

MH Consulting & Advisory Discovery

Company Overview and Insights: Clarity for digital transformation and AI adoption in regulated Life Sciences

Martin
Heitmann



Consulting
& Advisory

Navigate strategic and impactful Data, Digital and AI endeavours in regulated Life Sciences areas with clarity, not noise.



Martin Heitmann

Managing Director

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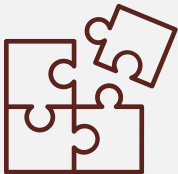
Location

Ernst-August-Platz
Bahnhofstr. 8
30159 Hanover
Germany



Coverage

Services provided globally, including European Union, UK, Switzerland, Canada, USA, APAC & LatAm



Expertise

10+ years of experience in data, digital & AI across industries, trained Business Mathematician, GAMP Guidance contributor¹



Engagements

Project-based consulting (T&M or fixed-price), speaker engagements, fractional advisor, trainer/instructor

MH combines strategy, business, governance, regulatory, and technology expertise to help you move forward in data, digital, and AI with confidence.



¹ Incl. contributions to over 2 dozen peer-reviewed publications with focus on AI Governance in the Life Sciences; examples include the ISPE GAMP Guide: Artificial Intelligence (lead author), various ISPE GAMP Good Practice Guides (core team member & contributor), and many more

Overview of service lines in Data, Digital & AI

Consulting Services, Training & Upskilling, Technology Partnerships



CONSULTING SERVICES

- **Structured path** from readiness through strategy and governance to QMS transformation
- Effectively supporting **business and quality objectives**
- Alignment with **industry practices and regulatory expectations** to achieve regulatory confidence
- **Tailored to the organization:** Stakeholder alignment, clear roles and responsibilities, risk-based life-cycle practices



TRAINING & UPSKILLING

- Flexible training programme spanning various audiences: **practitioner to executive**
- **90-minute briefings to multi-day** programmes: choose the modules matching your interest
- Rooted both in **practical experience and good practice methodology**
- **Aligned with regulatory and industry guidance** (e.g., US FDA CSA guidance, GAMP 5 SE, GAMP Guide: AI)



TECHNOLOGY PARTNERSHIPS

- Identify and **effectively leverage** technology and service providers
- Help ensuring **fit to QMS** and risk posture and establishing adequate oversight
- Enable **faster and sound adoption** of data & digital innovation
- **Focus areas include** data management, data integration and data integrity, digital validation tools, EU AI Act compliance solutions, etc.

Approach to Data, Digital & AI in regulated areas

Understand the full picture – do not operate in isolation

01

Business-driven selection of data, digital & AI initiatives

- Avoid Data, digital and AI initiatives for their own sake
- Consider impact, process understanding, maturity

Enable organisations shaping their own path in data, digital, and AI with confidence

02

Full perspective from strategy to operational reality

- Strategy, Governance, and Quality in tandem
- Effective feedback loops for sustainable success

Help operational teams to work effectively and apply scalable, risk-based approaches

03

GxP thinking from the start - as enabler, not impediment

- Quality by Design to avoid rework
- Align with GxP regulation and leading guidance

Seek an edge in efficient quality and compliance operations through innovative digital ways of working

04

Stakeholder alignment and cross-functional clarity

- Translate across Business / Quality / IT / Data Science
- Reduce friction; enable joint decisions

Facilitate a shared vision and understanding, overcoming scepticism and barriers and achieve effective collaboration

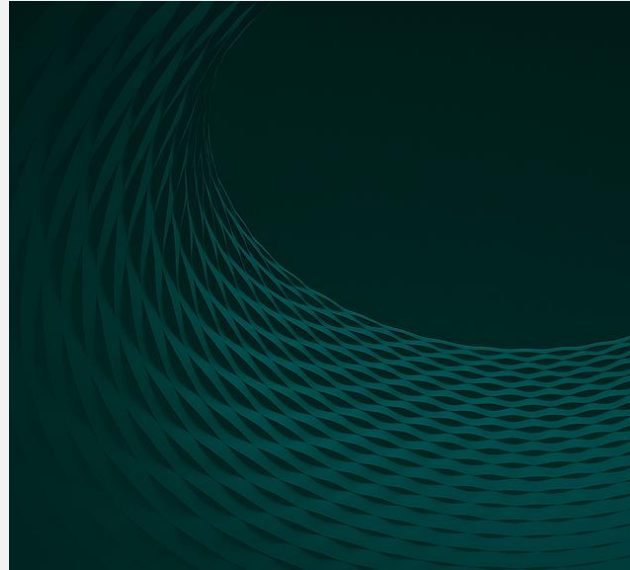
3 core pillars as foundation to trustful and sustainable partnerships

The MH Consulting & Advisory Moral Compass



INTEGRITY

Act in the
client's interests



RELIABILITY

Keep promises;
on time



COLLABORATION

Unite people
behind one goal



Let's stay in touch – feel
free to reach out anytime

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