MAIN 5

Where strategic vision
becomes operational reality

Who we are

MAIN5 is a European Life Sciences consulting firm that transforms strategic visions for Regulatory, Quality and Clinical R&D into operational reality.

We deliver holistic process design, system implementation and change enablement across the full product lifecycle – combining deep regulatory and quality expertise with proven IT implementation capabilities.

Where traditional consultancies focus narrowly on either strategy or technical implementation, MAIN5 leaves no gaps. We help pharmaceutical organisations translate leadership vision into effective, accepted and sustainable processes that actually work on the ground.

What we do

MAIN5 delivers holistic, business-focused solutions across three core areas: Regulatory Affairs, Quality and Clinical R&D process design and implementation; IT system mapping; and implementation and strategic implementation partnership.

List of services

Regulatory Affairs

IDMP Readiness & Implementation

Quality Management

Knowledge Support

Project Management

Training Management

Program tailored training concept

Application Maintenance Services

Regulatory Affairs

- Analysis, harmonization, design, and implementation of efficient Regulatory end-to-end submission processes
- Development of global Regulatory Submission & Product Strategies, ensuring compliance with Health Authority requirements
- Performance, compliance and inspection readiness monitoring (audits and inspections)
- Design and business-led implementation of Regulatory processes and enabling IT Systems, including:
  - Regulatory Information Management System (RIMS)
  - Document Management System (DMS)
  - Publishing and Submission solutions, etc.
  - Integration with cross-functional business processes, including Clinical, Safety, and Supply Chain systems
- Ongoing application management and support, including continuous release management for Veeva Vaults and other RIM systems, ensuring smooth operations and timely adoption of new features.
- Leveraging data-driven insights and automation to streamline Regulatory operations and improve submission efficiency

IDMP Readiness & Implementation

- IDMP strategy definition (compliance driven vs. value-driven approaches)
- IDMP Awareness, stakeholder mapping and role-based training
- IDMP gap analysis across:
  - Processes
  - Data and data quality
  - Ownership and governance
  - Systems and integration
  - Including actionable remediation roadmaps
- Definition and implementation of IDMP data governance, processes and ownership models
- Support of IDMP-related requirements and technical implementations, including:
  - Master Data Management (MDM)
  - System upgrades or replacements
  - System integrations (internal and with Health Authorities
  - Advanced data analytics and AI/ML applications to enhance substance and product data quality, validation, and decision support.
- IDMP data enrichment, maintenance and life cycle management

