Excellence in GxP

Services

- QA/QC
- Medical Devices
- Project Management
- Validation
- Automation / IT
- Strategic Compliance & Risk Management
- Courses & Training

Examples of what we do

- QRM analyses (ICH Q9 and FMECA)
- Risk management and mitigation
- Product recalls
- Interim management
- Production support (pharmacists, chemists, engineers)
- Client representative project management
- QP assignments
- PQ/PV & Cleaning validation (EU GMP Annex 15, new)
- IQ, OQ, VMP, VPL, URS
- Serialisations / UDI
- Supplier and internal audits
- Contractor and vendor sourcing and management

AlfaNordic
Excellence in GMP

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AlfaNordic

MANAGEMENT CONSULTING

STRATEGIC COMPLIANCE & RISK MANAGEMENT

OUR INSIGHTS

- ✓ QRM Risk Assessment – ICHQ9
- ✓ Failure Mode Effects and Criticality
- ✓ Analysis (FMECA)
- ✓ GMP/GDP GAP Analysis
- ✓ Training
- ✓ Project Management
- ✓ Management Consulting
- ✓ Interim Management
- ✓ Facilitation (project and organization)
- ✓ Strategy & Business Management
- ✓ Board Support
- ✓ Purchase Compliance

YOUR BUSINESS PARTNER FROM IDEA THROUGH PRODUCTION TO MANAGEMENT.

CLIENT ADVANTAGE

Our team of consultants offers a solid base of "lessons learned" knowledge and experience from related industry and markets.

Our services are customized to meet the unique needs of each client.

Systematic analysis through shopfloor and workshops.

WHY US?

- Our mission is to keep you out of the news, unless it's where you want to be!
- Unique methodology using proven tools to analyse business and quality processes and ensure that QRM benefits both compliance and profitability.
- Decades of experience helping clients make critical business decisions.

OUR TRACK RECORD

- Our project managers all have extensive experience within GXP projects.
- Many years of national and international project experience.
- Our customer base includes both head offices and sub- sidiaries of the world leading companies in the Pharma and biotech industry.

LEARN MORE FROM

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AlfaNordic

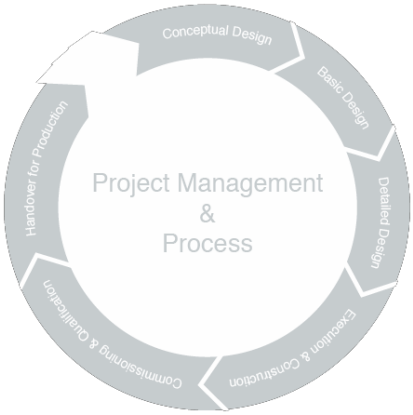
PROJECT MANAGEMENT

PROJECT MANAGEMENT FOR CLIENTS

OUR INSIGHTS

- ✓ Project management
- ✓ Package & discipline leads
- ✓ Programming, master planning and conceptual design
- ✓ Master budget development & follow up
- ✓ Procurement planning and RFQ development
- ✓ Sub-contracting & vendor sourcing
- ✓ Permit Engineering assistance
- ✓ Project team & stakeholder facilitation
- ✓ Contract administration
- ✓ Contractor management
- ✓ Risk management & mitigation
- ✓ Maintenance plans
- ✓ Assessment of compliance HSE and GMP
- ✓ Regulations and standards

YOUR BUSINESS PARTNER FOR PHARMACEUTICAL PROJECTS EXECUTED, WITH THE RIGHT QUALITY, ON TIME, WITHIN BUDGET.



CLIENT ADVANTAGE

Project Managers who have the competences needed for the specific project.

Fully dedicated to the project. Project manager who truly manages all the stakeholders and reports to the steering committee.

Demands for quality, time schedule and budget are managed at the agreed level.

WHY US?

- We are fast to match your demands to one of our project managers.
- Our project managers all have more than 10 years experience within pharma.
- Our project managers all have an additional strong competence e.g. process, mechanical, chemical or El/ Aut. Engineering.

OUR TRACK RECORD

- Our project managers all have extensive experience with GMP projects.
- National and international experience.
- We have executed projects for Novo Nordisk, Novozymes, FeF-Chemicals, Bavarian Nordic, Pfizer, Leo Pharma and other leading companies.

