

EDG Expertise & SME Service Leads

Introduction to the Objectives:

Making Quality Data/Information Actionable while remaining compliant – inside & outside

Since its inception in March 2003, **LSCP** has grown significantly and established itself as a recognized leader in the biopharmaceutical market. We are a global, professional network of currently 65 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 will be deployed across functions, departments and systems but also beyond the corporate boundaries, e.g. in the case of alliances, out-sourcing and off-shoring, it is vital that teams of professionals possess strong domain knowledge and on the latest to be applied. Standards driven transparency and operability will allow quality information to flow to patients and back to research – **e- & Digital Health** will become reality, as well as **Real World Data** (RWD) & Real World Evidence (RWE)!

At the same time, team members need to develop a **holistic view** be able to break down the “silo” or the “not invented-here” mentality and keep sight of the big picture opportunities and challenges. This is precisely what **LSCP** is able to offer through our combined knowledge and teamwork. According to the customer objectives, the best available teams will be composed for rapid knowledge sharing and transfer!

Who we are and what we do

The list below shows the **LSCP** domains of expertise, with content, including applied **ISO IDMP / SPL / ICSR** (herein referred to as IDMP+) in multiple communication targets: **Web interaction/transaction & real-time evidence/archiving** in top demand, part of Enterprise Data Governance (**EDG**), with the lead and associated SMEs from our network for each domain. We all work according to a proven and shared methodology, follow a global approach and are able to carry out projects from Proof-of-Value (PoV) to Pilot with accompanying full deployment and solid, measurable milestone deliverables. However, where required, our involvement can be limited to a single step of a project.

With increasing flow of multiple type of information there is remarkable progress in applying **Advanced Semantic Technologies** (ST) to effective “find-in-context” processes effectively, e.g. In Structured Content Authoring (SCA), semantically enriched: Increased precision to enable real Knowledge Management (KM). Quality/Risk Management (RMP) & QMS DIA Reference Model based. **Change Management** (CM+ Communication) is going to be vital: **LSCP** is well positioned to assist. A strategic methodology for **Market Access** to get advanced products to patients is a complementary domain of expertise! All multi-functional, 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):

Please note that this information contains status as of early September 2020. Confirmation and more information, e.g. CVs of the individuals listed below may be obtained through info@lsconsultingpartners.com and have a look at “Our Current Thinking” on our Website. Thanks.

EDG Expertise & SME Service Leads

Vision & Strategy V&S) Management

(*Prof. Dr. Peter Aiken, Strategic Partner since 2016)

Domain	Lead	Contributor(s)	Domain Description
Vision & Strategy (V&S)	Ruedi F. Blattmann	Peter Aiken* Beat Widler Althea Davis Peter Schiemann Thomas Schuetz	<i>Defining the "Future State" for the current to the future Corporate Business Model</i> We help you review or develop the enterprise Vision related to Information Management, elaborate options, identify and execute Strategic Work Streams for step-by-step implementation. Our method is focused on a pragmatic approach and always with the holistic view in mind, all IDMP+ & EDG/PV & RWD/RWE driven
Benchmarking Total Cost of Ownership (TCO, Economic Models)	Rolf Porsche	James Averback Matthias Nanzer Thomas Schuetz Althea Davis Jerry Quinn	<i>A cost/benefit driven model for information systems</i> Today, companies spend considerable amounts for the creation and maintenance of information systems. 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.
Web Content Interaction / Transaction Archiving	Ruedi F. Blattmann	Beat Widler Jim Cook Steve Gardener Jerry Quinn	<i>Compliance calls for control of Product and related Data/Information interaction/transaction > Format Free Initiative (FFI) > global novel approach</i> More and more Data/Information (any type!) is crossing your boarder, on the web and social media > Social Media Records Management becomes a topic

The Business & Information Management Systems

Domain	Lead	Contributor(s)	Domain Description
Enterprise Data Governance (EDG) + Digital Transformation	Ruedi F. Blattmann / Peter Aiken	Paula Petrone Beat Widler Peter Schiemann Althea Davis Gabriella Skala	<i>Pragmatic approach</i> *Partnering with Peter Aiken (www Position Paper: learn more) EDG and the V&S process, review of Corporate Business Model(s), this overarching activity is dealing with all types of Information creation (email etc.) to archiving, including owners, collaboration rules, SCM, metadata, taxonomy, ontology, security, mobility; AI & ML; Communication & Social Media
Enterprise Data/Information Architecture (EIA) in EDG	Peter Aiken Matthias Nanzer	Ruedi F. Blattmann Peter Schiemann Althea Davis Thomas Schuetz	<i>A major contribution to Vision & Strategy</i> EIA organizes how you create, structure, search (in context), access, use (apply) and re-use Data/Information, inside the enterprise and outside The approach includes a focus on ePRO & AI

