

Introduction

Since its inception in March 2004, **LSCP** has grown significantly and established itself as a recognized leader in the biopharmaceutical market. We are a global, professional network of 64 SMEs with recognized expertise in our respective domains. We work together in the fields shown below, following a set of Guiding Principles and a common methodology, with a primary focus on maximizing the value of information, especially when it is related to regulated content. As global standards are deployed across functions, departments and systems but also beyond the corporate boundaries in the case of alliances, out-sourcing and off-shoring, it is vital that teams of professionals possess strong domain knowledge and use the latest standards. At the same time team members need to develop a holistic view, be able to break the “silo” or “not invented-here” mentality and keep sight of the big picture challenges. This is precisely what **LSCP** is able to offer through our combined knowledge and team work.

Vision & Strategy

for

Structured Content Authoring (SCA) & Enterprise Information Management (EIM)

The following list shows the **LSCP** domains of expertise with the leads and associated SMEs from our network for each domain. We all work according to a shared and proven methodology, follow a global approach and are able to carry out projects from Proof-of-Concept (PoC) to Full Deployment based on solid and measurable milestone deliverables. However, where required, our involvement can be limited to a single step of a project. Additionally, we offer professional global services on **eCTD** and it's forthcoming new **version 4** (e.g. granularity)!

Multi-functional and cross-geography engagements are coordinated by a dedicated **LSCP** Management Team Member or an Associate Partner to best respond to customer needs.

Hitoshi Matsui, member of our Management Team, assumes the lead in all disciplines in **Japan/Asia-Pacific**, supported by the appropriate domain expert(s) as listed below.

Please note that this information contains the status as of August 2012. Confirmation and more information, e.g. CVs of the individuals listed below may be obtained through info@lsconsultingpartners.com

Domain	Lead	Contributor(s)	Domain Description
Vision & Strategy (V&S)	Ruedi F. Blattmann	Don Rosen Beat Widler Andrew Marr	<i>Defining the "Future State"</i> Developing or confirmation of the enterprise Vision related to Information Management; Elaborating options; Identification and execution of Strategic Work Streams for step-by-step implementation. The method is focused on pragmatic approaches, always with the holistic view in mind
Corporate Information Governance (CIG)	Don Rosen	Ruedi F. Blattmann Matthias Nanzer	<i>A pragmatic approach needed:</i> A Work Stream based on the V&S process dealing with all types of Information (email, data, documents etc.) from creation, to archiving including owners, collaboration rules, metadata, taxonomy, security and mobility
Enterprise Information Architecture (EIA)	Don Rosen	Matthias Nanzer Curtis Newkirk	<i>Contributing to make V&S happen:</i> EIA organizes how you search, create, access, use (apply) and re-use Information, inside the enterprise and outside
Enterprise Information Modeling (ECMo)	Don Rosen	Curtis Newkirk	<i>Understanding the dynamics and dependencies of information:</i> Enterprise content (Information) analysis and modeling enables the organization of documents components and other types of information in dedicated repositories for optimal utilization
Enterprise Process Modeling (EPM)	Paul Willer	Don Rosen Curtis Newkirk	<i>New cross-function process owners define outcome:</i> Controlling the information flow within business processes. Breaking down silos and achieving the full range of cross-functional (holistic) scope with a true organizational impact
Structured Content Authoring (SCA)	Joe Jenkins	Malcolm Barrett-Johnson Anne Sexton Cynthia Davenport Curtis Newkirk	<i>The basics to reach agility:</i> SCA experienced many attempts with limited success in the recent past. The latest technology improvements have enabled greater adoption and opportunities along the entire product lifecycle. Document vs. Information-centric approaches combined with semantic information models, are yielding greater content re-use, increased content flexibility and accurate, context-driven search results
Intelligent Content Design (ICD)	Jim Averback (ICD Service lead)	Sidney Kahn Andrew Marr	<i>Method to understand structuring:</i> Effective XML Authoring (within any system) needs to start with the proven methodology of ICD: Only with such an engagement users can become aware of the benefits of content re-use (granularity, regulatory communication perspective).

Domain	Lead	Contributor(s)	Domain Description
Label based Development (LbD)	Don Rosen	Beat Widler	<i>Effective through SCA:</i> Basing decision making in drug development on a transparent and robust methodology that measures and compares study progress and knowledge gain from clinical trials with the desired product's target profile, "claim(s)" We help you monitor trial success
Quality by Design (QbD)	Beat Widler	Malcolm Barrett-Johnson Andrew Marr	<i>Getting consistent Quality results:</i> We are the experts in Clinical & pharmacovigilance (PV) processes, Quality Risk Management, Quality by Design and related GCP process and issue management
Risk and Mitigation Management (RMM)	Beat Widler	Ruedi F. Blattmann Andrew Marr Jim McKiernan Sidney Kahn	<i>Identifying, managing and mitigating risks:</i> RMM is a prerequisite for continuous business success in any GxP domain by minimizing compliance risks. In addition, any transition plan needs to identify the risks of change and their likelihood, detectability and severity, in order to implement a timely monitoring and mitigation strategy
Change Management (CM)	Kathy Hagen	Ruedi F. Blattmann Matthias Nanzer Jim McKiernan Steve Gens	<i>A proactive strategy:</i> Introducing and managing culture change must be an integral part of any major program to introduce new business practices, processes and systems. Ownership and buy-in to the new processes is essential to success. People are the key to ensuring that technology delivers its promises and our approach to Change Management ensures the human and cultural aspects are properly addressed
Knowledge Management (KM) & Knowledge Retention	Kathy Hagen	Ruedi F. Blattmann Matthias Nanzer Paul Willer	<i>Re-using valuable Knowledge</i> Organizations have the tools to access and re-use the data and information they have amassed. We offer proactive strategies to harness and integrate the information held in the organization and processes to retain and re-use the experiential knowledge (retention) held by employees for better decision making, effective use of talent and competitive advantage
Regulatory Strategy & Communication (RSC)	Andrew Marr	Ruedi F. Blattmann Beat Widler Deanna Murden (CMC)	<i>Changing markets – higher communication agility:</i> This domain covers the following topics: <ul style="list-style-type: none"> - E-Regulatory Affairs; e.g. Scientific Advice & Strategy for eCTD NMV (4) - Regulatory Operations, including multiple labeling - Eudravigilance and IDMP to ISO Drug Substance Code - CMC harmonization and agility for re-use

Domain	Lead	Contributor(s)	Domain Description
			- Internal standards development
Information & Communication Technology (ICT)	Matthias Nanzer	Curtis Newkirk Joe Jenkins	<i>ICT supporting business value creation:</i> Establishing cost effective, secure, and reliable information & communication infrastructure supporting the business objectives by following aligned transition plans
eHealth & ePatient Dossier (EHR & ePD)	Ruedi F. Blattmann	Matthias Nanzer Beat Widler Curtis Newkirk	<i>Transparent communication & actionable Information:</i> Electronic Health Records (EHR) and Electronic Patient Dossier (ePD):: Reaching transparent, interoperable exchange of information between multiple stakeholders such as Patients, Health Care Providers, Industry and Health Authorities to ensure that different requirements and needs can be addressed without duplication of efforts or by collecting the same information multiple times
Total Cost of Ownership (TCO, Economic Models)	Steve Gens	Matthias Nanzer	<i>Cost/benefit driven model:</i> Considering the level of integration and interoperability (Alliances, Partners, eHealth Stakeholders and Regulators) will factor a lower TCO – the ultimate goal of a cost control approach