Quality Management

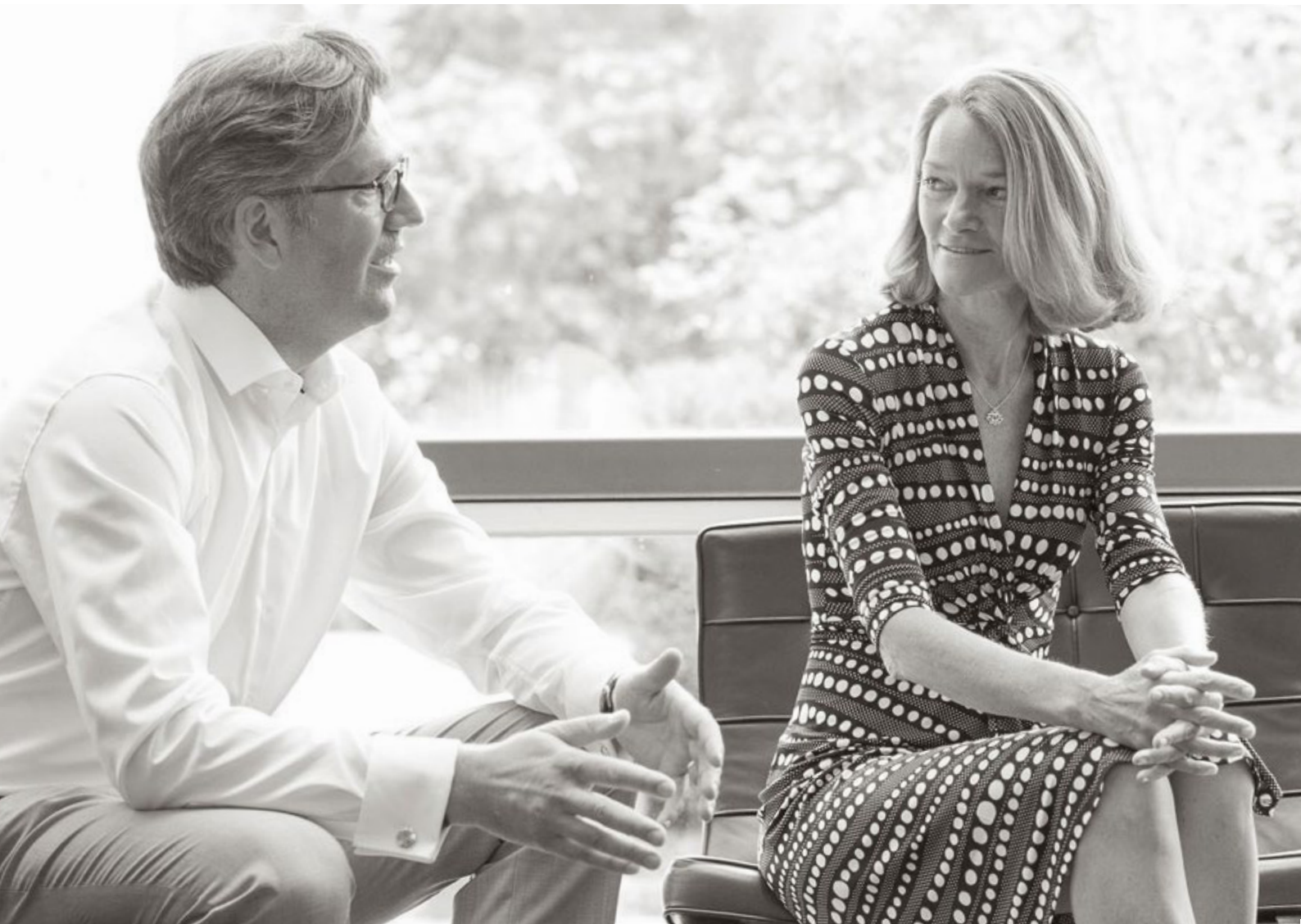
- We support your Quality Management Activities
  - eQMS Implementation
  - Vendor Selection
  - Requirement Definitions
  - Validation
  - Migration
  - Post-go live Maintenance
  - Release Management
  - Business Process Development
  - Harmonisations and Enhancements
  - Inspection Readiness
  - Audits and Inspections
  - Risk Management and Trending

Project Management

- Manage your regulatory and quality driven projects like pro cess harmonization, mergers and divestures, or database transfers and implementations.

