



Biopharma industry

Innovative consulting services for **managing patient risk**
through People and Expertise



*Drug Lifecycle Performance
for Patient Safety*

1.

AKTEHOM team of specialists with a wide range of skills and in-depth experience

- Your products
- Your company

Pharmaceutical industry, medical device...

AKTEHOM
expert advising

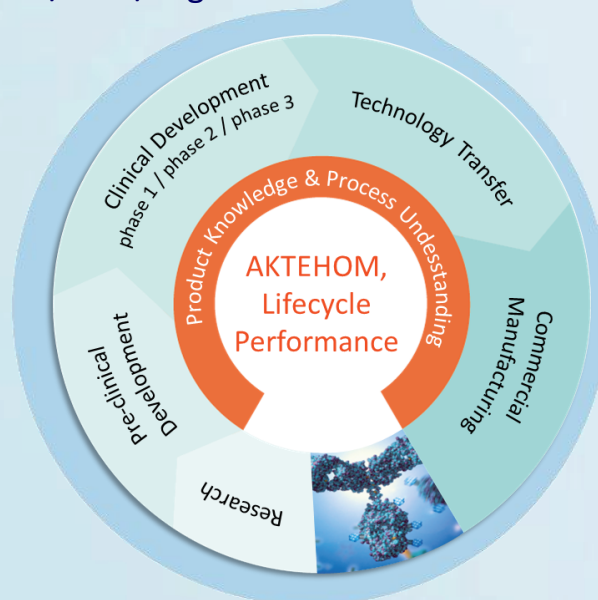
2.

Providing expert advice and operational support facing regulatory and industrial changes through the management of impacts on **Product/Process/Systems/Data/Organization**

- Your projects
- Your challenges

Business stakes Management

AKTEHOM
project team



Who are we?



More info ?

www.aktehom.com

<http://www.societe.com/societe/aktehom-480609635.html>

3.

Acting along the overall product lifecycle :
from early stages of development to commercial manufacturing

Our common target : Lifecycle Performance

Your challenges AKTEHOM can support

Strategy definition (Product/Process/Regulatory Affairs...)

Compliance

Product/Process transfer

Optimized and secured filings

Investigation and problems solving

Quality System –Process Control and Validation

Continuous improvement

AKTEHOM ability to enhance methods



Quality by Design (QbD)
Quality Risk Management (QRM)
Validation and comparability
Filing (CTD)
Technology Transfer
Quality System (PQS)
Knowledge Management
Organization and cultural change
Data Management / Data Integrity

Committed People at your side

Outsourced solution provider,

A new consulting mode to succeed in your projects
A team embedding **science**, **risk-based methods** and **behaviors**

A **single project manager** who

- is your privileged spokesperson
- leads the multidisciplinary AKTEHOM project team
- calls upon AKTEHOM experts

A central and **dynamic allocation** of people to engage appropriate skills in your project, according day-to-day projected activity

A **back-up expert team** to face unforeseen circumstances or needs in your project

The **AKTEHOM commitment** on defined activities, deadlines and deliverables



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AKTEHOM mission scope

Project Management

- 1) Project support (URS, RFP)
- 2) Project lead, Technical member
- 3) Transfer (Production, Analytical)

Quality by Design

- 1) Product/process Characterization
- 2) Analytical Development support
- 3) Design Space (DoE)
- 4) Control Strategy

Quality System

- 1) PQS (Policies & SOPs)
- 2) Process Monitoring
- 3) CAPA / Change / Continuous improve.
- 4) Data Management / Data Integrity
- 5) Continued/Ongoing Process Verification

Technical Support

- 1) Methodological support
- 2) Technical contribution
- 3) Team extension

Risk Management

- 1) QRM Product
- 2) QRM Process & Materials
- 3) QRM Systems

Audits

- 1) Technical / Regulatory
- 2) Organizational

Systems

- 1) Zoning & Flows
- 2) Utilities (WFI, HVAC,...)
- 3) IS (ERP, MES, LIMS,...)

Comparability

- 1) Chemical entities
- 2) Biotech products
- 3) Biological products

Organization

- 1) Structure improvement
- 2) Inter-job communication
- 3) Knowledge Management

Validation

- 1) ASTM E2500 Qualification
- 2) Computerized System Validation /GAMP5
- 3) Process Validation
- 4) Cleaning Validation
- 5) Analytical Methods Validation

Filing

- 1) Initial file(CTD-3)
- 2) Variation file (CTD-3)
- 3) Filing support
- 4) Inspection support

Human Resources

- 1) Cultural Changes
- 2) Skills Assessment
- 3) Team building
- 4) Coaching
- 5) Specific training

Our teams, next to you



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