

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.



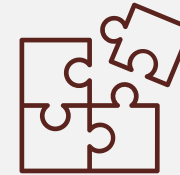
Martin Heitmann

Managing Director
MH Consulting & Advisory GmbH



Homebase

Ernst-August-Platz
Bahnhofstr. 8
30159 Hanover
Germany



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



Network

Cooperating with various partners in the Life Sciences and in regular exchange with health authorities

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



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

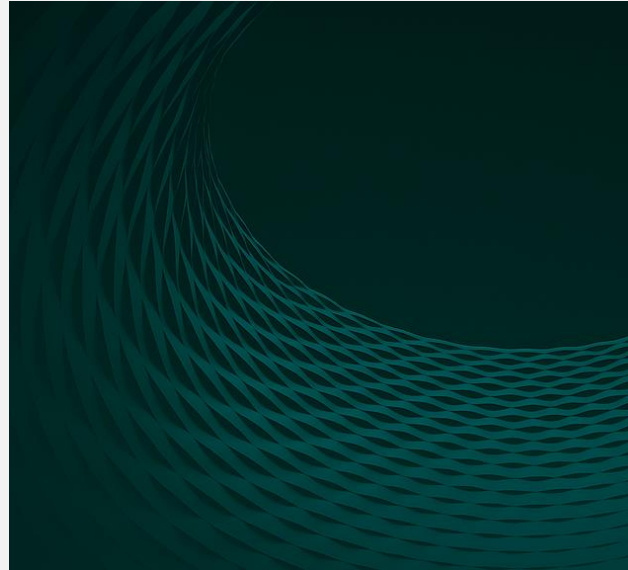
3 core pillars as foundation to trustful and sustainable partnerships

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

Martin Heitmann
Managing Director



Consulting
& Advisory