmaceutical Content Subcommittee
Short Name: DITA-PC-SC

(1)(a) Prepared By

James Averback – Life Science Integration Partners
Steffen Frederiksen – Content Technologies
Ole Andersen – Content Technologies

(1)(b) Purpose

This document is intended to be a charter regarding the creation of the DITA Pharmaceutical Content Subcommittee (DITA-PC-SC). After review, the intent is to finalize a formal charter for the DITA-PC-SC.

(1)(b) Business Problem

Evolution of Product Information

Authorization to market a pharmaceutical product for use in humans requires 3 – 8 years of nonclinical and clinical studies to adequately assess both safety and effectiveness of the product. As a task of each study conducted documentation is created which may range from a simple scientific memo for an early pharmacology study to hundreds of documents for a major phase III clinical study. The study report for some clinical studies may contain thousands of pages including data tabulations, charts and medical images. A dossier submitted to a Regulatory Authority on application to market a new product can easily require 2000 – 3000 authored documents assembled from the thousands of supporting documents that have been created during the product's development over a 5 – 10 year period. The challenge is enormous to manage this continuously growing body of product information expressed over time in thousands of documents. As new studies are conducted and product knowledge evolves, the content of documents from earlier work may become obsolete or less relevant. Hence, the body of documentation is continuously evolving throughout the lifecycle of the product.

In addition to nonclinical and clinical studies, information related to manufacturing processes, formulation design and materials of manufacture and packaging for the pharmaceutical product evolve throughout its lifecycle. Hundreds of additional documents result from the extensive testing and validation of pharmaceutical development activities which are required to ensure the pharmaceutical product's delivery of the active ingredient is both safe and effective.

(1)(c) Scope

The OASIS DITA Pharmaceutical Content Subcommittee (DITA-PC-SC) will define DITA topics, maps, associated metadata properties and terminology to streamline design and creation of the complete body of pharmaceutical documentation required to present a product for scientific and regulatory purposes throughout its lifecycle. These constructs will include:

- a pharmaceutical content taxonomy of DITA topics,
- the metadata and terminology to be associated with each topic instance
- a taxonomy of DITA maps all of which are defined to optimize reuse and re-purposed content

Initial objectives are to define topics and maps as required to implement:

a) ICH CTD (Common Technical Document) content specification

b) US IND (Investigational New Drug) content specification

c) EU CTA (Clinical Trial Authorization) content specification

d) FDA Structured Product Labeling content specification

e) EU Product Information Management content specifications.

To optimize the value of DITA it is an objective to support these specializations with additional topics and maps for facilitating the business processes of content design, authoring, document review and submission assembly.

The subcommittee will also determine the possible need for pharmaceutical DITA specializations as well as define these specializations and submit them to the main DITA Technical Committee (TC) for consideration.

Specific elements of content which may be considered for analysis are outlined in Appendix 1: Potential List of Areas for Evaluation of Pharmaceutical Specific DITA Constructs

(1)(d) Deliverables

DITA-PC-SC will deliver recommendations for DITA constructs on a periodic basis as they complete a standard process of draft, review, capture of industry feedback and approval for release. The schedule for specific topics will be determined by DITA-PC-SC participants based on availability of resources with adequate domain expertise and capacity to undertake work on a defined schedule. A 12 month plan of deliverables will be provided with updates at 6 month intervals.

Deliverables from this SC will include:

- A set of best-practice recommendations on how to implement the DITA standard content architecture in each pharmaceutical domain
- DITA constructs to include:
    - A series of map, topic, and metadata templates along with a systematic taxonomy of pharmaceutical content
    - A submission of draft specifications of required pharmaceutical DITA specializations to the main DITA TC

DITA constructs provided will be organized into a standard package format to include:

a) Statement of business need
b) Content scope addressed
c) Process scope addressed
d) Concept in operation – how the DITA constructs are envisioned to be used
e) Glossary of terms
f) DITA construct specification provided

    For each DITA construct, a specification in standard format describing the construct at a high level and each element of the construct at a level adequate to enable implementation.

g) DITA construct implementation information provided

    For each DITA construct, if an implementation has been completed a description will be provided with contact information should a viewer wish to gain access to the implementation.

(1)(e) IPR Mode

(to be determined)

(1)(f) Audience

DITA-PC-SC will be of interest to the following constituencies in the pharmaceutical industry:

a) Scientists and laboratory personnel responsible for design and conduct of nonclinical studies in pharmacology, pharmacokinetics, pharmacodynamics and toxicology.
b) Physicians and clinical study scientists responsible for design of clinical studies and documenting these designs in the form of a study protocol, data management plan, statistical analysis plan, monitoring plan or a clinical supply plan
c) Personnel responsible for writing nonclinical study reports
d) Personnel responsible for medical writing clinical study reports including medical writers
e) Personnel responsible for program and project management and for providing status and decision support information required throughout the conduct of a product's lifecycle.
f) Personnel responsible design and assembly of a product dossier suitable for regulatory submission for both pre-market and post-marketed products
g) Personnel responsible for providing product safety information to meet post-marketed regulatory obligations for periodic safety reporting
h) Personnel responsible for providing post-marketed manufacturing information including changes being effected and any other major changes in the manufacturing process
i) Personnel responsible for development of product labeling including the company core data sheet and target product label profile
j) Personnel responsible for DITA technology implementation

(1)(g) Language

DITA-PC-SC shall conduct all discussions and provide documentation in English.

