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Service profile

Advanced Analytics for Pharma & Biotech Process Optimization

The Challenge: De-risking process Development and Scale-Up

In the pharma and biotech sectors, scaling processes from the lab to manufacturing is a critical challenge. Process variability, incomplete datasets from sensors, and the inherent complexity of biological systems can lead to costly batch failures, project delays, and challenges in ensuring consistent product quality. Success depends on robust process understanding and data-driven decision-making.

Our Solution: Data-Driven Intelligence for Complex Bioprocesses

ComPSE Consulting provides expert advisory services that combine Process Systems Engineering (PSE), advanced statistics, and AI to optimize and de-risk biomanufacturing processes. We help clients build robust data frameworks, extract critical insights, and develop reliable models to achieve more efficient and scalable operations with minimal risk.

Case Study: A Methodology for Robust Process Data Frameworks

This project showcases our methodology for building a scientifically-sound data analysis framework, a process directly applicable to challenges in fermentation and biomanufacturing.

- **Client**: IHE Delft Institute for Water Education.

- **Objective**: To provide scientific advisory for the development of a robust Sludge Data Management Framework, ensuring scientific integrity and analytical robustness.

- **Our Contribution & Methodology**:
  - Advised on the database structure to ensure it captures key statistical parameters (e.g., ANOVA, p-value testing) derived from process characteristics.
  - Recommended suitable Machine Learning (ML) models for handling missing data and advised on a full training strategy, including data preprocessing and evaluation metrics.
  - Guided the creation and review of synthetic datasets to test the framework's functionality against real-world process variability.
    Provided guidance on rigorous statistical and ML-based validation methods to ensure the final database and tools were accurate and reliable.

- **Outcome**: The project resulted in a scientifically validated framework, providing a reliable foundation that prevents future data-related errors and accelerates all subsequent analysis and modeling tasks.

Core Capabilities for Pharma & Biotech

- **PSE Modeling & Optimization**
  - **What**: Optimize and scale up your processes (e.g., fermentation, biotech, DSP) with mechanistic, machine learning, or statistical models.
    Outcome: Achieve efficient, reliable processes that scale with minimal risk.

- **Applied Statistics for Process Insights**
  - **What**: Leverage ANOVA, response surface methodology (RSM), and global sensitivity analysis for data-driven process insights.
  - **Outcome**: Enable faster, more effective R&D and robust decision-making by understanding and modeling process variability.

About Prof. Gürkan Sin

With over 30 years in Process Systems Engineering, I bring a wealth of academic and industry experience. As a Professor of PSE at DTU (Denmark), I have raised over €15M for process innovation and coordinate major European projects in Life Sciences Modeling (ModLife) and AI Safety (PROSAFE).

Next Step: Ensuring End-to-End Methodological Rigor

Choosing the right analytical path is critical. My service provides scientific oversight across the entire project lifecycle to ensure quality from strategy to conclusion. If you are asking any of the following questions, we should talk:

- How do we select the most appropriate and powerful modeling strategy (mechanistic, statistical, ML or composite AI) for our specific challenge?
- During implementation, how do we ensure the chosen methods are being **executed with scientific rigor** to guarantee reliable results?
- How do we make **sound, defensible interpretations** of complex results to guide our next concrete actions?
- How can we bring in an independent expert to validate our approach across the entire project—from planning and execution to final review?

My advisory service is designed to provide **end-to-end methodological veritas**. We don't just help you create the plan; we provide ongoing scientific oversight during implementation. By allocating advisory hours for periodic consultation, you ensure the **quality of execution** is maintained and your team **draws sound conclusions**, maximizing the value and minimizing the risk of your project.

Let's schedule a scoping call to discuss a specific challenge. We can outline a collaborative project that builds in checkpoints for strategic guidance, execution review, and support.