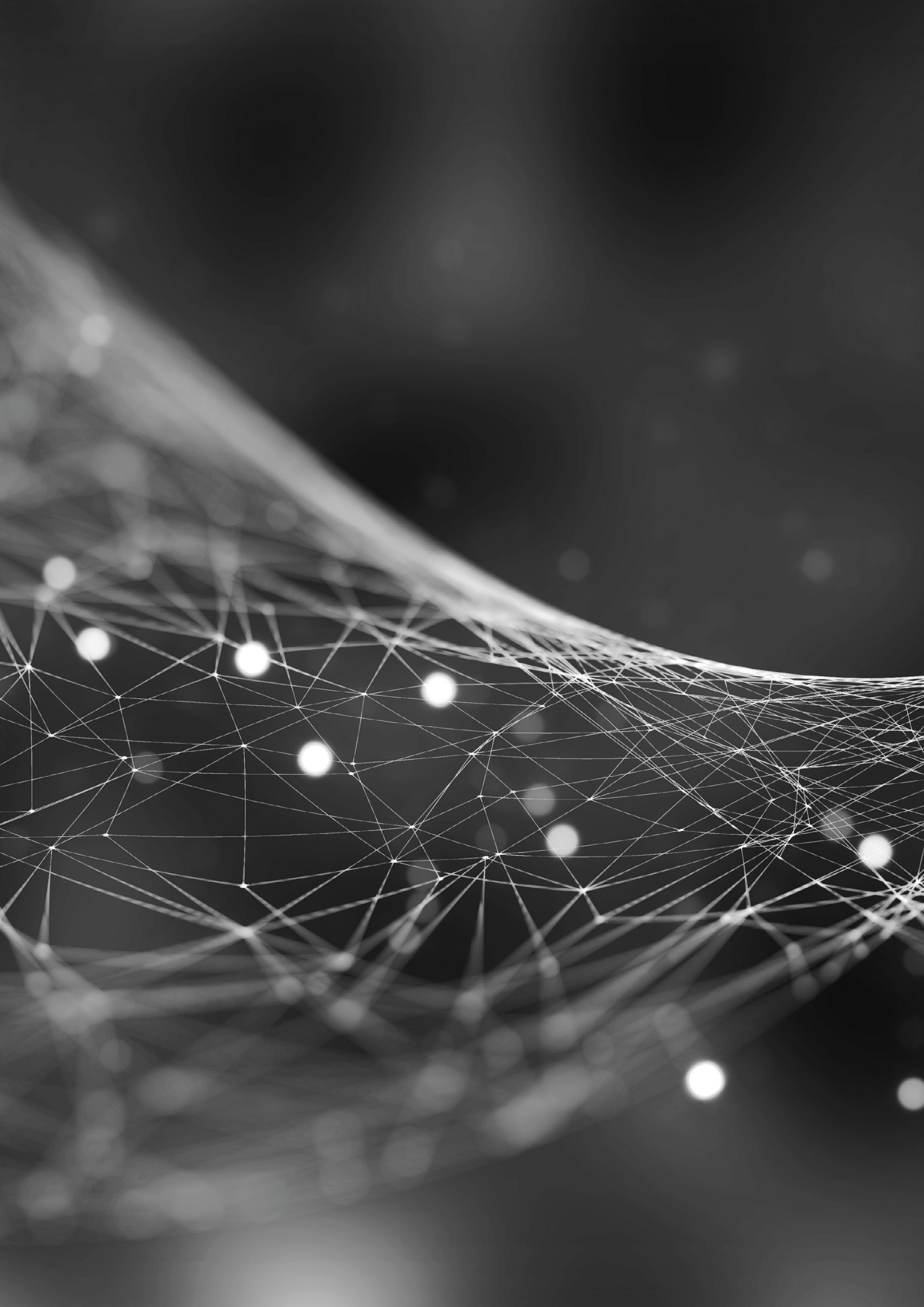
Training Management

- Enable your employees to fulfil their assigned tasks and to utilize new electronic systems in an efficient and meaningful manner.



Program tailored training concept

- Train-the-trainer
- End-User training material creation
- Just-in-time learning
- Material generation and roll-out



Application Maintenance Services

- Application Interfaces and Integration Support
- Vulnerability Management – Service Governance and Operational Approach
- Configuration Management
- Change Request and Release Management
- Knowledge Transfer and Service Handover

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.

Why Top Pharma Companies Choose MAIN5?

1
Execution That Moves the Needle

We don't produce concepts—we deliver operational impact. MAIN5 designs, implements, and embeds solutions that are adopted, measurable, and sustainable in highly regulated environments.

2
Regulatory-Grade Industry Expertise

Our consultants bring hands-on leadership experience from pharmaceutical organizations. We understand the science, the compliance pressure, the data complexity—and the internal realities of global pharma.

3
Senior Continuity, No Dilution

The team you start with stays accountable.
No handovers, no junior substitutions, no loss of context—just consistent ownership from strategy to implementation.

4

Capability Transfer by Design

We strengthen your organization while delivering results. Our model builds internal competence, decision clarity, and governance maturity—so performance endures beyond the project.

5

Trusted Delivery in Complex Stakeholder Landscapes

From global RIM or QMS transformations to regulated system implementations, we align functions, moderate conflicting interests, and ensure momentum—where complexity and business sensitivity are highest.

Ready To Partner For Excellence?

Let’s turn your strategic vision into operational reality.

Contact us!
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