LEARN MORE FROM

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AlfaNordic

MEDICAL DEVICE

FROM IDEA TO PATIENT AND STAYING IN COMPLIANCE

OUR INSIGHTS

- ✓ Compliance with ISO 13485
- ✓ Compliance with FDA 21 CFR Part 820
- ✓ Compliance with MDD, MDR, IVD & IVDR
- ✓ Combination products
- ✓ Regulatory Strategy
- ✓ Marked approval incl. CE Marking and 510K
- ✓ Clinical evaluation
- ✓ Design Control
- ✓ Unique Device Identification (UDI)
- ✓ Risk Management / ISO 14971
- ✓ Product & Process Validation (IQ, OQ, PQ)
- ✓ Software validation
- ✓ Change Control
- ✓ Internal & External Quality Audits
- ✓ Complaint handling & NC & CAPA
- ✓ QP – Qualified Person(s)

YOUR BUSINESS PARTNER THROUGH THE ENTIRE LIFE CYCLE OF YOUR MEDICAL DEVICE.

CLIENT ADVANTAGE

AlfaNordic delivers first class quality through educated people with experience within the Medical Device area.

Medical Device consultants who have the competences needed for the specific challenge through the entire product life cycle.

WHY US?

- Specialists in all MD classes (I, II and III).
- Ensure up-to-date knowledge with regulations and guidelines.
- Large professional network.
- Consultants with different professional backgrounds ensures the right people for the right job.
- Experienced quality auditors.

OUR TRACK RECORD

- QA track lead.
- Implementation and application of QMS.
- Interpretation of ISO13485, ISO14971, MDD and FDA 21 CFR Part 820 -> Securing compliance.
- GMP training and compliance analysis.
- Process analysis incl. validation, mapping and monitoring.
- Analysis of existing root causes and CAPA's.

LEARN MORE FROM

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AlfaNordic

VALIDATION

MANAGEMENT, SUPPORT AND EXECUTION OF QUALIFICATION & VALIDATION

OUR INSIGHTS

- ✓ Risk analysis
- ✓ Equipment qualification (VMP, VPL,URS, IQ, OQ, PQ, PV)
- ✓ Cleaning validation
- ✓ Qualification of sterile production
- ✓ Qualification of medical devices
- ✓ Qualification of utility
- ✓ Room qualification (temperature mapping)
- ✓ Cleanroom validation
- ✓ IT validation (automation)
- ✓ Validation management
- ✓ Management, support and execution of validation documents (User and QA)

YOUR BUSINESS PARTNER FROM CONCEPTUAL DESIGN TO RELEASED PRODUCT.

CLIENT ADVANTAGE

AlfaNordic delivers strong and knowledgeable people with experience and knowhow within validation, validation management, validation QA, production support and more.

We deliver solutions, experts and flexible people to help our clients.

WHY US?

- Highly professional internal/external networking.
- Knowledge transfer to customer during projects.
- Quick learning trainees ensures up-to-date technology and quality mindset.
- Experienced within lifecycle • validation.
- Always up-to-date with current guidelines.

OUR TRACK RECORD

- Inter-/national and highly experienced consultants.
- Successful management inter-/national projects at Novo Nordisk, Agilent, Xellia, Novozymes, Bavarian, and others.
- Management of qualifications.

LEARN MORE FROM

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AlfaNordic

QA SERVICES

SERVICES FOR QA AND SUPPORT FUNCTIONS

OUR INSIGHTS

- ✓ Compliance EMA, FDA GMP & ISO
- ✓ QMS / QRM
- ✓ QP – Qualified Person(s)
- ✓ QA – Product, Production and Documentation Approval
- ✓ QA of validation documents (xQ P&R)
- ✓ Production Support – Batch Documentation, NC, CR & CAPA
- ✓ Production Chemists – Various Support Functions
- ✓ Audits – Supplier and Internal Audits
- ✓ SOP – Writing and Training SOPs
- ✓ cGMP Training

YOUR BUSINESS PARTNER FROM CONCEPTUAL DESIGN TO RELEASED PRODUCT.

CLIENT ADVANTAGE

AlfaNordic delivers strong and knowledgeable people with experience and knowhow within QA, production and support functions.

We deliver solutions, experts and flexible people to help our clients.

WHY US?

- The right people for the right challenge.
- Quick and flexible manning.
- Reliable.
- Knowledgeable.

OUR TRACK RECORD

- Batch documentation approval.
- Validation document approval for new and existing equipment and processes.
- Writing or approval of non-conformities, change control & CAPA.
- Bundling and root cause analysis for non-conformities.
- SOP writing or approval.
- QA assignments.
- QP assignments.

