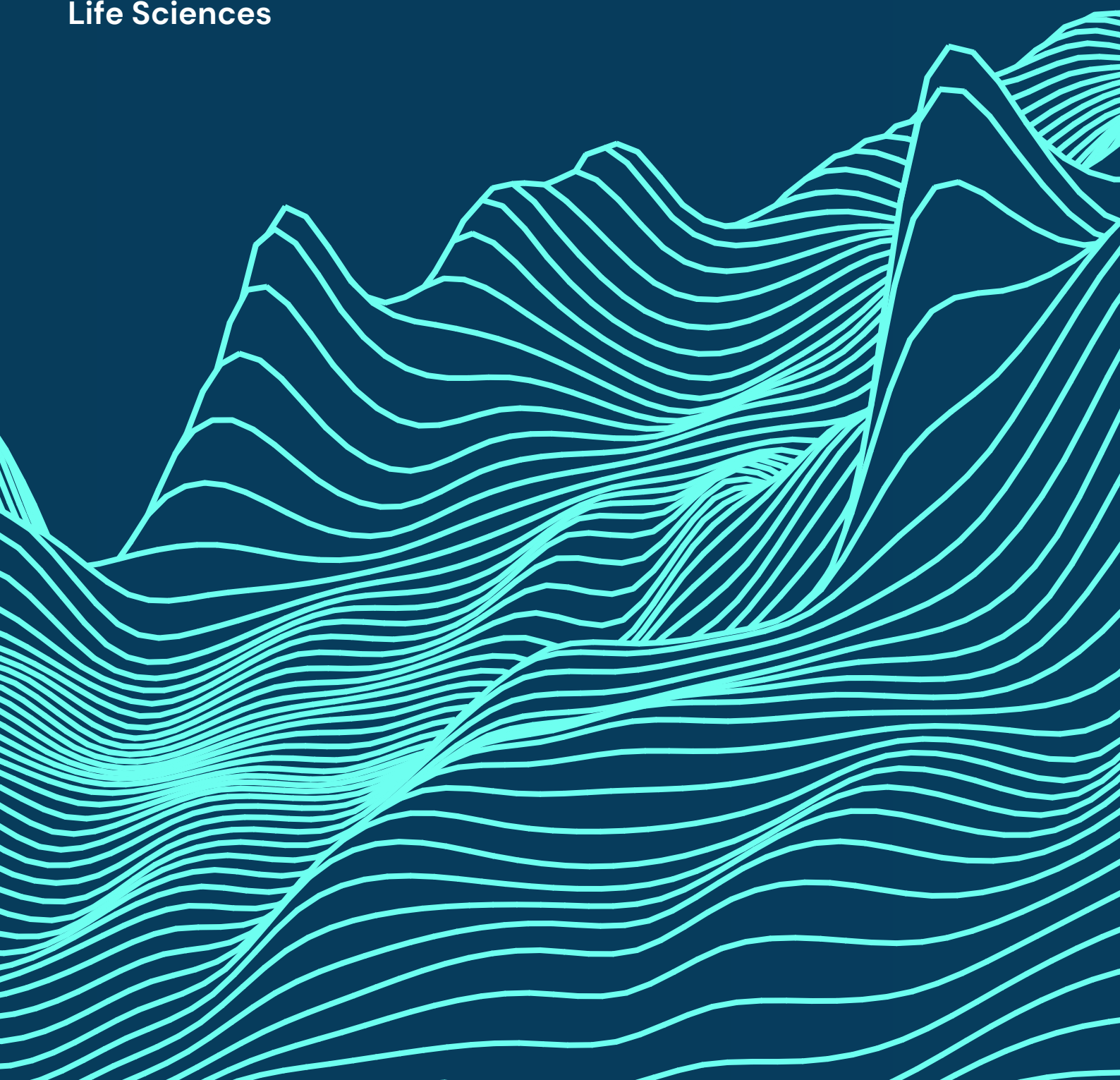# KNG
PARTNERSHIP

amalia

JOINT CAPABILITY STATEMENT

Life Sciences

KNG Expertise

Finance

Operations Transformation
Change Management
Programme Management
Project Management
Risk & Compliance
Regulatory
Identity Management
Services

Life Sciences

Strategy
Divestments
Transformation
Change
Operations
Programme Management
Project Management
Business Alignment
Quality
GxP Compliance
Regulatory
Mentoring – IT Management

Construction & Housebuild

Strategy
Mergers
Acquisitions
Change
Financial
Commercial
Operations
(including Land,
Financial, Commercial,
Sales and Build,
Budgeting, Forecasting,
Housebuild Estimate)
Mentoring – IT Management

Manufacturing & Logistics

Strategy Transformation
Acquisitions Mergers
Change Operations
Business Alignment
Risk & Compliance
Mentoring – IT Management
Quality

