

Discovery Booklet

AI Foundation Building



Consulting
& Advisory

2026

Navigate Ambitious Data, Digital and AI Endeavours in regulated Life Science Areas with Clarity



Consulting
& Advisory

INFO

MH guides life science organisations and their suppliers in aligning stakeholders, meeting regulatory expectations, and implementing data, digital, and AI initiatives across GxP environments. MH's approach focuses on clear strategy, solid governance, well-defined roles and processes, evidence-based decisions and shared knowledge – so choices stand up to internal and external scrutiny. This results in initiatives that move faster, fit operational and regulatory reality, and deliver impact and business value.



SERVICES

MH provides 3 lines of service:

1. **Consulting Services in Data, Digital and AI:** Readiness Assessments, Strategy and Governance Implementation, Quality System Transformation, Platform Architecture Design, Vendor Assessment Support
2. **Upskilling, AI Literacy Building & Training**
3. **Technology and Solution Partnerships Services**



WHY MH

MH's approach integrates the full view from strategy to operational reality, driven by business needs while understanding quality as innovation enabler.

Applying expertise recognized world-wide, MH's work is based on 3 pillars:

- ✓ **Integrity:** Act in service of clients' interests
- ✓ **Reliability:** Keep promises made; on time
- ✓ **Collaboration:** Unite people to achieve 1 joint goal

