MAIN 5

Your partner for
driving Digital Transformation
and Compliance in Life Sciences

Your Strategic Ally
in Life Sciences Innovation

MAIN5 stands for tailor-made solutions, partnership-based collaboration and renowned industry expertise. With our unwavering commitment to the success of our clients, we guide Life Sciences organizations towards achieving their most ambitious goals.

Let MAIN5 be the catalyst for your organization's transformation and success in the competitive Life Sciences sector.

Our mission

At MAIN5, we redefine consulting with a dynamic and forward-thinking approach: We stand for unparalleled expertise, tailor-made solutions and partnership-based collaboration.

Our services

- **Regulatory Affairs**

- **IDMP Readiness**

- **FAIR Data**

- **Vendor Selection Services**

- **Learning Management Systems**

- **Migration and Data Integrity Services**

- **Quality Management Systems**

- **Computerized Systems Validation according to GAMP5**

- **Data Quality**

- **Data Governance**

- **Master Data Management**

Regulatory Affairs

- Analysis, harmonization, design, and implementation of efficient Regulatory end-to-end submission processes

- Development of Regulatory Submission and Product Strategies on a global scale, ensuring compliance with Health Authority requirements

- Assistance in performance and compliance monitoring to ensure readiness for Audits and Inspections

- Analysis, harmonization, design, and business-sided implementation of Regulatory processes and IT Systems, such as Regulatory Information Management System (RIMS), Document Management System (DMS), publishing solutions, etc.

- Provision of ancillary services, such as project management, preparation of training for Regulatory Affairs members, implementation of Change Management measures, etc. in the context of Regulatory-relevant Projects and initiatives

IDMP Readiness

- IDMP strategy (compliance vs. benefits beyond compliance)

- IDMP Awareness, stakeholder mapping and training

- IDMP gap analysis (processes, data, ownership, systems) incl. action plans to resolve gaps

- IDMP data governance, processes and data ownership

- Support of requirements and technical implementations related to IDMP (e.g. Master Data Management, System upgrades or replacements, Integrations, etc.)
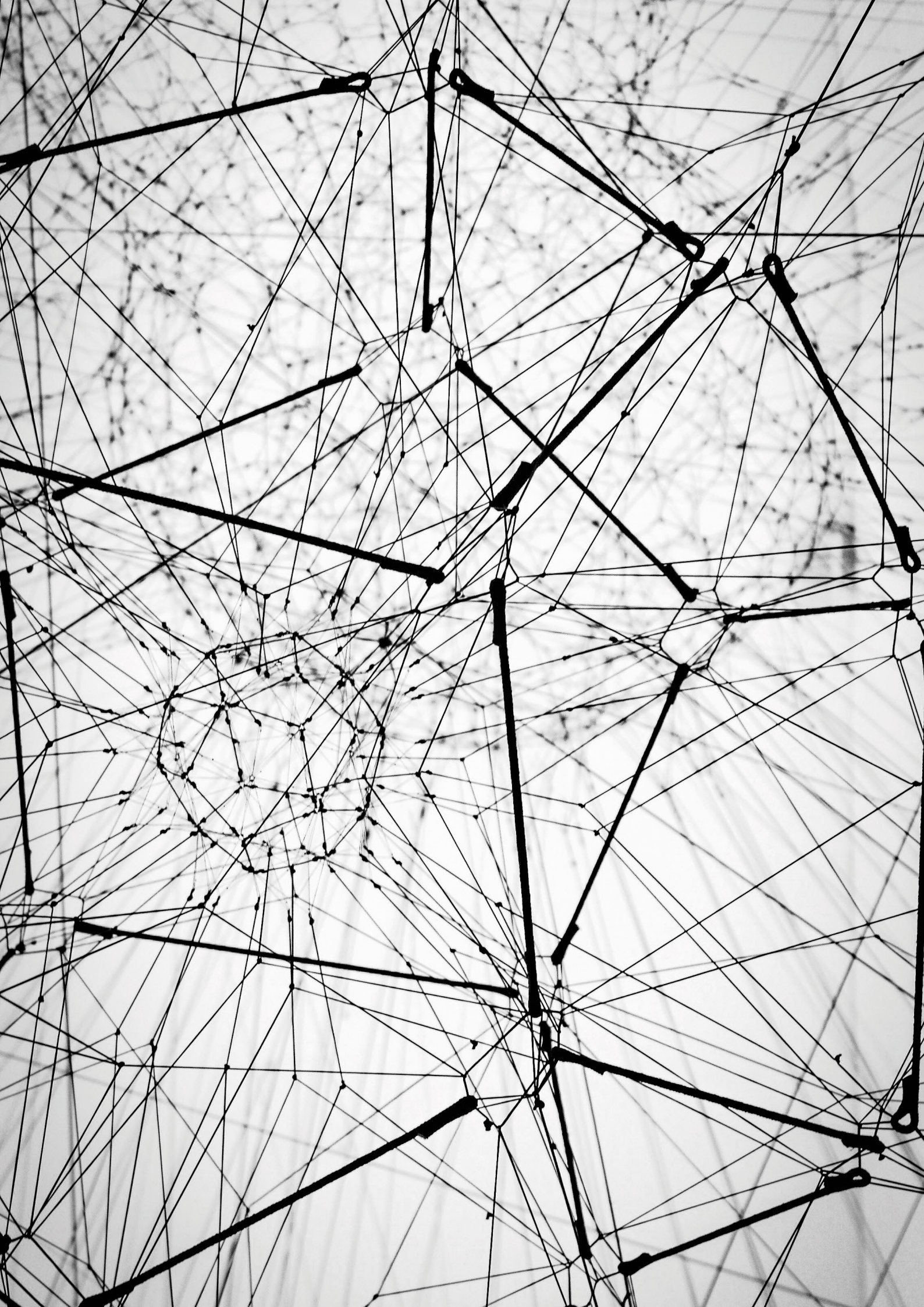
- IDMP data enrichment and maintenance

