

# Discovery Booklet

## AI Foundation Building



Consulting  
& Advisory

**2026**

Navigate Ambitious Data, Digital and AI Endeavours in regulated Life Science Areas with Clarity, not Noise.



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

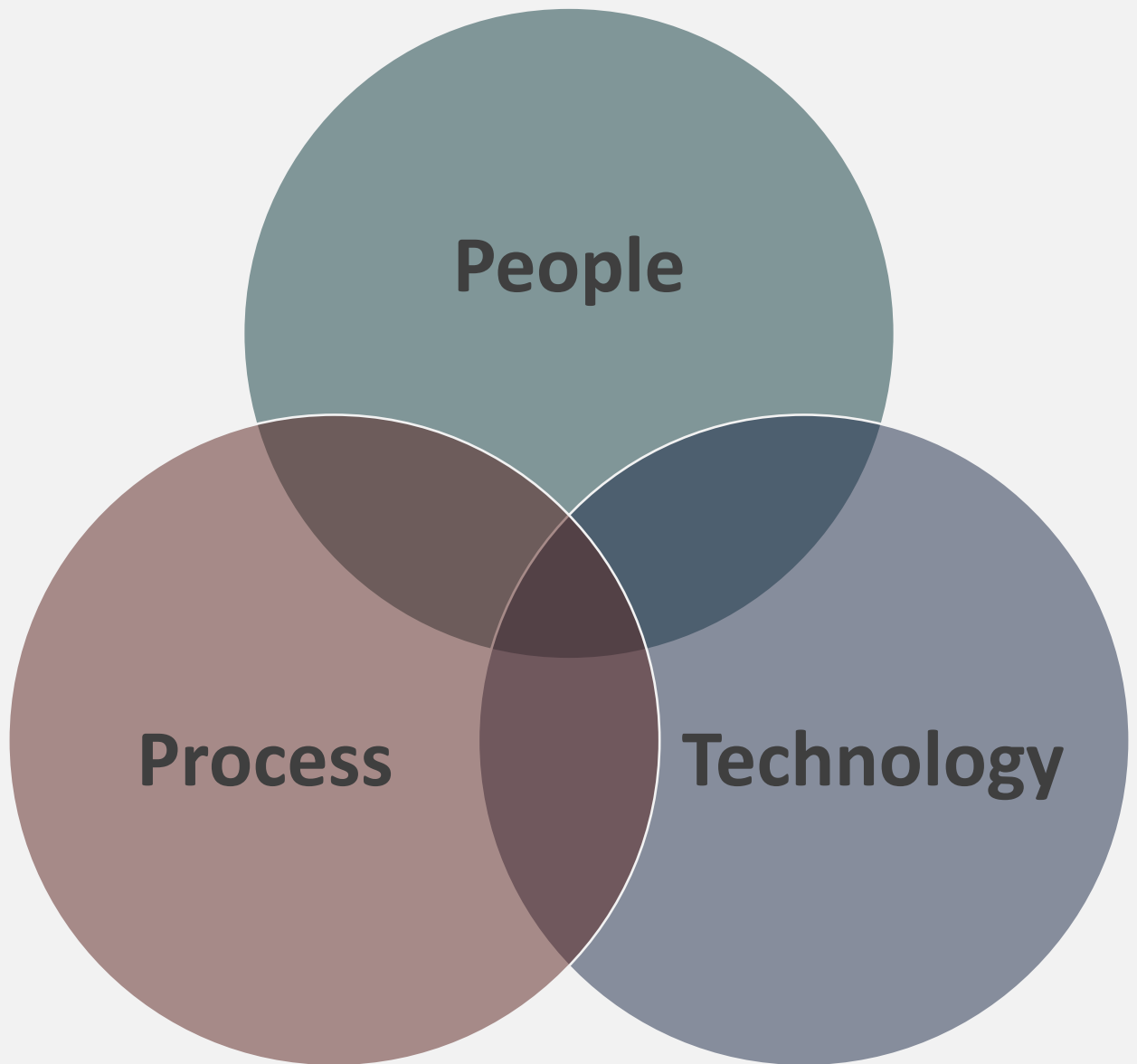


# Martin Heitmann

Managing Director of  
MH Consulting & Advisory GmbH

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# Three Foundational Pillars