Software, Systems & Technology

Strategy
Acquisitions
Mergers
Alignment
Project Management
Implementations
Infrastructure Upgrades
Cutover / Go-Live
Assistance
Business Alignment
Risk & Compliance
Mentoring – IT Management

Food & Agriculture

Strategy
Acquisitions
Mergers
Alignment
Project Management
Implementations
Infrastructure Upgrades
Cutover / Go-Live
Assistance
Business Alignment
Risk & Compliance
Mentoring – IT Management

Amalia Expertise

Compliance & Validation

- Computerised System Validation (CSV)
- Computerised System Assurance (CSA)
- Data Integrity
- Audits
- Requirement Engineering
- Business Process Modeling
- Governance: Standard Operating Procedures (SOPs), Work Instructions (WIs) and Guidances (GUI)
- Process Digitalisation & Automation
- Automated Testing
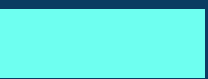- QMS Digitalisation
- IT System Quality

Track & Trace

- Regulatory Compliance
- EU FMD
- DSCSA
- Russia
- Brazil
- Saudi Arabia
- Bahrain
- System Experts
- TraceLink
- Movilitas Cloud
- SAP ATTP
- SAP OER
- SAP PI/PO
- SAP ERP
- SAP EWM
- Computerised System Validation & Assurance

Process Validation

- Industry Thought Leaders in Spectroscopic Tools & Techniques
- Process Analytical Technology (PAT) Tools
- Minimal & Enhanced Quality by Design (QbD)
- Science Risk–Based Approach
- Data Integrity
- Commissioning & Qualification
- Requirements Engineering
- Analytical Procedure Development and Validation
- Scientific/Validation Consulting on Analytical Methods

Trainings

- Computerised System Validation & Assurance
- Requirement Engineering
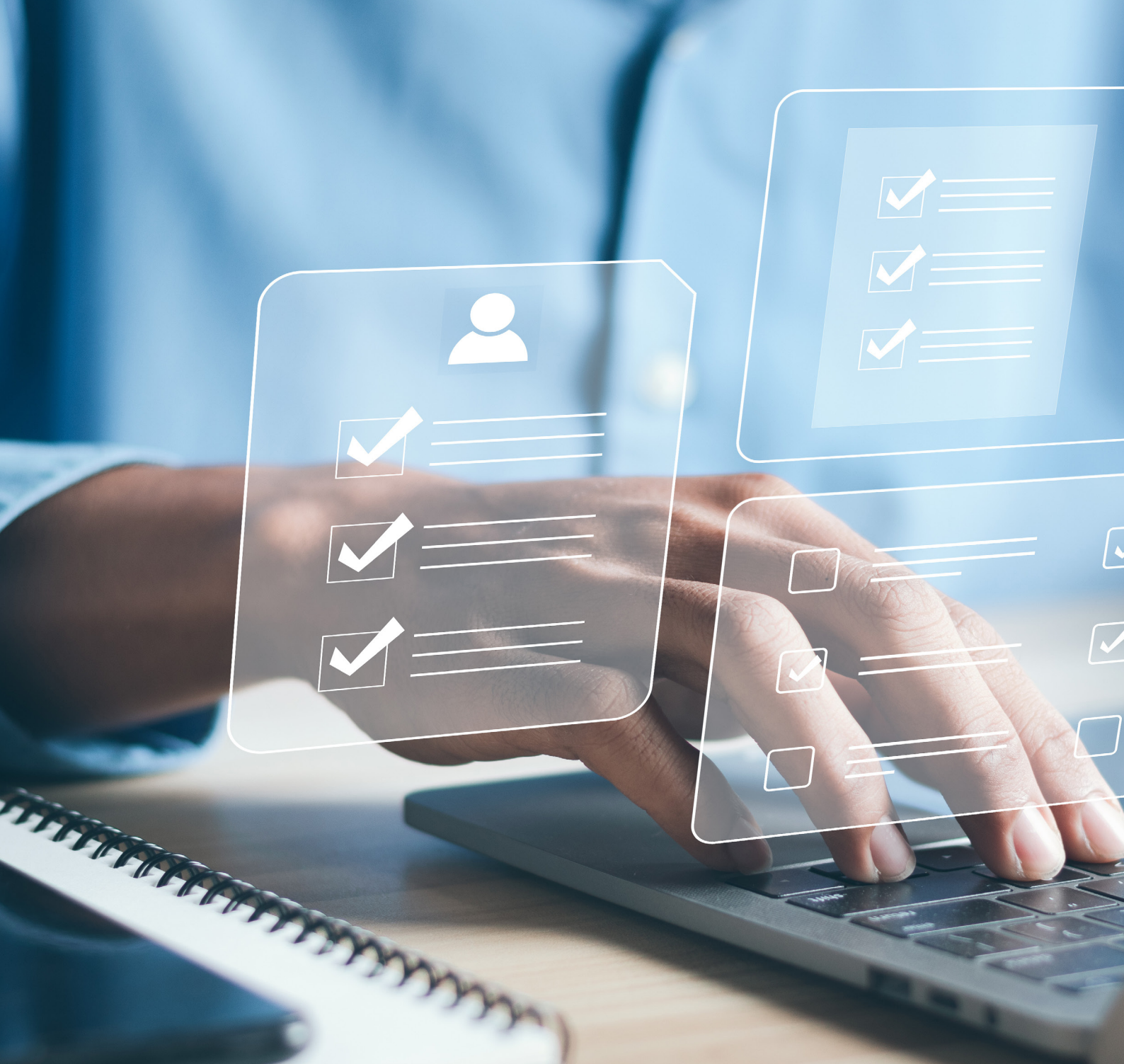- Governance & Regulations
- Data Integrity