FAIR Data

- Awareness and training

- Strategy to data FAIRification
  (business and technical architecture)

- Collection and evaluation of FAIR data use cases
  (business benefits, efforts, amount of data, ...)

- FAIR data Proof of Concepts

- FAIR data use case implementation

Vendor Selection Services

- Vendor Selection Strategy Development

- RFP (Request for Proposal) Preparation and Management

- Vendor Evaluation and Shortlisting

- Demo Sessions and Use Case Assessments

- Negotiation and Contract Finalization Support

- Implementation and Migration Plan Assessment

Learning Management Systems

- Digital Adoption Performance Tools

- Training Material Creation

- LMS / LXP Implementation

- Standard Training Library

- eLearning-as-a-Service

- MAIN5 Just In-time Learning (JIL)

Migration and Data Integrity Services

- Data Migration Strategy and Planning

- Data Cleansing and Preparation

- System Integration and Migration Execution

- Data Integrity and Compliance Checks

- Post-Migration Support and Validation

- Training and Knowledge Transfer

Quality Management Systems

- Requirements Definition

- Vendor Selection

- Reviewing OOTB processes and adapting to your needs

- Training Concept Setup

- Performing initial and continuous Computer System Validation

- Migration Support

Computerized Systems Validation according to GAMP5

- Validation Planning including Strategy and Concept

- CSV Service Development (i.e. CSV-as-a-Service, DevOps enablement, Periodic Review)

- Slim risk-based testing approach including Test Automation

- Tool Chain approach for Documentation and Reporting (i.e. ALM)

- Training and Support concept and execution

- Post-Validation Support for Audit and Inspection Readiness

Data Quality

- Regulatory Data Examination
- Data Quality Solution Support
- Root Cause Analysis
- Data Quality Rules Definition

Data Governance

- Develop Data Governance concepts, strategies and roadmap
- Data Governance Roles and Responsibilities
- Adopt and implement existing Governance Frameworks according to functional area's needs
- Training on Data Governance and Data Literacy

Master Data Management (MDM)

- Analyze existing master data in functions and cross-functional
- Identify data flows and sources of original (internal + external) for Master Data
- Define MDM concepts, strategies and roadmap
- Support MDM implementation
- Mapping and standardization of data
- Define and implement governance processes for Master Data Management

Why MAIN5?

Choosing MAIN5 means embarking on a journey towards strategic growth, operational excellence, and regulatory compliance, guided by a partner renowned for its industry expertise, customized solutions, and proven success.

1 Innovation

In a world shaped by rapid advancements, MAIN5 stands at the forefront of industry trends. We embrace innovation as a guiding principle, ensuring our clients stay ahead in the competitive Life Science sector. Our commitment to cutting-edge technologies is unwavering, making us your strategic partner in navigating the digital age.
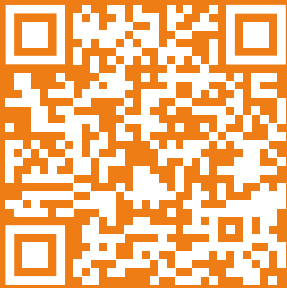
2 Expertise

With a team of seasoned professionals, MAIN5 brings unparalleled expertise to the table. Our consultants are adept in Regulatory Affairs, Quality, Safety, Clinical, and other critical areas along the R&D value chain. We provide tailored solutions that align with your unique challenges, leveraging our deep industry knowledge to drive success.

3 Excellence

At MAIN5, excellence is not just a goal; it's our standard. We pride ourselves on delivering tangible and sustainable results for our clients. Our track record showcasing a history of successful projects in Change Management, Business Process Management, System implementations, eLearning, Quality and Compliance that have empowered organizations to thrive in the face of complexity.

Our contact

Explore how MAIN5 can support
your organization's journey to excellence.

Contact us!
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