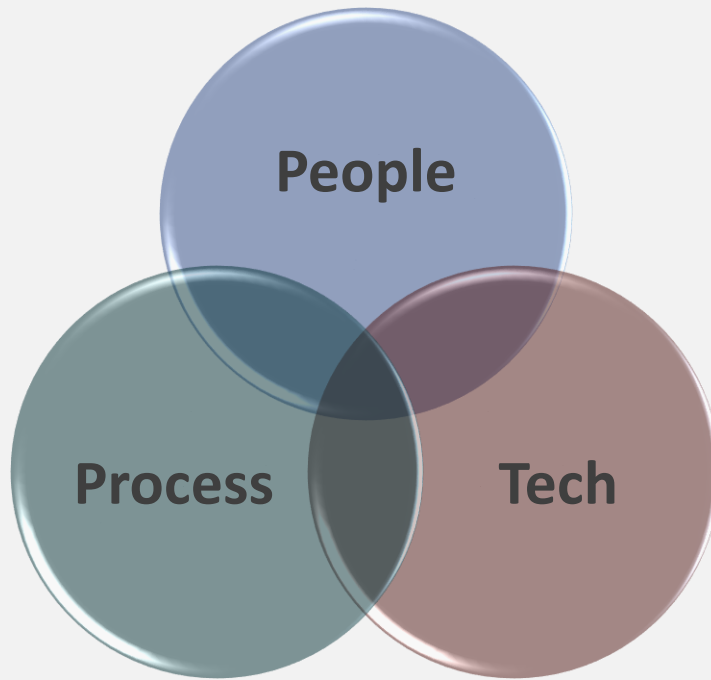


Martin Heitmann

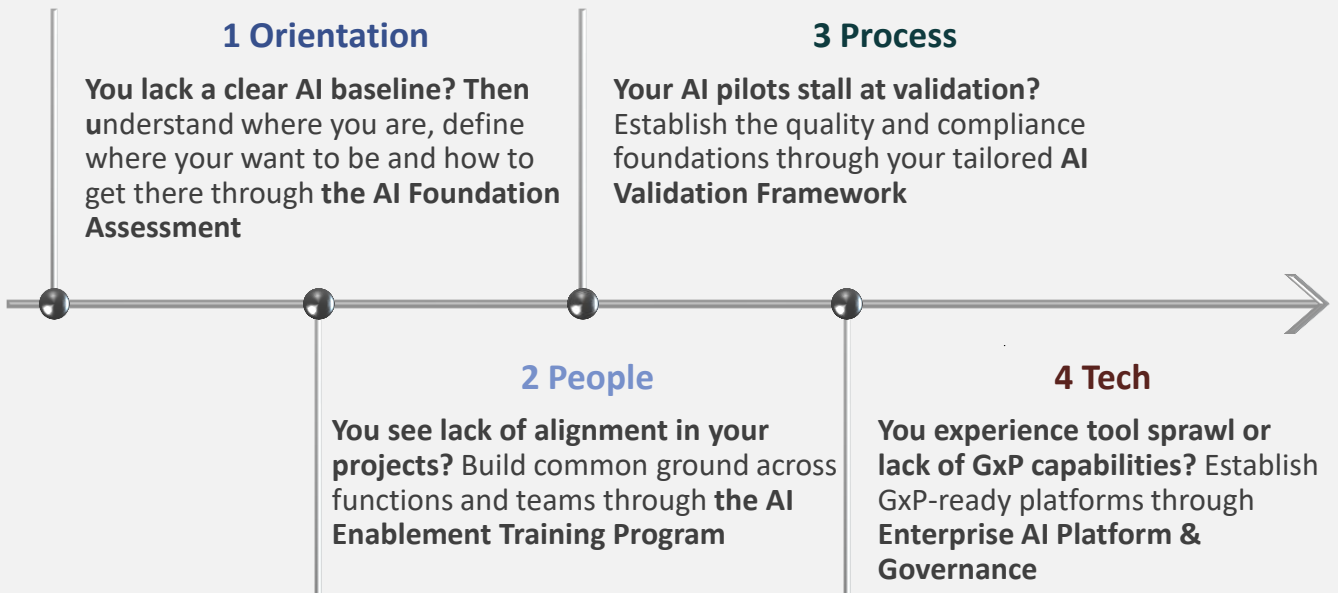
Managing Director of
MH Consulting & Advisory GmbH

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A GxP aware strategy integrates 3 foundational pillars



MH supports you, wherever you are on your journey.
Where should you start?



Not sure where to start? Then the AI Executive Alignment Sprint is just the right option for you.

AI Executive Alignment Sprint



Establishing decision-ready clarity for AI adoption under real GxP constraints

Who is this for?



- Organizations in regulated environments seeking to structure their AI starting point
- Leadership teams across Business, Quality, IT, and Data/AI
- Organizations experiencing fragmentation, despite ongoing initiatives

Why This Matters



- AI strategies often lack clarity on how to structure the starting point
- Fragmented discussions across functions slow down decision-making
- Early initiatives without alignment lead to duplication, delays, or rework

Approach



A structured executive process to reveal constraints and enable decision-ready AI adoption under real GxP conditions. The sprint uses a use case-based stress testing approach to expose dependencies, risks, and gaps before they impact implementation.

How It Works



- Discovery and preparation
- Structured mapping of initiatives
- Use case-based stress testing under GxP conditions
- Structured identification of gaps
- Alignment on 3–5 priority areas

Deliverables



- Structured view of initiatives
- Identified tensions and structural gaps
- Clear prioritization of 3–5 focus areas
- Concise executive summary report

A decision-ready basis for progressing on your AI enablement & adoption journey

Engagement Model



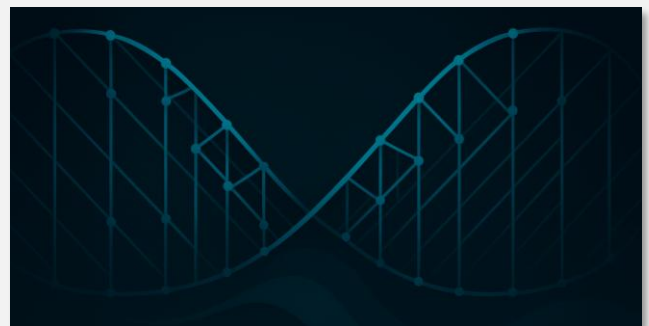
- Duration: 2 days
- Format: on-site or virtual
- Participants: Leadership and selected key stakeholders

Fixed-price – starting at 7,500 EUR

Why MH?



- Deep experience aligning stakeholders in regulated Life Sciences environments
- Recognized expertise in AI governance and GxP-relevant frameworks
- Proven ability to translate between Business, Quality, IT, and Data/AI



The sprint focuses on making execution constraints visible before they lead to delay, rework, or failure.

AI Foundations Assessment

Ensuring compliance-ready foundations for scalable, high-impact AI adoption



Who is this for?