KNG Experience

- **Systems Skills** IT systems implementations, including but not limited to: SAP, JDE, Microsoft Dynamics 365 F&O, Salesforce, Workday, Oracle Fusion, PeopleSoft, Chordiant CRM, TraceLink, DocuSign, IBM Maximo, Siemens Polarion, Symbio, and ARIS.

- **GxP Quality** Management of GxP Quality Change projects to digitise process modeling and requirement engineering. This allows our Clients to focus on Agile IT Quality Control strategies rather than Computerised System Validation.

- **Mentoring** CIO | IT Director | IT Manager | IT Team

- **Business As Usual and Specialist Tech Support** BAU support services in a MicroFocus IDM/NetIQ environment.
  Technical Lead on IAM specialist application upgrades.

- **Programme Management & PMO Services** Multi-Disciplinary and Global Programme and Project Management Services.

- **Procurement** Inception and Tendering: Business case compiling | Bid lead | Vendor selection | Contract negotiation | Supplier / Vendor Management Procurement

- **Migration** Led infrastructure builds, migrations and outsourcing from telephony and desktop services to server farms, mainframes and cloud systems.

- **Transformation / ERP** Managed business transformation / ERP projects replacing legacy systems with Tier 1, Tier 2 and sector niche solutions.

- **Small–to Medium–Enterprises (SMEs) Company Sale**
  S1 FFP (Fitness For Purpose) Business Assessment KNG will ready the business for sale, preparing it well in advance of the challenges presented by the due diligence processes.
  S2 Information Memorandum KNG introduces the business to the buyer audience by gathering information in the form of adverts, teaser, and the information memorandum. This includes appointing a broker and researching prospects.
  S3 Sale Finally, KNG assists with building a shortlist, guiding you through the due diligence, and negotiating the final agreement.

Amalia
Experience

- Led numerous infrastructure qualification, Computerised System Validation (CSV) and Assurance (CSA) projects for a wide range of manufacturing and laboratory system and processes.

- Led the creation of several Standard Operating Procedures (SOP), Work Instructions (WI) and Guidances (GUI) to establish well-rounded governance.

- Industry thought leaders on Spectroscopic Tools to implement in/on-line quality control and empower continued manufacturing.

- Led a business change project in updating the Computerised System Validation (CSV) to Computerised System Assurance (CSA) and digitalising the Process Modeling, Requirement Engineering and Testing processes.

- Led multiple system change projects to meet global Track & Trace and Serialisation regulations.

- Leading a TraceLink systems merger project, requiring alignment between 50 CMO/MAH partners.

- Leading a validation product creation for a SaaS IT supplier to use Test Automation and Computerised System Assurance (CSA) to create a standard documentation package that is updated continuously following a rigorous system update release cycle.

- Running training on Computerised System Validation & Assurance, Governance & Regulations, Requirement Engineering and Data Integrity.

- Led audits on Good Manufacturing, Distribution and Laboratory Practices.

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Combined Experience

■ As a combined team, we led a divestment programme to divest a highly complex, integrated and critical manufacturing application environment from a global Life Sciences brand, within a regulated framework (ISO 13485 GxP). Our strategy was to embed ourselves with the local teams and become closely aligned to the operations business, allowing us to plan the work around the Client manufacturing calendar.

Our Approach

Phase 1

- Qualify and build new Infrastructure
- Build network bridge between parties
- Move critical Databases
- Re-Direct critical applications and qualify

Phase 2

- Move critical applications
- GxP validation of critical applications
- Move critical line hardware
- GxP qualification of critical line hardware
- Global Application Migrations

This included working with partners in the USA, Switzerland and India to manage the successful transitioning of all critical events and milestones on time and to budget.

■ Project Management and regulatory control of IBM Maximo divestment, transfer, upgrade and data cleanse.

■ Managed Quality Change projects to digitalise process modelling & requirement engineering and to allow Agile IT Quality Control strategies rather than Computerised System Validation.

Contact us

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