



How Outsourcing Drives Transformative Improvements

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MINDSET IS ESSENTIAL

- ▶ outsourcing is widely considered a strategic business plan
- ▶ answering the typical 5 Ws questions, you will see your plan taking shape
- ▶ ... actually, reduce to the 3Ws questions that matters:
 - Why?
 - What?
 - When?
- ▶ Most importantly, know the “how” and master it

...BUT IT HAS TO SHIFT!



WORD OF THE DAY: «TRANSFORMATIONAL»

THE NEW ERA:

Systemic Change
Proactive Value Creation
Fundamental Rethinking
Long-Term Cultural Shift

MODERN organizations: R&D-driven + emphasize AI

Transformative Improvements

TRANSFORMATIONAL CONSULTANTS:

Strategic Advisory
Performance Optimization
Implementation Support
Cultural Alignment

Outputs:

SCALABILITY
ORGANIZATIONAL RESILIENCE
COMPETITIVE ADVANTAGE

Case Study 1



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- ▶ Long-standing outsourced LRA model ensuring compliance and high-quality delivery
- ▶ Recent significant achievement in Switzerland:
approval for two new device presentations for chronic immune-mediated inflammatory conditions
 - Pen and pre-filled syringe (safety syringe)
 - Full authorization for both involved manufacturers of the drug product
- ▶ Approval granted five months earlier than the internal best-case expectations.

- ▶ *Preliminary Decision* phase by-passed => remarkably smooth and accelerated assessment.
- ▶ Success enabled by:
 - Dossier quality
 - Transparent and proactive communication and coordination
 - Robust procedural knowledge and local leadership
- ▶ Strong precedent for future submissions
- ▶ Outsourcing model => integrated extension of the client's organization.

Case Study 2



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Transformation of EU Translation & Linguistic Review 1/2

- ▶ Major transformation of EU labeling ops => streamline the Linguistic Review (LR) and translation process across 24 languages.
 - From email-based, fragmented workflows to digitally integrated, auditable, end-to-end process.
- ▶ Challenges with old process:
 - Manual handoff, inconsistent communication, limited traceability
 - High deviation rates (~40% related to labeling and translation)
 - Inconsistent reviewer involvement, multiple tools, manual file transfers = inconsistency + risk.

Transformation of EU Translation & Linguistic Review 1/2

► Goals

- reduce complexity,
- ensure regulatory compliance,
- enable technology

► Actions

- new translation vendor + digital interface (eDMS+translation platform)
- updated process documentation and training + KPI monitoring
- Pilot phase

► Achievements

- Translations improved, cycle times reduced, manual steps eliminated
- Fully auditable workflows
- Cost saving



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Thank you!

"Your life does not get better by chance; it gets better by change." — Jim Rohn

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