- Organizations in the regulated Life Sciences ecosystem seeking clarity for safe and scalable AI adoption
- Target audiences incl. senior leadership, quality & compliance representatives, IT/platform owners, and use case owners

Why This Matters



- Fragmented efforts across functions and units slow down enterprise adoption
- Uncertainty whether GxP-relevant AI use cases are sufficiently covered
- Different levels of maturity create barriers for enterprise-wide scaling

Approach



Holistic, structured assessment grounded in proven industry good practices to achieve a 360° view: (1) Strategy, (2) Business, (3) Governance, (4) Quality Management & Processes, (5) People & Culture, (6) Technology & Capabilities, (7) Data

How It Works



- Kickoff: Scope, stakeholders, priorities
- Information gathering: Interviews and document review
- Benchmarking & Gap Identification
- Executive Report-Out: Summaries, risks, and next steps

Deliverables



- Current state across all seven domains
- Strengths and improvement areas
- Risks, dependencies, and alignment opportunities
- Prioritized recommendations and roadmap for implementation

Engagement Model



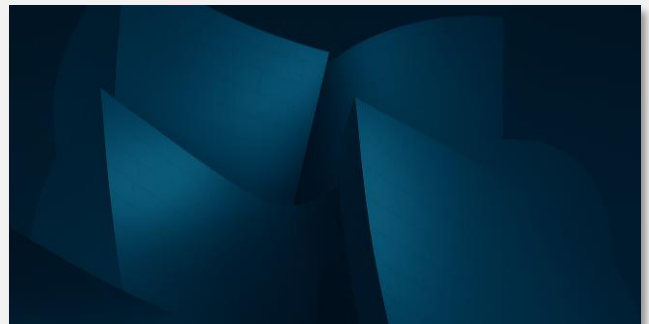
- Typical duration: 2–8 weeks
- Tailoring of timeframe according to complexity, scope, depth and availability of stakeholders

Fixed-price – clear goal, clear delivery

Why MH?



- Cross-sector perspective bridging enterprise needs with GxP requirements
- Translation among all stakeholders: Management, Business, Quality, IT
- Successfully delivered assessments for global Life Science organizations



The AI Foundation Assessment helps you navigate on your AI adoption journey.

AI Enablement Training Program



Building shared understanding, alignment,
and AI-ready capabilities across all functions

Who is this for?



- Pharmaceutical companies
- Medical device manufacturers
- Service providers focusing on Life Sciences
- Technology and platform partners

Designed to build common ground across
Business, Quality, IT, Data and AI teams

Why This Matters



- Stakeholders often “don’t know what they don’t know”, provoking fragmentation
- Varying levels of understanding across functions slow down AI progress
- Shared understanding helps aligning decisions, governance & implementation

Approach



A flexible, modular training program offering a structured overview of AI in Life Sciences, covering (1) AI Fundamentals, (2) Strategy & Governance, (3) Life Cycles and Quality, (4) Technology & Operations, (5) Regulatory Insights, (6) Deep-Dive Topics & Case Studies

How It Works



- Scoping & alignment
- Selection of modules based on core syllabus + extensions (*custom on request*)
- Instructor-led delivery
- Certificates processing
- Wrap-up & debriefing

Deliverables



- Shared vocabulary and unified understanding across functions
- Actionable perspectives enabling meaningful discussions and next steps
- Presentation materials & recordings
- Customized and named certificates

Engagement Model



- Instructor-led training (virtual or on-site)
- Duration tailored to audience needs (90-minute executive briefs to multi-day)
- Optional case study elements

Pricing based on hours and # of participants

Why MH?



- Shaped AI governance in Life Sciences, incl. authorship of leading GxP AI guidance
- Alignment with regulatory and industry publications (FDA, EMA, GAMP, EU AI Act)
- Practical experience delivering AI training for global Life Sciences organizations



The AI Enablement Training Program creates the
fertile ground for effective collaboration in AI.

AI Validation Strategy Framework



Allowing your AI pilots to fly — not fail when hitting the validation brick wall

Who is this for?



- Organizations in regulated or business-critical Life Sciences environments seeking to develop, deploy or scale AI capabilities
- Quality leads aiming for scalable procedural foundations so that AI use cases achieve and keep a validated state

Why This Matters



- Many AI pilots stall when approaching validation (“the validation brick wall”)
- Traditional CSV alone is not sufficient for adaptive, data-driven AI capabilities
- Fragmented responsibilities between functions create delays and rework

Approach



The framework provides a single, flexible structure accommodating predictive / analytical, generative, and agentic AI — whether supplier-led or developed in-house, accommodating varying levels of system’s autonomy and adaptiveness.

