



Biopharma industry

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



*Drug Lifecycle Performance
for Patient Safety*

Independent consulting company dedicated to Life Science Industries



Expert in
Product / Process
understanding



Anticipation of
regulatory
requirements



Committee
involvement
& publications



Official on-site &
off-site Training



≈ 50 people



4 agencies : *Paris,*
Lyon, Colmar, Brussels



Turnover : ≈ 6 M€

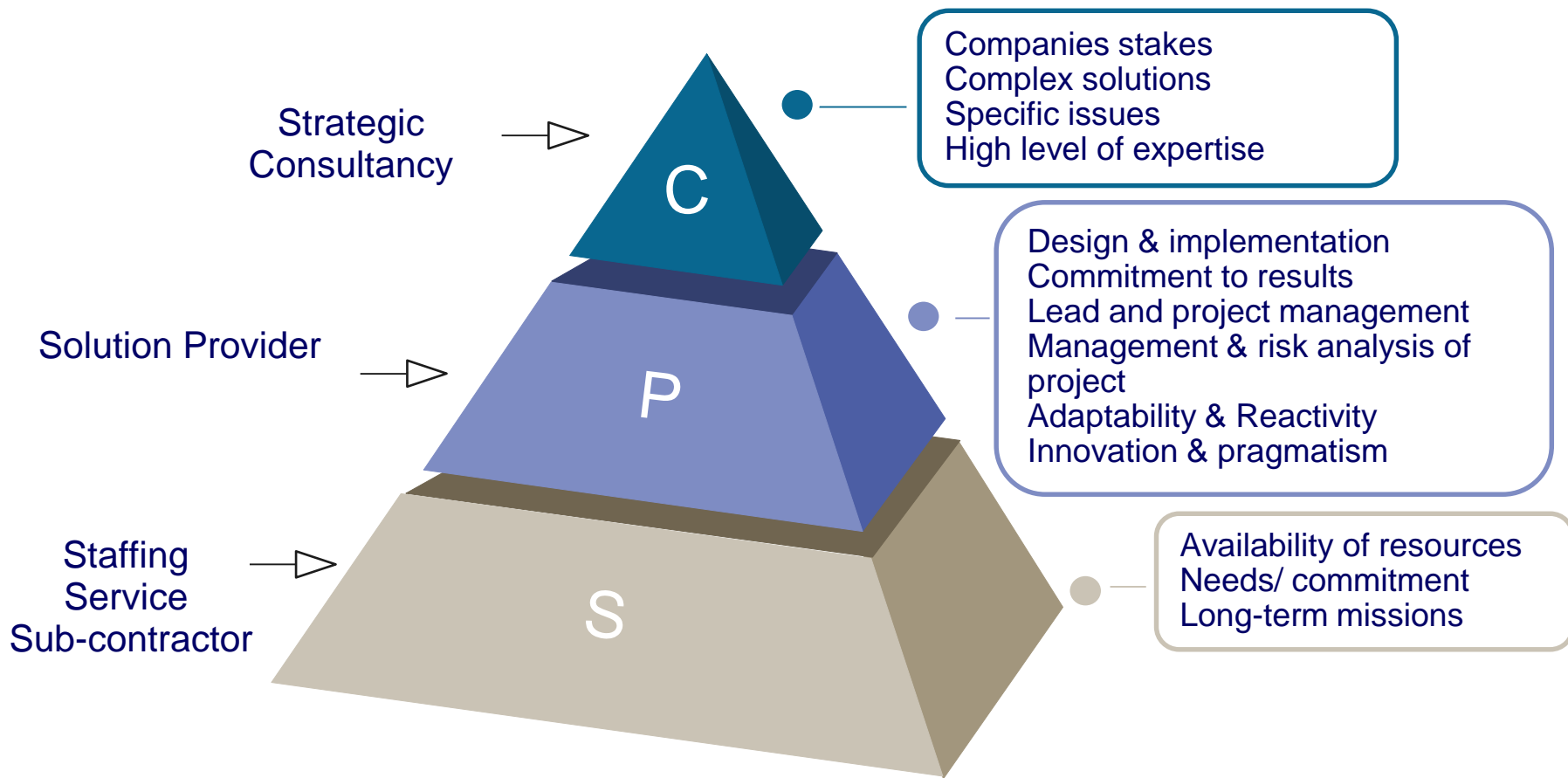


Interventions
Worldwide

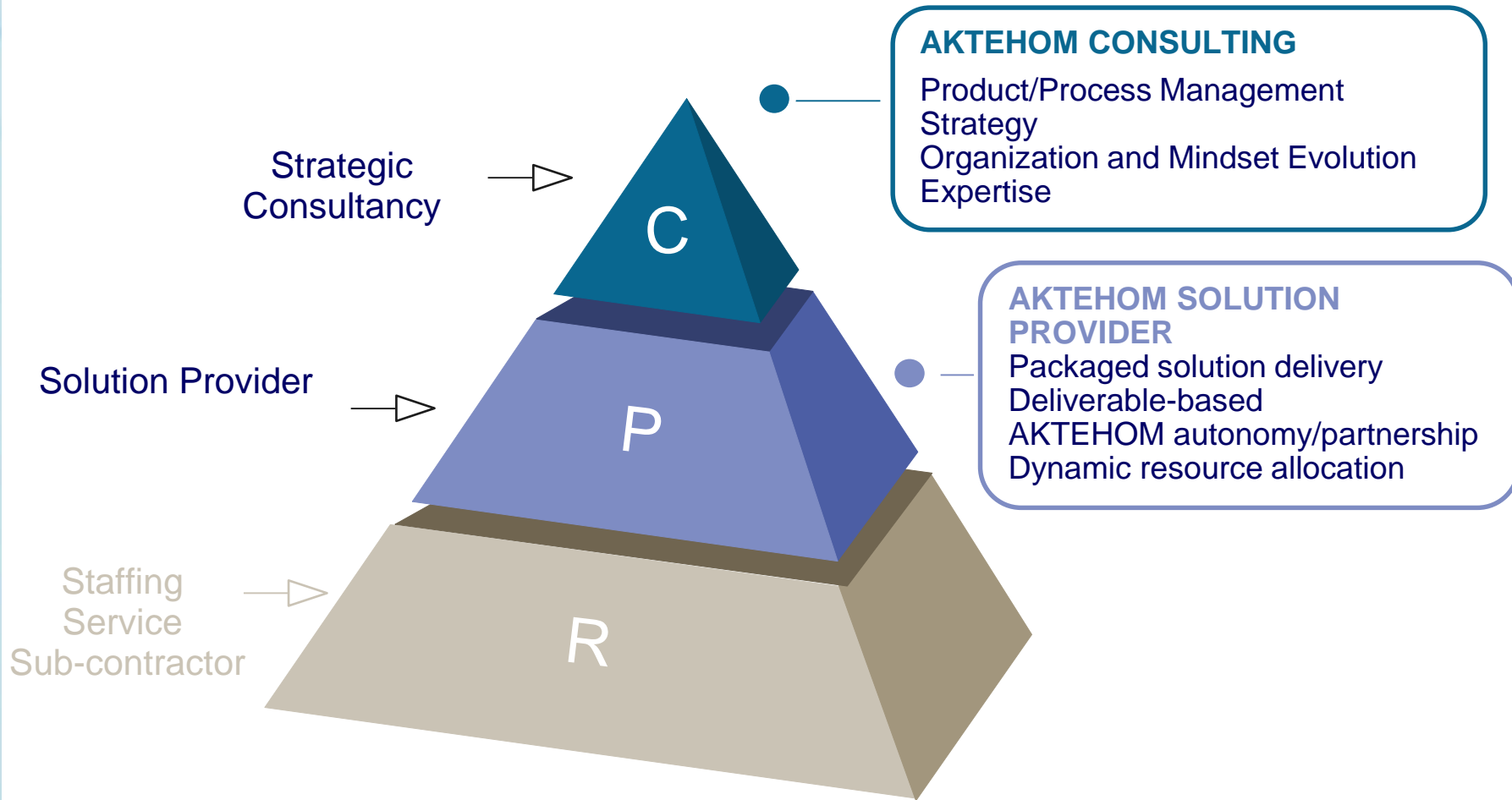
Supporting our clients in the understanding and control of product/process link, to achieve patient safety, drug quality and performance