EDG Expertise & SME Service Leads

Domain	Lead	Contributor(s)	Domain Description
conjunction			
Information & Communication Technology (ICT)	Matthias Nanzer	Jim Cook Joe Jenkins Steve Gardener Gabriella Skala	<i>ICT supporting/enabling business value creation</i> Establishing cost effective, secure, and reliable information & communication infrastructure supporting the business objectives by following aligned transition plans

Organizational Development to Change-, Risk- & Knowledge Management

Organizational Development	Peter Schiemann	Beat Widler Paul Willer Josef Leuchtner Althea Davis Gabriella Skala	<i>Global Standardization requires re-thinking</i> Set-up of an organization that allows effective, defined outcome with a transparent flow of information across all functions; controlling risk while changing in the aim: No innovation without quality information!
Change Management (CM) Knowledge Management (KM)	Kathy Hagen	Ruedi F. Blattmann Matthias Nanzer James Averback Gabriella Skala Peter Schiemann	<i>A proactive approach to change</i> Managing cultural change is an integral part of any major program introducing new business practices, e.g. enabled/applied KM, processes or systems. Ownership and buy-in are essential to success. Because people are the key to ensuring that technology delivers its promises, the human and cultural aspects are at the center of our approach to CM and KM. Such activities also lead to re-visiting the business model and organization structure

Regulatory, eHealth, Quality & Market Access

eHealth & ePatient Dossier Digital Health (EHR & ePD)	Ruedi F. Blattmann	Matthias Nanzer Beat Widler Jim Cook Thomas Schuetz Rolf Porsche Josef Leuchtner	<i>Transparent communication & actionable Information</i> We are involved in the development of Electronic Health Records (EHR) and Electronic Patient Dossier (ePD) to help reach transparent, interoperable exchange of information between multiple stakeholders such as Patients, Health Care Providers, Industry & HAs to ensure that different requirements & needs can be addressed without duplication of efforts or by collecting the same information multiple times, respecting privacy rules. Applying semantic technology is critical!
--	---------------------------	---	--

EDG Expertise & SME Service Leads

eHealth Concepts	Jim Cook	Ruedi F. Blattmann Matthias Nanzer Beat Widler	<i>The foundation to reach transparency and agility:</i> Develop Vision & Strategy to include better patient/provider/pay or care through all aspects of e.g. bedside care, mobility, fact (information) based decision making, resulting in quality and cost reductions
Quality by Design (QbD) & Quality System design/ QMS	Beat Widler	Peter Schiemann Malcolm Barrett-Johnson Steve Gardener Jerry Quinn	<i>Getting consistent Quality</i> We are globally recognized experts in Clinical & Pharmacovigilance (PV) processes, Quality Risk Management, Quality by Design and related GCP process and issue management QMS & DIA Reference Model <i>Effectiveness and Efficiency</i> Agility in creating content for e.g. SOPs, management and change implementation
Risk Management Plan (RMP)	Peter Schiemann	Beat Widler Ruedi F. Blattmann Jorge Wernli	<i>Patient Safety – plus</i> In this changing world risk identification, management and mitigation is an Enterprise Management task, not limited to CT or PV only. We have a proven methodology to assist in this important, regulatory process
Market Access	Jorge Wernli	Beat Widler Gabiella Skala Ruedi F. Blattmann	Supporting pharmaceutical companies, healthcare providers, payers, governments towards win-win solutions to improve patient outcomes and contribute to efficiency improvements of HC systems. Key dimensions are the build-up, maintenance of access, technical market access capabilities, evidence-based negotiation, quality and reputation building

Process Re-design & Optimization

Enterprise Process Modeling (EPM)	Paul Willer	Peter Schiemann Curtis Newkirk Steven Gardener	<i>We help process owners to define the outcome</i> This Work Stream focuses on 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
EDG AI/ML & Analytics Decision-making	Peter Aiken Jim Cook	Ruedi F. Blattmann Beat Widler Thomas Schuetz Jorge Wernli	<i>Set-up a lean decision-making structure for speed and efficiency</i> Poor decision-making processes, too many stakeholders or unclear responsibilities can paralyze entire professional teams. We help you organize your Quality data Analytics (AI/ML), decision structure, increase quality of accountability and build a performance-driven organization