(2a) Non-normative Information - Other Relevant Work

Other Work Relevant to DITA-PC-SC

Document and Records Management SIAC of the Drug Information Association

A group is working to establish a reference model for pharmaceutical content under the auspices of the Document and Records Management SIAC of the Drug Information Association. The EDM Reference Model working group is complementary to the proposed DITA-PC-SC as it defines content, metadata and terminology while DITA-PC-SC works to define DITA constructs such as specializations and DITA maps.

It is anticipated DITA-PC-SC will work collaboratively with the DIA EDM Reference Model working group (DIA-EDM-RM) to include:

a) DITA-PC-SC to request DIA-EDM-RM assessment of proposed DITA constructs

b) DITA-PC-SC to request DIA-EDM-RM participation in joint session to assess business need, requirements and approach for DITA construct definition in specific business processes related to but not limited by:

- optimized granularity of topic based content for nonclinical information
- optimized granularity of topic based content for clinical information
- optimized granularity of topic based content for chemistry, manufacturing and control information

Medical Writing SIAC of the Drug Information Association

The Medical Writing SIAC is working to establish best practices in medical writing under the auspices of Drug Information Association. The Medical Writing SIAC is complementary to the proposed DITA-PC-SC as it defines authoring practices and style of writing for medical writers in the pharmaceutical industry. DITA-PC-SC will work with the Medical Writing SIAC to design DITA maps and relationships applying standards for medical writing style and automation to cross-reference implementation in written materials.

h) DITA-PC-SC to request Medical Writing SIAC participation in joint session to assess business need, requirements and approach for DITA construct definition in specific business processes related to but not limited by:

- optimized granularity of topic based content for nonclinical information
- optimized granularity of topic based content for clinical information
- optimized granularity of topic based content for chemistry, manufacturing and control information
- standard cross-reference implementation for nonclinical information
- standard cross-reference implementation for clinical information
- standard cross-reference implementation for chemistry, manufacturing and control information

HL7 Regulated Product Submission Technical Group

(to be provided)

Structured Product Labeling

(to be provided)

Product Information Management

(to be provided)

(2b) Initial Meetings

Initial meeting of a core planning group is scheduled for May 2009

A kickoff meeting for general participants is scheduled for June 2009

Meetings will generally be conducted via conference call with presentations being distributed in advance. A telephone bridge for the meeting will be provided by (meeting sponsor – to be determined)

(2c) Meeting Schedule

At least one face to face meeting will be conducted on an annual basis. Sponsorship for the annual meeting will be sought from supporting contributors.

Periodic meetings via conference call with all participants invited will be once every 4 weeks. These meetings will require a conference bridge (sponsor to be determined)

(2d) Participant List

A core group of participants will be assembled from the following list

TBD

Additional participating members will be engaged as the plan for topics is defined and will be based on domain expertise

(2e) Convener and Technical Committee Roles

The DITA-PC-SC convener will be Steffen Frederiksen, Content Technologies.

Roles in the DITA-PC-SC are:

- TBD

Meeting minutes will be taken by volunteers on a rotating basis for the full TC and the topic or process based subcommittees.

(2f) Member Section

(2)(f) The name of the Member Section with which the SC intends to affiliate, if any.

(to be determined)

(2g) Contributions of Existing Work

(2)(g) Optionally, a list of contributions of existing technical work that the proposers anticipate will be made to this TC.

- The EDM Reference Model published by the EDM Reference Model working group of the Document and Records Management SIAC of the Drug Information Association.

(2h) Frequently Asked Questions

(2)(h) Optionally, a draft Frequently Asked Questions (FAQ) document regarding the planned scope of the TC, for posting on the TC's website.

(2i) Working Title and Acronym Convention for Specifications

(2)(i) Optionally, a proposed working title and acronym for the specification(s) to be developed by the TC.

Appendix 1: Potential List of Areas for Evaluation of Pharmaceutical Specific DITA Constructs

Process Platform: Clinical Studies

- Structural elements of clinical study design including those addressing:
    - inclusion/exclusion criteria
    - subject/patient population and demographics including screening
    - study scientific design and controls
    - study regulatory design
    - study regulatory design for consideration of ethics including statements required by external and internal ethics review bodies and patient consent
    - study drug formulation including dosage strength, dosage form and investigational labeling
    - study drug supply plan and distribution procedures including regulatory waivers required for distribution of investigational medicinal products
    - study risk management approach, methods and safety review bodies
    - study site monitoring standards and procedures
    - study data management methods and procedures
    - study data analysis methods and procedures for efficacy
    - study data analysis methods and procedures for safety

NOTE: Suggested below are considerations for both regulatory and scientific reviewers. The differences are intended only to be with respect to format, degree of detail and specific content requirements which may differ for a sponsor company as opposed to a Regulatory Authority.