Integrated through a holistic  
GxP aware Strategy

# AI Foundations Assessment

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



## Who is this for?



- Pharmaceutical companies
- Medical device manufacturers
- Global service providers
- Technology and platform partners seeking clarity and alignment for safe and scalable AI adoption

## 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



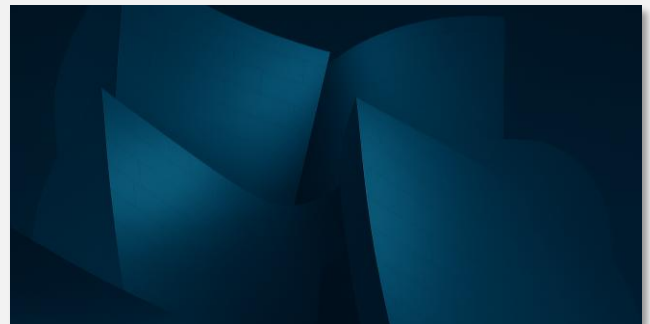
- Typical duration: 2–8 weeks depending on complexity
- Fixed-price engagement tailored to your context

**Pricing available on request**

## Why MH?



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



Interested to learn more about your AI foundations' state?

# AI Enablement Training Program



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

## Who is this for?



- Pharmaceutical companies
- Medical device manufacturers
- Global service providers
- Technology and platform partners

Designed for all functions incl. Executives,  
Business, Quality, IT, Technical Staff, etc.

## 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
- Wrap-Up & Discussion

## Deliverables



- Shared vocabulary and unified understanding across all functions
- Actionable perspectives enabling meaningful discussions and next steps
- Stronger alignment between business, quality, IT, and data science teams

## Engagement Model



- Instructor-led training (virtual or on-site)
- For executives and practitioners alike
- Duration tailored to audience needs (90-minute sessions to multi-day workshops)

**Pricing available on request**

## Why MH?



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



Interested in enabling your organization  
with shared understanding on AI?

# AI Validation 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
- Target audiences incl. senior leadership, quality & compliance representatives, IT/platform owners, and use case owners

## 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.

## 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

## 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

## 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

## How It Works



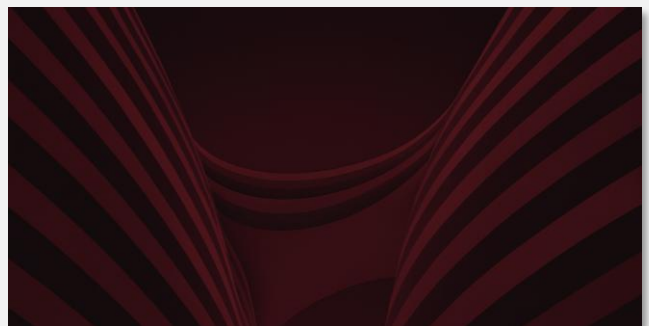
- Overarching Framework Design
- Full Validation Framework Creation (preferably developed alongside use cases)
- Pilot Application & Refinement
- Organizational Integration — embedded into the QMS with trained stakeholders

## Engagement Model



- Typical timeframe: 8 weeks to 6 months (depending on scope, complexity, agility)
- Recommended to combine framework design with a pilot implementation

**Pricing available on request**



Interested in ensuring your AI pilots can fly — not fail at validation?

# 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

## 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

## 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

## 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

## Deliverables



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

## Engagement Model



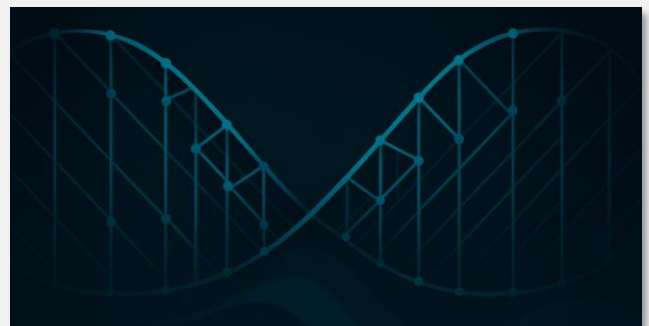
- Assessment: 1–4 weeks depending on scope and maturity
- Platform and governance design: 2–4 months depending on complexity

**Pricing available on request**

## Why MH?



- Cross-functional translation across business, IT, data science, and quality
- Practical experience designing and qualifying platforms at global pharma
- Independent and vendor-agnostic perspective ensuring client-fit architectures



Ready to build an enterprise AI platform you can trust — and scale?

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



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