

Widler & Schiemann

Your Partner in Custom Quality Management Solutions
&
Strategic Drug Development

Our Global Management Team

Co-Founders and Managing Partners:

[Beat Widler, PhD](#) & [Peter Schiemann, PhD](#)

Managing Directors:

[Henk de Wilde, RPh, Managing Director & Partner, Europe](#)

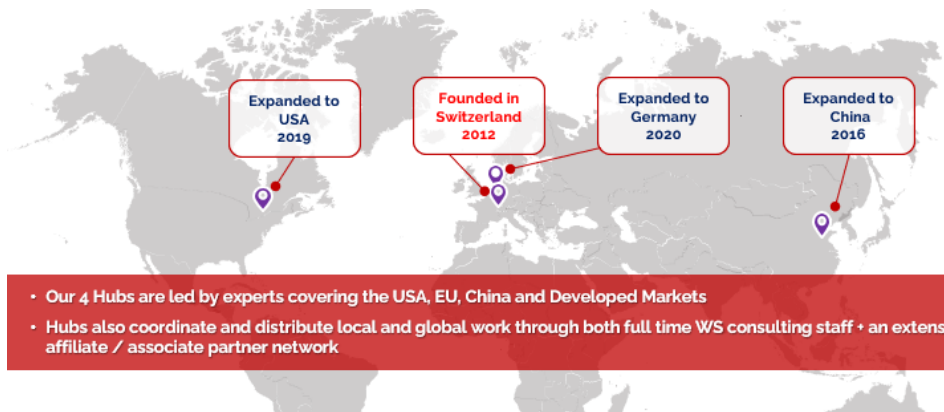
[Estelle Chao, MBA, Managing Director, APAC](#)

[Dr Andreas Fischer, Managing Director, Germany](#)

[Martin E. Zuzulo, Managing Director, Americas](#)

Website: www.wsqms.com

Our Global Reach



Widler & Schiemann At a Glance

Deep Expertise

WS has expanded its expertise and diversity across the entire R&D and post-approval value chain, supporting our clients in all aspects of clinical and pharmaceutical development and commercialization

Significant Value Chain Scope

Significant experience across the full range of life sciences companies (biopharma, pharma, device, consumer, and generics)

Extensive Collaborations

Our extensive track record and advisory role with regulators and organizations (e.g. WHO, OECD, CTTI & ACRES) position us uniquely to support our clients in their projects

Unparalleled Assets & Accelerators

We boast an enviable library of proprietary "assets" (extensive, best of breed SOP library complete with forms, checklists, WI's, templates, etc.),

Drug Development & Other Consultancy Services

Drug Development Consultancy

- Technical Development, IMP Management, Scale-up & Manufacturing
- Strategic Drug Development Consulting
- Regulatory Affairs
- Clinical Operations
- Pharmacovigilance

Organizational Design Consultancy

- Define ➤ Develop ➤ Discover ➤ Deliver

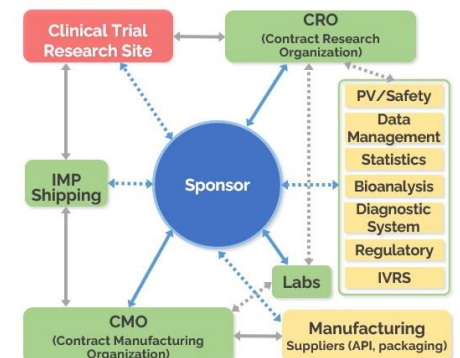
Due Diligence Advisory Services

- Patient Safety & Data Integrity
- Quality & Risk Management
- Product & Process Quality

Quality Management Systems Design

WSQMS can support you with a comprehensive suite of Quality Management services, including:

1. Collaboration Evaluation
2. Gap Analysis & QMS Design
3. SOP Delivery
4. Training Program/Process Improvement
5. Extended SOP Support



Audit/Assessment Scope: Vendor Vendor Sponsor Site

Audit Scope & Process

- **Global coverage:** With our strategic locations and our network of GxP experts and auditors, we can offer audits in all relevant countries
- **Focus areas:** All quality aspects, including GCP, GVP, GMP, GDP, GLP and ISO13485
- **Types of audits:** Vendor and Site qualification audits, Sponsor's internal audits, Vendor and site compliance audits, TMF QC / completeness audit, Clinical Study Report audit, "for cause" audits
- **Approach:** An audit plan will outline the scope of the audit and align expectations from sponsor and auditee. After completion of the audit, a comprehensive audit report will detail all findings and recommendations to improve compliance