LEARN MORE FROM

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AlfaNordic

IT SERVICES

RISK BASED LIFE CYCLE MANAGEMENT OF IT SYSTEMS

OUR INSIGHTS

- ✓ Compliance with 21 CFR Part 11, Eudralex vol. 4 Annex 11, GAMP 5, GDPR
- ✓ Business Case and Benefit Realisation
- ✓ Project Management (PMP, SCRUM, Agile)
- ✓ Audit and Vendor Management
- ✓ Risk Assessment
- ✓ Validation and Test Management
- ✓ Compliance Assessment and Analysis of legacy systems
- ✓ Support for system implementation
- ✓ Training and OCM
- ✓ Trouble shooting and process optimization
- ✓ Decommissioning

YOUR BUSINESS PARTNER THROUGH OUT THE ENTIRE SYSTEM LIFECYCLE

CLIENT ADVANTAGE

Through our intimate understanding of our clients business and the pharmaceutical value chain, we help our clients efficiently source, implement and operate IT solutions and realize business benefits from their investments.

We are a strategic partner to all of our clients, providing counseling and services, free from affiliations with system suppliers.

WHY US?

- Highly skilled and reliable IT consultants with large professional networks.
- Ability to cover all aspects of the pharmaceutical value chain.
- Independent counseling and services, free from affiliation with system suppliers.
- Providing best practice insights gather from across the industry.
- Always up to date with current guidelines and regulations
- Focused on value adding through continuous knowledge transfer to our clients.

OUR TRACK RECORD

- IT Project management and validation of cloud based system
- Implementation of network security infrastructure.
- IT VMP and Validation for multiple system implementations
- IT SOP's and audit of suppliers
- IT QMS and organizational change management

LEARN MORE FROM

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AlfaNordic

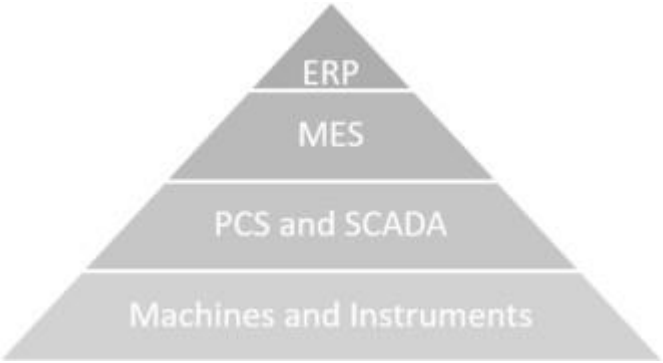
AUTOMATION

IMPLEMENTATION-, OPERATION- AND OPTIMIZATION SUPPORT FOR PRODUCTION

OUR INSIGHTS

- ✓ MES, SCADA, DCS, Serialization, FMS, OEE, PLC, RTU, Network
- ✓ Project Management (PMP, SCRUM, Agile)
- ✓ Vendor Management and Audit
- ✓ Implementation and Process Support
- ✓ VMP, URS, RSK, FS, DS, DQ, FAT, SAT, IQ, OQ, PQ, PV, PSE
- ✓ Continuous Process Improvement and LEAN
- ✓ Data Analysis and Reporting
- ✓ Compliance Assessment and Analysis of legacy systems
- ✓ GAMP 5, Compliance with 21 CFR Part 11, Eudralex vol. 4 Annex 11

YOUR BUSINESS PARTNER FOR THE CONTINOUS IMPROVEMENT OF YOUR PRODUCTION



CLIENT ADVANTAGE

Consultants with broad experience from pharmaceutical production.

Pragmatic and best practice approach to achieving compliance.

Consultants walking the extra mile to keep our clients production running or implement solutions.

WHY US?

- Highly skilled and reliable automation consultants with large professional networks.
- Providing best practice insights gathered from across the industry.
- Always up to date with current guidelines and regulations.
- Always fast response to client requests

OUR TRACK RECORD

- Design of MES and SCADA control systems
- Analysis and implementation of OEE reporting for production optimization.
- Validation and technical implementation support for serialization of multiple packaging lines.
- Testing and documentation of process equipment.
- Programming of several PLC types including Siemens, Allan Bradley, Rockwell, and OMRON.