- Structural elements of clinical study reporting
    - tabular data presentations for line listings of safety information
    - tabular data presentations for line listings of efficacy information
    - tabular data presentations for summarized safety information
    - tabular data presentations for summarized efficacy information
    - graphical data presentations for safety information
    - graphical data presentations for efficacy information
    - content for a simple scientific study synopsis element
    - content for a complex scientific study synopsis element
    - content for a simple regulatory study synopsis element
    - content for a complex regulatory study synopsis element
    - content for a study statement of ethics general and special considerations
    - content for a study statement of patient consent general and special considerations
    - content for a study statement of introduction for regulatory reviewers
    - content for a study statement of introduction for scientific reviewers
    - content for a study statement of objectives for regulatory reviewers
    - content for a study statement of objectives for scientific reviewers
    - content for a study statement of investigational plan overview for regulatory reviewers
    - content for a study statement of investigational plan overview for scientific reviewers
    - content for a study statement of investigational plan time and events schedule for regulatory reviewers
    - content for a study statement of investigational plan time and events schedule for scientific reviewers

- content for a study statement of investigational plan subject/patient screening for regulatory reviewers
- content for a study statement of investigational plan subject/patient screening for scientific reviewers
- content for a study statement of investigational plan dosing regimen for regulatory reviewers
- content for a study statement of investigational plan dosing regimen for scientific reviewers
- content for a study statement of investigational plan subject/patient pre-treatment for regulatory reviewers
- content for a study statement of investigational plan subject/patient pre-treatment for scientific reviewers
- content for a study statement of investigational plan subject/patient post-treatment for regulatory reviewers
- content for a study statement of investigational plan subject/patient post-treatment for scientific reviewers
- content for a study statement of disposition of subject/patient population for regulatory reviewers
- content for a study statement of reason for discontinuation of subject/patient population for regulatory reviewers
- content for a study statement of reason for exclusion of subject/patient data for regulatory reviewers
- content for a study statement of subject/patient demographics for regulatory reviewers
- content for a study statement of measurements of subject/patient treatment compliance for regulatory reviewers
- content for a study statement of efficacy results for the primary endpoint for regulatory reviewers
- content for a study statement of efficacy results for the primary endpoint for scientific reviewers
- content for a study statement of efficacy results for the secondary endpoint(s) for regulatory reviewers
- content for a study statement of efficacy results for the secondary endpoint(s) for scientific reviewers
- content for a study statement of overview of safety results for regulatory reviewers
- content for a study statement of overview of safety results for scientific reviewers
- content for a study statement of safety results for adverse events related to study drug for regulatory reviewers
- content for a study statement of safety results for adverse events related to study drug for scientific reviewers
- content for a study statement of safety results for adverse events leading to discontinuation for regulatory reviewers
- content for a study statement of safety results for adverse events leading to discontinuation for scientific reviewers
- content for a study statement of safety results for adverse events leading to death for regulatory reviewers
- content for a study statement of safety results for adverse events leading to death for scientific reviewers
- content for a study statement of discussion of data findings for regulatory reviewers
- content for a study statement of discussion of data findings for scientific reviewers

- content for a study statement of conclusions from data for regulatory reviewers
- content for a study statement of conclusions from data for scientific reviewers

Process Platform: Preclinical Studies

- Structural elements of nonclinical study design including those addressing:
  - assay design including reporting of validation studies
  - study scientific design and controls
  - study regulatory design including that required for compliance with Good Laboratory Practice
  - study regulatory design for consideration of ethics in using animal models for testing
  - study drug formulation including dosage strength and dosage form
  - study media reference standards
  - study data management methods and procedures
  - study data analysis methods and procedures for efficacy
  - study data analysis methods and procedures for toxicity
  - study data analysis methods and procedures for pharmacokinetics
  - study data analysis methods and procedures for pharmacodynamics

- Structural elements of nonclinical study reporting
  - tabular data presentations for pharmacokinetics information
  - tabular data presentations for pharmacodynamics information
  - tabular data presentations for toxicology information
  - tabular data presentations for summarized safety information
  - tabular data presentations for summarized efficacy information
  - tabular data presentations for submission presentations
  - content for a study statement of study drug formulation including dosage strength and dosage form
  - content for a study statement of animal care
  - content for a study statement of animal model group composition
  - content for a study statement of animal dosing rationale
  - content for a study statement of experimental procedure
  - content for a study statement of analysis procedure
  - content for a study statement of discussion of data findings for regulatory reviewers
  - content for a study statement of discussion of data findings for scientific reviewers

Process Platform: Chemistry, Manufacturing and Controls Information

- (to be provided)

Process Platform: Medical Communications and Education

- (to be provided)