Consultancy Market

Three main categories of needs that require a **specific approach**:



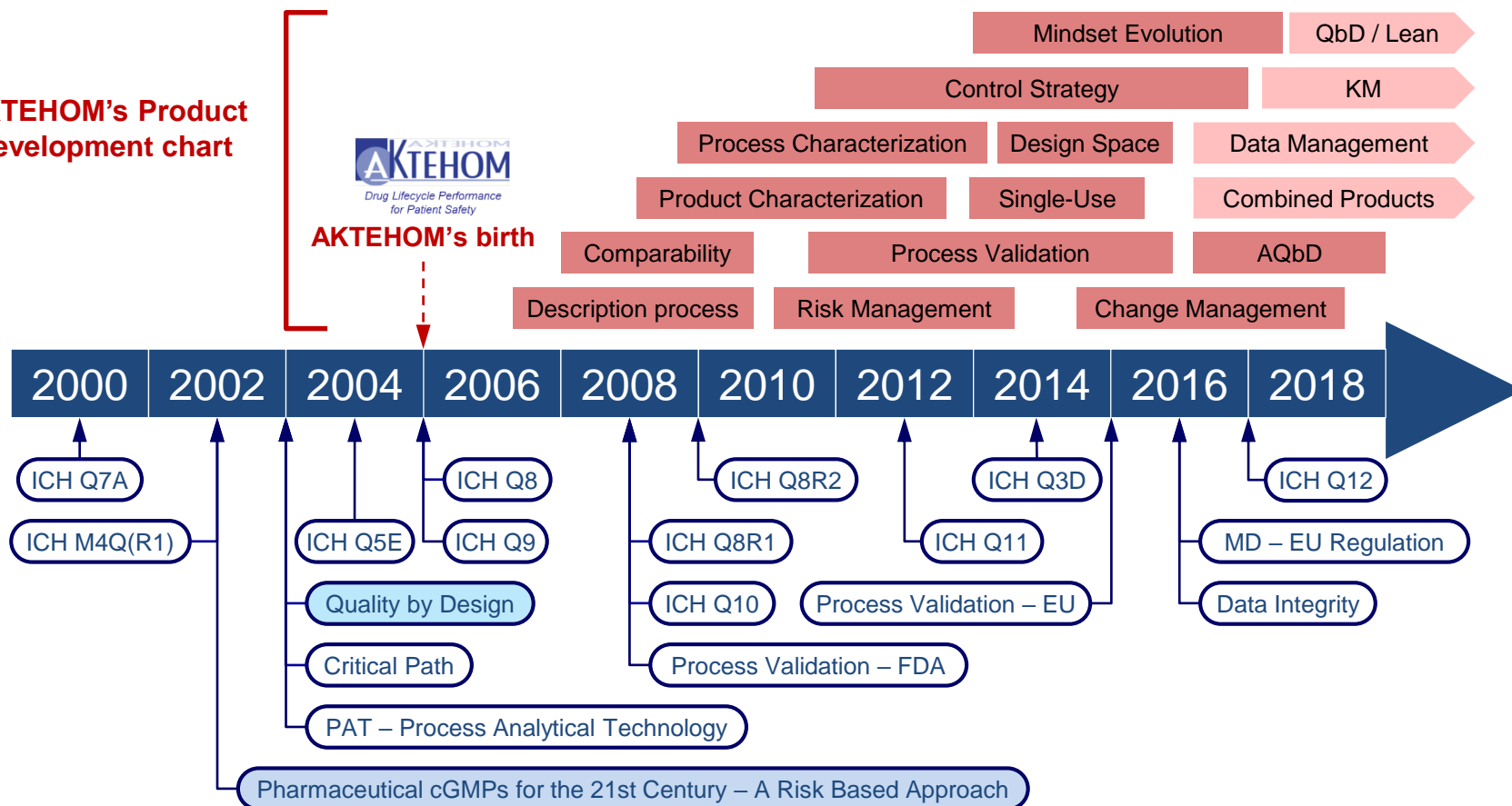
AKTEHOM's position



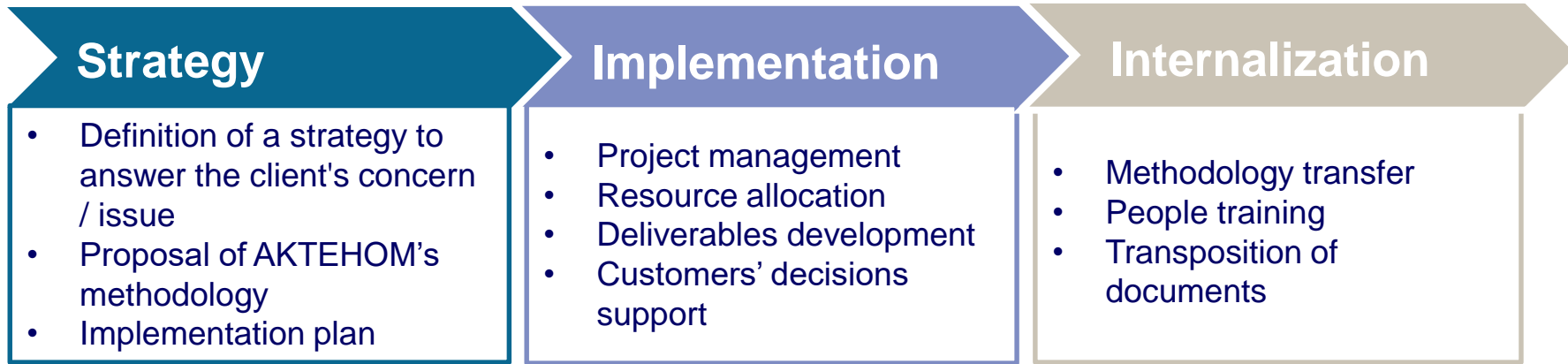
AKTEHOM Continuous Innovation

Operational tools implementing Regulatory Requirements to anticipate future industrial needs

AKTEHOM's Product development chart



How does AKTEHOM act ?



Mission lead

- Skills engagement
- Methodology implementation 'know-how'
- Front office / back office optimized mix
- Dynamic workload, day-to-day management



Single interface & AKTEHOM team autonomy



Optimal efficient client input



Applying right skills at the right time



Optimized cost & Project Risk Management



Commitment on results



Guaranteed results



AKTEHOM's mission scope



Product / Process

- Implementation of Quality by Design
- Characterization studies (DoE, Design Space)
- Process optimization
- Drafting of technical data (CMC) for regulatory submission



Commissioning & Qualification

- Equipment / Sites / Utilities
- Laboratory equipment
- Information Systems Validation



Process Validation

- Product / Process Risk Analysis
- Control Strategy
- Process Validation
- Process Transfer
- Monitoring of products / processes



Analytics

- Analytical QbD
- Technical Transfer and Validation of analysis

Product & Process Understanding & Control

Biological & Biotechnologies
Small Molecules
Medical Devices



Contamination Control

- Cross Contamination
- Microbiological and particles Contamination
- Cleaning Process, Decontamination & Sterilization
- Extractables and leachables (Single Use Systems)



Compliance

- Regulatory surveillance & Interpretation of regulations
- Inspections / compliance assessment
- Support for injunction procedures



People & Organization

- Cultural change
- Technical and personal development coaching, mindset evolution
- Training



Quality Systems

- Risk Management
- Process Control (deviation, Change, CAPA...)
- Management of third parties
- Data management / Data integrity
- Quality Systems and Product Lifecycle requirements

Your AKTEHOM team is closer than you think...



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