LEARN MORE FROM

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AlfaNordic Academy

PHARMA ACADEMY™

GRADUATE PROGRAMME

OUR INSIGHTS

9 one-week modules, each completed with an exam:

- ✓ cGMP
- ✓ Qualification/ Validation
- ✓ Documentation practice
- ✓ Process flow
- ✓ Risk Management
- ✓ Project Management
- ✓ LEAN principles
- ✓ ISO 13485 & ISO 14971
- ✓ Outdoor Boot Camp
- ✓ Master Thesis

YOUR BUSINESS PARTNER FROM GRADUATE TO EXCELLENCE IN GMP.

CLIENT ADVANTAGE

The recruitment process is coordinated by AlfaNordic.

Administrative tasks (payroll, contract, etc.) are handled by AlfaNordic.

Each graduate is assigned a trained AlfaNordic mentor for the first 2 years, every 2 weeks.

A unique employee for a unique company.

WHY US?

- Targeted and individualised training programme in collaboration with the pharma industry.
- A 2+2 year graduate programme during which the graduate works exclusively for your Company.
- After the second year the graduate could be employed by you.
- Individual development plan for each graduate based on a personality test focusing on stress handling, leadership and team spirit.

OUR TRACK RECORD

- Our instructors and mentors all possess extensive experience within the pharma industry.
- The recruitment process is conducted in cooperation with educational institutions and universities in Denmark.
- Our customer base includes both head offices and subsidiaries of world leading companies within the pharma and biotech industry.

LEARN MORE FROM

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AlfaNordic Academy

LIFE SCIENCE ACADEMY™

TALENT TRAINEE PROGRAMME

OUR INSIGHTS

We offer a 9 months programme focused on quality-driven and risk-based approach within regulated production facilities in a broad spectrum of life science companies.

Professional training within speciality fields such as:

- ✓ Quality and cGMP
- ✓ Documentation practice
- ✓ Industrial processes
- ✓ Professional identity
- ✓ Project Tools
- ✓ Qualification/Validation
- ✓ LEAN principles

YOUR BUSINESS PARTNER FOR AN EXCLUSIVE TALENT MATCH.

ADVANTAGES

We match top talents with ambitious life science companies, and handle the entire recruitment process from 1st meeting to contract signature.

We ensure focused education and personal growth of candidates to be job-ready to fulfill company needs for young professionals.

Each trainee is assigned a mentor from AlfaNordic´s consultants.

Enrollment uptake every quarter.

WHY US?

- Targeted training programme for talents 'with-in-job' in the life science industry.
- Recruitment from top-of-class of e.g. engineers, pharmacists, IT & automation specialists.
- Matching trainee and life science company with unique opportunity to develop job-related skills and maintain the best employees.
- Individual development plan for each trainee based on a personality profile, coaching and bi-weekly mentor sessions.

OUR TRACK RECORD

- Our instructors and mentors have extensive hands-on experience from the life science industry.
- The recruitment process is supported by our contacts to relevant universities in Denmark.
- We have a large network and a strong knowledge of company needs and requirements within the pharma, food, biotech and medical device industry.
- AlfaNordic is known for excellence in GxP and we value knowledge sharing – especially with you.

LEARN MORE FROM

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AlfaNordic

COURSES & TRAINING

Customer tailored education

OUR INSIGHTS

- ✓ Quality Risk Management
- ✓ General GMP
- ✓ GDP
- ✓ GAP Analysis
- ✓ Handling CMO & Quality
- ✓ Basic Lean
- ✓ Medical Devices ISO13485
- ✓ Writing and Handling NC
- ✓ Auditing GMP & Quality
- ✓ Management Consulting Workshop
- ✓ FMEA Model in practice
- ✓ Qualification & Validation

YOUR BUSINESS PARTNER FROM IDEA TO EXECUTION

CLIENT ADVANTAGE

Our team of consultants offers a solid base of "lessons learned" knowledge and experience from related industry and markets.

Our services are customized to meet the unique needs of each client.

Systematic analysis through shop floor inspection and client documentation.

WHY US?

- Keep up with current practice.
- Customer tailored courses using clients own examples and documentation.
- Up to date knowledge of the current GMP from practical application across industry.
- Presentations are customized according to target audience.
- We share knowledge.

OUR TRACK RECORD

- Evaluation grade point average for GMP courses in 2015 = 4,27 on 1-5 scale.
- 24 courses held in 2015.
- We design courses according to client needs and on request within the range of our expertise.

LEARN MORE FROM

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