How It Works



- Overarching Framework Design
- Full Validation Framework Creation (preferably developed alongside use cases)
- Pilot Application & Refinement
- Organizational Integration — embedded into the QMS with trained stakeholders

Deliverables



- Unified AI validation framework consistent with usual CSV processes and practices
- Tailored, operational AI lifecycle model and supporting processes
- Roles, responsibilities, and scalable, risk-based lifecycle activities

Engagement Model



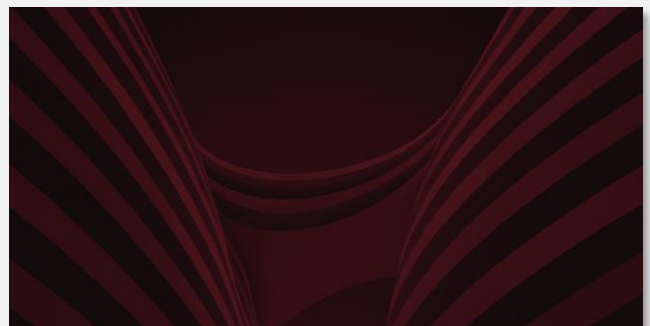
- Typical timeframe: 8 weeks to 6 months (depending on complexity and scope)
- Options include framework strategy only, or QMS integration or pilot add-ons

Fixed-price or T&M options available

Why MH?



- GAMP AI Guidance authorship shaping AI governance in Life Sciences
- Practical experience implementing AI validation frameworks with global scope
- Pragmatic, industry-aligned approach enabling AI adoption with confidence



An AI Validation Strategy Framework is the basis for repeated success of AI use case implementation.

Enterprise AI Platform & Governance



Build robust foundations once to conquer many use cases — spanning technology to quality

Who is this for?



- Organizations in business-critical or regulated Life Sciences environments seeking to design, implement, and govern an enterprise AI platform
- CIO/CTO and Platform Owners, Heads of Data/AI, Quality & Compliance Leadership

Approach



- A vendor-agnostic enterprise AI platform blueprint and governance model integrating technology, data, and quality
- Domains include Data, Models & Experiments, Runtime & Operation, Monitoring & Guardrails, Governance & Qualification

Deliverables



- Target-state enterprise AI platform architecture blueprint
- Governance model including guardrails, workflows, and decision structures
- Risk-based platform qualification strategy and supplier management

Why MH?



- Cross-functional translation across business, IT, data science, and quality
- Practical experience designing and qualified platforms at global pharma
- End-to-end perspective from data & digital strategy over governance to technology

Why This Matters



- Tool sprawl increases cost, risk, and inconsistencies across business units
- Platforms should be qualified once and leveraged often to provide real synergies
- Unified approach needed to align across business, IT, data science, and quality

How It Works



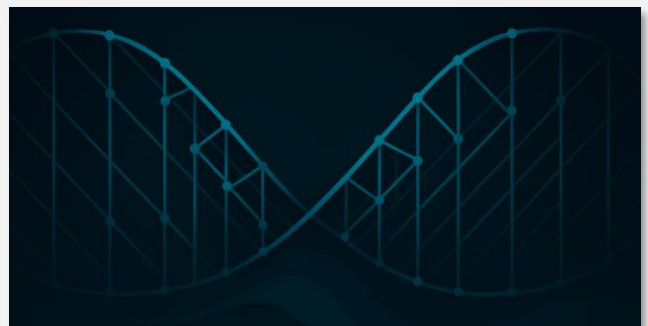
- Assessment & Orientation (1–4 weeks)
- Architecture & Governance Design: platform blueprint, roles and processes
- Qualification Approach: Integration with QMS and with validation practices
- Pilot to representative use cases

Engagement Model



- Assessment: 1–4 weeks depending on scope and maturity
- Platform and governance design: 2–4 months depending on complexity

Fixed-price or T&M options available



Build an enterprise AI platform your teams can actually use in GxP to let your use cases scale.

Any further ideas?
[Open to discuss!](#)



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